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Enforcement Actions: Significant Actions Resolved

Quarterly Progress Report
July–September 1993

U.S. Nuclear Regulatory Commission

Office of Enforcement

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ABSTRACT

This compilation summarizes significant enforcement actions that have been resolved during one quarterly period (July - September 1993) and includes copies of letters, Notices, and Orders sent by the Nuclear Regulatory Commission to licensees with respect to these enforcement actions. It is anticipated that the information in this publication will be widely disseminated to managers and employees engaged in activities licensed by the NRC, so that actions can be taken to improve safety by avoiding future violations similar to those described in this publication.

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ENFORCEMENT ACTIONS: SIGNIFICANT ACTIONS RESOLVED

April - June 1993

INTRODUCTION

This issue of NUREG-0940 is being published to inform NRC licensees about significant enforcement actions and their resolution for the third quarter of 1993. Enforcement actions are issued by the Deputy Executive Director for Nuclear Materials Safety, Safeguards and Operations Support (DEDS), the Deputy Executive Director for Nuclear Reactor Regulation, Regional Operation and Research (DEDR), and the Regional Administrators. The Director, Office of Enforcement, may act for the DEDS or DEDR in the absence of the DEDS or DEDR or as directed. The actions involved in this NUREG involve NRC's civil penalties as well as significant Notices of Violation.

An objective of the NRC Enforcement Program is to encourage licensees to improve their performance and, by example, the performance of the licensed industry. Therefore, it is anticipated that the information in this publication will be widely disseminated to managers and employees engaged in activities licensed by NRC, so all can learn from the errors of others, thus improving performance in the nuclear industry and promoting the public health and safety as well as the common defense and security.

A brief summary of each significant enforcement action that has been resolved in the third quarter of 1993 can be found in the section of this report entitled "Summaries." Each summary provides the enforcement action (EA) number to identify the case for reference purposes. The supplement number refers to the activity area in which the violations are classified according to guidance furnished in the U.S. Nuclear Regulatory Commission's "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C, 57 Fed. Reg. 5791 (February 18, 1992). Violations are categorized in terms of five levels of severity to show their relative importance within each of the following activity areas:

Supplement I	- Reactor Operations
Supplement II	- Facility Construction
Supplement III	- Safeguards
Supplement IV	- Health Physics
Supplement V	- Transportation
Supplement VI	- Fuel Cycle and Materials Operations
Supplement VII	- Miscellaneous Matters
Supplement VIII	- Emergency Preparedness

Part I.A of this report consists of copies of completed civil penalty or Order actions involving reactor licensees, arranged alphabetically. Part I.B includes copies of Notices of Violation that were issued to reactor licensees for a Severity Level III violation, but for which no civil penalties were assessed. Part I.C includes a copy of a Notice of Violation that was issued to a non-licensed vendor for a Severity Level III violation, but for which no civil penalty was assessed. Part II.A contains civil penalty or Order actions involving materials licensees. Part II.B includes copies of Notices of Violation that have been issued to material licensees, but for which no civil penalty was assessed.

Part III contains enforcement actions taken against an individual. In promulgating the regulations concerning deliberate misconduct by unlicensed persons (55 FR 40664, August 15, 1991), the Commission directed that a list of all persons who are currently the subject of an order restricting their employment in licensed activities be made available with copies of the Orders. Part III of this volume contains that information. These enforcement actions will be included for each person as long as the actions remain effective. The Commission believes this information may be useful to licensees in making employment decisions.

SUMMARIES

I. REACTOR LICENSEES

A. Civil Penalties and Orders

Centerior Service Company, Perry, Ohio
(Perry Nuclear Power Plant), Supplement I, EA 93-176

A Notice of Violation and Proposed Imposition of Civil Penalty in the amount of $200,000 was issued August 31, 1993, to emphasize the need for appropriate operability determinations, and prompt recognition, adequate assessment, and correction of nonconforming conditions. The action was based on the licensee's failure to correct cleanliness problems in the suppression pool and drywell which resulted in the clogging of the RHR system suction strainers as well as on the licensee's inadequate corrective actions once those problems were initially identified. The licensee responded and paid the civil penalty on September 30, 1993.

Commonwealth Edison Company, Downers Grove, Illinois
(Dresden Nuclear Power Plant) Supplement I, EA 93-019

A Notice of Violation and Proposed Imposition of Civil Penalty in the amount of $75,000 was issued July 15, 1993, to emphasize the need to ensure that the facility as described in the FSAR is maintained or properly changed in accordance with the provisions of 10 CFR 50.59. The action was based on two violations. The first involved the licensee's acceptance, without prior NRC approval, of changes made to Unit 3, specifically modifications to the containment cooling service water system, that involved unreviewed safety questions. The second violation involved the inadequate safety evaluation that was performed, pursuant to 10 CFR 50.59, which led the licensee to conclude that the changes to the containment cooling service water system did not involve unreviewed safety questions. The licensee paid the civil penalty on August 13, 1993, and responded on September 3, 1993.

Commonwealth Edison Company, Downers Grove, Illinois
(Quad Cities Station, Unit 2) Supplement I, EA 93-127

A Notice of Violation and Proposed Imposition of Civil Penalty in the amount of $100,000 was issued July 30, 1993, to emphasize the need for management involvement and oversight of activities affecting safety-related systems and to ensure adequate engineering reviews and maintenance activities involving safety system performance. The action was based on two violations. In the first the shared emergency diesel generator was

inoperable under certain conditions, due to a design deficiency in some associated logic circuitry. In the second, the Unit 2 emergency generator was determined to be inoperable because the associated cooling water pump was incapable of performing its intended function. The licensee responded and paid the civil penalty on August 30, 1993.

Commonwealth Edison Company, Downers Grove, Illinois (Quad Cities Station, Units 1 and 2), Supplement I EA 93-162

A Notice of Violation and Proposed Imposition of Civil Penalty in the amount of $50,000 was issued August 6, 1993, to emphasize the need for increased management attention to the fire protection and safe shutdown programs, including appropriate prioritization of known problems, and increased system engineer continuity for oversight of critical systems. The action was based on a number of violations identified in the licensee's fire protection program. The violations include the failure to test safe shutdown equipment, the failure to track the operability of opposite unit/shared unit safe shutdown components and the failure to promptly correct identified problems. The licensee responded and paid the civil penalty on August 30, 1993.

Consumers Power Company, Jackson, Michigan (Palisades Nuclear Plant), Supplement I, EA 93-178

A Notice of Violation and Proposed Imposition of Civil Penalty in the amount of $50,000 was issued September 14, 1993, to emphasize the need for increased management attention to licensed activities and strict adherence to procedures. The action was based on a June 15, 1993 event in which the licensee failed to uncouple a control rod prior to removal of the reactor vessel head. The violation involved (1) the failure of a shift Supervisor to preprief the auxiliary operators involved in the control rod uncoupling evolution; (2) failure of the auxiliary operators to conduct a dry run on a mock-up prior to the evolution as required by procedures; (3) the failure to notify the control room after each control rod drive mechanism was uncoupled, as required by procedures; (4) a failure to retain the working copy of the rod uncoupling procedure as required by procedures; and (5) an inadequate procedure for verifying that the rods were uncoupled during removal of the reactor vessel head. The failures represent a breakdown in the controls that are essential for the safe conduct of the vessel head removal activities. The licensee paid the civil penalty on September 21, 1993.

Gulf States Utilities, St. Francisville, Louisiana
(River Bend Station), Supplement I, EA 93-167

A Notice of Violation and Proposed Imposition of Civil Penalty in the amount of $100,000 was issued August 5, 1993, to emphasize the importance of ensuring that maintenance on safety-related components and systems does not adversely affect operability and the importance of pursuing test discrepancies to ensure the operability of such components and systems. The action was based on (1) the June 1992 failure to verify post-maintenance internal clearances on a main steam isolation valve (MSIV), (2) the subsequent failure to pursue MSIV closure discrepancies on the same valve during February and April 1993 surveillance tests, and (3) the resultant failure to meet Technical Specification requirements for MSIV operability from February 27 to April 18, 1993. The licensee responded and paid the civil penalty on September 3, 1993.

Nebraska Public Power District, Columbus, Nebraska
(Cooper Nuclear Station), Supplements VII and I, EA 93-030

A Notice of Violation and Proposed Imposition of Civil Penalties in the amount of $200,000 was issued March 30, 1993, to emphasize the licensee's need to improve its problem identification and resolution programs, as well as its need to assure that information provided to the NRC is complete and accurate in all material respects. The action was based on two violations associated with (1) providing inaccurate information to the NRC in response to a Notice of Violation and (2) the failure to identify and correct a potentially significant condition adverse to quality, after the 1992 discovery of a strainer that had been left in a safety system since initial startup. The licensee responded April 29, 1993 and after consideration of the response, an Order Imposing Civil Monetary Penalties was issued June 23, 1993. The licensee paid the civil penalties on July 20, 1993.

New York Power Authority, White Plains, New York
(Indian Point, Unit 3), Supplement I, EA 93-036

A Notice of Violation and Proposed Imposition of Civil Penalties in the amount of $300,000 was issued July 21, 1993, to emphasize the significance of the conditions that existed at IP-3, and the need to ensure that (1) the plant is operated and maintained safely and in accordance with Technical Specifications, and (2) the existing management, human performance and AMSAC system deficiencies are corrected. The action is based on

violations associated with (1) the failure to design and maintain the ATWS mitigation system in a reliable manner, (2) violations of procedures during mid-loop conditions, and (3) violations of various technical specifications. The licensee responded and paid the civil penalties on August 27, 1993.

University of Virginia, Charlottesville, Virginia
Supplement I, EA 93-153

A Notice of Violation and Proposed Imposition of Civil Penalty in the amount of $2,000 was issued July 28, 1993, to emphasize the importance of ensuring that the reactor is operated within the bounds of the safety analysis and that all components of the safety system channels are maintained in an operable state for all expected design basis conditions. The action was based on the operation of the licensee's reactor for approximately 5 1/2 hours without a number of the scram safety channels being operable. During the trouble-shooting of a problem with the reactor instrumentation, a senior reactor operator switched two mixer-driver modules which, because of the presence of internal electrical jumpers, were not identical. This resulted in the disabling of the scram functions. The licensee responded and paid the civil penalty on August 26, 1993.

Vermont Yankee Nuclear Power Corporation
Brattleboro, Vermont, (Vermont Yankee Nuclear Power Plant)
Supplement I, EA 93-112

A Notice of Violation and Proposed Imposition of Civil Penalty in the amount of $50,000 was issued August 2, 1993, to emphasize the importance of timely and adequate evaluation of operational and test data, proper comparison of that data to regulatory requirements and prompt determination of the root causes of test discrepancies so that corrective measures could be implemented. The action was based on three violations associated with the licensee's failure to take corrective actions for an out-of-specification scram time that occurred in October 1992 and was not identified until questions were raised by the NRC staff in April 1993. The licensee responded and paid the civil penalty on August 24, 1993.

Wolf Creek Nuclear Operating Corporation, Burlington, Kansas
(Wolf Creek Nuclear Power Plant), Supplement I, EA 93-129

A Notice of Violation and Proposed Imposition of Civil Penalty in the amount of $50,000 was issued June 25, 1993, to emphasize the importance of ensuring the availability of required safety equipment prior to

making mode changes, and the importance of operators paying close attention to detail in the performance of their duties. The action was based on the licensee's failure to ensure that the two motor-driven auxiliary feedwater pump control room hand switches were correctly aligned before entering mode 3 during startup following an outage. The licensee responded and paid the civil penalty on July 15, 1993.

B. Severity Level I, II, III Violations, No Civil Penalty

Arizona Public Service Company, Phoenix, Arizona
(Palo Verde Nuclear Generating Station)
Supplement III, EA 93-065

A Notice of Violation was issued August 6, 1993, based on inadequate training of security personnel. A civil penalty was not proposed because the licensee identified the violations and the licensee took comprehensive and timely corrective actions. In particular, the licensee strengthened the management of the security program and implemented corrective actions for most of the security training problems prior to completion of the NRC investigation.

The Detroit Edison Company, Newport, Michigan
(Fermi 2), Supplement I, EA 93-154

A Notice of Violation was issued August 13, 1993, based on a number of procedural inadequacies in implementing a modification to a reactor system. Two channels of the drywell pressure post accident monitoring instrumentation system were inoperable from November 4, 1992, until January 7, 1993. A civil penalty was not proposed because of the licensee's identification of the inoperable recorders and the licensee's comprehensive corrective actions.

C. Non-licensed Vendor (Part 21)

Shur-Kut Supply Corporation, Morton, Pennsylvania
Supplement VII, EA 91-162

A Notice of Violation and Notice of Nonconformance was issued August 16, 1993, based on an investigation which was initiated to review the procedures and policies used by Shur-Kut to control the quality of safety-related fasteners supplied to the nuclear industry. The inspection was prompted by the rejection by the Philadelphia Electric Company in September 1989 of certain batches of stainless steel machine screws, because of dimensional and material deficiencies related to specification requirements in the purchase order. A

civil penalty was not proposed because the conditions of 10 CFR 21.61 necessary for a civil penalty were not satisfied.

II. MATERIALS LICENSEES

A. Civil Penalties and Orders

Atec Associates of Virginia, Alexandria, Virginia
Supplement IV, EA 93-089

A Notice of Violation and Proposed Imposition of Civil Penalty in the amount of $375 was issued May 24, 1993, to emphasize the importance of ensuring that gauges containing licensed radioactive material are controlled in accordance with regulatory requirements and license conditions. The action was based on a violation that involved the failure to ensure licensed material was under constant surveillance and immediate control while not in storage. On April 9, 1993, a moisture/density gauge containing approximately 10 millicuries of cesium-137 and 50 millicuries of americium-241 was damaged at a construction site while unattended. The licensee responded and paid the civil penalty on July 8, 1993.

Babcock and Wilcox Company, Lynchburg, Virginia
Supplement VI, EA 93-012

A Notice of Violation and Proposed Imposition of Civil Penalties in the amount of $37,500 was issued April 6, 1993, to emphasize the importance of appropriate management attention to, and oversight of, the nuclear criticality safety program to ensure that operational activities are conducted safely and in accordance with requirements. The action was based on a number of violations concerning the failure to establish or adhere to nuclear criticality safety limits and controls, and the failure to conduct audits and correct audit findings. The licensee responded on May 6, 1993, and after consideration of the licensee's response, an Order Imposing Civil Monetary Penalty was issued August 20, 1993. The licensee paid the civil penalty on September 9, 1993.

Berkshire Health Systems, Inc., Pittsfield, Massachusetts
Supplements IV and VI, EA 93-186

A Notice of Violation and Proposed Imposition of Civil Penalties in the amount of $7,500 was issued August 9, 1993, to emphasize the importance of (1) adequate implementation of the licensee's medical quality management program, and (2) aggressive management oversight of the radiation safety program, so as to ensure that licensed activities are conducted safely and

in accordance with requirements. The action was based on a violation involving a substantial failure to implement the quality management program, as required by 10 CFR 35.32, in that written directives signed and dated by the authorized user were not prepared prior to administration of certain radioactive materials to patients. Also included in the enforcement action was an aggregate of ten violations of the radiation safety program which represented a breakdown in the control of licensed activities. The licensee responded and paid the civil penalty on August 26, 1993.

Capital Materials Testing, Inc., Ballston Spa, New York
Supplement VI, EA 92-203

A Notice of Violation and Proposed Imposition of Civil Penalty in the amount of $7,500 was issued November 20, 1992, to emphasize (1) the importance of appropriate management attention to regulatory responsibilities to ensure that all personnel strictly adhere to all regulatory requirements, and (2) the need to ensure that all corrective actions are properly implemented and are long-lasting. The action was based on a violation involving the failure to adequately perform a survey of a radiographic device after the completion of a radiography operation. The licensee responded December 9, 1992, and after consideration of the response, an Order Imposing Civil Monetary Penalty was issued February 3, 1993. The licensee responded again in March 1993, requesting remission of the civil penalty based on financial hardship and to pay the penalty in installments. An Order Modifying an Order Imposing a Civil Monetary in the amount of $5,000 was issued April 26, 1993. The licensee signed a Promissory Note and the first installment payment was received June 1, 1993.

Cassia Memorial Hospital, Burley, Idaho
Supplement VI, EA 93-121

A Notice of Violation and Proposed Imposition of Civil Penalty in the amount of $2,500 was issued June 11, 1993, to emphasize (1) the need for increased and improved management attention to the radiation safety program to ensure that licensed activities are conducted safely and in accordance with NRC regulatory requirements and (2) the need for lasting corrective action to ensure that the violations do not recur. The action was based on a violation involving the licensee's failure to establish a written medical quality management program and 10 additional violations that were viewed collectively as representing a significant

lack of attention toward licensed responsibilities. The licensee responded and paid the civil penalty on June 29, 1993.

Castle Medical Center, Kailua, Hawaii
Supplement VI, EA 93-040

A Notice of Violation and Proposed Imposition of Civil Penalties in the amount of $7,500 was issued March 31, 1993, to emphasize the need for effective management oversight of the licensee's medical quality management program (QMP) and Radiation Safety Program. The action was based on: (1) failures to effectively implement the licensee QMP involving preparation of written directives prior to administration of radiopharmaceuticals, recording of recordable events, and instructing personnel in the written QMP, and (2) a significant breakdown in the licensee's radiation safety program, as evidenced by numerous violations of NRC requirements. The licensee responded in two letters dated April 30, 1993, and after consideration of the response, an Order Imposing Civil Penalties was issued July 2, 1993. The licensee paid the civil penalties on July 23, 1993.

Columbus Hospital, Great Falls, Montana
Supplement VI, EA 93-164

A Notice of Violation and Proposed Imposition of Civil Penalty in the amount of $2,500 was issued July 8, 1993, to emphasize the importance of maintaining compliance with the licensee's Quality Management Program as to written directives. The licensee responded and paid the civil penalty on August 19, 1993.

Community Hospital South, Indianapolis, Indiana
Supplements IV and VI, EA 93-022

A Notice of Violation and Proposed Imposition of Civil Penalty in the amount of $6,875 was issued March 10, 1993, to emphasize the need for effective management and oversight of NRC licensed activities. The action was based on violations of the licensee's radiation safety program. The violations included failure to perform an annual review of the radiation safety program and quarterly reviews of the ALARA program, failure to provide required training, failure to have correct instrumentation, and failure to perform area surveys at the end of the day. The licensee responded April 5, 1993, and, after consideration of the response, an Order Imposing Civil Penalty in the amount of $5,625 was issued August 11, 1993. The licensee paid the civil penalty on August 26, 1993.

Eastern Testing and Inspection, Inc., Thorofare, New Jersey
Supplement VI, EA 92-136

A Notice of Violation and Proposed Imposition of Civil Penalty in the amount of $7,500 was issued September 17, 1992, to emphasize the importance of adequate attention to, and oversight of, the radiation safety program, so as to ensure that (1) licensed activities are conducted safely and in accordance with requirements, and (2) violations, are promptly identified and corrected. The action was based on the failure to (1) perform audits at the required quarterly frequency for radiographers, (2) calibrate pocket dosimeters and alarm rate meters at intervals not to exceed one year, (3) update the Operating and Emergency Procedure Manual to provide instructions concerning the use of the alarm ratemeters, (4) post a high radiation area that existed above the side walls of the permanent radiographic cell at the Thorofare facility, (5) survey the entire circumference of an iridium-192 exposure device after each exposure while it was being used at the field site in Carney's Point, (6) properly block and brace radiographic exposure devices while in transport to and from field sites, (7) register with the NRC as a user of an NRC approved package, and (8) transport a cobalt-60 exposure device in a package approved by the DOT or the NRC when the licensee moved from the previous facility. The licensee responded in two letters dated October 16 and 26, 1992. After consideration of the responses, an Order Imposing a Civil Penalty was issued January 25, 1993. On February 17, 1993, the licensee requested a hearing, however, on March 16, 1993, the licensee requested the hearing be placed in abeyance pending submittal of additional information. The licensee was allowed to pay the penalty in monthly payments. The licensee signed the Promissory Note July 12, 1993 and is making monthly payments.

Environmental Protection Agency, Port Orchard, Washington
Supplements IV and VI, EA 93-181

A Notice of Violation and Proposed Imposition of Civil Penalty in the amount of $1,000 was issued August 18, 1993, to emphasize the need for effective management oversight regarding control of activities involving licensed radioactive materials. The action was based on violations involving improper disposal of licensed material, failure to conduct periodic inventories of licensed material, inadequate control of licensed material in storage, and inadequate training of personnel working in restricted areas. The licensee responded and paid the civil penalty on September 14, 1993.

Gray Wireline Service, Inc., Levelland, Texas
Supplement VII, EA 93-073

A Notice of Violation and Proposed Imposition of Civil Penalty in the amount of $1,500 was issued June 9, 1993, to emphasize the significance of intentionally providing false information to the NRC and the importance of ensuring that all future communications with the NRC are materially accurate. The action was based on deliberate false statements to an NRC representative concerning conduct of licensed activities in NRC jurisdiction by an Agreement State licensee. The licensee responded and paid the civil penalty on July 5, 1993.

Hazleton Wisconsin, Inc., Madison, Wisconsin
Supplement VI, EA 93-141

A Notice of Violation and Proposed Imposition of Civil Penalty in the amount of $500 was issued June 24, 1993, to emphasize the need for strict adherence to NRC regulations and especially to those for the control of radioactive material. The action was based on the loss of licensed material. In May 1992, while conducting a semiannual leak test of sealed sources, the licensee's RSO determined that a source had been accidently discarded to a local landfill in January 1992. The licensee's attempts to locate and retrieve the source were unsuccessful. One of the corrective actions was to post a more prominent label on each of the gas chromatographs to alert workers to the presence of radioactive sources, but the licensee decided to wait and post them at the next routine leak test. As a result, another source was accidently discarded in September 1992 and was not discovered until the November 1992 leak test. The licensee responded and paid the civil penalty on July 23, 1993.

Mayo Foundation, Rochester, Minnesota
Supplements IV and VI, EA 93-079

A Notice of Violation and Proposed Imposition of Civil Penalty in the amount of $6,000 was issued June 9, 1993, to emphasize the importance the NRC places on the performance of necessary surveys and the unacceptability of willful violations. The action was based on the willful failure of a researcher to perform contamination surveys when working with phosphorous-32. The researcher knew that a survey was required; however, the batteries in the survey instrument were low and the researcher was in a hurry to leave the laboratory, so he chose not to perform the survey. As a result, contamination was spread off-site to a church, private automobiles, clothing, and homes. A second violation

involved inadequate surveys to detect the extent of off-site contamination. The licensee responded in letters dated June 30 and July 1, 1993. After consideration of the licensee's responses, an Order Imposing Civil Penalty was issued August 24, 1993. The licensee paid the civil penalty on September 1, 1993.

Mercy Memorial Medical Center, St. Joseph, Michigan
Supplements IV and VI, EA 93-179

A Notice of Violation and Proposed Imposition of Civil Penalties in the amount of $6,250 was issued August 2, 1993, to emphasize NRC's concern with the lack of adequate oversight of the licensee's program. The action was based on violations involving the licensee's medical quality management program and radiation safety program that resulted in a misadministration to a patient and an unwarranted exposure to the attending nurse. The licensee responded and paid the civil penalties on August 20, 1993.

Mobile Cardiovascular Testing, Milwaukee, Wisconsin
Supplement VI, EA 93-150

A Notice of Violation and Proposed Imposition of Civil Penalty in the amount of $2,500 was issued July 9, 1993, to emphasize the licensee's responsibility for radiation safety at each facility, and to ensure that management effectively oversees the implementation of its NRC licensed program. The action was based on violations that included the failure to conduct area radiation surveys at the end of the work day, the failure to control licensed material, the failure to conduct training, and the failure to properly dispose of radioactive waste. The licensee responded and paid the civil penalty on August 3, 1993.

Pike Community Hospital, Waverly, Ohio
Supplement VI, EA 92-247

A Notice of Violation and Proposed Imposition of Civil Penalty in the amount of $3,750 was issued January 22, 1993, to emphasize the need for effective management oversight of NRC licensed activities by the licensee's administration, the Radiation Safety Committee, and the Radiation Safety Officer. The action was based on a significant breakdown in the control of licensed activities involving the failure to: assess personal contamination of a technologist, investigate spills and implement corrective actions, perform calculations to estimate the occupational dose from aerosols, review the ALARA program, review the radiation safety program by the Radiation Safety Committee, possess appropriate radiation detection survey equipment, maintain complete

records of sealed source leak tests and inventories, conduct dose calibrator tests and maintain complete records, conduct area surveys at the end of the day and maintain appropriate records of daily and weekly surveys, and post NRC requirements. The licensee responded in letters dated February 22 and 24, 1993. After consideration of the licensee's responses, an Order Imposing Civil Penalty was issued May 24, 1993. The licensee paid the civil penalty on July 20, 1993.

Ponce I&M Engineering Lab., Inc., Coto Laurel, Puerto Rico
Supplement VI, EA 92-240

A Notice of Violation and Proposed Imposition of Civil Penalty in the amount of $2,000 was issued June 23, 1993, to emphasize that a licensee should not benefit economically by willful violation of regulatory requirements. The action was based on a violation that involved willful use of licensed material after an NRC license had expired and before a new license was issued. The licensee responded and paid the civil penalty on July 13, 1993.

Princeton Community Hospital, Princeton, West Virginia
Supplements IV and VI, EA 93-212

A Notice of Violation and Proposed Imposition of Civil Penalties in the amount of $5,000 was issued September 16, 1993, to emphasize the importance of maintaining effective control over the radiation safety program and complying with regulatory requirements and license conditions. The action was based on violations that involved: (1) the failure to secure radiopharmaceuticals and sealed sources against unauthorized removal, and (2) the failure to prepare written directives for patient dose administrations of iodine-131 greater than 30 microcuries as required by the licensee's written medical quality management program. The licensee responded and paid the civil penalties on September 28, 1993.

Scientific Inspection Technology, Inc., Hixson, Tennessee
Supplements IV and VI, EA 93-116

A Notice of Violation and Proposed Imposition of Civil Penalty in the amount of $4,000 was issued July 22, 1993, to emphasize the importance of ensuring that appropriate emergency procedures are followed and to ensure that operational activities are conducted safely and in accordance with requirements. The action was based on an incident in which a radiographer received an estimated 275 rem extremity overexposure. The radiographer did not follow the licensee's emergency procedures, which required that he stop all activity and

notify the Radiation Safety Officer for assistance. The licensee responded and paid the civil penalty on August 20, 1993.

Siemens Power Corporation, Richland, Washington
Supplement VI, EA 93-085

A Notice of Violation and Proposed Imposition of Civil Penalty in the amount of $12,500 was issued July 2, 1993, to emphasize the importance of ensuring that activities are conducted in compliance with NRC regulations and that equipment important to criticality safety is correctly maintained. The action was based on several violations identified as a result of a spill of about 124 kilograms of low enriched uranium powder on February 7, 1993. The violations involved the installation and unauthorized bypass of an interlock switch, the failure to perform a required criticality safety analysis and the failure to identify and maintain adequate moderator exclusion controls. The licensee responded and paid the civil penalty on August 17, 1993.

St. Elizabeth Medical Center, Dayton, Ohio
Supplements IV and VI, EA 93-165

A Notice of Violation and Proposed Imposition of Civil Penalty in the amount of $1,250 was issued July 13, 1993, to emphasize the need for strict adherence to NRC requirements for the proper disposal of radioactive materials. The action was based on violations that involved the transfer of iodine-125 to a non-licensee, disposal of xenon-133 and technetium-99(m) in ordinary trash, and allowing unauthorized access to the radwaste storage area. The licensee responded and paid the civil penalty on August 5, 1993.

Steel Warehouse Company, Inc., South Bend, Indiana
Supplement V, EA 93-115

A Notice of Violation and Proposed Imposition of Civil Penalty in the amount of $250 was issued June 8, 1993, to emphasize the need for strict adherence to all NRC regulations and especially to those for the transportation of radioactive material. The action was based on a violation involving the shipment of a damaged fixed gauging device back to a vendor in violation of several DOT regulations for labelling and packaging. The licensee responded and paid the civil penalty on July 16, 1993.

U.S. Department of Agriculture, Washington, D.C.
Supplements Iv and VI, EAs 92-232 and 93-028

A Notice of Violation and Proposed Imposition of Civil Penalty in the amount of $10,000 and Confirmatory Order Modifying License (Effective Immediately) was issued March 26, 1993, to emphasize the importance of management, the Radiation Safety Committee, and the Radiation Safety Officer (1) aggressively monitoring and evaluating licensed activities to assure that activities are conducted safely and in accordance with the terms of the license, and (2) assuring that the corrective actions are long-lasting. The action was based on violations involving the failure: (1) by management to ensure that all facilities were inspected by the licensee's radiation safety staff at the required frequencies, (2) to perform leak tests of sealed sources at the required frequency and maintain required records of the results, (3) to evaluate incinerator ash and failure to maintain records of licensed material disposed of by incinerator, (4) to secure licensed material at certain locations, to post required documents at certain facilities, (5) to provide training to ancillary personnel, (7) to maintain shipping papers within the driver's reach at one facility, (8) to collect and review quarterly survey results, (9) to report inventories of unsealed material, and (10) to perform six-month inventories of sealed sources. Two other violations involved the transfer of licensed material to persons who were not authorized to possess the material and possession or use of licensed material in quantities or applications other than those authorized by USDA permits. The licensee responded in two letters dated April 22. After consideration of the licensee's responses, an Order Imposing Civil Penalty in the amount of $10,000 was issued June 23, 1993. The licensee paid the civil penalty on July 14, 1993.

B. Severity Level I, II, III Violations, No Civil Penalty

Children's Hospital, Columbus, Ohio
Supplement VI, EA 93-183

A Notice of Violation was issued July 30, 1993, based on the failure of the licensee to include in its medical quality management plan policies and procedures for the preparation of a written directive by an authorized user prior to the administration of iodine-125 or iodine-131 in excess of 30 microcuries for diagnostic procedures. The licensee immediately corrected the violation by modifying the QMP; developing a form to be used by the licensee's authorized users and a second form to verify that the written directive was followed; and training

the staff in those changes. A civil penalty was not proposed because of the licensee's good corrective actions and the licensee's good past performance.

Childress Service Corporation, Beaver, West Virginia
Supplement VI, EA 93-213

A Notice of Violation was issued September 13, 1993, based on a violation involving the relocation of a fixed nuclear density gauge containing approximately 100 millicuries of cesium-137. This relocation, performed because the facility was being dismantled, was done by an employee who was not authorized by NRC or an Agreement State to do so. Furthermore, as a result of the relocation, control of the gauge was lost and it was apparently stolen. A civil penalty was not proposed because the license identified the loss of the gauge, notified the NRC and took prompt corrective action. The corrective action included retraining all company personnel in the safety and regulatory requirements associated with fixed nuclear density gauges and informing company personnel of the circumstances associated with the unauthorized relocation of the gauge.

DePaul Medical Center, Norfolk, Virginia
Supplement VI, EA 93-185

A Notice of Violation was issued August 13, 1993, for a violation involving the administration of 106 radiopharmaceutical dosages consisting of quantities greater than 30 microcuries of sodium iodine I-131 to patients without a written directive or verification of that directive, as required by the licensee's medical quality management program (QMP). A civil penalty was not proposed because of the licensee's good corrective actions and good prior performance. The corrective actions included immediate cessation of sodium iodide I-131 procedures, retraining of all nuclear medicine technologists and authorized users in the QMP requirements, and providing copies of policies, procedures and forms related to the administration of radiopharmaceuticals.

E.S.C. Resources, Inc., Naperville, Illinois
Supplement VI, EA 93-189

A Notice of Violation was issued July 26, 1993, involving conducting licensed activities in non-Agreement States without filing the proper forms with the NRC prior to conducting these activities. A civil penalty was not proposed because the General Licensee identified the violation and promptly notified the NRC,

visited the Regional office to discuss the issues, and during the visit filed the proper forms and paid the required fees.

Hull and Associates, Toledo, Ohio
Supplement IV, EA 93-208

A Notice of Violation was issued August 20, 1993, involving the failure of a technician to secure or maintain constant surveillance of the gauge while at a temporary jobsite. A civil penalty was not proposed because of (1) the licensee's prompt and comprehensive corrective measures which included disciplining and retraining the technician involved in the incident and providing a written reminder to the other technicians of their responsibility to maintain constant surveillance or control of NRC licensed materials, and (2) the licensee's past good performance.

Jersey Shore Medical Center, Neptune, New Jersey
Supplement VI, EA 92-256

A Notice of Violation was issued August 20, 1993, for a violation involving a lack of clear procedures in the licensee's medical quality management program that led to a therapeutic misadministration to a patient undergoing teletherapy treatment. A civil penalty was not issued because: (1) the licensee instituted extensive corrective actions which included retraining of the therapy technologists in the requirements of the QM program, revision to the weekly patient chart check procedures to increase the likelihood of detection of errors prior to the initial treatment, and generation of a memorandum to the staff requiring a verification procedure for TP calculations, and incorporating that requirement as a QM procedure; (2) the licensee identified the violation; and (3) the licensee had a good prior enforcement history.

Lahey Clinic Foundation, Burlington, Massachusetts
Supplement VI, EA 92-258

A Notice of Violation was issued August 4, 1993, for violations involving a failure of the licensee's medical quality management program requirements. A civil penalty was not proposed because the licensee identified the misadministration, had a good prior enforcement history, and took prompt and comprehensive corrective actions which included: (1) initiation of a requirement that a second physicist verify the information on the computer screen prior to institution of the treatment to ensure that the parameters have been properly incorporated, (2) establishment of a written procedure

to incorporate the above requirement, and (3) prompt training of all authorized users and physicists shortly after the event to preclude a recurrence.

Paulus, Sokolowski and Sartor, Inc., Warren, New Jersey
Supplement IV, EA 93-196

A Notice of Violation was issued August 27, 1993, involving the loss of a nuclear gauge containing approximately 10 millicuries of cesium-137 and 50 millicuries of americium-241. A civil penalty was not proposed because the licensee identified the violation and took prompt and extensive corrective actions which included (1) reinstructing all gauge users in the proper methods for securing and maintaining proper surveillance of the gauge, (2) reinforcing the policy of maintaining control over the gauges, and (3) revising the management policy to require disciplinary action upon recurrence of the event.

Radiation Protection Services, Ltd., Naperville, Illinois
Supplement VI, EA 93-211

A Notice of Violation was issued August 23, 1993, involving the General Licensee who on at least 20 occasions since 1992 had engaged in licensed activities in non-Agreement States without filing the required forms. A civil penalty was not issued because the licensee identified the violation and promptly notified the NRC and corrected the problem.

Sacred Heart Hospital, Yankton, South Dakota
Supplement VI, EA 93-081

A Notice of Violation was issued July 9, 1993, involving the failure of the licensee to establish and maintain a quality management program as required by 10 CFR 35.32. A civil penalty was not proposed because the licensee took prompt corrective action by submitting the quality management plan, and the licensee's most recent good inspection history.

Sharlin Radiological Associates, Hackensack, New Jersey
Supplement VI, EA 93-018

A Notice of Violation was issued September 1, 1993, for violations involving failures of the licensee's medical quality management program that led to a therapeutic misadministration to a patient undergoing cobalt-60 teletherapy treatment. A civil penalty was not proposed because the licensee identified the violation, had a good prior enforcement history, and took corrective actions which included (1) institution of a requirement that for all treatments consisting of a single fraction,

the treatment time calculations will be verified by the technologist who measured the patient and that all calculations and treatment parameters will be checked by the physicist before treatment is given; and (2) prompt performance of the annual review of the licensee's QM program by the licensee, the licensee's physicist, the entire technical staff, including a review of this misadministration and the licensee's corrective actions.

Soil Engineers and Scientists, Inc., Trenton, Michigan
Supplement IV, EA 93-221

A Notice of Violation was issued September 22, 1993, involving damage to a soil moisture/density gauge containing licensed material. The gauge technician left the device on the ground unattended to prepare some paperwork. While he was doing this, a foreman from another construction company stopped to talk to him. When the foreman drove away he hit the gauge, causing damage to the case but not to the source or source rod. A civil penalty was not proposed because of the licensee's prompt and comprehensive corrective actions which included terminating the technician, providing a written reminder to the other technicians of their responsibility to maintain constant surveillance and control of NRC-licensed materials, conducting a special meeting with all gauge users to discuss the incident, and improving an existing audit program to include a monthly, announced audit of each gauge user by the Radiation Safety Officer. The licensee also had good past performance.

St. John's Medical Center, Anderson, Indiana
Supplement VI, EA 93-132

A Notice of Violation was issued July 28, 1993, involving a teletherapy misadministration. A civil penalty was not proposed because of the licensee's identification and corrective actions which included a change to the procedures to add an additional independent check of the dose calculation, and shortening the time of review from three to two days when administering more than three fractions. The licensee also had good past performance.

University of Massachusetts, Worcester, Massachusetts
Supplement IV, EA 93-177

A Notice of Violation was issued July 21, 1993, involving the failure of the licensee to maintain constant surveillance and immediate control of a cobalt-60 teletherapy unit. The keys to the teletherapy suite were provided to contractor personnel to permit removal

of furniture and the key to the teletherapy console was left in the suite. A civil penalty was not proposed because the licensee identified the violation and initiated immediate actions to enhance the security of the teletherapy unit and because the licensee also had a good past enforcement history.

III. INDIVIDUAL ACTIONS

Richard J. Gardecki IA 93-001

An Order Prohibiting Involvement in Certain NRC-Licensed Activities was issued May 4, 1993 to the above individual. The Order was based on the deliberate submittal of false information to former employers to obtain employment in licensed activities and to NRC investigators. The Order prohibits the individual, for a period of five years, from being named on an NRC license as a Radiation Safety Officer or supervising licensed activities for an NRC licensee or an Agreement State licensee while conducting activities within NRC jurisdiction. It also requires for the same period notice by copy of the Order to prospective employers engaged in licensed activities and notice to the NRC on acceptance of employment in licensed activities.

I.A. REACTOR LICENSEES, CIVIL PENALTIES AND ORDERS

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
799 ROOSEVELT ROAD
GLEN ELLYN, ILLINOIS 60137-5927

August 31, 1993

Docket No. 50-440
License No. NPF-58
EA 93-176

Cent or Service Company
ATTN Mr. D. C. Shelton
Senior Vice President
Nuclear - Perry
c/o The Cleveland Electric
Illuminating Company
10 Center Road
Perry, OH 44081

Dear Mr. Stratman:

SUBJECT: PERRY NUCLEAR POWER PLANT
NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY - $200,000
(NRC INSPECTION REPORT NO. 50-440/93011(DRP))

This refers to the inspection conducted during the period of May 1 through June 23, 1993, at Perry Nuclear Power Plant. The inspection reviewed the circumstances surrounding fouling and deformation of the Residual Heat Removal (RHR) suction strainers. The report documenting this inspection was sent to you by letter dated July 12, 1993. An enforcement conference was held on July 20, 1993, and a report summarizing the conference was sent to you by letter dated July 26, 1993.

During the first refueling outage in 1989, you identified that the cleanliness of the suppression pool was poor, and the RHR A and B strainers were flushed of debris. On May 22, 1992, during the third refueling outage, you again found the RHR A and B suppression pool strainers fouled and excessive debris on the suppression pool floor. However, the effects of this fouling and debris on operability of the RHR system was not adequately evaluated, nor were the strainers or suppression pool cleaned prior to plant startup in June 1992. After operating with the fouled strainers for approximately 7 months, your staff cleaned the strainers and the containment side of the suppression pool during the mid-cycle outage which began in January 1993. After cleaning the strainers, you found that they were deformed and cracked. Therefore, in February 1993 you replaced them prior to startup. However, despite the fact that video tapes of the

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original strainers showed that the debris that was removed from the stainers had been entangled with fibrous material, you failed to determine the source of that fibrous material.

As a result of the service water pipe rupture and subsequent reactor scram in March 1993, the RHR B pump was operated for approximately 7 hours in the suppression pool cooling mode. The RHR B strainer was later found to be again fouled and deformed. The material fouling the RHR B strainer was subsequently identified as predominately filter media from the drywell ventilation system. On April 19, 1993, your engineering evaluation determined that excessive differential pressure across the RHR A and B strainers could have compromised the ability of the RHR system to perform its required 100 days of post loss-of-coolant accident cooling.

In response to NRC Confirmatory Action Letter RIII-93-007 dated April 16, 1993, you committed to ensuring acceptable levels of cleanliness in the suppression pool and in the containment and drywell (which directly affect suppression pool cleanliness) prior to plant startup. However, during an NRC inspection on May 25, 1993, substantial cleanliness discrepancies were identified in the drywell and containment even though your cleanup of these areas was essentially complete. The items identified had the potential for significant fouling of the strainers had they fallen into the suppression pool.

Section I of the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice) describes a violation involving (a) the failure to take appropriate corrective action following identification of debris in the suppression pool on July 17, 1989, and May 22, 1992, and following observation of RHR A and B strainer fouling on May 22, 1992; (b) the failure to identify and remove fibrous material from the suppression pool, drywell, and containment following the identification of the RHR A and B strainer deformation on January 16, 1993, and identification of debris entangled with fibrous material on the strainers in February 1993; and (c) the failure to adequately clean the drywell and containment to your acceptance standards developed in response to Confirmatory Action letter RIII-93-007.

This violation resulted from your failure to promptly recognize, adequately assess (including an appropriate operability determination), and correct the fouling, deformation, and cracking of the RHR strainers and the unacceptable level of cleanliness of the suppression pool. Additionally, management involvement in identifying and eliminating the source of fibrous materials in the suppression pool was inadequate. Finally, management coordination of the cleaning activities in the drywell and containment was insufficient. The potential safety consequence of the violation is that as a result of debris in the

drywell, containment, and suppression pool, the RHR A and B strainers became fouled beyond their design basis such that the RHR system may not have been able to provide long term cooling for the design assumed 100 days of continuous post loss-of-coolant accident operation without operator intervention.

The failure of your personnel to quickly recognize the safety significance of suppression pool cleanliness is of particular concern in light of the serious safety consequences of strainer fouling and prior NRC and industry notifications addressing this matter. The repeated missed opportunities to identify and correct unacceptable suppression pool cleanliness conditions and to fully and effectively implement all of your corrective actions after the conditions had been identified reflect weaknesses in your ability to promptly identify and correct conditions that could degrade operability of plant safety equipment, a significant failure to effectively communicate your management expectations to supervisors and workers and to assure those expectations are properly implemented. In addition, your failure to assure proper cleanup of the containment and drywell is of particular concern given your commitments to the NRC and the resulting high visibility of this activity within your company, as well as your substantial commitment of resources.

At the enforcement conference we acknowledged your most recent corrective actions for the violations, including the programs and initiatives you are undertaking to improve performance at Perry. While you now appear to be taking appropriate steps, proper oversight by you and your management team is needed to assure that the desired results are achieved. Many of these programs and initiatives involve changes in the operating philosophy of the organization. The success of these changes depends on the ability of you and your management team to maintain a proper safety focus, to instill sound safety values at all levels of the organization, and to translate those values into improved plant performance.

The violation represents a significant failure to take corrective actions which resulted in the RHR system being degraded to the extent that it may not have been capable of performing its accident response function. Therefore, in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy) 10 CFR Part 2, Appendix C, this violation has been categorized at Severity Level III.

To emphasize the need for appropriate operability determinations, and prompt recognition, adequate assessment, and correction of nonconforming conditions, I have been authorized after consultation with the Director, Office of Enforcement, and the Deputy Executive Director for Nuclear Reactor Regulation, Regional Operations and Research to issue the enclosed Notice of

Violation and Proposed Imposition of Civil Penalty (Notice) in the amount of $200,000 for the violation described in the Notice. The base value of a civil penalty for a Severity Level III violation is $50,000. The civil penalty adjustment factors in the Enforcement Policy were considered.

The base civil penalty was escalated 50 percent because the NRC identified the violation. The base civil penalty was mitigated 50 percent for your comprehensive corrective actions as presented at the enforcement conference. The base civil penalty was escalated 100 percent for your poor past performance. In the most recent SALP 12 report covering the period of November 1, 1991, through January 31, 1993, Safety Assessment and Quality Verification was rated Category 3. The areas of Maintenance and Surveillance, and Engineering and Technical Support were rated Category 2, but declining trends were noted in each area. Furthermore, you were cited for a Severity Level III violation with a civil penalty (reference EA 91-118, dated October 30, 1991), and several Severity Level IV violations in the past two years, dealing with ineffective management control and oversight, and engineering related problems. Additional escalation of 100 percent was applied for the opportunity to identify the problem provided by the issuance of NRC Information Notice 92-71 "Partial Plugging of Suppression Pool Strainers at a Foreign BWR" on September 30, 1992. The base civil penalty was further escalated 100 percent for duration. The significant potential for the RHR system not being able to perform its intended safety function existed from initial plant startup until March 1993. The other adjustment factor in the Policy was considered and no further adjustment to the base civil penalty is considered appropriate. Therefore, based on the above, the base civil penalty has been increased 300 percent.

Section II of the Notice describes a violation not assessed a civil penalty involving an inadequate work order for performing a test run of RHR pump "B" on April 15, 1993.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. In your response, you should document the specific actions taken and any additional actions you plan to prevent recurrence. After reviewing your response to this Notice, including your proposed corrective actions and the results of future inspections, the NRC will determine whether further NRC enforcement action is necessary to ensure compliance with NRC regulatory requirements.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter, its enclosure, and your responses will be placed in the NRC Public Document Room.

The responses directed by this letter and the enclosed Notice are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, Public Law No. 96-511.

Sincerely,

John B. Martin
Regional Administrator

Enclosure:
Notice of Violation and Proposed
Imposition of Civil Penalty

cc w/enclosure:
R. A. Stratman, Vice President, Nuclear
R. W. Schrauder, Director, Nuclear
Services Department
D. P. Igyarto, General Manager,
Perry Nuclear Power Plant
K. P. Donovan, Manager,
Licensing and Compliance Section
N. L. Bonner, Director, Perry
Nuclear Engineering Dept.
H. Ray Caldwell, General
Superintendent Nuclear Operations
Licensing Fee & Debt Collection
Branch
Resident Inspector, RIII
Terry J. Lodge, Esq.
James R. Williams, State of Ohio
Robert E. Owen, Ohio
Department of Health
A. Grandjean, State of Ohio
Public Utilities Commission

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

Cleveland Electric Illuminating Company
Perry Nuclear Power Plant
Unit 1

Docket No. 50-440
License No. NPF-58
EA 93-176

During an NRC inspection conducted from May 1 through June 23, 1993, violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C, the Nuclear Regulatory Commission proposes to impose a civil penalty pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (Act), 42 U.S.C. 2282, and 10 CFR 2.205. The particular violations and associated civil penalty are set forth below:

I. Violation Assessed a Civil Penalty

10 CFR Part 50, Appendix B, Criterion XVI, "Corrective Action," requires, in part, that measures be established to assure that conditions adverse to quality are promptly identified and corrected. In the case of significant conditions adverse to quality, the measures shall assure that the cause of the condition is determined and corrective action taken to preclude repetition. The identification of the significant condition adverse to quality, the cause of the condition, and the corrective action shall be documented and reported to the appropriate levels of management.

Contrary to the above:

A. On July 17, 1989, and May 22, 1992, following the identification of debris in the suppression pool, and on May 22, 1992, following observation of debris on the Residual Heat Removal (RHR) A and B strainers, significant conditions adverse to quality, the licensee failed to promptly identify the cause for the poor cleanliness of the suppression pool and strainer fouling and failed to take adequate corrective action to prevent repetition. Further, the debris and strainer fouling were not documented and reported to the appropriate levels of management.

B. Subsequent to the identification of RHR A and B strainer deformation on January 16, 1993, and identification of debris entangled with fibrous material as observed in video tapes of the strainers taken in February 1993, significant conditions adverse to quality, the licensee failed to identify the presence of fibrous material in the suppression pool as the cause of the strainer fouling and failed to take

adequate corrective action to remove the fibrous material from the suppression pool, drywell, and containment.

C. After identifying the strainer fouling in May 1993 the licensee undertook a drywell cleanup effort and during that effort and the subsequent inspection in the drywell failed to identify a condition adverse to quality. Specifically, on May 25, 1993, following the licensee's efforts, numerous discrepancies, which constituted a condition adverse to quality, were identified during an NRC inspection of the drywell using the licensee's cleanliness standards. For example, the NRC identified numerous items loose in the drywell that could have impacted the performance of the suppression pool including tools, nuts, bolts, plastic bags, rags, tape, a sign, a bottle, a tube of lubricant, and dirt and dust accumulations behind ventilation units. Furthermore, the licensee had not identified the containment rattle space as an area requiring cleaning.

This is a Severity Level III violation (Supplement I). Civil Penalty - $200,000.

II. Violation Not Assessed a Civil Penalty

10 CFR Part 50, Appendix B, Criterion V, "Instructions, Procedures, and Drawings," requires, in part, that activities affecting quality be prescribed by documented instructions, procedures, or drawings, of a type appropriate to the circumstances. Instructions, procedures, or drawings shall include appropriate quantitative or qualitative acceptance criteria for determining that important activities have been satisfactorily accomplished.

Contrary to the above, on April 15, 1993, Work Order 930011944, for performing a test run of Residual Heat Removal (RHR) pump "B" to monitor suction pressure (with known debris on the suction strainer), an activity affecting quality, was not appropriate to the circumstances in that it did not specify expected suction pressure values or what action to take upon observation of abnormal suction pressure values.

This is a Severity Level IV violation (Supplement I).

Pursuant to the provisions of 10 CFR 2.201, Cleveland Electric Illuminating Company (Licensee) is hereby required to submit a written statement of explanation to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, within 30 days

of the date of this Notice of Violation and Proposed Imposition of Civil Penalty (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each alleged violation: (1) admission or denial of the alleged violation, (2) the reasons for the violation if admitted, and if denied, the reasons why, (3) the corrective steps that have been taken and the results achieved, (4) the corrective steps that will be taken to avoid further violations, and (5) the date when full compliance will be achieved. If an adequate reply is not received within the time specified in this Notice, an Order or a Demand for Information may be issued as to why the license should not be modified, suspended, or revoked or why such other action as may be proper should not be taken. Consideration may be given to extending the response time for good cause shown. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, this response shall be submitted under oath or affirmation.

Within the same time as provided for the response required under 10 CFR 2.201, the Licensee may pay the civil penalty by letter addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, with a check, draft, money order, or electronic transfer payable to the Treasurer of the United States in the amount of the civil penalty proposed above, or may protest imposition of the civil penalty in whole or in part, by a written answer addressed to the Director, Office of Enforcement, U. S. Nuclear Regulatory Commission. Should the Licensee fail to answer within the time specified, an order imposing the civil penalty will be issued. Should the Licensee elect to file an answer in accordance with 10 CFR 2.205 protesting the civil penalty, in whole or in part, such answer should be clearly marked as an "Answer to a Notice of Violation" and may: (1) deny the violations listed in this Notice in whole or in part, (2) demonstrate extenuating circumstances, (3) show error in this Notice, or (4) show other reasons why the penalty should not be imposed. In addition to protesting the civil penalty in whole or in part, such answer may request remission or mitigation of the penalty.

In requesting mitigation of the proposed penalty, the factors addressed in Section V.B of 10 CFR Part 2, Appendix C, should be addressed. Any written answer in accordance with 10 CFR 2.205 should be set forth separately from the statement or explanation in reply pursuant to 10 CFR 2.201, but may incorporate parts of the 10 CFR 2.201 reply by specific reference (e.g., citing page and paragraph numbers) to avoid repetition. The attention of the Licensee is directed to the other provisions of 10 CFR 2.205, regarding the procedure for imposing a civil penalty.

Upon failure to pay any civil penalty due which subsequently has been determined in accordance with the applicable provisions of 10 CFR 2.205, this matter may be referred to the Attorney

General, and the penalty, unless compromised, remitted, or mitigated, may be collected by civil action pursuant to Section 234c of the Act, 42 U.S.C. 2282c.

The responses noted above (Reply to Notice of Violation, letter with payment of civil penalty, and Answer to a Notice of Violation) should be addressed to: Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555 with a copy to the Regional Administrator, U.S. Nuclear Regulatory Commission, Region III, 799 Roosevelt Road, Glen Ellyn, Illinois 60137, and a copy to the NRC Resident Inspector at the Perry Nuclear Power Plant.

Dated at Glen Ellyn, Illinois
this 31st day of August 1993

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
799 ROOSEVELT ROAD
GLEN ELLYN, ILLINOIS 60137-5927

July 15, 1993

Docket Nos. 50-237 and 50-249
License Nos. DPR-19 and DPR-25
EA 93-019

Commonwealth Edison Company
ATTN: Mr. Michael J. Wallace
Vice President
Chief Nuclear Officer
Executive Towers West III, Suite 300
1400 Opus Place
Downers Grove, Illinois 60515

Dear Mr. Wallace:

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY - $75,000
(INSPECTION REPORT NO. 50-457/93006)

This refers to the routine safety inspection conducted during the period of December 14, 1992, to January 29, 1993, at the Dresden Nuclear Power Plant Units 2 and 3. This inspection included a review of the circumstances surrounding the degraded containment cooling service water (CCSW) system flow identified on April 2, 1992. The report documenting the inspection findings was mailed to you by letter dated February 12, 1993. During the inspection, apparent violations of NRC requirements were identified. An enforcement conference was held at the NRC's Region III office on February 22, 1993, to discuss the apparent violations. The enforcement conference report was sent to you by letter dated February 25, 1993. By letter dated March 5, 1993, you provided additional documentation to the NRC which supported your position. The Office of Nuclear Reactor Regulation (NRR) provided its response to that submittal in its July 12, 1993, letter from John Zwolinski.

On April 2, 1992, a test disclosed that the Dresden Unit 3 CCSW train flow (with two CCSW pumps running) was 5,600 gallons per minute (gpm) instead of the expected 7,000 gpm. After determining that the system met the Technical Specification operability requirements by demonstrating that each of the individual CCSW pumps would provide 3,500 gpm at 180 psig, the degraded flow issue was referred to your engineering staff for evaluation. Your subsequent evaluations, culminating with the 10 CFR 50.59 Safety Evaluation of December 1, 1992, concluded

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that reductions in the CCSW heat removal capability were justified and that the design bases configuration of the CCSW system was one pump.

Two violations are described in Section I of the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice) which have collectively been categorized as a Severity Level III problem. Both violations involve your failure to adequately evaluate changes made to the CCSW system described in the Final Safety Analysis Report (FSAR) in accordance with 10 CFR 50.59. The first violation pertains to your failure to recognize the change as an unreviewed safety question. The second violation pertains to inadequacies with your analyses which formed the bases for your conclusion that no unreviewed safety questions existed. The failure to perform adequate safety evaluations and to obtain Commission approval prior to accepting changes to important systems such as the Dresden Station ultimate heat sink represents a significant safety and regulatory concern.

While changes to the CCSW system may have occurred without adequate evaluations several years ago, the focus of this action is on the performance of your staff after identifying the degraded flow conditions in April 1992. Specifically, we are concerned that your engineering staff put its effort toward explaining away the unexpected flow conditions, rather than fully and promptly exploring safety ramifications of the situation and taking corrective actions to restore the reduced flow. Instead, from April to December 1992 you engaged in a series of partial or incomplete assessments to justify the as-found condition of the CCSW system. Each assessment ended when it appeared, at least on the surface, that there was no problem. The assessments were inadequate in that they either (a) failed to address important factors which reduced the margins of safety or (b) involved incorrect interpretation of licensing commitments. More specifically, with regard to the latter concern, your assessments were based on statements in the FSAR and other documents taken out of context.

Your handling of this issue reflects significant weaknesses in technical support activities at Dresden. It underscores the importance of fully understanding the design of your facility. We, therefore, strongly encourage continued efforts to improve your knowledge of plant design including, among other things, the ongoing and planned initiatives to reconstitute key design documents and parameters.

The violations in Section I represent a significant failure to meet the requirements of 10 CFR 50.59. Therefore, in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy) 10 CFR Part 2, Appendix C, these violations have been categorized as a Severity

Level III problem.

To emphasize the need to ensure that the facility as described in the FSAR is maintained or properly changed in accordance with the provisions of 10 CFR 50.59, I have been authorized, after consultation with the Director, Office of Enforcement and the Deputy Executive Director for Nuclear Reactor Regulation, Regional Operations and Research to issue the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice) in the amount of $75,000 for the violations set forth in Section I of the Notice.

The base value of a civil penalty for a Severity Level III problem is $50,000. The adjustment factors in the Enforcement Policy were considered. The civil penalty was increased 50% ($25,000) because the NRC identified the violation. The other factors were considered and no other adjustment to the base was considered appropriate.

Section II of the Notice contains a violation involving the failure to perform an adequate post-modification test on the Unit 2 CCSW when the system was modified to supply the backup control room ventilation system with cooling.

Finally, in light of the significant concerns raised above and in Mr. Zwolinski's letter concerning your submittal, I will be contacting you to arrange a meeting to discuss the quality of CECo submittals to the NRC.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. In your response, you should document the specific actions taken and any additional actions you plan to prevent recurrence. In light of your staff's statements at the enforcement conference, your response should also address the specific actions you have taken or will take to ensure that the FSAR contains the necessary CCSW system design basis information and notes the presence of any FSAR information that should not be interpreted as system design basis information. After reviewing your response to this Notice, including your proposed corrective actions and the results of future inspections, the NRC will determine whether further NRC enforcement action is necessary to ensure compliance with NRC regulatory requirements.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter, its enclosure, and your response will be placed in the NRC Public Document Room.

The response directed by this letter and the enclosed Notice are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, Public Law No. 96-511.

Sincerely,

John B. Martin
Regional Administrator

Enclosure:
Notice of Violation and Proposed
Imposition of Civil Penalty

cc w/enclosure:
DCD/DCB (RIDS)
M. Lyster, Site Vice President
L. DelGeorge, Vice President,
Nuclear Oversight and Regulatory
Services
C. Schroeder, Station
Manager
J. Shields, Regulatory Assurance
Supervisor
D. Farrar, Nuclear Regulatory
Services Manager
OC/LFDCB
Resident Inspectors LaSalle,
Dresden, Quad Cities, Clinton
Richard Hubbard
J. W. McCaffrey, Chief, Public
Counsel, State of Illinois Center

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

Commonwealth Edison Company
Dresden Station,
Units 2 and 3

Docket Nos. 50-237 and 50-249
License Nos. DPR-19 and DPR-25
EA 93-019

During an NRC inspection conducted from December 14, 1992, to January 29, 1993, violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C, the Nuclear Regulatory Commission proposes to impose a civil penalty pursuant to Section 234 of the Atomic energy Act of 1954, as amended (Act), 421 U.S.C. 2282, and 10 CFR 2.205. The particular violations and associated civil penalty are set forth below:

I. Violations Assessed a Civil Penalty

10 CFR 50.59, Changes, Tests and Experiments allows a licensee to make changes to the facility as described in the final safety analysis report (FSAR) without prior Commission approval unless the proposed change involves a change in the technical specifications incorporated in the license or an unreviewed safety question. A proposed change is deemed, in part, to involve an unreviewed safety question if the margin of safety as defined in the basis for any technical specification is reduced.

10 CFR 50.59 also requires, in part, that the licensee maintain records of changes in the facility and these records must include a written safety evaluation which provides the bases for the determination that the proposed change does not involve an unreviewed safety question.

FSAR Section 5.2.3.3 (Rev. June 1990), "Containment Characteristics After Reactor Blowdown," stated, in part, the long-term pressure and temperature response of the primary containment was analyzed for a minimum of two containment cooling service water (CCSW) pumps available to mitigate the design basis accident (DBA).

FSAR Table 6.2.4:1 (Rev. June 1992), "LPCI/Containment Coolant Equipment Specifications," stated the train heat load was 95 million BTU/hr and the train CCSW flow was 7,000 gpm.

1. Contrary to the above, on December 1, 1992, changes were accepted to the facility as described in the FSAR, reducing the specified (CCSW) train flow below 7000 gpm and the CCSW heat load below 95 million BTU/hr, which involved the following unreviewed safety questions and prior Commission approval was not obtained:

(a) Containment overpressure was required to provide adequate emergency core cooling system (ECCS) pump net positive suction head (NPSH). As a result of the change, the margin to safety as defined in the basis for Technical Specification 3.7.A. was reduced by now requiring containment pressure to provide adequate NPSH. Specifically, Technical Specification Basis 3.7.A stated: "For an initial maximum suppression chamber water temperature of 95°F and assuming the normal complement of containment cooling pumps (2 LPCI pumps and 2 containment cooling service water pumps) containment pressure is not required to maintain adequate net positive suction head (NPSH) for the core spray, LPCI and HPCI pumps."

(b) Long-term containment pressure was increased above eight psig. As a result of the change, the margin to safety as defined in the basis for Technical Specification 3.5.B. was reduced by that increase above eight psig. Specifically, Technical Specification Basis 3.5.B stated: "For the flow specified, the containment long-term pressure is limited to less than eight psig and, therefore, is more than ample to provide the containment heat removal capability."

2. Contrary to the above, on December 1, 1992, the licensee accepted changes to the CCSW, reduction of the train flow below 7,000 gpm and heat load below 95 million BTU/hr, without performing an adequate written safety evaluation to provide the bases that these changes did not constitute an unreviewed safety question. Specifically, the safety evaluation was deficient in the following areas:

(a) New containment performance and decay heat computer codes were used for the safety evaluation without adequate validation that the codes properly modeled the Dresden Nuclear Station plant configuration. Benchmarking was limited to a comparison with the results of the old codes using different inputs for key parameters.

(b) Net positive suction head (NPSH) calculations for core cooling pumps were not performed for the most limiting conditions that could occur. Potentially more severe accidents were not considered, flows were not corrected for instrument inaccuracies to provide the most limiting conditions, and the limiting pump (core spray) was not considered in the calculations.

(c) Methodologies were employed which resulted in non-conservative conclusions to the NPSH calculations. Specifically, the acceptance criterion for adequate NPSH was defined as being one percent below the vendor specified value.

This is a Severity Level III problem (Supplement I).
Civil Penalty - $75,000

II. Violation Not Assessed a Civil Penalty

10 CFR Part 50, Appendix B, Criterion XI, "Test Control," requires, in part, that a test program be established to assure that all testing required to demonstrate that systems and components will perform satisfactorily in service is identified and performed in accordance with written test procedures which incorporate the requirements and acceptance limits contained in the applicable design documents.

Contrary to the above, the testing performed to demonstrate the acceptability of modification M12-2/3-82-1, which allowed the Unit 2 Containment Cooling Service Water System (CCSW) pumps to supply cooling to the backup control room ventilation system under accident conditions, failed to demonstrate that the affected systems would perform satisfactorily in service. Specifically, the written test procedure failed to incorporate acceptance limits such as minimum CCSW system discharge pressure and flow rate.

This is a Severity Level IV violation (Supplement I).

Pursuant to the provisions of 10 CFR 2.201, Commonwealth Edison Company (Licensee) is hereby required to submit a written statement or explanation to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, within 30 days of the date of this notice of Violation and Proposed Imposition of Civil Penalty (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each alleged violation: (1) admission or denial of the alleged violation, (2) the reasons for the violation if admitted, and if denied, the reasons why, (3) the corrective steps that have been taken and results achieved, (4) the corrective steps that will be taken to avoid further violations, and (5) the date when full compliance will be achieved. If an adequate reply is not received within the time specified in this Notice, an order or a Demand for Information may be issued as to why the license should not be modified, suspended, or revoked or why such other action as may be proper should not be taken. Consideration may be given to extending the response time for good cause shown. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, this response shall be submitted under oath or affirmation.

Within the same time as provided for the response required above under 10 CFR 2.201, the Licensee may pay the civil penalty by letter addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, with a check, draft, money order, or electronic transfer payable to the Treasurer of the United States in amount of the civil penalty proposed above, or may protest imposition of the civil penalty in whole or in part, by a written answer addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission. Should the Licensee fail to answer within the time specified, an order imposing the civil penalty will be issued. Should the Licensee elect to file an answer in accordance with 10 CFR 2.205 protesting the civil penalty, in whole or in part, such answer should be clearly marked as an "Answer to a Notice of Violation" and may: (1) deny the violation listed in this Notice, in whole or in part, (2) demonstrate extenuating circumstances, (3) show error in this Notice, or (4) show other reasons why the penalty should not be imposed. In addition to protesting the civil penalty in whole or in part, such answer may request remission or mitigation of the penalty.

In requesting mitigation of the proposed penalty, the factors addressed in Section VI.B.2 of the 10 CFR Part 2, Appendix C, should be addressed. Any written answer in accordance with 10 CFR 2.205 should be set forth separately from the statement or explanation in reply pursuant to 10 CFR 2.201, but may incorporate parts of the 10 CFR 2.201 reply by specific reference (e.g., citing page and paragraph numbers to avoid repetition. The attention of the licensee is directed to the other provisions of 10 CFR 2.205, regarding the procedure for imposing a civil penalty.

Upon failure to pay any civil penalty due which subsequently has been determined in accordance with the applicable provisions of 10 CFR 2.205, this matter may be referred to the Attorney General, and the penalty, unless compromised, remitted, or mitigated, may be collected by civil action pursuant to Section 234c of the Act, 42 U.S.C. 2282c.

The response noted above (Reply to Notice of Violation, letter with payment of civil penalty, and Answer to a Notice of Violation) should be addressed to: Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington D. C. 20555 with a copy to the Regional Administrator, U.S. Nuclear Regulatory Commission, Region III, 799 Roosevelt Road, Glen Ellyn, Illinois 60137, and with a copy to the NRC Resident Inspector at the Dresden Station.

FOR THE NUCLEAR REGULATORY COMMISSION

John B. Martin
Regional Administrator
Region III

Dated at Glen Ellyn, Illinois
the 15 day of July 1993

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
799 ROOSEVELT ROAD
GLEN ELLYN, ILLINOIS 60137-5927

July 30, 1993

Docket No. 50-265
License No. DPR-30
EA 93-127

Commonwealth Edison Company
ATTN: Mr. M. J. Wallace
Vice President and
Chief Nuclear Officer
Executive Towers West III
1400 Opus Place, Suite 300
Downers Grove, Illinois 60515

Dear Mr. Wallace:

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTIES - $100,000
(NRC INSPECTION REPORT NO. 50-265/93012(DRP))

This refers to the special safety inspection conducted during the period of March 29 through May 11, 1993, at Quad Cities Station, Unit 2. The inspection included a review of the circumstances surrounding the inoperability of the Unit 2 and Unit 1/2 diesel generators. The report documenting this inspection was sent to you by letter dated May 25, 1993. During this inspection violations of NRC requirements were identified.

An enforcement conference was held on June 2, 1993, to discuss the violations, their causes, and your corrective actions. The report summarizing the conference was sent to you by letter dated June 10, 1993. You reported the Unit 1/2 diesel generator event by telephone on April 22, 1993, and subsequently submitted a written report dated May 14, 1993. You also submitted a written report dated June 30, 1993, regarding the Unit 2 diesel generator event.

On April 22, 1993, operators were performing an undervoltage functional test on the Unit 1/2 diesel generator. While performing the test, the Unit 1/2 diesel generator cooling water pump failed to start as required. Subsequently, you identified an original plant design deficiency in the Unit 1/2 diesel generator cooling water pump Bus 28 close logic circuitry that would not allow the pump to automatically restart if it had been fed from Bus 28 and received an undervoltage trip signal. This

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deficiency resulted in the Unit 1/2 diesel generator being inoperable for a Unit 2 loss of coolant accident coincident with a loss of offsite power.

On March 29, 1993, an operator identified that the oiler for the Unit 2 diesel generator cooling water pump was not installed at a sufficient height to lubricate the pump bearings. Upon pump disassembly, you identified significant damage to the bearings making the cooling water pump and Unit 2 diesel generator inoperable. You determined that during pump maintenance in January 1992, the mechanic reversed the piping to the oiler, which resulted in the oiler being located lower than the required level. Your investigation concluded that the cooling water pump and Unit 2 diesel generator were operable until at least February 16, 1993, following completion of a diesel generator operability surveillance.

Three violations are described in the enclosed Notice of Violation and Proposed Imposition of Civil Penalties (Notice). Violation I.A involves operation of Unit 2 between August 15, 1972, and March 6, 1993, with the Unit 1/2 diesel generator inoperable contrary to Technical Specifications. Violation I.B involves operation of Unit 2 between February 16 and March 6, 1993, with the Unit 2 diesel generator inoperable, contrary to Technical Specifications. Violation II concerns your failure to submit a Licensee Event Report within 30 days of discovery of the cooling water pump bearing problem.

The root cause of Violation I.A was an original plant design error. Your inadequate review of Information Notice 88-75 and its associated supplement, and your failure to perform equipment operability tests following degraded voltage modifications in 1992 were missed opportunities to identify the violation. Furthermore, the inadequate anti-pump circuit logic design was not identified during the performance of several 4kV undervoltage functional tests (QOS 6500-1 and 6500-4) in 1992, due in part to ambiguous instructions for aligning the power select switches and the failure of test personnel to thoroughly question unexpected results encountered during the March test. Had more perceptive engineers been involved, the design deficiency likely would have been identified at that time.

The root cause of Violation I.B was failure of management to ensure the assigned mechanic had adequate training to disassemble and reassemble the Unit 2 diesel generator cooling water pump in accordance with plant procedures. This was particularly a problem in view of the fact that other mechanics were also unaware of the proper way to install the type of oiler used on the diesel generator cooling water pump.

Regarding Violation I.A, you took a number of corrective actions including a modification to prevent breaker lock-up, reevaluation of the applicability of Information Notice 88-75, proposed procedure upgrades, and issuance of lessons learned to all Commonwealth Edison sites. You acknowledged at the enforcement conference that your modification testing program at the time of the 1985 Appendix R modification was not as rigorous as present standards, and you improved your program in 1986. However, you proposed limiting your review sample to only those modifications made during the past two years. Such a limited review would not look at the modifications that were made prior to the upgrade of your modification testing program.

Regarding Violation I.B, your corrective actions included replacing the pump, promptly inspecting other safety related pump oilers, and initiating training for all mechanics and plant operators on proper oiler installation.

Violations I.A and I.B each represent a significant failure to comply with the action statement for a Technical Specification Limiting Condition for Operation. Therefore, in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy) 10 CFR Part 2, Appendix C, each violation has been categorized at Severity Level III.

I am concerned with the history of safety system failures at Quad Cities and your inability to identify root causes and prevent occurrence. To emphasize the need for management involvement and oversight of activities affecting safety related systems and to ensure adequate engineering reviews and maintenance activities involving safety system performance, I have been authorized after consultation with the Director, Office of Enforcement, and the Deputy Executive Director for Nuclear Reactor Regulation, Regional Operations and Research to issue the enclosed Notice of Violation and Proposed Imposition of Civil Penalties (Notice) in the amount of $100,000 for the violations described in the Notice. The base value of a civil penalty for a Severity Level III violation is $50,000. The civil penalty adjustment factors in the Enforcement Policy were considered for each violation.

Regarding Violation I.A, the base civil penalty was mitigated 50 percent since you identified the violation. The base civil penalty was not mitigated for your corrective actions since the corrective actions were not particularly extensive. The base civil penalty was escalated 100 percent for your prior opportunities to identify the violation. These included your inadequate review of Information Notice 88-75 and its associated supplement, and your failure to perform adequate equipment operability tests following degraded voltage modifications in 1992. The other adjustment factors in the Policy were considered

and no further adjustment to the base civil penalty is considered appropriate. Therefore, based on the above, the base civil penalty for Violation I.A has been increased by 50 percent.

Regarding Violation I.B, the base civil penalty was mitigated by 50 percent for identification because of the excellent performance by the operator who observed the abnormal oiler hookup and initiated your investigation. The scope of your corrective actions was considered prompt and extensive; therefore, the base civil penalty was also mitigated by 50 percent for corrective action. However, since 1991, Quad Cities Units 1 and 2 have experienced a high number of safety system failures (six unit specific per year and five common per year). At an April 1993 management meeting held at the Quad Cities station we specifically discussed our concern over your inability to improve the performance of safety systems. Therefore, the base civil penalty was escalated 50 percent for prior performance. The other adjustment factors in the Policy were considered and no further adjustment to the base civil penalty is considered appropriate. Therefore, based on the above, the base civil penalty for Violation I.B has been reduced by 50 percent.

In addition to the above, Violation II has been categorized at a Severity Level IV. In accordance with the Enforcement Policy, the failure to make a required report is normally classified at the same severity level as the reportable item. Such a classification is not being made in this case since the pump condition was properly logged and the NRC inspector became aware of the event through a review of those logs the next morning, and you have since made a late report. However, appropriate enforcement action will be considered for any similar violation in the future.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. In your response, you should document the specific actions taken and any additional actions you plan to prevent recurrence. After reviewing your response to this Notice, including your proposed corrective actions and the results of future inspections, the NRC will determine whether further NRC enforcement action is necessary to ensure compliance with NRC regulatory requirements.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter, its enclosure, and your responses will be placed in the NRC Public Document Room.

The responses directed by this letter and the enclosed Notice are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, Public Law No. 96-511.

Sincerely,

John B. Martin
Regional Administrator

Enclosure:
Notice of Violation and Proposed
Imposition of Civil Penalties

cc w/enclosure:
L. DelGeorge, Vice President, Nuclear
Oversight and Regulatory Services
R. Pleniewicz, Site Vice President
R. Dax, Station Manager
A. Misak, Regulatory Assurance
Supervisor
D. Farrar, Nuclear Regulatory
Services Manager
OC/LFDCB
Resident Inspectors, Quad Cities,
Dresden, LaSalle, Clinton
Richard Hubbard
J. W. McCaffrey, Chief, Public
Counsel, State of Illinois Center
Licensing Project Manager, NRR
R. Newmann, Office of Public Counsel,
State of Illinois Center
State Liason Officer
H. J. Miller, Region III

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTIES

Commonwealth Edison Company
Quad Cities Station
Unit 2

Docket No. 50-265
License No. DPR-30
EA 93-127

During an NRC inspection conducted from March 29 through May 11, 1993, violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C, the Nuclear Regulatory Commission proposes to impose civil penalties pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (Act), 42 U.S.C. 2282, and 10 CFR 2.205. The particular violations and associated civil penalties are set forth below:

I. VIOLATIONS ASSESSED CIVIL PENALTIES

A. Technical Specification 3.9.A.1 requires that the reactor shall not be made critical unless the Unit 1/2 diesel generator is operable.

Technical Specification 3.9.E.1 requires, in part, that whenever the reactor is in Startup/Hot Standby or Run mode and the shared diesel generator is inoperable, continued reactor operation is permissible only during the succeeding 7 days provided that certain requirements are met.

Technical Specification 1.0-2.M defines a system, subsystem, train, component, or device as operable when it is capable of performing its specified function(s), assuming that all necessary attendant cooling water equipment, among other things, that is required for the system, subsystem, train, component, or device to perform its function(s) are capable of performing its related support function.

Contrary to the above, on numerous occasions from August 15, 1972, until March 6, 1993, the Unit 1/2 diesel generator was inoperable in relation to Unit 2, and Unit 2 was made critical, or was in Startup/Hot Standby or Run modes for periods of time greater than 7 days. Specifically, the Unit 1/2 diesel generator cooling water pump, required for the Unit 1/2 diesel generator to perform its function, was incapable of starting during a Unit 2 loss of coolant accident coincident with a total loss of offsite power.

This is a Severity Level III violation (Supplement I).
Civil Penalty - $75,000.

B. Technical Specification 3.9.A.1 requires that the reactor shall not be made critical unless the Unit diesel generator is operable.

Technical Specification 3.9.E.1 requires, in part, that whenever the reactor is in Startup/Hot Standby or Run mode and the Unit diesel generator is inoperable, continued reactor operation is permissible only during the succeeding 7 days provided that certain requirements are met.

Technical Specification 1.0-2.M defines a system, subsystem, train, component, or device as operable when it is capable of performing its specified function(s), assuming that all necessary attendant cooling water equipment, among other things, that is required for the system, subsystem, train, component, or device to perform its function(s) are capable of performing its related support function.

Contrary to the above, from February 16 until March 6, 1993, the Unit 2 diesel generator was inoperable, and Unit 2 was made critical, or was in Startup/Hot Standby or Run modes for periods of time greater than 7 days. Specifically, the Unit 2 diesel generator cooling water pump, required for the Unit 2 diesel generator to perform its function, was incapable of performing its related support function due to an indeterminate oil level in the pump bearing housing.

This is a Severity Level III violation (Supplement I). Civil Penalty - $25,000.

II. VIOLATION NOT ASSESSED A CIVIL PENALTY

A. 10 CFR 50.73 (a)(2)(i)(B) requires, in part, that the licensee submit a Licensee Event Report within 30 days of discovery of any operation or condition prohibited by the plant's Technical Specifications.

Contrary to the above, on March 29, 1993, the licensee discovered a condition prohibited by plant Technical Specifications, but did not submit a Licensee Event Report within 30 days. Specifically, the licensee discovered that the oilers on the Unit 2 diesel generator were not placed at a sufficient height to lubricate the pump bearings, and upon disassembly, that the bearings were severely damaged. However, the licensee did not identify the damaged cooling water

pump bearings, which occurred during the course of the previous reactor operation cycle, as a condition prohibited by the plant's Technical Specifications.

This is a Severity Level IV violation (Supplement I).

Pursuant to the provisions of 10 CFR 2.201, Commonwealth Edison Company (Licensee) is hereby required to submit a written statement of explanation to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, within 30 days of the date of this Notice of Violation and Proposed Imposition of Civil Penalties (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each alleged violation: (1) admission or denial of the alleged violation, (2) the reasons for the violation if admitted, and if denied, the reasons why, (3) the corrective steps that have been taken and the results achieved, (4) the corrective steps that will be taken to avoid further violations, and (5) the date when full compliance will be achieved. If an adequate reply is not received within the time specified in this Notice, an order or a demand for information may be issued as to why the license should not be modified, suspended, or revoked or why such other actions as may be proper should not be taken. Consideration may be given to extending the response time for good cause shown. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, this response shall be submitted under oath or affirmation.

Within the same time as provided for the response required under 10 CFR 2.201, the Licensee may pay the civil penalties by letter addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, with a check, draft, money order, or electronic transfer payable to the Treasurer of the United States in the amount of the civil penalties proposed above, or may protest imposition of the civil penalties in whole or in part, by a written answer addressed to the Director, Office of Enforcement, U. S. Nuclear Regulatory Commission. Should the Licensee fail to answer within the time specified, an order imposing the civil penalties will be issued. Should the Licensee elect to file an answer in accordance with 10 CFR 2.205 protesting the civil penalties, in whole or in part, such answer should be clearly marked as an "Answer to a Notice of Violation" and may: (1) deny the violations listed in this Notice in whole or in part, (2) demonstrate extenuating circumstances, (3) show error in this Notice, or (4) show other reasons why the penalties should not be imposed. In addition to protesting the civil penalties in whole or in part, such answer may request remission or mitigation of the penalties.

In requesting mitigation of the proposed penalties, the factors addressed in Section V.B of 10 CFR Part 2, Appendix C, should be addressed. Any written answer in accordance with 10 CFR 2.205

should be set forth separately from the statement or explanation in reply pursuant to 10 CFR 2.201, but may incorporate parts of the 10 CFR 2.201 reply by specific reference (e.g., citing page and paragraph numbers) to avoid repetition. The attention of the Licensee is directed to the other provisions of 10 CFR 2.205, regarding the procedure for imposing civil penalties.

Upon failure to pay any civil penalties due which subsequently has been determined in accordance with the applicable provisions of 10 CFR 2.205, this matter may be referred to the Attorney General, and the penalties, unless compromised, remitted, or mitigated, may be collected by civil action pursuant to Section 234c of the Act, 42 U.S.C. 2282(c).

The responses noted above (Reply to Notice of Violation, letter with payment of civil penalties, and Answer to a Notice of Violation) should be addressed to: Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555 with a copy to the Regional Administrator, U.S. Nuclear Regulatory Commission, Region III, 799 Roosevelt Road, Glen Ellyn, Illinois 60137, and a copy to the NRC Resident Inspector at the Quad Cities Station.

Dated at Glen Ellyn, Illinois
this 30th day of July 1993

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
799 ROOSEVELT ROAD
GLEN ELLYN, ILLINOIS 60137-5927

August 6, 1993

Docket Nos. 50-254 and 50-265
License Nos. DPR-29 and DPR-30
EA 93-162

Commonwealth Edison Company
ATTN: Mr. Michael J. Wallace
Vice President,
Chief Nuclear Officer
Executive Towers West III
1400 Opus Place, Suite 300
Downers Grove, Illinois 60515

Dear Mr. Wallace:

SUBJECT: QUAD CITIES STATION - UNITS 1 AND 2
NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY - $50,000
(NRC INSPECTION REPORT NO. 50-254/265/93009(DRS))

This refers to the special safety inspection conducted during the periods of February 24-26, April 19-23, and May 27, 1993, at Quad Cities Station, Units 1 and 2. The report documenting this inspection was sent to you by letter dated June 11, 1993. An enforcement conference was held on June 21, 1993, and a report summarizing the conference was sent to you by letter dated June 23, 1993.

During an October 1992 fire protection system engineer turnover, the new system engineer identified that QAP 1170-19, "Administrative Requirements for Fire Protection," was not being followed. A deviation report was written which prompted your staff to further investigate the adequacy of the fire protection and safe shutdown programs. This ultimately resulted in your submittal of voluntary Licensee Event Report (LER) 92-032 dated January 7, 1993.

During the NRC inspection of the LER, four violations were identified as described in the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice). The violations involve: (1) operation of Unit 2 with the Unit 1 RHR service water system loop A (opposite unit/shared safe shutdown component) inoperable for greater than 67 days; (2) failure to establish and implement certain fire protection procedures, and procedures to track opposite unit/shared unit safe shutdown components when equipment was taken out-of-service; (3) failure

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to establish a test program to periodically demonstrate satisfactory performance of certain safe shutdown components; and (4) failure to correct deficiencies in safe shutdown equipment status tracking and equipment testing although the deficiencies were specifically identified in 1989 and 1990.

The root cause of the violations was management's failure to place a proper safety emphasis on fire protection and safe shutdown issues. This resulted in failure to effect corrective actions for known fire protection and safe shutdown deficiencies and ineffective fire protection engineer performance. Specifically, Quad Cities management had information, as early as 1986, that indicated deficiencies existed in the safe shutdown equipment control and testing and as early as 1989 for the fire protection deficiencies. The deficiencies went uncorrected and were reconfirmed during audits in 1989 and 1990. It was not until late 1992, when a new system engineer again identified the problems, that corrective actions were proposed. However, it was not until NRC followup on the issues in 1993 that actions appropriate to the circumstances were implemented. There were deficiencies in the system engineering program in that the fire protection system engineers were not thoroughly knowledgeable of their systems, a high turnover rate exacerbated knowledge deficiencies and resulted in a lack of continuity, and a heavy workload hampered the engineers' ability to properly analyze problems. In general, weakness in engineering expertise at Quad Cities has been a continuing problem as evidenced by comments in the SALP 9 report, your response to the SALP 10 report, and most recently by the findings of a review conducted by NRC AEOD personnel in November 1992.

We acknowledge your corrective actions for the violations in the Notice, which included functional testing of detection systems, review of QAP 1170-19, qualification of the fire protection system engineer, review of a sample of pre-1986 modifications to ensure that testing requirements have been incorporated into procedures, removal of the turbine rotor unstacking transformers, issuance of a policy on assigning priority for resolution of code deviations, testing of opposite unit/shared unit safe shutdown systems and equipment, and implementation of administrative technical requirements. However, your initial approach for testing safe shutdown components, following identification of problems in October 1992, was not proactive. Your initial plans were to wait until procedures were implemented in December 1993, rather than prepare interim test procedures. You did not accelerate the testing of these components until prompted to do so during the NRC inspection.

From a plant equipment standpoint, the potential safety consequences of the violations was determined to be low as your subsequent testing of the fire detection and safe shutdown

equipment found only a few problems. The testing did identify deficiencies in three out of ten turbine bearing deluge systems, and the alternate feed to the 2B RHR room cooler fan, although the Unit 1 RHR service water system loop A was available to supply RHR service water to Unit 2 prior to expiration of the 67 day limiting condition for operation. However, it should be noted that it had not been declared operable as defined by your Technical Specifications. Finally, while you did determine that there was another means to achieve and maintain Unit 2 in a safe shutdown condition following a design basis fire without the Unit 1 RHR service water system loop A, that method was not reflected in the appropriate implementing procedures.

Sufficient plant equipment, that would be relied on to achieve safe shutdown, was ultimately determined to be available. Nevertheless, the violations in the Notice represent a breakdown in the control of licensed activities and a significant lack of attention towards licensed responsibilities. Of particular concern is the violation that relates to programmatic deficiencies which were previously identified on a number of occasions. Therefore, in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy) 10 CFR Part 2, Appendix C, the violations are classified in the aggregate as a Severity Level III problem.

To emphasize the need for increased management attention to the fire protection and safe shutdown programs, including appropriate prioritization of known problems, and increased system engineer continuity for oversight of critical systems, I have been authorized, after consultation with the Director, Office of Enforcement, and the Deputy Executive Director for Nuclear Reactor Regulation, Regional Operations and Research, to issue the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice) in the amount of $50,000 for the violations described in the Notice. The base value of a civil penalty for a Severity Level III violation is $50,000. The civil penalty adjustment factors in the Enforcement Policy were considered as discussed below.

The base civil penalty was mitigated 50 percent because your staff identified the violations. In particular, the new fire protection engineer demonstrated the type of questioning attitude that you should expect from all your personnel. The base civil penalty was not mitigated for your corrective actions because, as discussed above, your corrective actions were not originally scheduled to be promptly implemented. The civil penalty was escalated 50 percent because of the prior opportunities your staff had to respond to the programmatic concerns discussed in the Notice. The other adjustment factors in the Policy were considered and no further adjustment to the base civil penalty is considered appropriate. Therefore, based on the above, a civil

penalty equal to the base civil penalty is proposed.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. In your response, you should document the specific actions taken and any additional actions you plan to prevent recurrence. After reviewing your response to this Notice, including your proposed corrective actions and the results of future inspections, the NRC will determine whether further NRC enforcement action is necessary to ensure compliance with NRC regulatory requirements.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter, its enclosure, and your responses will be placed in the NRC Public Document Room.

The responses directed by this letter and the enclosed Notice are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, Public Law No. 96-511.

Sincerely,

John B. Martin
Regional Administrator

Enclosure:
Notice of Violation and Proposed
Imposition of Civil Penalty

cc w/enclosure:
L. DelGeorge, Vice President,
Nuclear Oversight and Regulatory
Services

cc w/enclosure: See Next Page

cc w/enclosure: (Con't)
R. Pleniewicz, Site Vice President
R. Bax, Station Manager
A. Misak, Regulatory Assurance
Supervisor
D. Farrar, Nuclear Regulatory
Services Manager
OC/LFDCB
Resident Inspectors, Quad Cities,
Dresden, LaSalle, Clinton
Richard Hubbard
J. W. McCaffrey, Chief, Public
Counsel, State of Illinois Center
Licensing Project Manager, NRR
R. Newmann, Office of Public Counsel,
State of Illinois Center
State Liason Officer

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

Commonwealth Edison Company	Docket Nos. 50-254 and 50-265
Quad Cities Station	License Nos. DPR-29 and DPR-30
Units 1 and 2	EA 93-162

During an NRC inspection conducted from February 24-26, April 19-23 and May 27, 1993, violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C, the Nuclear Regulatory Commission proposes to impose a civil penalty pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (Act), 42 U.S.C. 2282, and 10 CFR 2.205. The particular violations and associated civil penalty are set forth below:

I. 10 CFR 50, Appendix R, Section III, Paragraph G.3 states that alternative or dedicated shutdown capability and its associated circuits, independent of cables, systems or components in the area, room or zone under consideration, shall be provided where the protection of systems whose function is required for hot shutdown does not satisfy the requirement of Paragraph G.2 of this section; or where redundant trains of systems required for hot shutdown located in the same fire area may be subject to damage from fire suppression activities or from the rupture or inadvertent operation of fire suppression systems.

Quad Cities Technical Specification 6.2.A.7 requires written procedures be established, implemented, and maintained for Fire Protection Program implementation.

Quad Cities Fire Protection Report (FPR), Amendment 8 (December 1990), Table 4.16-1, "Opposite Unit Equipment Review," designates Unit 1 RHR service water system loop A as an opposite unit/shared replacement equipment for Unit 2.

Quad Cities FPR, Paragraph 4.16.2, "Out of Service Equipment Administrative Technical Requirements," requires that if either the safe shutdown component or the opposite unit/shared replacement equipment has not been returned to service within 67 days, the unit must be shut down.

Contrary to the above, prior to May 27, 1993, procedures were not established to track opposite unit/shared unit safe shutdown components when equipment was taken out-of-service. Consequently, from January 1, 1991 to March 14, 1991, Quad Cities Unit 2 was operated at power with the Unit 1, RHR service water system loop A inoperable, a period greater than 67 days, and Unit 2 was not shut down.

II. Quad Cities Technical Specification 6.2.A.7 requires written procedures be established, implemented, and maintained for Fire Protection Program implementation.

Contrary to the above, written procedures were not established or implemented as evidenced by the following examples:

A. Quad Cities Procedure QAP 1170-19, Section C.3.a, requires that the fire detection instruments listed in Table QAP 1170-T5 be demonstrated operable at least once per six months by performing a functional test.

From February 28, 1991 until April 23, 1993 (November 9, 1992 for the MG Set Water Curtain), the fire detection instruments from Table QAP 1170-T5 listed below were not demonstrated operable at least once per six months by performing a functional test. Specifically, no functional testing was performed during the specified periods.

345 KV Relay House
U1/U2 Aux Transformers
U1/U2 Turbine Oil Tanks
U1/U2 Hydrogen Seal Oil
MG Set Water Curtain
U1/U2 Main Transformers
U1/U2 Reserve Aux Transformers
U1/U2 Turbine Bearings
U1/U2 Exciter Housings

B. QAP 1170-19, Section C.3.b, requires, for sprinkler systems, that at least once per operating cycle a system functional test be performed which includes simulated automatic actuation of the system to verify that any automatic valves in the flow path actuate to their correct position, inspection of the sprinkler system piping to verify its integrity, and inspection of each sprinkler head or nozzle to verify that the discharge spray pattern is not blocked or obstructed.

From February 28, 1991 until April 23, 1993 (November 9, 1992 for the MG Set Water Curtain), for the U1 & U2 Rotor Unstacking Transformer and the MG Set Water Curtain sprinkler systems, system functional tests and inspections of system piping, sprinkler heads and nozzles were not performed at least once per operating cycle.

C. QAP 1170-19, Section C.1.g, states that changes may be made to the approved fire protection program without prior approval of the NRC only if those changes do not adversely affect the ability to achieve and maintain safe shutdown conditions in the event of a fire.

As of May 27, 1993, an existing change to the approved fire protection program that could adversely affect the ability to achieve safe shutdown had not received prior NRC approval. Specifically, a critical fire protection zone which contains a 13.8 kv transformer fire protection system located on the main turbine floor which must remain operable to protect safe shutdown cables or equipment, had been changed from the system as designed. For example, the system as installed left open penetrations in the floor of the oil containment area which would allow liquid to flow to the floor below, failed to include certain control valves in the surveillance program, had inadequate curb heights in the oil containment area to handle the flow of both transformer oil and fire protection water, and failed to have certain alarms connected to the station's central fire alarm system.

III. 10 CFR 50, Appendix B, Criterion XI, "Test Control," requires that a test program be established to assure that all testing required to demonstrate that structures, systems, and components will perform satisfactorily in service is identified and performed in accordance with written test procedures.

Contrary to the above, from June 1, 1990, until May 27, 1993, a written test program had not been established to demonstrate satisfactory performance of the safety related safe shutdown components identified in Attachment 2, Paragraphs B and C, of a licensee letter from B. Rybak to all Commonwealth Edison Station Managers dated August 29, 1986.

IV. 10 CFR 50, Appendix B, Criterion XVI, "Corrective Action," requires that measures be established to assure that conditions adverse to quality are promptly identified and corrected.

Contrary to the above, the licensee failed to promptly correct identified conditions adverse to quality. Specifically, an August 29, 1986, letter to all Commonwealth Edison Station Managers (B. Rybak Letter) stated, in part, that controls should be imposed on opposite unit/shared unit safe shutdown components not covered by technical specifications and that periodic testing should be implemented on safe shutdown components. The failure to implement these recommendations was identified in a fire protection assessment report dated December 7, 1989, and in a follow-up fire protection assessment report dated May 29, 1990. At Quad Cities Station, as of May 27, 1993, the controls had not been imposed for the equipment identified in Attachment 2, Paragraph A, of the B. Rybak Letter and the testing had not been implemented for the equipment

identified in Attachment 2, Paragraphs B and C of that letter.

This is a Severity Level III problem (Supplement I).
Civil Penalty - $50,000.

Pursuant to the provisions of 10 CFR 2.201, Commonwealth Edison Company (Licensee) is hereby required to submit a written statement of explanation to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, within 30 days of the date of this Notice of Violation and Proposed Imposition of Civil Penalty (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each alleged violation: (1) admission or denial of the alleged violation, (2) the reasons for the violation if admitted, and if denied, the reasons why, (3) the corrective steps that have been taken and the results achieved, (4) the corrective steps that will be taken to avoid further violations, and (5) the date when full compliance will be achieved. If an adequate reply is not received within the time specified in this Notice, an order or a demand for information may be issued as to why the license should not be modified, suspended, or revoked or why such other actions as may be proper should not be taken. Consideration may be given to extending the response time for good cause shown. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, this response shall be submitted under oath or affirmation.

Within the same time as provided for the response required under 10 CFR 2.201, the Licensee may pay the civil penalty by letter addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, with a check, draft, money order, or electronic transfer payable to the Treasurer of the United States in the amount of the civil penalty proposed above, or may protest imposition of the civil penalty in whole or in part, by a written answer addressed to the Director, Office of Enforcement, U. S. Nuclear Regulatory Commission. Should the Licensee fail to answer within the time specified, an order imposing the civil penalty will be issued. Should the Licensee elect to file an answer in accordance with 10 CFR 2.205 protesting the civil penalty, in whole or in part, such answer should be clearly marked as an "Answer to a Notice of Violation" and may: (1) deny the violations listed in this Notice in whole or in part, (2) demonstrate extenuating circumstances, (3) show error in this Notice, or (4) show other reasons why the penalty should not be imposed. In addition to protesting the civil penalty in whole or in part, such answer may request remission or mitigation of the penalty.

In requesting mitigation of the proposed penalty, the factors addressed in Section V.B of 10 CFR Part 2, Appendix C, should be addressed. Any written answer in accordance with 10 CFR 2.205 should be set forth separately from the statement or explanation in reply pursuant to 10 CFR 2.201, but may incorporate parts of

the 10 CFR 2.201 reply by specific reference (e.g., citing page and paragraph numbers) to avoid repetition. The attention of the Licensee is directed to the other provisions of 10 CFR 2.205, regarding the procedure for imposing a civil penalty.

Upon failure to pay any civil penalty due which subsequently has been determined in accordance with the applicable provisions of 10 CFR 2.205, this matter may be referred to the Attorney General, and the penalty, unless compromised, remitted, or mitigated, may be collected by civil action pursuant to Section 234c of the Act, 42 U.S.C. 2282c.

The responses noted above (Reply to Notice of Violation, letter with payment of civil penalty, and Answer to a Notice of Violation) should be addressed to: Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555 with a copy to the Regional Administrator, U.S. Nuclear Regulatory Commission, Region III, 799 Roosevelt Road, Glen Ellyn, Illinois 60137, and a copy to the NRC Resident Inspector at the Quad Cities Station.

Dated at Glen Ellyn, Illinois
this 6th day of August 1993

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
799 ROOSEVELT ROAD
GLEN ELLYN, ILLINOIS 60137-5927

September 14, 1993

Docket No. 50-255
License No. DPR-20
EA 93-178

Consumers Power Company
ATTN: Mr. David P. Hoffman
Vice President - Nuclear
Operations
1945 West Parnall Road
Jackson, Michigan 49201

Dear Mr. Hoffman:

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY - $50,000
(INSPECTION REPORT NO. 50-255/93016(DRP))

This refers to the special inspection conducted from June 15 through 25, 1993, at Palisades Nuclear Plant. The inspection included a review of the circumstances surrounding your failure to uncouple one control rod prior to removal of the reactor vessel head. The report documenting this inspection was sent to you by letter dated July 9, 1993. During the inspection, violations of NRC requirements were identified.

You voluntarily reported this event to the NRC Operations Center on the day it occurred, June 15, 1993, and subsequently submitted a written report by letter dated June 19, 1993. An enforcement conference was held on August 10, 1993, to discuss the apparent violations, their causes, and your corrective actions. The report summarizing the enforcement conference was sent to you by letter dated August 20, 1993.

On June 15, 1993, after lifting the reactor vessel head seven feet in preparation for refueling, you identified that one of forty-five control rods was still coupled to its drive mechanism and was lifted with the reactor vessel head.

Previously, on June 10, 1993, two teams, each consisting of a licensed operator and an auxiliary operator, had performed the control rod uncoupling evolution. The evolution was unorganized; and difficult working conditions, perceived schedule pressure, and a strained relationship between the operators and the Shift Supervisor were evident. Furthermore, the Shift Supervisor

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

sensed some problems with the evolution, but failed to recognize a significant failure to comply with procedures.

The enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice) describes five violations involving failure of the Shift Supervisor to brief the auxiliary operators prior to the uncoupling evolution, failure of the auxiliary operators to conduct a dry run on the mock-up prior to the evolution, failure to notify the control room after each control rod drive mechanism was uncoupled, failure to retain the working copy of the procedure, and an inadequate procedure for verifying the rods were uncoupled during removal of the reactor vessel head.

These violations represent a breakdown in the controls that are essential for the safe conduct of important activities. Any uncontrolled addition of positive reactivity is a significant safety concern even though, in this case, the reactor remained substantially subcritical and there were no adverse consequences to the public. Furthermore, the unorganized manner in which this evolution occurred is unacceptable for nuclear power plant operations; under other circumstances, such performance might have resulted in more significant consequences. In addition, our review of this matter disclosed broader weaknesses including a general lack of critical self-assessment of important activities and indications of organizational strife within the plant operations department. Although these broader issues go beyond the scope of this individual enforcement action, they mandate your prompt attention and resolution.

Collectively, the violations in the enclosed Notice represent a potentially significant lack of attention or carelessness toward licensed responsibilities. Therefore, in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy) 10 CFR Part 2, Appendix C, these violations are classified in the aggregate as a Severity Level III problem.

We acknowledge your corrective actions which included issuing a memorandum to all site supervisory personnel on lessons learned, monitoring of plant activities by onsite senior management until the plant returned to service, instituting a pre-job briefing checklist, revising refueling procedures, and communicating expectations to workers and supervisors by the Operations Manager and Operations Superintendent. We also acknowledge your planned actions to develop and implement a number of Nuclear Operations Department, Plant Management, and Operations Department action plans.

To emphasize the need for increased management attention to licensed activities and strict adherence to procedures, I have been authorized, after consultation with the Director, Office of Enforcement and the Deputy Executive Director for Nuclear Reactor

Regulation, Regional Operations, and Research to issue the enclosed Notice in the amount of $50,000 for the Severity Level III problem.

The base value of a civil penalty for a Severity Level III problem is $50,000. The adjustment factors in the Enforcement Policy were considered. While the event itself was self-disclosing, the NRC took the initiative in identifying the violations that were involved here, and we believe that no mitigation is warranted for the identification factor. Mitigation of the base civil penalty would have been appropriate for your comprehensive corrective actions and that mitigation would have resulted in a reduction in the amount of the civil penalty by 50 percent. Thus, a civil penalty of $25,000 could be proposed in a matter such as this. However, the NRC is concerned about the breakdown in the controls that are essential for the safe conduct of important activities that occurred in this case. In order to reflect the level of concern with which the NRC views your failure to instill in individuals a proper regard for strict procedural compliance and to emphasize the need for careful attention to the control and conduct of the licensed activities involved here, I have decided, pursuant to Section VII.A.1 of the Enforcement Policy, to exercise discretion and propose a civil penalty in the amount of the base civil penalty for this Severity Level III problem notwithstanding the application of the mitigation factors.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. In your response, you should document the specific action taken and any additional actions you plan to prevent recurrence. After reviewing your response to this Notice, including your proposed corrective actions and the results of future inspections, the NRC will determine whether further NRC enforcement action is necessary to ensure compliance with NRC regulatory requirements.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter, its enclosure, and your response will be placed in the NRC Public Document Room.

The response directed by this letter and the enclosed Notice are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, Public Law No. 96-511.

Sincerely,

John B. Martin
Regional Administrator

Enclosure:
Notice of Violation and Proposed
Imposition of Civil Penalty

cc w/enclosure:
Gerald B. Slade, General
Manager
David W. Rogers, Safety
and Licensing Director
OC/LFDCB
Resident Inspector, RIII
James R. Padgett, Michigan Public
Service Commission
Michigan Department of
Public Health
Palisades, LPM, NRR
SRI, Big Rock Point

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

Consumers Power Company
Palisades Nuclear Plant

Docket No. 50-255
License No. DPR-20
EA 93-178

During an NRC inspection conducted from June 15-25, 1993, violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C (1993), the Nuclear Regulatory Commission proposes to impose a civil penalty pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (Act), 42 U.S.C. 2282, and 10 CFR 2.205. The particular violations and associated civil penalty are set forth below:

Technical Specification 6.8.1.a requires, in part, that written procedures be established, implemented and maintained covering the applicable procedures recommended in Appendix A of Regulatory Guide 1.33, Revision 2 (February 1978), Quality Assurance Program Requirements, as endorsed by CPC-2A, Quality Program Description.

The Quality Program Description in CPC-2A endorses, among other things, the following applicable procedures listed in Appendix A of Regulatory Guide 1.33: Authorities and Responsibilities for Safe Operation and Shutdown (Section 1.b); Record Retention (Section 1.h); Preparation for Refueling and Refueling Equipment Operation (Section 2.k); and Removal of the Reactor Head (Section 9.d(6)).

A. Administrative Procedure 4.00, "Operations Organization, Responsibilities, and Conduct," Revision 10, Step 4.4.1.h, established to implement the procedure listed in Regulatory Guide 1.33, Appendix A, Section 1.b, requires, in part, that the Shift Supervisor explain plans, procedures and safety precautions to shift operating personnel prior to unusual or infrequent operations.

   Contrary to the above, on June 10, 1993, the Shift Supervisor failed to explain plans, procedures, and safety precautions to the auxiliary operators assigned to perform the control rod drive mechanism uncoupling evolution, an infrequent operation.

B. Special Operating Procedure CRDO-1, "Disconnecting Control Rods from CRDMS," Revision 8, Step 3.4, established to implement the procedure listed in Regulatory Guide 1.33, Appendix A, Section 2.k, requires that persons performing this activity complete a dry run of this procedure using the control rod drive mechanism disconnecting mock-up.

Contrary to the above, on June 10, 1993, the auxiliary operators performing control rod drive mechanism uncoupling had not completed a dry run of Procedure CRDO-1 using the control rod drive mechanism disconnecting mock-up.

C. Special Operating Procedure CRDO-1, "Disconnecting Control Rods from CRDMS," Revision 8, Step 5.1.3, established to implement the procedure listed in Regulatory Guide 1.33, Appendix A, Section 9.d(6), requires the notification of the control room to record on Attachment 1 the control rod drive mechanism which has been disconnected.

Contrary to the above, on June 10, 1993, during the uncoupling of control rod drive mechanisms, operators repeatedly failed to notify the control room after each control rod drive mechanism was disconnected, but only notified the control room after groups of control rod drive mechanisms were disconnected.

D. Special Operating Procedure CRDO-1, "Disconnecting Control Rods from CRDMS," Revision 8, Step 7.2.3, established to implement the procedure listed in Regulatory Guide 1.33, Appendix A, Section 1.h, requires that the control room working copy of this procedure be retained.

Contrary to the above, after completion of the control rod drive mechanism uncoupling evolution on June 10, 1993, the control room working copy of the procedure was not retained.

E. Regulatory Guide 1.33, Appendix A, Section 9, as endorsed by CPC-2A, Quality Program Description, requires, in part, that maintenance be properly performed in accordance with written procedures appropriate to the circumstances.

Contrary to the above, as of June 15, 1993, Maintenance Procedure RVG-M-2, "Removal of the Reactor Vessel Head," Revision 24, a portion of which serves to verify that all rack extensions are uncoupled, was inappropriate to the circumstances in that Steps 5.20.18 through 5.20.20 were not adequate to verify that all rack extensions were uncoupled.

This is a Severity Level III problem (Supplement I).
Civil Penalty - $50,000.

Pursuant to the provisions of 10 CFR 2.201, Consumers Power Company (Licensee) is hereby required to submit a written statement or explanation to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, within 30 days of the date of this Notice of Violation and Proposed Imposition of Civil Penalty (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each alleged violation: (1) admission or denial of the alleged violation, (2)

the reasons for the violation if admitted, and if denied, the reasons why, (3) the corrective steps that have been taken and the results achieved, (4) the corrective steps that will be taken to avoid further violations, and (5) the date when full compliance will be achieved. If an adequate reply is not received within the time specified in this Notice, an Order or a Demand for Information may be issued as to why the license should not be modified, suspended, or revoked or why such other actions as may be proper should not be taken. Consideration may be given to extending the response time for good cause shown. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, this response shall be submitted under oath or affirmation.

Within the same time as provided for the response required under 10 CFR 2.201, the Licensee may pay the civil penalty by letter addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, with a check, draft, money order, or electronic transfer payable to the Treasurer of the United States in the amount of the civil penalty proposed above, or may protest imposition of the civil penalty in whole or in part, by a written answer addressed to the Director, Office of Enforcement, U. S. Nuclear Regulatory Commission. Should the Licensee fail to answer within the time specified, an order imposing the civil penalty will be issued. Should the Licensee elect to file an answer in accordance with 10 CFR 2.205 protesting the civil penalty, in whole or in part, such answer should be clearly marked as an "Answer to a Notice of Violation" and may: (1) deny the violations listed in this Notice in whole or in part, (2) demonstrate extenuating circumstances, (3) show error in this Notice, or (4) show other reasons why the penalty should not be imposed. In addition to protesting the civil penalty in whole or in part, such answer may request remission or mitigation of the penalty.

In requesting mitigation of the proposed penalty, the factors addressed in Section V.B.2 of 10 CFR Part 2, Appendix C (1993), should be addressed. Any written answer in accordance with 10 CFR 2.205 should be set forth separately from the statement or explanation in reply pursuant to 10 CFR 2.201, but may incorporate parts of the 10 CFR 2.201 reply by specific reference (e.g., citing page and paragraph numbers) to avoid repetition. The attention of the Licensee is directed to the other provisions of 10 CFR 2.205, regarding the procedure for imposing a civil penalty.

Upon failure to pay any civil penalty due which subsequently has been determined in accordance with the applicable provisions of 10 CFR 2.205, this matter may be referred to the Attorney General, and the penalty, unless compromised, remitted, or mitigated, may be collected by civil action pursuant to Section 234c of the Act, 42 U.S.C. 2282c.

The responses noted above (Reply to Notice of Violation, letter with payment of civil penalty, and Answer to a Notice of Violation) should be addressed to: Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555 with a copy to the Regional Administrator, U.S. Nuclear Regulatory Commission, Region III, 799 Roosevelt Road, Glen Ellyn, Illinois 60137, and with a copy to the NRC Resident Inspector at the Palisades Nuclear Plant.

Dated at Glen Ellyn, Illinois
this 14th day of September 1993

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION IV
611 RYAN PLAZA DRIVE, SUITE 400
ARLINGTON, TEXAS 76011-8064

AUG - 5 1993

Docket: 50-458
License: NPF-47
EA 93-167

Gulf States Utilities
ATTN: P. D. Graham
Vice President (RBNG)
P.O. Box 220
St. Francisville, Louisiana 70775

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY - $100,000 (NRC INSPECTION REPORT NO. 50-458/93-18)

This refers to the inspection conducted April 21 through June 22, 1993, at the River Bend Station (RBS) nuclear power plant, St. Francisville, Louisiana. This inspection was conducted specifically to review circumstances surrounding Gulf States Utilities'(GSU's) discovery on April 19, 1993, during a plant outage, that Main Steam Isolation Valve (MSIV) 1B21*AOVF022B was stuck open. A report documenting the results of this inspection was issued on June 29, 1993. On July 6, 1993, you and other GSU representatives attended an enforcement conference in the NRC's Arlington, Texas office to discuss NRC's preliminary conclusion that potentially significant violations of NRC requirements and plant Technical Specifications had occurred.

GSU's investigation of the stuck-open MSIV determined that the valve had been machined in June 1992 and that, following repairs, the clearance between the valve poppet and the lower guide rib was less than specified in vendor guidance. GSU's investigation also determined that indications that the valve was stuck open were not recognized and pursued by plant operators during valve partial closure tests conducted in February and April 1993. As a result, the plant was operated from February 27 to April 18, 1993, a period of 51 days, with one MSIV stuck open.

Based on the information developed during the inspection and the information that GSU provided during the enforcement conference, the NRC has determined that the following violations occurred related to the stuck-open MSIV: 1) a failure in June 1992 to check the dimensions of the valve internals following machining; 2) failures in February and April 1993 to complete MSIV surveillance tests in accordance with RBS procedures; and 3) a failure from February 27 to April 18, 1993, to operate the plant in accordance with the Technical Specifications that require two MSIVs per main steam line to be operable.

The circumstances surrounding these violations are described in more detail in the inspection report. From the NRC's perspective, the June 1992 failure to ensure that the MSIV post-maintenance internal dimensions were in accordance with design, combined with the subsequent failure to pursue MSIV surveillance

test discrepancies in February and April 1993, is a matter of significant regulatory concern. These violations resulted in an important safety-related component being unable to function as designed to ensure the safety of the facility and to mitigate the consequences of an accident. In accident conditions, the MSIVs help to minimize both the loss of reactor coolant and the release of radioactive fission products to the environment. As GSU stated during the enforcement conference, certain postulated accidents with a stuck-open inboard MSIV could have resulted in significant radiation exposures to main control room personnel. The NRC acknowledges that the actual effect on facility safety is mitigated by MSIV redundancy, and by the relatively low probability of a failure of the second MSIV in the same steam line.

Nonetheless, because these violations resulted in a significant failure to comply with the plant's Technical Specifications and indicate a breakdown in the control of licensed activities (related to both operations and maintenance), these violations have been aggregated as a Severity Level III problem in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy) 10 CFR Part 2, Appendix C.

These violations occurred primarily because (1) plant personnel involved in MSIV maintenance failed to perform the work properly and in accordance with procedures and (2) plant personnel involved in performing and reviewing the MSIV surveillance tests failed to pursue test discrepancies that should have led them to discover that the MSIV was stuck open. The NRC recognizes that GSU took prompt action to repair the valve and conducted extensive analyses to determine the primary and contributing causes of this event. GSU's long-term corrective actions, which were discussed in detail during the enforcement conference, include a wide variety of actions to address these causes. These corrective actions are described in GSU's enforcement conference presentation, which was attached to the NRC's July 8, 1993 letter documenting the enforcement conference. As NRC personnel indicated during the conference, these actions appear to encompass the root and contributing causes.

To emphasize the importance of ensuring that maintenance on safety-related components and systems does not adversely affect operability and the importance of pursuing test discrepancies to ensure the operability of such components and systems, I have been authorized, after consultation with the Director, Office of Enforcement, and the Deputy Executive Director for Nuclear Reactor Regulation, Regional Operations and Research, to issue the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice) in the amount of $100,000 for this Severity Level III problem. The base value of a civil penalty for a Severity Level III problem is $50,000. The civil penalty adjustment factors in the Enforcement Policy were considered and resulted in a net increase of $50,000.

In considering the civil penalty adjustment factors, the NRC determined that a 50 percent decrease was warranted because the underlying problem (stuck-open MSIV) and associated violations were identified by GSU. An additional 50 percent decrease was warranted based on GSU's corrective actions, as

discussed above. However, these decreases were offset by a 100 percent increase based on GSU's having missed two opportunities to detect this problem through its normal surveillance activities. In addition, a 100 percent increase was warranted based on the duration of the Technical Specification violation, in that the MSIV was stuck open for 51 days with the plant operating. The remaining adjustment factors were considered, but no further adjustments were determined to be appropriate.

In addition to the violations discussed above, the Notice contains a Severity Level IV violation which has not been assessed a civil penalty. This violation involved maintenance performed on the MSIV after it was discovered stuck open. At the enforcement conference, GSU disagreed with the NRC's inspection report characterization of this violation as repetitive. Subsequent NRC review has determined that, while some commonality exists between this and previous violations, reasonable corrective actions completed for the previous violations would not have prevented the current violation. Therefore, the NRC concludes that this is not a repetitive violation.

Finally, an apparent violation identified in the inspection report involving the adequacy of the MSIV surveillance test procedure is not being cited. Although the NRC concludes, based on MSIV limit switch design, that the surveillance test procedure may not have detected valve movement problems under all circumstances, the test was adequate to detect the problems present on February 27 and April 1, 1993. Therefore, the NRC concludes that a violation did not occur on these dates with respect to the inadequacy of this surveillance test procedure. However, GSU should give additional attention to ensuring that future performances of this surveillance test are adequate to detect MSIV movement discrepancies and ensure valve closure capability. We understand that GSU has used the Nuclear Network to alert other boiling water reactor owners of the potential inadequacy in the surveillance test.

GSU is required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing its response. In your response, you should document the specific actions taken and any additional actions you plan to prevent recurrence. After reviewing your response to this Notice, including your proposed corrective actions and the results of future inspections, the NRC will determine whether further NRC enforcement action is necessary to ensure compliance with NRC regulatory requirements.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter and its enclosure will be placed in the NRC Public Document Room.

The responses directed by this letter and the enclosed Notice are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, Pub. L. No. 96-511.

Sincerely,

James L. Milhoan
Regional Administrator

Enclosure:
Notice of Violation and
Proposed Imposition of
Civil Penalty

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

Gulf States Utilities
River Bend Station
St. Francisville, Louisiana

Docket No. 50-458
License No. NPF-47
EA 93-167

During an NRC inspection conducted April 21 - June 22, 1993, violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C, the Nuclear Regulatory Commission proposes to impose a civil penalty pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (Act), 42 U.S.C. 2282, and 10 CFR 2.205. The particular violations and associated civil penalty are set forth below:

I. Violations Assessed a Civil Penalty

A. 10 CFR Part 50, Appendix B, Criterion X, states, in part, that a program for inspection of activities affecting quality shall be established and executed by or for the organization performing the activity to verify conformance with the documented instructions, procedures, and drawings for accomplishing the activity.

Contrary to the above, a program for inspection of activities affecting quality was not established or executed, in that, on or about June 16, 1992, Main Steam Isolation Valve 1B21*AOVF022B was not inspected to verify conformance with the valve manufacturer's drawings that were used to accomplish valve repairs.

B. Technical Specification 6.8.1. requires, in part, that written procedures be established, implemented, and maintained covering surveillance and test activities of safety-related equipment.

Administrative Procedure ADM-0015, "Station Surveillance Test Program," Section 4.6.4, states that the shift supervisor/control operating foreman is responsible for signing surveillance procedures signifying that the acceptance criteria have been met.

Surveillance Test Procedure (STP) 051-0201 is a monthly channel functional test performed to verify closure capability for main steam isolation valves (MSIVs), including MSIV 1B21*AOVF022B. Step 7.4.5 requires depressing the MSIV test push button until the double indication light is received. Step 8.1 lists satisfactory completion of Step 7.4.5 as one of the acceptance criteria for completing the channel functional test.

Contrary to the above, on February 27, 1993, and April 1, 1993, Administrative Procedure ADM-0015 was not properly implemented during performance of STP-051-0201. Specifically, the shift supervisor and control operating foreman signed the procedure as complete, when the acceptance criteria of Step 7.4.5 had not been met for MSIV 1B21*AOVF022B.

C. Technical Specification 3.4.7 states, in part, that two main steam line isolation valves (MSIVs) per main steam line shall be operable with closing times greater than or equal to 3 seconds and less than or equal to 5 seconds while in Operational Conditions 1, 2, and 3. With one or more MSIVs inoperable, this Technical Specification requires the licensee within 8 hours to restore the inoperable valve to operable status or isolate the affected main steam line by use of a deactivated MSIV in the closed position. Otherwise, the plant must be placed in at least hot shutdown within the next 12 hours and in cold shutdown within the following 24 hours.

Contrary to the above, from February 27 to April 18, 1993, with the plant in Operational Conditions 1, 2, and 3, Main Steam Line Isolation Valve 1B21*AOVF022B was not operable (in that the valve would not close) and the actions described in Technical Specification 3.4.7 were not taken.

These violations represent a Severity Level III problem (Supplement I).
Civil Penalty - $100,000

II. Violation Not Assessed a Civil Penalty

Technical Specification 6.8.1.a requires that written procedures be established, implemented, and maintained covering the applicable procedures recommended in Appendix A of Regulatory Guide 1.33, Revision 2, February 1978.

Regulatory Guide 1.33 recommends that maintenance that can affect the performance of safety-related equipment should be properly pre-planned and performed in accordance with written procedures, documented instructions, or drawings appropriate to the circumstances.

Corrective Maintenance Procedure CMP-9141, "Main Steam Isolation Valves 1B21*AOVF022A, B, C, D and 1B21*AOVF028A, B, C, D Disassembly, Inspection, Rework and Reassembly," Revision 4B, provides instructions for certain maintenance affecting the performance of safety-related main steam isolation valves (MSIVs). The procedure specifically requires the valve to be in the closed position prior to beginning disassembly.

Maintenance Work Order (MWO) R159695 provided instructions related to reassembly of safety-related MSIV 1B21*AOVF022A. Step 59 states:

> "Stroke the valve to assure the 11" stroke length. If adjustment is reqd. perform per Steps 43-48 pg. 23 of manual."

Contrary to the above:

1. On April 23, 1993, maintenance on safety-related MSIV 1B21*AOVF022B was not performed in accordance with written

procedures and documented instructions appropriate to the circumstances. Procedure CMP-9141 was used for disassembly with the valve in the open position, such that several actions taken by plant mechanics during the disassembly were not provided for, or were contrary to, the requirements of the procedure.

2. On May 11, 1993, during the reassembly of safety-related MSIV 1B21*AOVF022A, maintenance was not performed in accordance with MWO R159695, Step 59, in that the 11" stroke length was not ensured, nor was a required valve adjustment performed per Steps 43-48 of the applicable manual.

This is a Severity Level IV violation (Supplement I).

Pursuant to the provisions of 10 CFR 2.201, Gulf States Utilities (Licensee) is hereby required to submit a written statement or explanation to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, within 30 days of the date of this Notice of Violation and Proposed Imposition of Civil Penalty (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each alleged violation: (1) admission or denial of the alleged violation, (2) the reasons for the violation if admitted, and if denied, the reasons why, (3) the corrective steps that have been taken and the results achieved, (4) the corrective steps that will be taken to avoid further violations, and (5) the date when full compliance will be achieved.

If an adequate reply is not received within the time specified in this Notice, an order or demand for information may be issued as to why the license should not be modified, suspended, or revoked or why such other action as may be proper should not be taken. Consideration may be given to extending the response time for good cause shown. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, this response shall be submitted under oath or affirmation.

Within the same time as provided for the response required above under 10 CFR 2.201, the Licensee may pay the civil penalty by letter addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, with a check, draft, money order, or electronic transfer payable to the Treasurer of the United States in the amount of the civil penalty proposed above, or the cumulative amount of the civil penalties if more than one civil penalty is proposed, or may protest imposition of the civil penalty, in whole or in part, by a written answer addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission. Should the Licensee fail to answer within the time specified, an order imposing the civil penalty will be issued. Should the Licensee elect to file an answer in accordance with 10 CFR 2.205 protesting the civil penalty, in whole or in part, such answer should be clearly marked as an "Answer to a Notice of Violation" and may: (1) deny the violations listed in this Notice, in whole or in part, (2) demonstrate extenuating circumstances, (3) show error in this Notice, or (4) show other reasons why the penalty should not be imposed. In addition to protesting the civil

penalty, in whole or in part, such answer may request remission or mitigation of the penalty.

In requesting mitigation of the proposed penalty, the factors addressed in Section VI.B.2 of 10 CFR Part 2, Appendix C should be addressed. Any written answer in accordance with 10 CFR 2.205 should be set forth separately from the statement or explanation in reply pursuant to 10 CFR 2.201, but may incorporate parts of the 10 CFR 2.201 reply by specific reference (e.g. citing page and paragraph numbers) to avoid repetition. The attention of the Licensee is directed to the other provisions of 10 CFR 2.205, regarding the procedure for imposing a civil penalty.

Upon failure to pay any civil penalty due which subsequently has been determined in accordance with the applicable provisions of 10 CFR 2.205, this matter may be referred to the Attorney General, and the penalty, unless compromised, remitted, or mitigated, may be collected by civil action pursuant to Section 234c of the Act, 42 U.S.C. 2282(c).

The response noted above (Reply to Notice of Violation, letter with payment of civil penalty, and Answer to a Notice of Violation) should be addressed to: Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555 with a copy to the Regional Administrator, U.S. Nuclear Regulatory Commission, Region IV, 611 Ryan Plaza Drive, Suite 400, Arlington, Texas 76011 and a copy to the NRC Resident Inspector at River Bend Station.

Dated at Arlington, Texas
this 5th day of August 1993

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION IV
611 RYAN PLAZA DRIVE, SUITE 400
ARLINGTON, TEXAS 76011-8064

MAR 30 1993

Docket 50-298
License DPR-46
EA 93-030

Nebraska Public Power District
ATTN: Guy R. Horn, Nuclear Power
Group Manager
P.O. Box 499
Columbus, Nebraska 68602-0499

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTIES - $200,000 (NRC INSPECTION REPORT NO. 50-298/93-06)

This is in reference to the NRC's February 1-9, 1993, inspection at Cooper Nuclear Station (CNS), which was documented in a report issued on February 26, 1993. This inspection was conducted to review the circumstances surrounding Nebraska Public Power District's (NPPD) January 27, 1993, discovery of temporary strainers in the suction piping for Reactor Equipment Cooling pumps. The inspection found apparent violations involving: 1) a failure to provide complete and accurate information to the NRC in response to a previous, related Notice of Violation; and 2) a failure of NPPD's corrective action program to identify and resolve this potentially significant safety concern in the Reactor Equipment Cooling and other safety-related systems despite several opportunities. On March 4, 1993, you and other NPPD representatives discussed these apparent violations at an enforcement conference in the NRC's Region IV office in Arlington, Texas.

The circumstances surrounding these violations warrant some discussion. In August 1992, an NRC inspector found indications of a strainer in the alternate suction piping for the CNS Core Spray System. Although the system drawings did not indicate the presence of a strainer in this system, NPPD investigated and confirmed the presence of temporary strainers, i.e., strainers used during start-up testing and intended to be removed following such testing, in the alternate suction piping for both Core Spray System lines. This prompted NPPD's preparation of Nonconformance Report (NCR) 92-104 and an investigation to determine the root cause. On November 3, 1992, the NRC issued a Notice of Violation to NPPD, citing the failure of its corrective action program to identify and correct this non-conforming condition. In a December 1, 1992 response to the Notice of Violation, NPPD cited the root causes of the violation as: 1) a programmatic weakness in NPPD's actions in response to NRC Information Notice 85-96, entitled "Temporary Strainers Left Installed in Pump Suction Piping;" and 2) the failure of the Core Spray System pre-operational

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

testing procedure to include a specific step regarding the removal of the temporary strainers. NPPD's December 1, 1992, reply also stated that system walkdowns had been conducted to ensure that similar strainers were not located in other safety systems and that there were no visible indications of strainers in the Service Water, Reactor Equipment Cooling, Residual Heat Removal, or High Pressure Coolant Injection systems. With regard to the Reactor Core Isolation Cooling System, the reply stated that an unlabeled spacer plate was discovered in the flange to a spool piece used to install the original startup (temporary) strainer, but stated "A specific completed sign-off in the preoperational test procedure . . . indicates that the strainer had been removed prior to startup testing." Nonetheless, the reply stated, this conclusion would be physically verified by radiography or removal and inspection of the spool piece during the 1993 refueling outage.

On January 27, 1993, during the replacement of a Reactor Equipment Cooling pump, NPPD personnel discovered a temporary strainer installed in the pump suction piping. Radiography of the remaining three Reactor Equipment Cooling pumps confirmed that temporary strainers were present in the suction piping for each. This finding indicated that the system walkdowns relied upon in responding to the November 3, 1992, Notice of Violation may not have been adequate to determine the presence of temporary strainers. Thus, NPPD radiographed the suction piping to the Reactor Core Isolation Cooling pump and confirmed the presence of a temporary strainer in it, a finding which drew into question the statements made in response to the previous violation and discussed above. The facts that have emerged from the NRC's follow-up inspection and from discussions with NPPD personnel during the enforcement conference indicate: 1) that NPPD's December 1, 1992, reply was inaccurate and incomplete in several material respects; and 2) that NPPD had multiple opportunities to act on information that indicated the possibility of temporary strainers left in plant safety systems and failed to do so.

NRC regulations require licensees to ensure that information provided to the NRC is complete and accurate in all material respects. With regard to NPPD's December 1, 1992, letter, the NRC's inspection did not find a "specific completed sign-off in the preoperational test procedure" indicating that the Reactor Core Isolation Cooling pump strainer had been removed. In fact, the only document which would have indicated that the strainers had been removed was Startup Test Instruction (STI) 14. On the only available copy of this document, there was no signature in the block adjacent to Step 6.2.9, which said "Remove suction strainers at a convenient time after completion of all RCIC related tests." Although the individual who prepared NPPD's reply was aware of this documentation at the time the inaccurate reply was submitted, he stated that he relied on an interview with an engineer who had been involved in start-up testing and who assured him that a signed document existed verifying the removal of the temporary strainer. During the enforcement conference, NPPD indicated that the engineer may have been confused by his recollection of a signature on a Reactor Core Isolation Cooling preoperational test document, which indicated only that "Notation has been made to remove these strainers when appropriate." Had the information NPPD provided been

accurate, this information would have caused the NRC to conduct additional inspections or request NPPD to pursue further the question of whether temporary strainers were left in this system.

The NRC must be able to rely on information provided by licensees to make sound regulatory judgements about the safety of licensed activities. Although the submission of inaccurate information in this case appears not to have been willful, the circumstances surrounding it indicate a failure on the part of the Plant Engineering Department supervisor who prepared NPPD's response to the Notice of Violation and carelessness on the part of others who reviewed this information to ensure its accuracy before submission to the NRC. Therefore, in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy) 10 CFR Part 2, Appendix C, Violation A in the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice) has been categorized at Severity Level III.

In addition to the inaccurate statement in NPPD's reply to the Notice of Violation, the reply provided no information regarding other evidence that NPPD had obtained indicating that the possibility of temporary strainers having been left in safety systems could not be ruled out. This information, which was available to NPPD during the preparation of Nonconformance Report 92-104 and prior to the issuance of its December 1, 1992, letter, included: 1) the fact that temporary strainers had been found in the Residual Heat Removal system in 1986, a finding which apparently invalidated NPPD's confidence in its response to NRC Information Notice 85-96 but which resulted in no further efforts to check for the presence of strainers in other systems; 2) the fact that spacer rings were discovered during NPPD's September 1992 walkdown of the Reactor Equipment Cooling system, a finding which, according to the NRC's 1985 information notice, could indicate the presence of temporary strainers; and 3) the fact that NPPD's 1986 evaluation in response to the same information notice had recommended further evaluation of the possibility of temporary strainers in the Reactor Equipment Cooling system and that no further evaluation was done. The NRC believes that this information should have been provided in NPPD's December 1, 1992, response. However, NPPD's failure to provide this information is closely related to the failure of NPPD's corrective action program to evaluate the same information and question whether temporary strainers had been removed from all safety systems. Thus, the NRC has elected to exclude from Violation A in the Notice any reference to the incompleteness of NPPD's response.

The circumstances surrounding the failure of NPPD's corrective action program to identify and resolve the potential for temporary strainers left in safety systems are similar and equally significant. Although Violation B in the enclosed Notice refers only to the failure of NPPD's corrective action program subsequent to the discovery of temporary strainers in the Core Spray system and the issuance of the Notice of Violation in November 1992, the fact is that NPPD has had multiple indicators of the potential for this problem and multiple opportunities over an extended period of time to identify and resolve this issue. Beginning with the issuance of the NRC's information notice in

1985, these included: 1) NPPD's response to the information notice, which identified the possibility of strainers in the Reactor Equipment Cooling system but which resulted in no further evaluation; 2) NPPD's discovery in 1989 of temporary strainers in the Residual Heat Removal System, which also prompted no further evaluation; 3) NPPD's discovery in 1989 of what appeared to be temporary strainers which had affected flow in a fan coil unit; 4) the NRC's discovery in 1992 of temporary strainers in the Core Spray system; and 5) NPPD's awareness that it had no documented evidence of having removed the temporary strainers from the Reactor Core Isolation Cooling system.

Despite all of these indications, and information to the contrary, NPPD took no effective steps to positively ensure that the intended removal of temporary strainers from plant safety systems had been effected. NRC regulations in 10 CFR Part 50 require licensees to have measures in place to assure that "conditions adverse to quality," including deviations and nonconformances, are promptly identified and corrected. In this case, NPPD's program for identifying and resolving such nonconformances failed on multiple occasions. The NRC's 1985 information notice informed NPPD that there are several mechanisms by which temporary construction strainers could cause safety systems to be made inoperable. Although the temporary strainers found in CNS safety systems do not appear to have impacted system operability during normal plant operations, the potential problems discussed in Information Notice 85-96 still existed. Therefore, in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy) 10 CFR Part 2, Appendix C, Violation B has been deemed a failure to identity and resolve a potentially significant condition adverse to quality and has been categorized at Severity Level III.

As described at the enforcement conference, NPPD's short-term corrective actions amounted to an evaluation of the existence of additional strainers by reviewing system drawings, conducting system walkdowns, performing radiography of safety systems, and reviewing existing design basis documentation. NPPD's long-term corrective actions include: 1) plans to evaluate, and remove if necessary, all safety and support system strainers; 2) plans to update affected plant drawings; 3) plans to provide management's expectations to all personnel with respect to NRC submittals; 4) plans to include 10 CFR 50.9 requirements in continuing training programs; 5) plans to include the strainer issue in industry event training; and 6) plans to develop instructions for disposition of broad, multi-system issues.

At the enforcement conference, NPPD identified the root cause of both of these violations as a failure to assign ownership or responsibility for resolving broad, multi-system issues. With respect to the accuracy of information, NPPD identified a secondary root cause as a lack of sensitivity to the requirements of 10 CFR 50.9. NPPD's corrective actions are directed toward these two factors. While the NRC agrees that these factors played a role in these issues, individual performance and commitment to quality performance, may be a contributing root cause. The NRC recommends that NPPD examine these factors and supplement its corrective action as appropriate. In addition, with

respect to the failure of NPPD's corrective action program, the NRC recommends that NPPD focus more attention on the program itself to determine whether a more fundamental weakness exists with regard to the identification and resolution of potential problems. As you know, the NRC has been critical of various aspects of NPPD's corrective action program in the past. In the most recent Systematic Assessment of Licensee Performance report, dated March 16, 1992, we stated that ". . . the threshold for issuance of nonconformance reports was too high to ensure that all potential deficient conditions were identified." Other reports issued in the last year have cited untimely root cause analyses for identified problems, ineffective corrective actions to address copper contamination of station batteries, the failure to document annunciator problems in a nonconformance report, the failure to correct deficiencies in Emergency Operating Procedures and the failure to correct emergency preparedness deficiencies.

To emphasize NPPD's need to improve its problem identification and resolution programs, as well as its need to assure that information provided to the NRC is complete and accurate in all material respects, I have been authorized, after consultation with the Director, Office of Enforcement, and the Deputy Executive Director for Nuclear Reactor Regulation, Regional Operations and Research, to issue the enclosed Notice of Violation and Proposed Imposition of Civil Penalties (Notice) in the amount of $200,000 for the Severity Level III violations described above and in the Notice.

The base value of a civil penalty for a Severity Level III violation is $50,000. The civil penalty adjustment factors in the Enforcement Policy were considered for each violation and resulted in penalties twice the base value for each. For the violation of 10 CFR 50.9, the penalty was increased because it was identified through the pursuit of the NRC's inspectors and because NPPD had information available to it (prior opportunities to identify) that, if acted upon, could have prevented the violation from occurring. These increases were balanced against a decrease based on NPPD having no recent history of violations of this type. The adjusted civil penalty for this violation is $100,000. For the violation of 10 CFR Part 50, Appendix B, Criterion XVI, the penalty was decreased because NPPD identified the strainers that led to the recognition of this violation, but was increased because NPPD had information available to it that, if acted upon, could have prevented this violation from occurring, and because this violation appears to be another indication of generally poor performance in identifying and resolving problems. The adjusted penalty for this violation is $100,000. The remaining adjustment factors were considered for each violation but no additional adjustments were deemed to be warranted.

NPPD is required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing its response. In your response, you should document the specific actions taken and any additional actions you plan to prevent recurrence. In addition, you should include in your response, (1) the measures NPPD has taken, or plans to take, to ensure that NPPD employees involved in communicating with the NRC, and in particular

the aforementioned Plant Engineering Department supervisor, understand the importance of and will comply with the requirements of 10 CFR 50.9 in preparing information for submittal to the NRC and (2) the measures NPPD has taken or plans to take to address possible additional root causes of these violations including individual performance and attitudes, and weaknesses in the identification and resolution of potential deficiencies. After reviewing your response to this Notice, including your proposed corrective actions and the results of future inspections, the NRC will determine whether further NRC enforcement action is necessary to ensure compliance with NRC regulatory requirements.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter and its enclosure will be placed in the NRC Public Document Room.

The responses directed by this letter and the enclosed Notice are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, Pub. L. No. 96-511.

Sincerely,

James L. Milhoan

James L. Milhoan
Regional Administrator

Enclosure:
Notice of Violation and Proposed Imposition
of Civil Penalties

cc:
Nebraska Public Power District
ATTN: G. D. Watson, General Counsel
P.O. Box 499
Columbus, Nebraska 68602-0499

Cooper Nuclear Station
ATTN: John M. Meacham, Site Manager
P.O. Box 98
Brownville, Nebraska 68321

Nebraska Department of Environmental
Control
ATTN: Randolph Wood, Director
P.O. Box 98922
Lincoln, Nebraska 68509-8922

Nemaha County Board of Commissioners
ATTN: Richard Moody, Chairman
Nemaha County Courthouse
1824 N Street
Auburn, Nebraska 68305

Nebraska Department of Health
ATTN: Harold Borchert, Director
Division of Radiological Health
301 Centennial Mall, South
P.O. Box 95007
Lincoln, Nebraska 68509-5007

Kansas Radiation Control Program Director

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTIES

Nebraska Public Power District
Cooper Nuclear Station

Docket No. 50-298
License No. DPR-46
EA 93-030

During an NRC inspection conducted on February 1-9, 1993, violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C, the Nuclear Regulatory Commission proposes to impose civil penalties pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (Act), 42 U.S.C. 2282, and 10 CFR 2.205. The particular violations and associated civil penalties are set forth below:

A. 10 CFR 50.9 requires, in part, that information provided to the Commission by a licensee shall be complete and accurate in all material respects.

Contrary to the above, in a letter dated December 1, 1992, the licensee provided written information to the Commission that was inaccurate and incomplete in material respects. The information provided by the licensee was in response to a Notice of Violation issued by the NRC on November 3, 1992, involving the failure of the licensee to identify and remove temporary strainers in the Core Spray system. This information was inaccurate because the licensee's response stated, with respect to the Reactor Core Isolation Cooling system, that "A specific completed sign-off in the preoperational test procedure (unlike the CS System pre-operational test) indicates that the strainer had been removed prior to start up testing." In fact, no such document existed indicating that the Reactor Core Isolation Cooling pump strainer had been removed. The only document which would have indicated that the strainers had been removed was Startup Test Instruction (STI) 14. On the only available copy of this document, there was no signature in the block adjacent to Step 6.2.9, which said "Remove suction strainers at a convenient time after completion of all RCIC related tests." This information was material because the NRC relied upon it as evidence that no temporary strainers existed in this system. On January 29, 1993, the Reactor Core Isolation Cooling system temporary strainer was found to have been left in the system.

This is a Severity Level III violation (Supplement VII).
Civil Penalty - $100,000

B. 10 CFR Part 50, Appendix B, Criterion XVI, requires, in part, that measures shall be established to assure that conditions adverse to quality, such as deviations and nonconformances, are promptly identified and corrected.

Contrary to the above, between August 1992 and December 1992, measures established by the licensee to promptly identify and correct nonconformances did not assure the identification and correction of a potentially significant condition adverse to quality -- the presence of

temporary strainers in the Reactor Equipment Cooling and the Reactor Core Isolation Cooling systems. In response to the identification of temporary strainers in the Core Spray system in August 1992, the licensee became aware of an incomplete evaluation for temporary strainers on the Reactor Equipment Cooling system and observed unmarked spacer rings in the Reactor Equipment Cooling system, and did not identify and correct the nonconforming condition until January 1993 when a strainer was observed during corrective maintenance. In addition, the licensee became aware that there was a lack of documentation to substantiate its belief that temporary strainers in the Reactor Core Isolation Cooling system had been removed. In spite of the fact that documentation did not exist, as described in Violation A, the presence of temporary strainers, a nonconforming condition, was not identified until January 1993, following the identification of temporary strainers in the Reactor Equipment Cooling system.

This is a Severity Level III violation (Supplement I).
Civil Penalty - $100,000

Pursuant to the provisions of 10 CFR 2.201, Nebraska Public Power District (Licensee) is hereby required to submit a written statement or explanation to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, within 30 days of the date of this Notice of Violation and Proposed Imposition of Civil Penalties (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each alleged violation: (1) admission or denial of the alleged violation, (2) the reasons for the violation if admitted, and if denied, the reasons why, (3) the corrective steps that have been taken and the results achieved, (4) the corrective steps that will be taken to avoid further violations, and (5) the date when full compliance will be achieved.

If an adequate reply is not received within time specified in this Notice, an order or demand for information may be issued as to why the license should not be modified, suspended, or revoked or why such other action as may be proper should not be taken. Consideration may be given to extending the response time for good cause shown. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, this response shall be submitted under oath or affirmation.

Within the same time as provided for the response required above under 10 CFR 2.201, the Licensee may pay the civil penalties by letter addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, with a check, draft, money order, or electronic transfer payable to the Treasurer of the United States in the amount of the civil penalty proposed above, or the cumulative amount of the civil penalties if more than one civil penalty is proposed, or may protest imposition of the civil penalties in whole or in part, by a written answer addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission. Should the Licensee fail to answer within the time specified, an order imposing the civil penalties will be issued. Should the Licensee elect to file an answer in accordance with 10 CFR 2.205

protesting the civil penalties, in whole or in part, such answer should be clearly marked as an "Answer to a Notice of Violation" and may: (1) deny the violations listed in this Notice, in whole or in part, (2) demonstrate extenuating circumstances, (3) show error in this Notice, or (4) show other reasons why the penalties should not be imposed. In addition to protesting the civil penalties in whole or in part, such answer may request remission or mitigation of the penalties.

In requesting mitigation of the proposed penalties, the factors addressed in Section VI.B.2 of, 10 CFR Part 2, Appendix C, should be addressed. Any written answer in accordance with 10 CFR 2.205 should be set forth separately from the statement or explanation in reply pursuant to 10 CFR 2.201, but may incorporate parts of the 10 CFR 2.201 reply by specific reference (e.g., citing page and paragraph numbers) to avoid repetition. The attention of the Licensee is directed to the other provisions of 10 CFR 2.205, regarding the procedure for imposing civil penalties.

Upon failure to pay any civil penalties due which subsequently has been determined in accordance with the applicable provisions of 10 CFR 2.205, this matter may be referred to the Attorney General, and the penalties, unless compromised, remitted, or mitigated, may be collected by civil action pursuant to Section 234c of the Act, 42 U.S.C. 2282c.

The response noted above (Reply to Notice of Violation, letter with payment of civil penalties, and Answer to a Notice of Violation) should be addressed to: Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555 with a copy to the Regional Administrator, U.S. Nuclear Regulatory Commission, Region IV, 611 Ryan Plaza Drive, Suite 400, Arlington, Texas 76011, and a copy to the NRC Resident Inspector at the Cooper Nuclear Station.

Dated at Arlington, Texas
this 30th day of March 1993

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

JUN 23 1993

Docket No. 50-298
License No. DPR-46
EA 93-030

Nebraska Public Power District
ATTN: Guy Horn, Nuclear Power
Group Manager
Post Office Box 499
Columbus, Nebraska 68602-0499

SUBJECT: ORDER IMPOSING CIVIL MONETARY PENALTIES - $200,000

This refers to your letter dated April 29, 1993, in response to the Notice of Violation and Proposed Imposition of Civil Penalties (Notice) sent to you by our letter dated March 30, 1993. Our letter and Notice described violations of 10 CFR 50.9 and 10 CFR Part 50, Appendix B, Criterion XVI. To emphasize the need to improve the plant problem identification and resolution programs as well as the need to assure that information provided to the NRC is complete and accurate in all material respects, civil penalties of $100,000 for each of the violations were proposed.

In your response, you admitted the violations but requested that the NRC reconsider the penalties based on a number of factors you described in Attachment 2 to your letter. A summary of the reasons for your request for mitigation is contained in the Appendix to the enclosed Order.

After consideration of your request for mitigation of the penalties, we have concluded for the reasons given in the appendix to the enclosed Order Imposing Civil Monetary Penalties that the full amount of the penalties should be imposed. Accordingly, we hereby serve the enclosed Order on Nebraska Public Power District, imposing civil monetary penalties in the amount of $200,000. The NRC will review the effectiveness of your corrective actions during future inspections.

CERTIFIED MAIL
RETURN RECIEPT REQUESTED

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice", a copy of this letter and the enclosure will be placed in the NRC's Public Document Room.

Sincerely,

James H. Sniezek

James H. Sniezek
Deputy Executive Director
for Nuclear Reactor Regulation,
Regional Operations and Research

Enclosure: As Stated

cc w/enclosure:

Nebraska Public Power District
ATTN: G. D. Watson, General Counsel
P.O. Box 499
Columbus, Nebraska 68602-0499

Cooper Nuclear Station
ATTN: John M. Meacham, Site Manager
P.O. Box 98
Brownville, Nebraska 68321

Nebraska Department of Environmental
Control
ATTN: Randolph Wood, Director
P.O. Box 98922
Lincoln, Nebraska 68509-8922

Nemaha County Board of Commissioners
ATTN: Richard Moody, Chairman
Nemaha County Courthouse
1824 N Street
Auburn, Nebraska 68305

Nebraska Department of Health
ATTN: Harold Borchert, Director
Division of Radiological Health
301 Centennial Mall, South
P.O. Box 95007
Lincoln, Nebraska 68509-5007

Kansas Radiation Control Program Director

UNITED STATES
NUCLEAR REGULATORY COMMISSION

In the Matter of	)	
	)	
NEBRASKA PUBLIC POWER DISTRICT	)	Docket No. 50-298
COOPER NUCLEAR STATION	)	License No. DPR-46
	)	EA 93-030

ORDER IMPOSING CIVIL MONETARY PENALTIES

I

Nebraska Public Power District (Licensee) is the holder of NRC License No. DPR-46 issued by the Nuclear Regulatory Commission (NRC or Commission). The license authorizes the Licensee to operate Cooper Nuclear Station in accordance with the provisions of the license.

II

An inspection of the Licensee's activities was conducted February 1-9, 1993. The results of this inspection indicated that the Licensee had not conducted its activities in full compliance with NRC requirements. A written Notice of Violation and Proposed Imposition of Civil Penalties (Notice) was served upon the Licensee by letter dated March 30, 1993. The Notice described the nature of the violations, the provisions of the NRC's requirements that the Licensee had violated, and the amount of the civil penalties proposed for the violations.

The Licensee responded to the Notice in a letter dated April 29, 1993. In its response, the Licensee admitted the violations which resulted in the proposed civil penalties, but requested

mitigation for reasons that are summarized in the appendix to this Order.

III

After consideration of the Licensee's response and the statements of fact, explanation, and argument for mitigation contained therein, the NRC staff has determined, as set forth in the Appendix to this Order, that the violations occurred as stated and that the penalties proposed for the violations designated in the Notice should be imposed.

IV

In view of the foregoing and pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (Act), 42 U.S.C. 2282, and 10 CFR 2.205, IT IS HEREBY ORDERED THAT:

The Licensee pay civil penalties in the amount of $200,000 within 30 days of the date of this Order, by check, draft, money order, or electronic transfer, payable to the Treasurer of the United States and mailed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555.

V

The Licensee may request a hearing within 30 days of the date of this Order. A request for a hearing should be clearly marked as a "Request for an Enforcement Hearing," and shall be addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555. Copies also shall be sent to the Assistant General Counsel for Hearings and Enforcement at the same address and to the Regional Administrator, NRC Region IV, 611 Ryan Plaza Drive, Suite 400, Arlington, Texas 76011.

If a hearing is requested, the Commission will issue an Order designating the time and place of the hearing. If the Licensee fails to request a hearing within 30 days of the date of this Order, the provisions of this Order shall be effective without further proceedings. If payment has not been made by that time, the matter may be referred to the Attorney General for collection.

In the event the Licensee requests a hearing as provided above, the issue to be considered at such hearing shall be:

Whether, on the basis of the violations admitted by the Licensee, this Order should be sustained.

FOR THE NUCLEAR REGULATORY COMMISSION

James H. Sniezek
Deputy Executive Director
for Nuclear Reactor Regulation,
Regional Operations and Research

Dated at Rockville, Maryland
this 23rd day of June 1993

APPENDIX

EVALUATION AND CONCLUSION

On March 30, 1993, a Notice of Violation and Proposed Imposition of Civil Penalties (Notice) was issued for violations identified during an NRC inspection. Nebraska Public Power District (NPPD) responded to the Notice on April 29, 1993. NPPD admitted the violations that resulted in the proposed civil penalties, but requested mitigation. The NRC staff's evaluation and conclusion regarding NPPD's request follow:

Restatement of Violations

A. 10 CFR 50.9 requires, in part, that information provided to the Commission by a licensee shall be complete and accurate in all material respects.

Contrary to the above, in a letter dated December 1, 1992, the licensee provided written information to the Commission that was inaccurate and incomplete in material respects. The information provided by the licensee was in response to a Notice of Violation issued by the NRC on November 3, 1992, involving the failure of the licensee to identify and remove temporary strainers in the Core Spray system. This information was inaccurate because the licensee's response stated, with respect to the Reactor Core Isolation Cooling system, that "A specific completed sign-off in the preoperational test procedure (unlike the CS System pre-operational test) indicates that the strainer had been removed prior to start up testing." In fact, no such document existed indicating that the Reactor Core Isolation Cooling pump strainer had been removed. The only document which would have indicated that the strainers had been removed was Startup Test Instruction (STI) 14. On the only available copy of this document, there was no signature in the block adjacent to Step 6.2.9, which said "Remove suction strainers at a convenient time after completion of all RCIC related tests." This information was material because the NRC relied upon it as evidence that no temporary strainers existed in this system. On January 29, 1993, the Reactor Core Isolation Cooling system temporary strainer was found to have been left in the system.

This is a Severity Level III violation (Supplement VII).
Civil Penalty - $100,000

B. 10 CFR Part 50, Appendix B, Criterion XVI, requires, in part, that measures shall be established to assure that conditions adverse to quality, such as deviations and nonconformances, are promptly identified and corrected.

Contrary to the above, between August 1992 and December 1992, measures established by the licensee to promptly

identify and correct nonconformances did not assure the identification and correction of a potentially significant condition adverse to quality -- the presence of temporary strainers in the Reactor Equipment Cooling and the Reactor Core Isolation Cooling systems. In response to the identification of temporary strainers in the Core Spray system in August 1992, the licensee became aware of an incomplete evaluation for temporary strainers on the Reactor Equipment Cooling system and observed unmarked spacer rings in the Reactor Equipment Cooling system, and did not identify and correct the nonconforming condition until January 1993 when a strainer was observed during corrective maintenance. In addition, the licensee became aware that there was a lack of documentation to substantiate its belief that temporary strainers in the Reactor Core Isolation Cooling system had been removed. In spite of the fact that documentation did not exist, as described in Violation A, the presence of temporary strainers, a nonconforming condition, was not identified until January 1993, following the identification of temporary strainers in the Reactor Equipment Cooling system.

This is a Severity Level III violation (Supplement I).
Civil Penalty - $100,000

Summary of NPPD's Request for Mitigation

In its April 29, 1993, letter, NPPD admitted the above violations but requested mitigation of the penalty, citing the following reasons:

1. The magnitude and extent of the corrective actions taken and planned by NPPD are such that the NRC has already achieved its objectives in the matter without imposing the civil penalties;

2. NPPD has not had an "accuracy and completeness" related violation for many years; and

3. NPPD's previous enforcement history should not reasonably lead to civil penalties of the magnitude proposed.

NRC Staff's Evaluation of Licensee's Request for Mitigation

The NRC staff's evaluation of the Licensee's arguments for mitigation follows:

1. The NRC staff recognizes that NPPD has supplemented the corrective actions it described at the enforcement conference to address the concerns that the NRC staff described in the letter transmitting the March 30, 1993

Notice regarding individual performance issues and NPPD's problem identification and resolution programs. These additional actions, while important, do not serve as evidence that the NRC staff has achieved all of its objectives in this matter. The NRC's Enforcement Policy states that civil penalties are designed to emphasize the need for lasting remedial action and to deter future (emphasis added) violations. The fact that NPPD has taken steps toward preventing future violations is encouraging. However, since the NRC's letter appears to have been the reason for NPPD having developed these steps, and since the success of NPPD's corrective actions for the 10 CFR Part 50, Appendix B, Criterion XVI violation, which involved multiple opportunities to identify the strainer problem, remains to be determined, the NRC does not agree that these actions provide a basis for mitigation of the proposed penalties.

2. The NRC staff does not disagree with NPPD's statements about its history of compliance with 10 CFR 50.9 and the completeness and accuracy of information it has provided to the NRC staff. This information was recognized by the NRC staff in proposing the civil penalty for this violation and in fact, as alluded to in the Notice, resulted in the penalty being reduced. However, this reduction was more than offset by increases for prior opportunities to identify and NRC staff identification of the violation.

3. The NRC staff took NPPD's enforcement and performance history into account in determining the proposed penalties. As indicated above, the penalty for the violation of 10 CFR 50.9 reflected NRC staff's view that NPPD's performance in this specific area had been good. With regard to the violation of 10 CFR Part 50, Appendix B, Criterion XVI, the penalty reflected the NRC staff's view that NPPD's corrective action programs have not been completely effective in identifying and resolving conditions adverse to quality. This was discussed on pages 4-5 of the cover letter to the Notice. Several documented weaknesses in NPPD's corrective action programs were cited in that letter. These were considered evidence of generally poor performance in identifying and resolving problems and, in accordance with the Enforcement Policy, used as a basis for increasing the penalty under the Licensee Performance factor. The NRC staff finds that NPPD's performance was adequately considered in determining the size of the penalties.

NRC Staff's Conclusion

NPPD has not provided information sufficient to cause the NRC staff to consider a reduction in the size of the proposed civil penalties. Consequently, the proposed civil penalties in the amount of $200,000 should be imposed by order.

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PENNSYLVANIA 19406-1415

JUL 21 1993

Docket No. 50-286
License No. DPR-64
EA 93-036

Mr. Ralph Beedle
Executive Vice President - Nuclear
New York Power Authority
123 Main Street
White Plains, New York 10601

Dear Mr. Beedle:

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTIES - $300,000
(NRC INSPECTION REPORT NOS. 50-286/92-28, 93-03 AND 93-09)

This letter refers to NRC inspections conducted from November 15, 1992 to April 8, 1993, at Indian Point, Unit 3, Buchanan, New York. The inspection reports were sent to you on February 18, March 17, and April 14, 1993. During the inspections, multiple violations of NRC requirements were identified. On April 27, 1993, an enforcement conference was held with you and members of your staff to discuss these violations, their root causes, and your actions to correct the violations and prevent recurrence.

The violations are described in the enclosed Notice of Violation and Proposed Imposition of Civil Penalties (Notice) (Enclosure 1). The first violation, set forth in Section A of the Notice, involved the failure to ensure compliance with 10 CFR 50.62, which requires a reliable system to automatically initiate the auxiliary feedwater system and turbine trip under conditions indicative of an Anticipated Transient Without Scram (ATWS). Specifically, after the failed performance of a semiannual logic test on December 31, 1992, NRC inspectors identified that the ATWS Mitigation System Actuation Circuitry (AMSAC) system had not undergone the end-to-end testing or quality assurance oversight to which you committed in your response to the 10 CFR 50.62 requirements. As a result of these findings, you determined that the reliability of the AMSAC was questionable, and commenced a plant shutdown on February 26, 1993, to address this deficiency. Upon further review and investigation, you determined that the AMSAC system had been inoperable under certain conditions since June 12, 1989, when the system was originally placed in service. Your failure to correctly translate the design basis information into the design specifications prior to initial installation, as well as your failure to perform adequate testing and maintain adequate quality assurance oversight of the system, resulted in the failure to ensure that the AMSAC system would function in a reliable manner. This constitutes a violation of the requirements of 10 CFR 50.62.

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

The equipment required by 10 CFR 50.62 is intended to serve an important safety function in the event of a failure of the plant's principal reactor protection systems. This regulation was adopted following actual failures of the reactor trip system at another pressurized water reactor in 1983 and is intended to reduce the risk posed by such events. Your failure to ensure proper functioning and reliability of this system since the original installation is a significant regulatory concern. Therefore, in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy) 10 CFR Part 2, Appendix C, this violation has been categorized at Severity Level III.

The second problem, set forth in Section B of the Notice, involves multiple violations of plant procedures during testing of the reactor coolant system (RCS) level instrumentation with the RCS in the mid-loop condition on March 19, 1993. Several procedural violations resulted in a loss of reactor vessel water level monitoring and indication while in the mid-loop condition, after the operators isolated the only operable means of level indication to perform system flushing. Isolation of the level instrument under this condition was outside the scope of the procedure. Another procedural requirement to notify operations management when the level indications are unavailable or inconsistent was not followed. Concurrent with the level indicator problems, the ability to immediately raise the water level above the reduced inventory condition was prevented by work on the reactor coolant pump (RCP) seal, which was prematurely initiated without the knowledge of the operations department. Since the RCP seal work had been delayed by the RCS level testing, a management decision was made to initiate the motor work while the level testing was in progress. This management decision, not subject to the established work control and planning process that includes a safety determination to address plant conditions, resulted in work on the RCS boundary without the required prerequisites being met. The conduct of these work activities outside of your work control program are violations of 10 CFR Part 50, Appendix B, Criterion V.

The failure to properly monitor and control RCS level during mid-loop condition can result in a loss of decay heat removal capability and is a significant safety concern. In view of this potential degradation, Generic Letter 88-17 recommended, and NYPA committed to provide, at least two independent continuous RCS level indications whenever the RCS is in the reduced inventory condition. Further, your initiation of the RCP seal work with the RCS in mid-loop condition, while level instrumentation was not available, reflected poor management practice and a breakdown of work controls. Given the potential safety significance of mid-loop operation and the importance of adhering to the procedural controls, the three associated violations are also categorized in the aggregate at Severity Level III.

The remaining seven violations of plant technical specification requirements are set forth in Section C of the Notice. These violations include, but are not limited to the following: (1) bringing the plant to a hot shutdown condition without ensuring operability of the control room ventilation system; (2) exceeding the limiting condition of operation for the auxiliary boiler feedwater pumps (ABFPs) in that one pump was inoperable for 26 days, and on two occasions during this time period, two ABFPs were inoperable for more than twelve hours and the plant was not shut down; (3) exceeding the limiting conditions of operation for boric acid transfer pumps in that two such pumps were inoperable for over five days and the plant was not placed in a shutdown condition; (4) not performing periodic surveillance tests of the radwaste and the radioactive machine shop building effluent flow measurement devices; and (5) multiple violations of plant procedural requirements. To emphasize the high safety significance NRC assigns to plant technical specification limiting conditions of operation and the importance of following plant procedures, in accordance with the NRC Enforcement Policy these violations are also categorized in the aggregate as a Severity Level III problem.

The violations described above reflect an inadequate surveillance testing program, inadequate procedures, the failure to follow procedures, and an overall inattention to detail by plant personnel. NYPA management failed to address the root causes of these violations despite numerous violations and several civil penalties issued in the last two years involving similar issues. Management's failure to correct these problems is of significant concern to the NRC.

The NRC recognizes that NYPA shut the plant down after the AMSAC problem and initiated an extensive performance improvement program to address the deficiencies related to human performance, the lack of attention to detail, and the associated breakdown in management controls and processes that contributed to these and other deficiencies. The NRC also recognizes that you have decided not to restart the plant until after the completion of corrective actions. Although your initial corrective actions in addressing the AMSAC problem were slow, the corrective actions related to the plant evolution in the mid-loop condition were considered prompt and comprehensive. Further, your corrective actions taken after the identification of the violation of the ABFP technical specification requirements, were considered prompt and responsive.

Notwithstanding these corrective actions, to emphasize the significance of the conditions that existed at Indian Point 3, and the need to assure (1) the plant is operated and maintained safely and in accordance with Technical Specifications, and (2) the existing management, human performance and AMSAC system deficiencies are corrected, I have been authorized, after consultation with the Director, Office of Enforcement, the Deputy Executive Director for Nuclear Reactor Regulation, Regional Operations and Research, and the Commission, to issue the enclosed Notice of Violation and Proposed Imposition of Civil Penalties (Notice) of $100,000 for each of the three Severity Level III violations or problems set forth in the enclosed Notice, for a cumulative amount of $300,000.

The base civil penalty amount for a Severity Level III violation or problem is $50,000. Normal application of the enforcement policy could have resulted in significantly higher civil penalty amounts for each of the three Severity Level III violations or problems cited in the Notice. For example, escalation could be applied because of your poor overall past performance (four civil penalties with a cumulative amount of $462,500 issued in 1992), prior notice for the first two areas cited (Information Notice 92-06, "Reliability of ATWS Mitigation System and Other NRC Required Equipment Not Controlled by Plant Technical Specifications," dated January 15, 1992, and Generic Letter 88-17, "Loss of Decay Heat Removal"), and the duration of several of the violations in the third area. However, in light of your initiative to shut down the plant until you could successfully implement an extensive improvement program to address the underlying root causes of human performance deficiencies, your self-imposed commitment not to restart the plant without prior NRC approval and your significant management changes, the NRC has decided to exercise broad enforcement discretion and reduce the cumulative penalties to $300,000.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. In your response, you should document the specific actions taken and any additional actions you plan to prevent recurrence. After reviewing your response to this Notice, including your proposed corrective actions and the results of future inspections, the NRC will determine whether further NRC enforcement action is necessary to ensure compliance with NRC regulatory requirements.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter and its enclosure will be placed in the NRC Public Document Room.

The responses directed by this letter and the enclosed Notice are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, Pub. L. No. 96-511.

Sincerely,

Thomas T Martin
Regional Administrator

Enclosure: Notice of Violation and Proposed Imposition
of Civil Penalties

cc w/encl:
R. Schoenberger, President
W. Josiger, Vice President - Nuclear Operations
J. Garrity, Resident Manager
G. Goldstein, Assistant General Counsel
P. Kokolakis, Director, Nuclear Licensing - PWR
G. Begany, Mayor, Village of Buchanan
C. Jackson, Nuclear Safety and Licensing Manager (Con Ed)
C. Donaldson, Esquire, Assistant Attorney General, New York Department of Law
S. Galef, Assemblywoman, New York State (NYS) Assembly
Director, Energy and Water Division, Department of Public Service, State of New York
Chairman, Standing Committee on Energy, NYS Assembly
Chairman, Standing Committee on Environmental Conservation, NYS Assembly
Executive Chair, Four County Nuclear Safety Committee
K. Abraham, PAO-RI (2)
Public Document Room (PDR)
Local Public Document Room (LPDR)
Nuclear Safety Information Center (NSIC)
NRC Resident Inspector
State of New York, SLO Designee

ENCLOSURE

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTIES

New York Power Authority
Buchanan, New York

Docket No. 50-286
License No. DPR-64
EA 93-036

During NRC inspections conducted from November 15, 1992 to April 8, 1993, violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C, the Nuclear Regulatory Commission proposes to impose civil penalties pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (Act), 42 U.S.C. 2282, and 10 CFR 2.205. The particular violations and associated civil penalties are set forth below:

A. Violation of 10 CFR 50.62

10 CFR 50.62(c) requires, in part, that each pressurized water reactor must have equipment to automatically initiate the auxiliary feedwater system and initiate a turbine trip under conditions indicative of an anticipated transient without scram (ATWS). This equipment must be designed to perform its function in a reliable manner and be independent (from sensor output to the final actuation device) from the existing reactor trip system.

Contrary to the above, the ATWS mitigation system actuation circuitry (AMSAC), (i.e., the equipment installed to automatically initiate the auxiliary feedwater system and a turbine trip under conditions indicative of an ATWS) was not designed and maintained to perform its function in a reliable manner. Specifically, from June 12, 1989, to February 26, 1993, the AMSAC would not have automatically initiated a turbine trip within the required time under certain conditions because of a design error with the turbine ramp timer. Also, the automatic auxiliary feedwater initiation function of AMSAC was not available from July 8, 1992 to January 13, 1993, and no other independent system was provided.

This is a Severity Level III violation (Supplement I).

Civil Penalty - $100,000

B. Violations of the Procedures During Mid-loop Condition

10 CFR Part 50, Appendix B, Criterion V requires, in part, that activities affecting quality be prescribed by documented instructions, procedures, or drawings, of a type appropriate to the circumstances and shall be accomplished in accordance with these instructions, procedures, or drawings.

1. Procedures POP-4.2, "Draining the RCS," and SOP-RCS-10, "Operations with the RCS Drained or at Mid-Loop," provide instructions to control reactor coolant system (RCS) draindown to mid-loop operation, an activity affecting quality.

   Contrary to the above, on March 19, 1993, the operators isolated the only operable means of level indication to flush the instrument lines with the RCS in the mid-loop condition. This activity was not provided for in the above controlling procedures.

2. POP-4.2, "Draining the RCS," Step 4.5.2, states that if either the permanent level indicator or the ultrasonic level monitoring system (ULMS) is lost while draining the RCS, stop the drain and notify the Operations Manager to determine if draindown should be continued. Further, step 4.5.4 of the procedure states that if, in a steady state condition, the level indications from these two measurements do not agree within one inch, notify the Technical Services Manager to resolve the discrepancy.

   Contrary to the above, on March 19, 1993, while in a mid-loop condition and in the process of draining the RCS, the permanent level indicator was lost, operators stopped the draindown process but did not notify the Operations Manager. Further, after a steady state condition was established, and the level indications from the two measurements did not agree within one inch, the operators did not notify the Technical Services Manager to resolve the discrepancy.

3. AP-22, "Conduct of Maintenance," Section D.3, which prescribes an activity affecting quality, requires that prior to and during work performance, maintenance supervision should ensure that the personnel understand the written instructions, including all prerequisites and safety precautions, and that clearances are obtained and enforced.

Contrary to the above, on March 19, 1993, maintenance supervision did not ensure that personnel understood written instructions including prerequisites and safety precautions, and that the appropriate clearance was obtained and enforced. Specifically, work clearance No. 11308 obtained for the job was not enforced, in that, after uncoupling and removal of No. 32 and 33 Reactor Coolant Pump (RCP) motor, the maintenance personnel continued with the removal of the No. 32 and 33 RCP seal packages, when the clearance No. 11308 did not authorize removal of seal packages.

These violations are categorized in the aggregate as a Severity Level III problem (Supplement I).

Civil Penalty - $100,000

C. Violations of Technical Specifications

1. Indian Point 3 Technical Specification 3.3.H.1 requires that the control room ventilation system be operable at all times when containment integrity is required.

   Contrary to the above, on July 23, 1992, the control room ventilation system was inoperable, and the plant was brought to a hot shutdown condition, a condition that requires containment integrity. Specifically, the control room ventilation system was inoperable because 3PT-R32C, the surveillance test for demonstrating operability had not been completed. Further, system operability was not adequately demonstrated until December 16, 1992.

2. Indian Point 3 Technical Specification Section 3.4.A.2 requires that all three Auxiliary Boiler Feedwater pumps be operable when the reactor is above 350 degrees F. If one Auxiliary Boiler Feedwater pump is inoperable for more than 72 hours, the reactor must be placed in a hot shutdown condition within the next 12 hours. With two Auxiliary Boiler Feedwater pumps inoperable, the reactor is required to be placed in a hot shutdown condition within 12 hours.

   Contrary to the above, from December 3 to December 29, 1992, the 32 Auxiliary Boiler Feedwater pump was inoperable and the reactor was above 350 degrees F and was not placed in a hot shutdown condition. Additionally, during this time period a second Auxiliary Boiler Feedwater pump was inoperable for greater than 12 hours on two occasions, and the reactor was not placed in a hot shutdown condition.

3. Indian Point 3 Technical Specification Section 3.2.B.2 requires two Boric Acid Transfer pumps to be operable. If two Boric Acid Transfer pumps are inoperable, the plant must be placed in a hot shutdown condition by using normal operating procedures. If conditions are not met within 48 hours, the reactor shall be brought to a cold shutdown condition.

   Contrary to the above, two Boric Acid Transfer pumps were inoperable between February 19 and 25, 1993, a time period longer than 48 hours, but the reactor was not brought to a cold shutdown condition.

4. Indian Point 3 Environmental Technical Specification Table 3.1-1, Item 3.a, requires that liquid radwaste effluent flow measurement devices be tested once per quarter.

   Contrary to the above, as of December 4, 1992, a surveillance test of the liquid radwaste effluent flow measurement device had not been performed since June 24, 1992, a period longer than a quarter.

5. Indian Point 3 Environmental Technical Specification Table 3.1-1, Item 4.d, requires that the radioactive machine shop (RAMS) building effluent flow rate monitor be calibrated every refueling interval.

   Contrary to the above, as of December 4, 1992, the RAMS building effluent flow rate monitor had not been calibrated since September 21, 1989, a period exceeding two refueling intervals.

6. Indian Point 3 Environmental Technical Specification Section 1.4 requires that the Offsite Dose Calculational Manual (ODCM) contain the current methodology used for the conduct of dose calculations and the environmental monitoring program.

   Indian Point 3 Technical Specification 6.8.1.g requires that written procedures shall be established, implemented and maintained covering ODCM implementation.

   The ODCM, Section 2.1.5, implemented by plant procedure SOP-WDS-14 at Section 2.4, requires that two tank volumes be recirculated prior to sampling.

   Contrary to the above, during the time period between July and September 1992, on 32 occasions, two tank volumes were not recirculated prior to sampling.

7. Indian Point 3 Technical Specification Section 6.8.1 requires that procedures be established, implemented and maintained covering the activities referenced in Appendix A of Regulatory Guide 1.33, "Quality Assurance Requirements (Operation)," dated November 1972 and for surveillance and test activities of safety related equipment.

Section A of Appendix A of Regulatory Guide 1.33 requires procedures for equipment control, safe operation, and review and control of plant procedures. Section I of Appendix A requires procedures for the performance of maintenance on safety related equipment.

a. Procedure AP-19, "Surveillance Test Program," Section E.1.c, written to comply with TS 6.8.1 and Regulatory Guide 1.33, requires that when significant conditions are discovered which may be adverse to safety, the measures used for correction shall assure that documentation is completed, including Significant Occurrence Reports (SORs), and reported to appropriate levels of management.

Procedure AP-8, "Reportability Manual," Section VI.B.5, written to comply with TS 6.8.1 and Regulatory Guide 1.33, requires that a significant occurrence report (SOR) be written for deficiencies found during testing, or malfunctions, or failures of components or systems required to be operable by the plant's technical specifications.

Contrary to the above, on two occasions, NYPA did not write an SOR when deficiencies, adverse to safety, were found during testing, or failure of components or systems required to be operable by the plant's technical specification were identified. Specifically:

1. In November 1992, an SOR was not written when NYPA identified a test deficiency with surveillance test 3PT-R7, "Auxiliary Boiler Feed Water Pumps Full Flow Test." Auxiliary Boiler Feed Water Pumps were required to be operable by the plant technical specification 3.4.A.2.

2. On June 1, 1992, test 3PT-R22C, "Control Room Filtration System Functional Test," failed. On July 23, 1992, the system was required to be operable by plant technical specification 3.3.H.1 and a SOR had not been written.

b. Procedure AP-21.9, "Inoperable Technical Specification Equipment Tracking Log," Section II.D, written to comply with TS 6.8.1 and Regulatory Guide 1.33, requires that only the shift supervisor may declare equipment operable.

Contrary to the above, on August 4, 1992, a non-licensed individual, not the shift supervisor, declared the turbine-driven Auxiliary Boiler Feed Pump operable. Specifically the individual changed the shift supervisor's operability determination from "not operable" to "operable" for the Auxiliary Boiler Feed Pump Functional Test, 3PT-M20A.

c. Procedure PFM-49, "Startup Prerequisite List," Section IV, written to comply with TS 6.8.1 and Regulatory Guide 1.33, requires verification that the surveillance tests required for plant operation have been completed before plant startup from extended outages.

Contrary to the above, during the startup from refueling outage 8/9 in July 1992, NYPA did not use PFM-49, and thus did not verify that surveillance tests required for plant operation had been completed before startup.

d. Procedure AP-19, "Surveillance Test Program," Section IV.C.1.d, written to comply with TS 6.8.1 and Regulatory Guide 1.33, requires that whenever alternate or temporary instrumentations are used in a surveillance test, a Temporary Procedure Change (TPC) shall be generated that both installs and removes these temporary instruments and documents/justifies the use of alternate instrumentation.

Contrary to the above, on February 25, 1993, Indian Point 3 operators installed an alternate temporary test gauge while performing surveillance test 3PT-Q38, "Boric Acid Transfer Pump Functional Test," and a TPC was not generated prior to installation and use.

e. Procedure AP-3, "Procedure Preparation, Review and Approval," Section IV.B, written to comply with TS 6.8.1 and Regulatory Guide 1.33, requires that station procedures be reviewed every two years.

Contrary to the above, as of February 16, 1993, station Procedure PFM-49, "Startup Prerequisite List," had not received the required review every two years as the procedure was last reviewed on March 5, 1990.

f. Procedure AP-19, "Surveillance Test Program," Section IV.E.1, written to comply with TS 6.8.1 and Regulatory Guide 1.33, requires that upon completion of a test, a review shall be conducted to ensure that all data is entered satisfactorily and that the appropriate documentation is attached to the test. Additionally, a final review shall be performed to ensure that acceptance criteria and test reviews are properly completed and test comments are reviewed and appropriate actions are implemented

Contrary to the above, upon the completion of surveillance test 3PT-R123 "31 and 32 Residual Heat Removal Heat Exchanger Outlet Safety Relief Valves 819A and 819B," commenced on May 21, 1992, NYPA did not ensure that the test data was entered and reviewed satisfactorily, that appropriate documentation was provided, and that test comments were properly reviewed.

g. Procedure AP-25.2, "Nuclear Safety Evaluations, Environmental Impact Evaluations, and Classifications of Structures, Systems, Components and Subcomponents," Section B.2, written to comply with TS 6.8.1 and Regulatory Guide 1.33, requires the completion of safety evaluations in accordance with Modification Control Manual Procedure MCM-4. MCM-4, Section IV, requires the completion of safety reviews for all design changes as required by 10 CFR 50.59.

10 CFR 50.59 states that licensees may make changes in the facility as described in the safety analysis report, without prior Commission approval, unless a change in the technical specifications or an unreviewed safety question is involved. 10 CFR 50.59 requires, in part, that the licensee shall maintain records of changes in the facility made pursuant to this section including a written safety evaluation which provides the bases for the determination that the change does not involve an unreviewed safety question.

Contrary to the above, in 1989, NYPA removed, disabled and modified the service water system heat tracing, a system described in the final safety analysis report, without completing and maintaining the records of a written safety evaluation which provided the basis for the determination that the change did not involve an unreviewed safety question.

These violations are categorized in the aggregate as a Severity Level III problem (Supplement 1).

Civil penalty - $100,000

Pursuant to the provisions of 10 CFR 2.201, New York Power Authority (Licensee) is hereby required to submit a written statement or explanation to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, within 30 days of the date of this Notice of Violation and Proposed Imposition of Civil Penalties (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each alleged violation: (1) admission or denial of the alleged violation, (2) the reasons for the violation if admitted, and if denied, the reasons why, (3) the corrective steps that have been taken and the results achieved, (4) the

corrective steps that will be taken to avoid further violations, and (5) the date when full compliance will be achieved. If an adequate reply is not received within the time specified in this Notice, an order or a Demand for Information may be issued to show cause why the license should not be modified, suspended, or revoked or why such other action as may be proper should not be taken. Consideration may be given to extending the response time for good cause shown. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, this response shall be submitted under oath or affirmation.

Within the same time as provided for the response required above under 10 CFR 2.201, the Licensee may pay the civil penalties by letter addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, with a check, draft, money order, or electronic transfer payable to the Treasurer of the United States in the amount of the civil penalties proposed, or may protest imposition of the civil penalties in whole or in part, by a written answer addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission. Should the Licensee fail to answer within the time specified, an order imposing the civil penalties will be issued. Should the Licensee elect to file an answer in accordance with 10 CFR 2.205 protesting the civil penalties, in whole or in part, such answer should be clearly marked as an "Answer to a Notice of Violation" and may: (1) deny the violation(s) listed in this Notice, in whole or in part, (2) demonstrate extenuating circumstances, (3) show error in this Notice, or (4) show other reasons why the penalties should not be imposed. In addition to protesting the civil penalties in whole or in part, such answer may request remission or mitigation of the penalties.

In requesting mitigation of the proposed penalties, the factors addressed in Section VI.B.2 of 10 CFR Part 2, Appendix C, should be addressed. Any written answer in accordance with 10 CFR 2.205 should be set forth separately from the statement or explanation in reply pursuant to 10 CFR 2.201, but may incorporate parts of the 10 CFR 2.201 reply by specific reference (e.g., citing page and paragraph numbers) to avoid repetition. The attention of the Licensee is directed to the other provisions of 10 CFR 2.205, regarding the procedure for imposing civil penalties.

Upon failure to pay any civil penalties due which subsequently have been determined in accordance with the applicable provisions of 10 CFR 2.205, this matter may be referred to the Attorney General, and the penalties, unless compromised, remitted, or mitigated, may be collected by civil action pursuant to Section 234c of the Act, 42 U.S.C. 2282c.

The response noted above (Reply to Notice of Violation, letter with payment of civil penalties, and Answer to a Notice of Violation) should be addressed to: Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555 with a copy to the Regional Administrator, U.S. Nuclear Regulatory Commission, Region I, and a copy to the NRC Resident Inspector at the Indian Point 3 facility.

Dated at King of Prussia, Pennsylvania
this 21 day of July 1993

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION II
101 MARIETTA STREET, N.W.
ATLANTA, GEORGIA 30323

JUL 28 1993

Docket No. 50-62
License No. R-66
EA 93-153

University of Virginia
ATTN: Dr. R. U. Mulder, Director
Reactor Facility
Charlottesville, Virginia 22901

Gentlemen:

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY - $2,000 (NRC INSPECTION REPORT NO. 50-62/93-02)

This refers to the Nuclear Regulatory Commission (NRC) inspections conducted by Mr. P. T. Burnett on May 3, 1993, and Mr. C. H. Bassett on June 3 and 4, 1993, at the University of Virginia reactor facility. The inspections included a review of the facts and circumstances related to your staff's discovery that five protective scram functions required for automatic shutdown of the reactor were inoperable during full power operation for approximately five and one-half hours on April 28, 1993, as a result of modifications made to the reactor console circuitry. A Confirmation of Action Letter (CAL) was sent to you on April 30, 1993, documenting your actions to place the reactor in a shutdown condition and to initiate an evaluation to determine the cause of the event. The reports documenting the NRC inspections were sent to you by letters dated June 2 and June 18, 1993. As a result of these inspections, apparent violations of NRC requirements were identified. On June 29, 1993, an enforcement conference was conducted in the NRC Region II office with you and members of your staff that included the Reactor Administrator and the Senior Reactor Operator involved in the event to discuss the apparent violations, their cause, and your corrective actions to preclude recurrence. A summary of this conference was sent to you by letter dated July 6, 1993.

The event of April 28, 1993, resulted from an unintentional modification of the automatic shutdown logic circuitry by a Senior Reactor Operator who had been independently troubleshooting several spurious scrams that had occurred earlier. While the reactor was shut down, he performed a modification that involved switching two solid state relays within the reactor console which subsequently had no effect on the rate of spurious scrams. The Senior Reactor Operator then interchanged two mixer-driver modules and, after approximately 30 minutes, during which time no spurious scrams occurred, the Reactor Administrator authorized a restart of the reactor. Full power operations continued for approximately five and one-half hours with a change in Senior Reactor Operators every two hours. No scram signals were received during this time. The Senior Reactor Operator at the reactor controls during the time for

normal daily shutdown decided to complete the shutdown by introducing a spurious period scram. To do this, the operator activated a test switch on the intermediate range instrument channel. The expected scram did not occur and an investigation was initiated to determine the cause of the problem.

The violations are described in the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice). Violation A in the Notice involves the failure to comply with Technical Specification (TS) 3.2 which requires that the reactor be operated with all applicable safety system channels operable. The interchanging of the two mixer-driver modules was made with the assumption that they were identical based on observation of their exteriors. However, the mixer-driver modules had been modified internally with jumpers in the early 1970s. Consequently, when the mixer-driver modules were interchanged, five reactor scram functions, including both the power level and reactor period scrams, were not operable because of the internal jumper modification.

Violation B in the Notice involves the failure to comply with TS 4.5 which requires that following maintenance or modification of a control, a safety system, or a component, operability shall be verified before it is returned to service or during its initial operation. Neither the Senior Reactor Operator nor the Reactor Administrator recognized that the work performed during the troubleshooting activity was maintenance. Therefore, no post-maintenance testing was performed when the mixer-driver modules were switched in the scram logic drawer of the reactor console. Consequently, the system was not verified to be operable before it was returned to service.

The cause of the violations was personnel error in that your staff interchanged the mixer-driver modules and then failed to perform post-maintenance testing following that modification so as to ensure that the modification would not affect the safety system channels of the reactor. In addition to the evident informality associated with maintenance activities, other contributing causes were the failure of the Reactor Administrator to review and question the Senior Reactor Operator's independent work associated with changing the mixer-driver modules and the Senior Reactor Operator's erroneous assumption that the two modules were identical.

These violations are of significant regulatory concern to the NRC because the reactor was operated for five and one-half hours in a condition that was unanalyzed and outside the bounds of the safety analysis, the primary basis for the operating license. Although operational parameters were not exceeded during the five and one-half hours and no safety limits were violated, the potential for a significant event nevertheless existed. Therefore, in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy) 10 CFR Part 2, Appendix C, the violations have been categorized as a Severity Level II problem.

The NRC recognizes that actions were taken to assure a thorough understanding of the causes of the event. The NRC acknowledges that both internal and

independent party reviews of the event were performed. Finally, the NRC notes that the reactor remained shut down until the event and its contributing causes were fully understood and appropriate corrective actions initiated.

Nevertheless, in order to emphasize the importance of ensuring that the reactor is operated within the bounds of the safety analysis and that all components of the safety system channels are maintained in an operable state for all expected design basis conditions, I have been authorized, after consultation with the Director, Office of Enforcement, and the Deputy Executive Director for Nuclear Reactor Regulation, Regional Operations and Research, to issue the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice) in the amount of $2,000 for the Severity Level II problem. The base value of a civil penalty for a Severity Level II problem is $4,000. The escalation and mitigation factors in the Enforcement Policy were considered as discussed below.

Because your staff identified and reported this self-disclosing event, 25 percent mitigation under the identification factor is warranted. Mitigation of the base civil penalty by another 25 percent was warranted for your corrective actions that included maintaining the reactor in a shutdown condition, performing an analysis to determine the problems associated with the mixer-driver modules, management discussions with your staff to review operating expectations, initiation of appropriate actions related to the staff involved in the event, and the performance of the independent review of the event by the National Organization of Test, Research, and Training Reactors. Mitigation by the full 50 percent that is permitted for corrective actions was not applied because in several instances the corrective action or the completeness of the corrective action was prompted by NRC involvement. Neither escalation nor mitigation was warranted for previous licensee performance which was considered average for a non-power reactor licensee. The factors of prior opportunity to identify multiple occurrences and duration were not applicable in this case. Therefore, based on the above, the base civil penalty has been mitigated by 50 percent.

Based on information you presented to the NRC during the enforcement conference and subsequent evaluation by the staff, apparent violation 50-62/93-02-03, involving the apparent failure to have adequate procedures for performing troubleshooting and maintenance activities involving safety system components, and apparent violation 50-62/93-02-04, involving the failure to follow procedures for obtaining specific approval prior to installing/removing jumpers in the control console, will not be pursued further. The TS violations that have been cited in the Notice clearly cover the failures to properly control activities that are of concern to the NRC.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. In your response, you should document the specific actions taken and any additional actions you plan to prevent recurrence.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter and its enclosure will be placed in the NRC Public Document Room.

Should you have any questions concerning this letter, please contact us.

Sincerely,

Stewart D. Ebneter
Regional Administrator

Enclosure:
Notice of Violation and Proposed
Imposition of Civil Penalty

cc w/encl:
Commonwealth of Virginia

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

University of Virginia
Charlottesville, Virginia

Docket No. 50-62
License No. R-66
EA 93-153

During NRC inspections conducted on May 3, 1993, and June 3 and 4, 1993, violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C, the Nuclear Regulatory Commission proposes to impose a civil penalty pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (Act), 42 U.S.C. 2282, and 10 CFR 2.205. The particular violations and associated civil penalty are set forth below:

A. Technical Specification 3.2, Reactor Safety System, requires that the reactor shall not be operated unless the safety system channels in Table 3.1, Safety System Channels, are operable. Some of the safety system channels listed in Table 3.1 include: one operable power to primary coolant pump channel, one operable primary coolant flow channel, two operable reactor power level channels, and one operable reactor period channel.

Contrary to the above, on April 28, 1993, the reactor was operated for 5.5 hours without the required scram functions of the above identified safety system channels being operable.

B. Technical Specification 4.5, Maintenance, provides that, following maintenance or modification of a control or safety system or component, it shall be verified that the system is operable before it is returned to service or during its initial operation.

Contrary to the above, on April 28, 1993, maintenance or modification of a safety system component was performed by exchanging the mixer/driver modules in the scram logic drawer of the reactor console and the system was not verified to be operable before it was returned to service.

These violations have been categorized in the aggregate as a Severity Level II problem (Supplement I).

Civil Penalty - $2,000

Pursuant to the provisions of 10 CFR 2.201, the University of Virginia (Licensee) is hereby required to submit a written statement or explanation to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, within 30 days of the date of this Notice of Violation and Proposed Imposition of Civil Penalty (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each alleged violation: (1) admission or denial of the alleged violation, (2) the reasons for the violation if admitted, and if denied, the reasons why, (3) the corrective steps that have been taken and the results achieved, (4) the corrective steps that will be taken to avoid further violations, and (5) the date when full compliance will be achieved. If an adequate reply is not received within the

time specified in this Notice, an order or a Demand for Information may be issued as to why the license should not be modified, suspended, or revoked or why such other action as may be proper should not be taken. Consideration may be given to extending the response time for good cause shown. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, this response shall be submitted under oath or affirmation.

Within the same time as provided for the response required above under 10 CFR 2.201, the Licensee may pay the civil penalty by letter addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, with a check, draft, money order, or electronic transfer payable to the Treasurer of the United States in the amount of the civil penalty proposed above, or the cumulative amount of the civil penalties if more than one civil penalty is proposed, or may protest imposition of the civil penalty in whole or in part, by a written answer addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission. Should the Licensee fail to answer within the time specified, an order imposing the civil penalty will be issued. Should the Licensee elect to file an answer in accordance with 10 CFR 2.205 protesting the civil penalty, in whole or in part, such answer should be clearly marked as an "Answer to a Notice of Violation" and may: (1) deny the violation listed in this Notice in whole or in part, (2) demonstrate extenuating circumstances, (3) show error in this Notice, or (4) show other reasons why the penalty should not be imposed. In addition to protesting the civil penalty in whole or in part, such answer may request remission or mitigation of the penalty.

In requesting mitigation of the proposed penalty, the factors addressed in Section VI.B.2 of 10 CFR Part 2, Appendix C, should be addressed. Any written answer in accordance with 10 CFR 2.205 should be set forth separately from the statement or explanation in reply pursuant to 10 CFR 2.201, but may incorporate parts of the 10 CFR 2.201 reply by specific reference (e.g., citing page and paragraph numbers) to avoid repetition. The attention of the Licensee is directed to the other provisions of 10 CFR 2.205 regarding the procedure for imposing a civil penalty.

Upon failure to pay any civil penalty due which subsequently has been determined in accordance with the applicable provisions of 10 CFR 2.205, this matter may be referred to the Attorney General, and the penalty, unless compromised, remitted, or mitigated, may be collected by civil action pursuant to Section 234c of the Act, 42 U.S.C. 2282c.

The response noted above (Reply to Notice of Violation, letter with payment of civil penalty, and Answer to a Notice of Violation) should be addressed to: Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555 with a copy to the Regional Administrator, U.S. Nuclear Regulatory Commission, Region II, 101 Marietta Street, N.W., Suite 2900, Atlanta, Georgia 30323.

Dated at Atlanta, Georgia
this 28th day of July 1993

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PENNSYLVANIA 19406-1415

Docket No. 50-271
License No. DPR-28
EA 93-112

August 2, 1993

Mr. Donald A. Reid
Vice President - Operations
Vermont Yankee Nuclear Power Corporation
RD 5, Box 169
Ferry Road
Brattleboro, Vermont 05301

Dear Mr. Reid:

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY - $50,000
Inspection Report No. 50-271/93-09

This refers to the safety inspection conducted at the Vermont Yankee Nuclear Power Plant, Vernon, Vermont, on April 14-16, 1993, and completed in the NRC Region I office on May 11, 1993. The inspection was conducted to review the circumstances associated with a failure to properly evaluate test data, the failure to take corrective actions for a condition adverse to quality, and the earlier occurrence of a violation of the plant Technical Specifications (TS) for which the plant was not shut down as required. The inspection report was transmitted to you on May 24, 1993. On June 15, 1993, an enforcement conference was held in the Region I office with you and other members of your staff to discuss the potential violations, their causes and your corrective actions.

On October 15, 1992, a surveillance test was performed to verify that control rod average scram response times met the limits set forth in the TS. During that test, your staff found that although the average scram response time for the entire core met all appropriate scram response time limits, the average scram response time to Notch 46 (5% insertion) for the three fastest control rods of one of the two-by-two control rod arrays exceeded the TS limit by .012 seconds. Your staff erroneously concluded, based on a review of the test results, that the two-by-two array average scram time was outside the scope of the TS requirements because (1) the two-by-two scram time requirements were not addressed in the TS bases and were not part of the plant safety analysis assumptions, and (2) the Standard Technical Specifications for similar plants do not require the same actions. As a result of this erroneous conclusion, the reactor was not shut down, as required by the TS. Although a subsequent retest of the two-by-two array was satisfactory, it should not have been relied upon to demonstrate compliance with the TS. In this case, the potential safety consequences of the increased scram insertion time were minimal because the ability of the control rods to protect against fuel damage was not affected. Nevertheless, the NRC is concerned that no immediate actions were taken to identify the root causes of the deficiency and pursue corrective actions, and no reports were made to the NRC.

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

On April 6, 1993, another scram response time surveillance test was performed. On this occasion, the average scram response time for seven two-by-two arrays, as well as the core wide average, exceeded the TS limits for insertion to Notch 46. Following the testing, you requested that the NRC exercise enforcement discretion and not require a reactor shutdown since your safety analysis concluded that the average insertion time limits to Notch 46 could be increased to 0.500 seconds without impacting the ability of the control rods to protect against fuel damage, and all of the out-of-specification scram times identified during the October 1992 and April 1993 tests were within 0.500 seconds. Although the NRC exercised discretion for 48 hours, the NRC required that the root causes of the increased scram response time be identified before considering any further request for extension of the discretion. Subsequently, there was no request for extension of the discretion because on April 7, 1993, the plant was shut down due to an unrelated concern.

Your subsequent investigation into the control rod problem revealed that degraded elastomer components in the ASCO scram pilot valves were the root cause of the increased scram times. In addition, you determined that procedural weaknesses allowing the acceptance of retest results to satisfy TS requirements, an inadequate scram time trending program, and inherent errors in test recorders, were contributing causes for your failure to identify the increased scram insertion times sooner.

The violations associated with the above failures are described in the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice) (Enclosure). The first violation involved your failure to evaluate adequately the October 1992 test results to assure that test requirements had been satisfied. The second violation involved your failure to determine the root causes of the October 1992 test deficiency and take appropriate corrective actions to prevent recurrence. The third violation involved the failure to shut down the reactor in October 1992, as required by the TS, when the average insertion time of a two-by-two control rod array exceeded the TS limit. This deficiency was identified by you on April 6, 1993, and was reported to the NRC on that same day when the additional control rod scram insertion times were exceeded.

The NRC is concerned that although you recognized, after the October 1992 event, that the scram insertion times were showing an increasing trend, you did not adequately pursue the root causes of this increase until questioned by the NRC in April 1993. Your evaluation of the October test results was inadequate and indicates that your staff did not adequately compare the results with plant TS requirements. Notwithstanding the low potential safety consequences of the actual degradation in control rod insertion times, the incidents constitute a significant regulatory concern because of the programmatic weaknesses that resulted in these violations, as well as the fact that, the worsening condition would have continued to exist if the NRC did not raise questions in April 1993. Therefore, in accordance with the, "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy) 10 CFR Part 2, Appendix C, these violations are classified in the aggregate as a Severity Level III problem.

The NRC recognizes that after the April 6th event, immediate actions were taken to correct the violations and prevent recurrence. Three task teams were formed to evaluate the scram time deficiency and the associated failure to comply with the TS. All scram pilot valves were replaced and the scram insertion times were tested and found to be within the TS limits prior to plant restart. In addition, the practice of using retest data for scram time TS compliance has been discontinued. Further, a memorandum was issued by the Plant Manager which highlighted the problems in the management system that allowed the TS violation to occur, and also required an evaluation of TS and surveillance test practices to ensure that margin to TS limits is monitored and maintained, and that corrective actions and management notifications are made in a timely manner. As a long-term corrective action, an enhanced trending program for scram times and indicators for predictive maintenance are being developed.

Notwithstanding these actions, to emphasize the importance of timely and adequate evaluation of operational and test data, proper comparison of that data to regulatory requirements and prompt determination of the root causes of test discrepancies so that corrective measures can be implemented, I have been authorized, after consultation with the Director, Office of Enforcement, and the Deputy Executive Director for Nuclear Reactor Regulation, Regional Operation and Research, to issue the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice) in the amount of $50,000 for the Severity Level III problem.

The base value of a civil penalty for a Severity Level III problem is $50,000. The escalation and mitigation factors set forth in the Enforcement Policy were considered. The base civil penalty was mitigated 50% because of your prompt and comprehensive corrective actions once the TS violation was identified in April 1993. However, the base civil penalty was escalated 50% because of the decline in performance in areas specifically related to the violations as evidenced by declines in the SALP ratings of the areas of Engineering/Technical Support and Safety Assessment/Quality Verifications during the last SALP assessment. Additionally, such escalation is supported by your declining overall performance as evidenced by a Severity Level III violation without a civil penalty on January 10, 1992 and a $75,000 civil penalty issued on August 14, 1991. The other adjustment factors in the Policy were considered and no further adjustment to the base civil penalty was considered appropriate. On balance, no adjustment to the base civil penalty resulted from the application of the escalation and mitigation factors.

Since you erroneously concluded that average scram insertion time for the two-by-two array was outside the scope of the TS, this violation was not reported to the NRC as required. A violation for that failure to report could be issued. However, the NRC has decided not to issue a citation for that violation since your staff's failure to recognize that the condition constituted a TS violation directly contributed to your failure to report it to the NRC. The NRC is exercising its discretion on this reporting issue because (1) once the October 1992 violation was identified in April 1993, it was reported and (2) such a citation would not result in any corrective actions beyond those for your staff's failure to recognize that the plant was operated in violation of the TS.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. In your response, you should document the specific actions taken and any additional actions you plan to prevent recurrence. After reviewing your response to this Notice, including your proposed corrective actions and the results of future inspections, the NRC will determine whether further NRC enforcement action is necessary to ensure compliance with NRC regulatory requirements.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter and its enclosure will be placed in the NRC Public Document Room.

The responses directed by this letter and the enclosed Notice are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, Pub. L. No. 96-511.

Sincerely,

Thomas T. Martin
Regional Administrator

Enclosure: Notice of Violation and Proposed Imposition of Civil Penalty

cc w/encl:
R. Wanczyk, Plant Manager
J. Thayer, Vice President, Yankee Atomic Electric Company
L. Tremblay, Senior Licensing Engineer, Yankee Atomic Electric Company
J. Gilroy, Director, Vermont Public Interest Research Group, Inc.
D. Tefft, Administrator, Bureau of Radiological Health, State of New Hampshire
R. Gad, Esquire
G. Bisbee, Esquire
R. Sedano, Vermont Department of Public Service
T. Rapone, Massachusetts Executive Office of Public Safety
Chief, Safety Unit, Office of the Attorney General, Commonwealth of Massachusetts
Public Document Room (PDR)
Local Public Document Room (LPDR)
Nuclear Safety Information Center (NSIC)
K. Abraham, PAO-RI (2)
NRC Resident Inspector
State of New Hampshire, SLO Designee
State of Vermont, SLO Designee
Commonwealth of Massachusetts, SLO Designee

ENCLOSURE

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

Vermont Yankee Nuclear
Power Corporation
Vermont Yankee Nuclear Power Plant

Docket No. 50-271
License No. DPR-28
EA 93-112

As a result of an NRC inspection conducted on April 14-16, 1993, three violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C, the Nuclear Regulatory Commission proposes to impose a civil penalty pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (Act), 42 U.S.C. 2282, and 10 CFR 2.205. The particular violations and associated civil penalty are set forth below:

A. 10 CFR Part 50, Appendix B, Criterion XI, "Test Control," requires in part that the test results be evaluated to assure that test requirements have been satisfied.

Contrary to the above, on October 15, 1992, following the scram time testing of the control rods, the test results were not evaluated adequately to assure that test requirements have been satisfied. Specifically, the average scram insertion time for one two-by-two array for notch 46 exceeded the time required by Technical Specification 3.3.C.1.2, but the subject array was considered acceptable based on a successful second scram time test without an adequate evaluation of the first test failure.

B. 10 CFR Part 50, Appendix B, Criterion XVI, "Corrective Actions," requires, in part, that in case of significant conditions adverse to quality, measures shall assure that the cause of the condition is determined and corrective action taken to preclude repetition.

Contrary to the above, on October 15, 1992, the average control rod scram time for a two-by-two array was in excess of the Technical Specification limits, a significant condition adverse to quality, but the licensee did not take any measures to determine the cause of the condition and corrective actions to preclude repetition. (Subsequently, on April 6, 1993, the control rod scram times for core-wide average and seven two-by-two arrays exceeded the Technical Specification limits).

C. Vermont Yankee Technical Specification Limiting Conditions for Operation (LCO) Sections 3.3.C.1.1 and 3.3.C.1.2 state, in part, that the average of the scram insertion times for the three fastest control rods of all groups of four control rods in a two-by-two array shall be no greater than 0.379 seconds for drop-out of position No. 46.

Vermont Yankee Technical Specification LCO Section 3.3.C.3 states, in part, that if specification 3.3.C.1.2 can not be met, the reactor shall be shut down immediately upon determination that the average scram time is deficient.

Vermont Yankee Surveillance Procedure OP-4424, "Control Rod Scram Testing and Data Reduction," Revision 15, Final Conditions No. 4 and 6 state that if the scram time results are not within the limits specified in Technical Specification 3.3.C.1.2, the reactor, if operating, will be brought to hot shutdown.

Contrary to the above, on October 15, 1992, the average scram time for the three fastest control rods in one two-by-two control rod array was 0.391 seconds (thus, greater than 0.379 seconds for drop-out of position No. 46) and the reactor was not brought to hot shutdown, but continuously operated at power in this condition until April 7, 1993, when it was shut down for an unrelated issue.

These violations are classified in the aggregate as a Severity Level III problem (Supplement I).

Civil Penalty - $50,000

Pursuant to the provisions of 10 CFR 2.201, Vermont Yankee Nuclear Power Corporation (Licensee) is hereby required to submit a written statement or explanation to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, within 30 days of the date of this Notice of Violation and Proposed Imposition of Civil Penalty (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each alleged violation: (1) admission or denial of the alleged violation, (2) the reasons for the violation if admitted, and if denied, the reasons why, (3) the corrective steps that have been taken and the results achieved, (4) the corrective steps that will be taken to avoid further violations, and (5) the date when full compliance will be achieved. If an adequate reply is not received within the time specified in this Notice, an order or a Demand for Information may be issued as to why the license should not be modified, suspended, or revoked or why such other action as may be proper should not be taken. Consideration may be given to extending the response time for good cause shown. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, this response shall be submitted under oath or affirmation.

Within the same time as provided for the response required above under 10 CFR 2.201, the Licensee may pay the civil penalty by letter addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, with a check, draft, money order, or electronic transfer payable to the Treasurer of the United States in the amount of the civil penalty proposed above, or the cumulative amount of the civil penalties if more than one civil penalty is proposed, or may protest imposition of the civil penalty in whole or in part, by a written answer addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission. Should the Licensee fail to answer within the time specified, an order imposing the civil penalty will be issued. Should the Licensee elect to file an answer in accordance with 10 CFR 2.205 protesting

the civil penalty, in whole or in part, such answer should be clearly marked as an "Answer to a Notice of Violation" and may: (1) deny the violations listed in this Notice, in whole or in part, (2) demonstrate extenuating circumstances, (3) show error in this Notice, or (4) show other reasons why the penalty should not be imposed. In addition to protesting the civil penalty in whole or in part, such answer may request remission or mitigation of the penalty.

In requesting mitigation of the proposed penalty, the factors addressed in Section VI.B.2 of 10 CFR Part 2, Appendix C, should be addressed. Any written answer in accordance with 10 CFR 2.205 should be set forth separately from the statement or explanation in reply pursuant to 10 CFR 2.201, but may incorporate parts of the 10 CFR 2.201 reply by specific reference (e.g., citing page and paragraph numbers) to avoid repetition. The attention of the Licensee is directed to the other provisions of 10 CFR 2.205, regarding the procedure for imposing a civil penalty.

Upon failure to pay any civil penalty due which subsequently has been determined in accordance with the applicable provisions of 10 CFR 2.205, this matter may be referred to the Attorney General, and the penalty, unless compromised, remitted, or mitigated, may be collected by civil action pursuant to Section 234c of the Act, 42 U.S.C. 2282c.

The response noted above (Reply to Notice of Violation, letter with payment of civil penalty, and Answer to a Notice of Violation) should be addressed to: Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555 with a copy to the Regional Administrator, U.S. Nuclear Regulatory Commission, Region I, and a copy to the NRC Resident Inspector at Vermont Yankee.

Dated at King of Prussia, Pennsylvania
this 2nd day of August 1993

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION IV
611 RYAN PLAZA DRIVE, SUITE 400
ARLINGTON, TEXAS 76011-8064

JUN 25 1993

Docket: 50-482
License: NPF-42
EA 93-129

Wolf Creek Nuclear Operating Corporation
ATTN: Bart D. Withers
President and Chief Executive Officer
P.O. Box 411
Burlington, Kansas 66839

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY - $50,000 (NRC INSPECTION REPORT NO. 50-482/93-16)

This is in reference to the inspection conducted May 10-13, 1993, at the Wolf Creek Nuclear Generating Station (Wolf Creek) nuclear power plant, Coffey County, Kansas. This inspection was prompted by a Wolf Creek balance-of-plant operator's discovery on May 9, 1993, with the plant in Mode 3, that the control room handswitches for the motor-driven auxiliary feedwater (AFW) pumps were in the "pull-to-lock" position, rendering them unable to respond to an automatic start signal. A report documenting the results of this inspection was issued on May 26, 1993. On June 9, 1993, you and other Wolf Creek Nuclear Operating Corporation (WCNOC) representatives attended an enforcement conference in the NRC's Arlington, Texas, office to discuss NRC's preliminary conclusion that potentially significant violations of NRC requirements and plant Technical Specifications had occurred. This conference was open to public observation in accordance with the terms of a pilot program begun by the NRC in July 1992.

Based on the information developed during its inspection and the information gained from the enforcement conference, the NRC has determined that the violations occurred as described in the inspection report. The violations in the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice) include: 1) a failure to adhere to plant procedures requiring the handswitches for the motor-driven AFW pumps to be placed in their normal position prior to entry into Mode 3; and, as a result, 2) a failure to satisfy plant Technical Specifications by entering Mode 3 with the motor-driven auxiliary feedwater pumps inoperable (Technical Specification 3.0.4). The remaining four violations identified in the inspection report are not included because they are all enveloped by the cited violations. These included a failure to satisfy the related Technical Specification action statements (Technical Specification 3.7.1.2), failures on the part of the plant operations staff to perform adequate shift turnover briefings and main control board walkdowns, and a failure to use the equipment out-of-service log to track the status of the motor-driven AFW pumps. We recognize that it was not your intent to use the equipment out-of-service log in all modes of plant operations. However, as discussed at the enforcement conference, your procedures required its use. We understand that WCNOC plans to correct this error.

The circumstances surrounding these violations are described in more detail in the inspection report. However, it is clear from the discussions at the enforcement conference that inattention to detail on the part of the plant operations staff is the primary cause of this event. In its most basic form, this occurred because a supervising operator did not take the time necessary to read and understand what he was certifying, thus failing to recognize that a checklist designed to ensure, among other things, the proper positioning of the pump handswitches had not been completed. Pressure to enter Mode 3 prior to the end of the shift, whether real or perceived, may have contributed to the occurrence of this error. It is of equal concern to the NRC that this error was not detected or recognized by plant operators for more than 13 hours, despite multiple opportunities during two shift turnovers and routine control board walkdowns. In addition, WCNOC's investigation of this event revealed that various operators observed the position of the pump handswitches but failed to connect their observations to plant requirements for Mode 3.

The NRC acknowledges that the immediate safety significance of this event was mitigated by the fact that the steam-driven AFW pump was available and would have started automatically, by the fact that the motor-driven AFW pumps could have been started from the control room, and by the fact that the plant was in initial start-up following a refueling outage (low decay heat). However, as I emphasized during the enforcement conference, compliance with prerequisites for mode changes has broad safety significance as well as regulatory significance. The very purpose of ensuring the operability of such equipment prior to mode changes is to assure that equipment that is important to safety is available to operate as assumed in the design of the facility and technical specifications. We note, for example, that the checklist that was not properly completed prior to entry into Mode 3 in this case also contains steps for ensuring the proper alignment of the safety injection system. As WCNOC stated during the conference, the same mistake under other circumstances could have had more serious safety implications.

WCNOC took prompt action to restore compliance with plant Technical Specifications. In addition, although WCNOC personnel may not have initially appreciated the significance of this event, WCNOC conducted a thorough investigation to determine the primary and contributing causes, and initiated comprehensive corrective action to address the causes of this event and to prevent a recurrence. These actions include, but are not limited to: 1) a series of memoranda to plant operators and site personnel stressing the need to pay attention to detail, eliminate distractions in the control room during turnovers, control the volume of work activities, and eliminate unreasonable pressures on control room staff, real or perceived, to complete tasks during their shifts; 2) the conduct of training sessions on shift relief and turnover, and discussion sessions on the specific event to be led by the involved plant operations personnel; 3) enhancements to procedures by moving important requirements from checklists to the body of the procedures and by itemizing all Technical Specification requirements in one location in the involved procedures; 4) the conduct of an evaluation by Quality Assurance of operating crew turnovers and board walkdowns; and 5) the conduct of an

independent assessment of plant operations by a team made up of persons from within and outside the WCNOC organization to identify strengths and weaknesses and recommend improvements.

In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy) 10 CFR Part 2, Appendix C, the violations described above are classified in the aggregate as a Severity Level III problem. To emphasize the importance of ensuring the availability of required safety equipment prior to making mode changes, and the importance of operators paying close attention to detail in the performance of their duties, I have been authorized, after consultation with the Director, Office of Enforcement, and the Deputy Executive Director for Nuclear Reactor Regulation, Regional Operations and Research, to issue the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice) in the amount of $50,000 for this Severity Level III problem.

The base value of a civil penalty for a Severity Level III problem is $50,000. The civil penalty adjustment factors in the Enforcement Policy were considered and resulted in no net adjustment. The NRC's consideration of the identification factor resulted in a 50-percent decrease because the principal violation was discovered by WCNOC personnel. The NRC also considered WCNOC's corrective actions to warrant a 50-percent decrease. These decreases, however, were offset by a 100-percent increase because the operations staff had multiple opportunities to discover and correct this noncompliant condition earlier. The remaining adjustment factors were considered but no further adjustments were determined to be appropriate.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. In your response, you should document the specific actions taken and any additional actions you plan to prevent recurrence. After reviewing your response to this Notice, including your proposed corrective actions and the results of future inspections, the NRC will determine whether further NRC enforcement action is necessary to ensure compliance with NRC regulatory requirements.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter and its enclosure will be placed in the NRC Public Document Room. The responses directed by this letter and the enclosed Notice are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, Pub. L. No. 96-511.

Sincerely,

James L. Milhoan
Regional Administrator

Enclosure: (see next page)

Enclosure:
Notice of Violation and Proposed Imposition of Civil Penalty

cc w/enclosure:
Wolf Creek Nuclear Operating Corp.
ATTN: Otto Maynard, Vice President
Plant Operations
P.O. Box 411
Burlington, Kansas 66839

Shaw, Pittman, Potts & Trowbridge
ATTN: Jay Silberg, Esq.
2300 N Street, NW
Washington, D.C. 20037

Public Service Commission
ATTN: C. John Renken
Policy & Federal Department
P.O. Box 360
Jefferson City, Missouri 65102

U.S. Nuclear Regulatory Commission
ATTN: Regional Administrator, Region III
799 Roosevelt Road
Glen Ellyn, Illinois 60137

Wolf Creek Nuclear Operating Corp.
ATTN: Kevin J. Moles
Manager Regulatory Services
P.O. Box 411
Burlington, Kansas 66839

Kansas Corporation Commission
ATTN: Robert Elliot, Chief Engineer
Utilities Division
1500 SW Arrowhead Rd.
Topeka, Kansas 66604-4027

Office of the Governor
State of Kansas
Topeka, Kansas 66612

Attorney General
1st Floor - The Statehouse
Topeka, Kansas 66612

Chairman, Coffey County Commission
Coffey County Courthouse
Burlington, Kansas 66839-1798

Kansas Department of Health
and Environment
Bureau of Air Quality & Radiation
Control
ATTN: Gerald Allen, Public
Health Physicist
Division of Environment
Forbes Field Building 321
Topeka, Kansas 66620

Kansas Department of Health and Environment
ATTN: Robert Eye, General Counsel
LSOB, 9th Floor
900 SW Jackson
Topeka, Kansas 66612

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

Wolf Creek Nuclear Operating Corporation
Wolf Creek Nuclear Generating Station

Docket No. 50-482
License No. NPF-42
EA 93-129

During an NRC inspection conducted May 10-13, 1993, violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C, the Nuclear Regulatory Commission proposes to impose a civil penalty pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (Act), 42 U.S.C. 2282, and 10 CFR 2.205. The particular violations and associated civil penalty are set forth below:

A. Technical Specification 3.0.4 requires that entry into an operational mode shall not be made unless the conditions for the Limiting Condition for Operation are met without reliance on provisions contained in the action requirements. Technical Specification 3.7.1.2.b Limiting Condition for Operation requires that for Mode 3 operation, two motor-driven auxiliary feedwater pumps be operable.

Contrary to the above, on May 8, 1993, the reactor entered Mode 3 with both the motor-driven auxiliary feedwater pumps inoperable due to the pump controller handswitches being in the pull-to-lock position.

B. Technical Specification 6.8.1a requires, in part, that written procedures be established, implemented, and maintained covering the activities referenced in Appendix A of Regulatory Guide 1.33, Revision 2, February 1978.

Section 2.a. of Appendix A of Regulatory Guide 1.33, Revision 2, February 1978, requires safety-related activities to be covered by written procedures, which includes administrative procedures to govern mode changes from cold shutdown to hot standby.

Procedure GEN 00-002, Revision 25, "Cold Shutdown to Hot Standby," states, in part, that when the required portions of Checklist GEN-00-002-1B (Mode 4 to Mode 3 Checklist) have been completed, continue with the RCS Heatup and Pressurization. Checklist GEN-00-002-1B requires, in part, that the motor-driven auxiliary feedwater pump handswitches be placed in the normal position.

Contrary to the above, at 6:38 p.m. on May 8, 1993, licensed operators placed the plant in Mode 3 and continued the RCS Heatup and Pressurization without assuring that the required portions of Checklist GEN-00-002-1B had been completed. This resulted in the reactor being placed in Mode 3 with the motor-driven auxiliary feedwater pump handswitches in the pull-to-lock position, which is not the normal position. The handswitches remained in that condition until 7:53 a.m. on May 9, 1993.

These violations represent a Severity Level III problem (Supplement I).
Civil Penalty - $50,000

Pursuant to the provisions of 10 CFR 2.201, Wolf Creek Nuclear Operating Corporation (Licensee) is hereby required to submit a written statement or explanation to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, within 30 days of the date of this Notice of Violation and Proposed Imposition of Civil Penalty (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each alleged violation: (1) admission or denial of the alleged violation, (2) the reasons for the violation if admitted, and if denied, the reasons why, (3) the corrective steps that have been taken and the results achieved, (4) the corrective steps that will be taken to avoid further violations, and (5) the date when full compliance will be achieved.

If an adequate reply is not received within the time specified in this Notice, an order or demand for information may be issued as to why the license should not be modified, suspended, or revoked or why such other action as may be proper should not be taken. Consideration may be given to extending the response time for good cause shown. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, this response shall be submitted under oath or affirmation.

Within the same time as provided for the response required above under 10 CFR 2.201, the Licensee may pay the civil penalty by letter addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, with a check, draft, money order, or electronic transfer payable to the Treasurer of the United States in the amount of the civil penalty proposed above, or the cumulative amount of the civil penalties if more than one civil penalty is proposed, or may protest imposition of the civil penalty, in whole or in part, by a written answer addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission. Should the Licensee fail to answer within the time specified, an order imposing the civil penalty will be issued. Should the Licensee elect to file an answer in accordance with 10 CFR 2.205 protesting the civil penalty, in whole or in part, such answer should be clearly marked as an "Answer to a Notice of Violation" and may: (1) deny the violations listed in this Notice, in whole or in part, (2) demonstrate extenuating circumstances, (3) show error in this Notice, or (4) show other reasons why the penalty should not be imposed. In addition to protesting the civil penalty, in whole or in part, such answer may request remission or mitigation of the penalty.

In requesting mitigation of the proposed penalty, the factors addressed in Section VI.B.2 of 10 CFR Part 2, Appendix C should be addressed. Any written answer in accordance with 10 CFR 2.205 should be set forth separately from the statement or explanation in reply pursuant to 10 CFR 2.201, but may incorporate parts of the 10 CFR 2.201 reply by specific reference (e.g., citing page and paragraph numbers) to avoid repetition. The attention of the Licensee is directed to the other provisions of 10 CFR 2.205, regarding the procedure for imposing a civil penalty.

Upon failure to pay any civil penalty due which subsequently has been determined in accordance with the applicable provisions of 10 CFR 2.205, this matter may be referred to the Attorney General, and the penalty, unless compromised, remitted, or mitigated, may be collected by civil action pursuant to Section 234(c) of the Act, 42 U.S.C. 2282c.

The responses noted above (Reply to Notice of Violation, letter with payment of civil penalty, and Answer to a Notice of Violation) should be addressed to: Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555 with a copy to the Regional Administrator, U.S. Nuclear Regulatory Commission, Region IV, 611 Ryan Plaza Drive, Suite 400, Arlington, Texas 76011 and a copy to the NRC Resident Inspector at the Wolf Creek Nuclear Generating Station.

Dated at Arlington, Texas
this 25th day of June 1993

I.B. REACTOR LICENSEES, SEVERITY LEVEL I, II, III VIOLATIONS,
NO CIVIL PENALTY

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION V

1450 MARIA LANE
WALNUT CREEK, CALIFORNIA 94596-5368

August 6, 1993

Docket Nos. 50-528, 50-529 and 50-530
License Nos. NPF-41, NPF-51, and NPF-74
EA 93-065

Arizona Public Service Company
ATTN: Mr. William F. Conway
Executive Vice President, Nuclear
Post Office Box 53999, Station 9082
Phoenix, Arizona 85072-3999

SUBJECT: NOTICE OF VIOLATION
(NRC INVESTIGATION REPORT NOS. 5-91-009, 5-92-011R, AND 5-92-012R)

This refers to three investigations of Palo Verde security conducted by the NRC Office of Investigations (OI) from July 22, 1991, through February 26, 1993, at the Palo Verde Nuclear Generating Station (PVNGS). The OI investigations identified several violations of NRC requirements, as described in the OI report synopses transmitted to you by NRC letter dated April 23, 1993. An enforcement conference was held with members of your staff in Phoenix, Arizona, on May 10, 1993, and was summarized in Enforcement Conference Report No. 50-528/529/530/93-20, transmitted to you on July 12, 1993.

Six violations of NRC requirements were identified during the investigations conducted by you or by the NRC. The violations identified by the NRC were found subsequent to your identification of the underlying problem, involving inadequate training of security personnel. Specifically: (a) both you and NRC identified different members of your 1991 initial security training classes A and B as not being properly trained to perform all crucial security tasks required for their assignments, as required by your approved training and qualification plan (T&Q Plan); (b) both you and NRC identified different aspects of crucial task training records for these classes as not being accurate in all material respects, in violation of 10 CFR 50.9: (c) the NRC determined that two security officers received improper weapons qualification in violation of your security training procedures; (d) you identified that safeguards information was not properly protected as required by 10 CFR 73.21, although the NRC identified that you had not reported this event to the NRC; (e) the NRC identified two failures to properly log security events, involving a security officer departing his assigned compensatory post, and the same officer's failure to properly protect safeguards information, as required by 10 CFR

73.71; and (f) you identified that security compensatory measures were improperly implemented for a degraded vital area barrier.

As noted during the May 10, 1993, enforcement conference, the NRC is particularly concerned that your failure to provide adequate training to the 1991 security training classes was the direct consequence of your expediting the training of temporary security personnel who were hired in connection with an anticipated labor dispute. This problem was further compounded by your failure to completely and accurately document the training actually provided to these personnel. Violations (a) through (c) above collectively demonstrate a significant breakdown in the training of temporary security personnel, and thus represent a breakdown in the security training program. Therefore, to emphasize the need to train temporary security personnel with the same standards that are required for permanent security personnel and the need for more diligent management attention to your security program, we have decided to classify violations (a) through (c) above as a Severity Level III problem.

In accordance with the "General Statement of Policy and Procedures for NRC Enforcement Actions" (Enforcement Policy), 10 CFR Part 2, Appendix C, a civil penalty is considered for a Severity Level III problem. The base value of a civil penalty for a Severity Level III violation (problem) is $50,000. However, after consultation with the Director, Office of Enforcement, the Deputy Executive Director for Nuclear Reactor Regulation, and the Commission, I have been authorized not to propose a civil penalty based on the application of the following civil penalty adjustment factors.

On your own initiative, you identified the major and most important aspects of the Severity Level III problem, involving inadequate training of security personnel, before the NRC began its investigation. Because of the extent of your work in this regard, 50% mitigation is warranted for the identification factor. In addition, your corrective actions, as discussed during the enforcement conference, appear to have been comprehensive and timely. In particular, we note that you had already strengthened the management of your security program and implemented corrective actions for most of the security training problems prior to completion of the NRC investigations. Therefore, mitigation of 50% for corrective action is warranted. The other adjustment factors were considered, and no further adjustment to the base civil penalty is considered appropriate. Accordingly, the base civil penalty has been mitigated a total of 100%.

Violations (d) and (e) have been categorized as Severity Level IV violations. Although these are security violations, they appear

not to be directly related to inadequate training and therefore were classified as separate violations.

Violation (f) involved an improper implementation of security compensatory measures. Specifically, when the compensatory security officer, posted at a vital door, walked away from his assigned post on July 20, 1991, not only was safeguards information left unattended but the vital door was left unguarded. This violation would normally be classified as a Severity Level IV violation. However, because you identified and took prompt corrective actions for this violation we have decided to classify this as a non-cited violation in accordance with the criteria set forth in 10 CFR Part 2, Appendix C, Section VII.B. This violation was not promptly recorded in the security log; however, unlike violation (d), this event was reported to the NRC.

As noted in the synopsis of OI's Investigation Report No. 5-92-012R, numerous security officers at PVNGS believed that there might be some form of retaliation by management if they brought safety concerns to the NRC. OI found insufficient evidence to support a violation of 10 CFR 50.7 in this regard and did not substantiate an allegation of threats against a security officer in relation to contacts with the NRC. Nevertheless, as noted in our July 7, 1993 letter we are concerned with the chilling effect. Therefore, you should ensure that your response to that letter addresses your corrective actions for all plant departments including security.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. In your response, you should document the specific actions taken and any additional actions you plan to prevent recurrence. After reviewing your response to this Notice, including your proposed corrective actions and the results of future inspections, the NRC will determine whether further NRC enforcement action is necessary to ensure compliance with NRC regulatory requirements.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter and its enclosure will be placed in the NRC Public Document Room.

The responses directed by this letter and the enclosed Notice are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, Pub. L. No. 96-511.

Should you have any questions concerning this letter, please contact us.

Sincerely,

B. H. Faulkenberry
Regional Administrator

Enclosure: Notice of Violation
cc:
Mr. P. Caudill, APS
Mr. T. Bradish, APS
Mr. F. Kroll, Security Manager, APS
Mr. Steve Olea, Arizona Corporation Commission
Mr. James A. Boeletto, Esq., Southern California Edison Company
Mr. Charles B. Brinkman, Manager, ABB Combustion Engineering Nuclear Power
Mr. Aubrey Godwin, Director, Arizona Radiation Regulatory Agency
Chairman, Maricopa County Board of Supervisors
Mr. Jack R. Newman, Esq., Newman & Holtzinger, P.C.
Mr. Curtis Hoskins, Executive Vice President and Chief Operating Officer, Palo Verde Services
Mr. Roy P. Lessey, Jr., Mr. Bradley W. Jones, Esq., Akin, Gump, Strauss, Hauer and Feld

NOTICE OF VIOLATION

Arizona Public Service Company	Docket Nos. 50-528, 50-529, 50-530
Palo Verde Nuclear Generating Station	License Nos. NPF-41, NPF-51, NPF-74
Wintersburg, Arizona	EA 93-065

During three NRC investigations conducted from July 22, 1991, through February 26, 1993, violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C, the particular violations are set forth below:

A. Paragraph 2.E. of Operating License Nos. NPF-41, NPF-51, and NPF-74, requires in part that the licensee fully implement and maintain in effect all provisions of the Commission-approved security training and qualification plan (T&Q Plan).

Section 3.2.3 (Duty Qualification) of the T&Q Plan requires that all security personnel successfully perform, prior to assignment, all crucial security tasks identified for that assignment, under the conditions and to the standards specified in the T&Q Plan.

Appendix B (Crucial Tasks) of the T&Q Plan in part identifies the following crucial tasks for all security personnel assigned to shift duty: Operate Communications Equipment; Conduct X-ray Package Search; Conduct Vehicle Search; and Respond To and Assess Alarms. Appendix B also identifies conditions and standards for successful performance of those tasks.

Contrary to the above, between July 1991 and February 1992, security personnel from the 1991 initial security training classes A and B were assigned to shift duty without having successfully performed the crucial tasks of Operate Communications Equipment, Conduct X-ray Package Search, Conduct Vehicle Search, and Respond to and Assess Alarms, under the conditions and to the standards specified in the T&Q Plan, in that:

(1) Communication equipment training did not individually test students on the use of a hand-held radio to the T&Q Plan standard of being able to "communicate clearly."

(2) X-ray equipment training did not individually test students to the T&Q Plan standard of being able to "recognize objects by image on the X-ray screen," or to "recognize explosives or incendiary devices."

(3) Vehicle search training did not individually test students to the T&Q Plan standard of being able to "recognize unauthorized materials."

(4) Alarm response training did not individually test students to the T&Q Plan standard of being able to "utilize techniques of deployment, tactical movement, and withdrawal," or "being a team member, operating a vehicle, running, carrying a portable radio and weapon, and wearing a bullet-proof vest and riot helmet."

B. 10 CFR 50.9(a) requires in part that information required by a license condition to be maintained by a licensee be complete and accurate in all material respects.

Paragraph 2.E. of Operating License Nos. NPF-41, NPF-51, and NPF-74, requires in part that the licensee fully implement and maintain in effect all provisions of the Commission-approved training and qualification plan (T&Q Plan).

Section 3.2.4 (Individual Qualification) of the T&Q Plan requires that the Security Training and Support Supervisor/Designee confirm that all crucial tasks...have been successfully demonstrated, by documenting (1) identified crucial task, (2) the date of successful performance, and (3) the signature of the examiner and examinee.

Appendix B (Crucial Tasks) of the T&Q Plan in part identifies the following crucial tasks for security personnel assigned to shift duty: Operate Communications Equipment; Conduct X-ray Package Search; Conduct Vehicle Search; Respond To and Assess Alarms; Adjust and Test Hand-Held Metal Detectors; and Conduct Hand-Held Metal Detector Search. Appendix B also identifies conditions and standards for successful performance of those tasks.

Contrary to the above, as of September 17, 1991, the crucial task training records maintained by the licensee for members of the 1991 initial security training classes A and B were not complete and accurate in all material respects. Specifically, students and instructors signed training records for the crucial tasks of Operate Communication Equipment, Conduct X-ray Package Search, Conduct Vehicle Search, Respond To and Assess Alarms, Adjust and Test Hand-Held Metal

Detectors, and Conduct Hand-Held Metal Detector Search, attesting that the students had completed "qualifying performance demonstration," when in fact there had been no such demonstrations. This information was material in that a demonstration of the ability to perform the crucial tasks is required by the licensee's NRC approved T&Q Plan in order to satisfy the training requirements.

C. Licensee Technical Specification 6.8.1 requires that written procedures be established, implemented, and maintained covering security plan implementation.

Paragraph 3.15 of Security Plan Implementing Procedure No. 20DP-0TR01, "Security Personnel Training," dated July 1, 1989, provides for a maximum of three attempts for any individual to qualify at the firing range with any one weapon on the individual's range-day at the firing range. Further, individuals failing to qualify on the first range day in which they were permitted a maximum of three qualifying attempts, shall be retested on a second and if necessary, a third range-day.

Contrary to the above, on June 14 and 15, and July 7, 1991, two students were given more than three attempts to qualify with any one weapon on the individual's range-day at the firing range. In particular, on June 14 and 15, 1991, one student was allowed six attempts to qualify with his rifle and five attempts to qualify with his revolver. On July 7, 1991, another student was allowed four attempts to qualify with his rifle.

Violations A through C represent in the aggregate a Severity Level III problem (Supplement III).

D. 10 CFR 73.21(a) requires that each power reactor licensee ensure that Safeguards Information (SGI) be protected against unauthorized disclosure. 10 CFR 73.21(d)(2) requires that while unattended, SGI be stored in a locked security storage container.

Contrary to the above, on July 20, 1991, the licensee failed to protect SGI against unauthorized disclosure, in that a security officer posted at vital Door 1G-103 left his compensatory post order book containing SGI unattended for approximately two and one-half minutes.

This is a Severity Level IV violation (Supplement III).

E. 10 CFR 73.71(c) and 10 CFR Part 73, Appendix G, Part II, require recording of safeguards events in a log

within 24 hours of discovery of: (1) any failure in a safeguards system that could allow unauthorized or undetected access to a protected area or vital area for which compensatory measures have not been employed; and (2) any other...committed act not previously defined in Appendix G with the potential for reducing the effectiveness of the safeguards system.

10 CFR 73.71(c) requires that every three months, each licensee submit to the NRC copies of a safeguards event log for this event.

Contrary to the above:

(1) On July 20, 1991, the licensee failed to record in a log within 24 hours of discovery, an event in which a security officer departed his assigned compensatory post. In particular, this event was not recorded until three days following discovery.

(2) On July 20, 1991, the licensee failed to record in a log, an event in which a security officer failed to properly protect safeguards information. Further, as of February 26, 1993, the licensee had not submitted to the NRC copies of a safeguards event log for this event, a period exceeding three months.

This is a Severity Level IV violation (Supplement III).

Pursuant to the provisions of 10 CFR 2.201, Arizona Public Service Company (Licensee) is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555 with a copy to the Regional Administrator, Region V, and a copy to the NRC Resident Inspector at Palo Verde, within 30 days of the date of the letter transmitting this Notice of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each violation: (1) the reason for the violation, or, if contested, the basis for disputing the violation, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken to avoid further violations, and (4) the date when full compliance will be achieved. If an adequate reply is not received within the time specified in this Notice, an order or a Demand for Information may be issued to show cause why the license should not be modified, suspended, or revoked, or why such other action as may be proper should not be taken. Where good cause is shown, consideration will be given to extending the response time.

Under the authority of Section 182 of the Act, 42 U.S.C. 2232, this response shall be submitted under oath or affirmation.

Dated at Walnut Creek, California
this 6th day of August 1993

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
799 ROOSEVELT ROAD
GLEN ELLYN, ILLINOIS 60137-5927

August 13, 1993

Docket No. 50-341
License No. NPF-43
EA 93-154

The Detroit Edison Company
ATTN: Mr. D. R. Gipson
Senior Vice President
Nuclear Generation
6400 North Dixie Highway
Newport, Michigan 48166

Dear Mr. Gipson:

SUBJECT: NOTICE OF VIOLATION
(NRC INSPECTION REPORT 50-341/93012(DRP))

This refers to the inspection conducted during the period of May 24 through June 8, 1993, at your Fermi 2 facility, to review the circumstances surrounding your determination that both divisions of the Post Accident Monitoring System for wide range drywell pressure had been inoperable. During this inspection a violation of NRC requirements was identified, and on July 1, 1993, an open enforcement conference was held in the Region III office.

The report documenting the inspection was sent to you by letter dated June 18, 1993. The report summarizing the conference was sent to you by letter dated July 8, 1993.

You identified a problem with the Division 2 Post Accident Monitoring System recorders for wide range drywell pressure on January 19, 1993, and submitted a written licensee event report (LER) on February 18, 1993. On May 15, 1993, after finding installation errors associated with the transmitters that provide signals to these recorders, you initiated a review of the engineering design package (EDP) for the installation of the recorders and transmitters. On May 19, 1993, your review determined that the Division 1 recorder also had some problems associated with its installation. Additionally, the review found that the emergency operating procedures (EOP) had not been properly revised to reflect the implementation of the EDP, and were inadequate. On June 18, 1993, you submitted a second LER describing the findings of your full review of the installation problems with the wide range drywell pressure recorders.

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

The root cause for the problems discussed above was a breakdown in the modification process associated with the EDP covering installation of the transmitters and recorders for the wide range drywell pressure channels. This breakdown was reflected in numerous instances where procedures were inadequate or personnel failed to correctly implement them, material controls were insufficient, the independent verification process was insufficient, and design changes were not properly reflected in procedures. Additionally, your initial corrective actions upon the discovery of the first division being inoperable were insufficient.

Some of the errors, deviations from proper procedures, or inadequacies in the process were so obvious and fundamental that they clearly should have been avoided. For example, craft personnel, with the approval from Plant Engineering, assumed the EDP to be in error and modified the simulator recorder mounting bracket to make it fit in the control room panel. This modification was performed without issuing an Engineering Change Request as required. Another example involved the Quality Control inspector's verifying that the Division I control room recorder was plugged into a receptacle when in fact it was not. Similarly, the failure of the EDP to include instructions to change the water level versus drywell pressure curve in the EOP in accordance with the change in location of the transmitters is significant. Even if the hardware change had been implemented correctly, the failure to update the curves could have rendered the whole design change meaningless.

The NRC recognizes that, through your followup and corrective actions, you have confirmed that this apparent breakdown in the modification process for the Post Accident Monitoring System drywell pressure monitors does not appear to extend to other engineering design packages and/or modifications. Nevertheless, the NRC considers the problems in the implementation of this particular design change package/modification to be of significant regulatory concern because of the number of failures and the numerous organizations and personnel involved in these modification process errors. This breakdown ultimately resulted in the violation, which is described in the enclosed Notice of Violation (Notice), concerning the inoperability of both divisions of the post accident monitoring system from November 4, 1992, when the plant entered operational Mode 2, until January 7, 1993.

We acknowledge your immediate corrective actions, which included installation of a seismically-qualified recorder for Division 2 in January 1993 and connection of the Division 1 recorder to vital power in May 1993; correction of the associated EOP curve calculations and updating the EOPs and Emergency Response Information System; tightening of the transmitter caps and replacement of the shipping plugs; verification that other control room instruments were appropriately qualified and connected to vital power; checking other transmitters for loose covers and performing an analysis that confirmed the operability of those transmitters found with loose covers; and improving work packages and identification and control of material. Additional corrective actions included walkdowns of similar modifications; improving labeling of electrical outlets; a comprehensive engineering assessment of this modification for other potential errors; and communication of this event to site employees.

We also acknowledge your long-term corrective actions, which included a comprehensive review of the modification process to ensure that proper post-modification testing was specified and that components were included in the preventive maintenance system; development of a formal turnover process to operations; initiation of the joint engineering, operations, construction walkdown of field completed modifications; identification of a specific point of contact for each modification; a redesign of the modification process to reduce opportunities for mistakes; improvement of configuration control and the process by which design changes are incorporated in programs and procedures; improvement in the self-assessment capabilities of the quality assurance organization when it comes to evaluating modifications; and improvement in the verification process for modifications.

Nevertheless, in order to emphasize the importance of a questioning attitude, careful attention to the development of adequate design modification procedures, and strict adherence to proper procedures throughout the modification process, I have been authorized, after consultation with the Deputy Executive Director for Nuclear Reactor Regulation, Regional Operations and Research and the Director, Office of Enforcement, to issue this Notice of Violation which, in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions, (Enforcement Policy) 10 CFR Part 2, Appendix C, has been categorized at Severity Level III. In accordance with the Enforcement Policy, a civil penalty is considered for a Severity Level III violation. However, we have decided not to propose a civil penalty in this case after considering the adjustment factors in the NRC Enforcement Policy. Specifically, we determined that full mitigation of the base civil penalty was appropriate due to your identification of the inoperable recorders and your comprehensive corrective actions. The remaining factors in the Enforcement Policy were considered and no further adjustment to the base civil penalty was considered appropriate.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice of Violation (Notice) when preparing your response. In your response, you should document the specific actions taken and any additional actions you plan to prevent recurrence. Your response should focus on corrective actions planned or taken to address the breakdown during the implementation of the EDP described above and describe how those corrective actions will ensure that a similar breakdown in your modification process will be prevented. After reviewing your response to this Notice, including your proposed corrective actions and the results of future inspections, the NRC will determine whether further NRC enforcement action is necessary to ensure compliance with NRC regulatory requirements.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter and its enclosure will be placed in the NRC Public Document Room.

The responses directed by this letter and the enclosed Notice are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, Pub. L. No. 96-511.

Sincerely,

Charles E. Norelius
for John B. Martin
Regional Administrator

Enclosure:
Notice of Violation

cc w/enclosure:
John A. Tibai, Supervisor
of Compliance
P. A. Marquardt, Corporate
Legal Department
OC/LFDCB
Resident Inspector, RIII
James R. Padgett, Michigan Public
Service Commission
Michigan Department of
Public Health
Monroe County Office of
Civil Preparedness
T. Colburn, LPM, NRR
H. Miller, RIII
T. Martin, RIII
B. Jorgensen, RIII
W. Dean, PDIII-1, NRR

NOTICE OF VIOLATION

Detroit Edison Company
Fermi 2

Docket No. 50-341
License No. NPF-43
EA 93-154

During an NRC inspection conducted during the period of May 24 through June 8, 1993, a violation of NRC requirements was identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C, the violation is listed below:

Technical Specification 3.3.7.5 requires, in part, that the accident monitoring instrumentation channels shown in Table 3.3.7.5-1 shall be operable. Item 7 of Table 3.3.7.5-1 requires, in part, that in operational conditions 1 and 2, the required number of channels for wide range drywell pressure is two and that the minimum number of channels operable for wide range drywell pressure is one.

Action 80 of Table 3.3.7.5-1 requires that with the number of operable accident monitoring instrumentation channels less than the required number of channels shown in Table 3.3.7.5-1, restore the inoperable channel(s) to operable status within 7 days or be in at least hot shutdown within the next 12 hours; and with the number of operable accident monitoring instrumentation channels less than the minimum channels operable requirements of Table 3.3.7.5-1, restore the inoperable channel(s) to operable status within 48 hours or be in at least hot shutdown within the next 12 hours.

Contrary to the above, through a number of procedural inadequacies in implementing a modification to the system, two channels of the wide range drywell pressure post accident monitoring instrumentation system were inoperable from November 4, 1992, when the facility entered operational condition 2, until January 7, 1993.

This is a Severity Level III violation (Supplement I).

Pursuant to the provisions of 10 CFR 2.201, Detroit Edison Company is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555 with a copy to the Regional Administrator, Region III, and a copy to the NRC Resident Inspector at the facility that is the subject of this Notice, within 30 days of the date of the letter transmitting this Notice of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each violation: (1) the reason for the violation, or, if contested, the basis for disputing the violation, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken to avoid further violations, and (4) the date when full compliance will be achieved. If an adequate reply is not received within the time specified in this Notice, an order or a Demand for Information may be issued to show cause why the license should not be modified, suspended, or revoked, or why such other action as may be proper should not be taken. Where good cause is shown, consideration will be given to extending the response time.

Under the authority of Section 182 of the Act, 42 U.S.C. 2232, this response shall be submitted under oath or affirmation.

Dated at Glen Ellyn, Illinois
this 13th day of August 1993

I.C. VENDOR (PART 21),
NO CIVIL PENALTY

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

AUG 16 1993

Docket No. 99901174
EA 91-162

Shur-Kut Supply Corporation
ATTN: Mr. Joseph P. Saddic
General Manager
241 Woodland Avenue
Morton, Pennsylvania 19070

Dear Mr. Saddic:

SUBJECT: NOTICE OF VIOLATION AND NOTICE OF NONCONFORMANCE
(NRC Inspection Report No. 99901174/90-01 and NRC Investigation Report 4-90-015)

This letter addresses the inspection of Shur-Kut Supply Corporation (S-K) in Morton, Pennsylvania conducted by Messrs. Walter P. Haass, Harvey M. Wescott and Stewart L. Magruder of this office on June 18 through 20, 1990, the discussion of the findings with yourself and other personnel in your company at the conclusion of the inspection, and the subsequent investigation of S-K's activities by the NRC Office of Investigations (OI). The purpose of these activities was to review the procedures and policies used by S-K to control the quality of safety-related fasteners supplied to the nuclear industry.

Areas examined during the NRC inspection and our findings are discussed in the enclosed report. The inspection consisted of an examination of procedures and representative records, interviews with personnel, and observations by the inspectors. The inspection was prompted by the rejection by the Philadelphia Electric Company (PECo) in September 1989 of certain batches of stainless steel machine screws supplied by S-K, because of dimensional and material deficiencies relative to specification requirements in the purchase orders.

During this inspection, it was found that the implementation of your Quality Assurance (QA) program failed to meet certain NRC requirements. Specifically, the Certificates of Conformance (CoC) issued by S-K for the screws supplied to PECo attested to adherence to the purchase order requirements for safety-related parts when, in fact, the actual order shipped consisted of commercial-grade screws. The inspection also identified additional examples of the nonconformance with past purchase orders from PECo in which CoCs, issued by S-K, attested to the quality of parts that, in fact, did not conform to the purchase order.

Based on the results of the subsequent OI investigation conducted during the period of March 6 through April 18, 1991, as summarized in the enclosed synopsis, it was found that the above described activities were deliberately performed in violation of NRC requirements. In addition, it was determined that these deviations should have been identified to your customer, PECo, in accordance with the provisions of 10 CFR Part 21.21. In accordance with the

"General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy) 10 CFR Part 2, Appendix C, this violation would normally be classified at Severity Level IV. However, because of the willfulness of your actions, the violation was escalated to Severity Level III, in accordance with the Enforcement Policy. A civil penalty is not being proposed because the conditions of 10 CFR 21.61 have not been satisfied. Nevertheless, the NRC considers any willful violation to be significant. You should be aware that subsequent to the events described herein, the NRC issued a regulation (10 CFR 50.5) that provides for enforcement actions against any individual who, through deliberate misconduct, places or could have placed an NRC licensee in violation of NRC requirements. A copy of the regulation is provided for your information.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice of Violation and the enclosed Notice of Nonconformance when preparing your response. In your response, you should document the specific actions taken and any additional actions you plan to prevent recurrence and provide the basis upon which the NRC should allow S-K to be involved in future 10 CFR Part 21 and 10 CFR Part 50, Appendix B activities, given the conclusion that the violation and the nonconformance discussed in the Notice of Nonconformance were willfully committed. We will consider extending the response time if you can show good cause for us to do so. After reviewing your response, including your proposed corrective actions and the results of future inspections, the NRC will determine whether further NRC enforcement action is necessary to ensure compliance with NRC regulatory requirements.

The responses requested by this letter and the enclosed notices are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, Public Law 96-511.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of the letter and the enclosures will be placed in the NRC's Public Document Room.

Should you have any questions concerning this inspection, we will be pleased to discuss them with you.

Sincerely,

James Lieberman, Director
Office of Enforcement

Enclosures:
1. Notice of Violation
2. Notice of Nonconformance
3. Inspection Report No. 99901174/90-01
4. Report of Investigation Case No. 4-90-015 - Synopsis
5. 10 CFR 50.5

NOTICE OF VIOLATION

Shur-Kut Supply Corporation (S-K)
Morton, Pennsylvania

Docket No. 99901174
EA 91-162

Based on the results of an NRC investigation conducted during the period of March 6 through April 18, 1991, a violation of NRC requirements was identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions" 10 CFR Part 2, Appendix C, the violation is as follows:

Section 21.21 (b), "Notification of failure to comply or existence of a defect and its evaluation," of 10 CFR Part 21 states, in part, that if a deviation or failure to comply is discovered by a supplier of basic components, and the supplier does not have the capability to perform the evaluation to determine if a defect exists, then the supplier must inform the affected licensee within five working days of this determination so that the affected licensee may evaluate the defect or failure to comply.

Contrary to the above, between September 1987 and September 1989, S-K supplied the Philadelphia Electric Company (PECo) fasteners that did not meet the technical specifications of the PECo purchase orders that imposed 10 CFR Part 50, Appendix B, and 10 CFR Part 21 requirements, S-K deliberately supplied certificates of conformance which specified that the fasteners did meet the purchase order technical specifications for dimension and/or chemistry, and S-K did not inform PECo of deviations from the technical specifications, for which it could not perform evaluations, within five working days.

This is a Severity Level III violation (Supplement VII).

Pursuant to the provisions of 10 CFR 2.201, S-K is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555 with copies to the Director, Office of Enforcement and the Chief, Vendor Inspection Branch, Division of Reactor Inspection and Licensee Performance, Office of Nuclear Reactor Regulation, within 30 days of the date of the letter transmitting this Notice of Violation. This reply should be clearly marked as a "Reply to a Notice of Violation" and should include: (1) the reason for the violation, or if contested , the basis for disputing the violation, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken to avoid further violations, (4) the date when full compliance will be achieved, and (5) the basis upon which the NRC should allow S-K to be involved in future safety-related activities given the conclusion that this violation was committed willfully. Where good cause is shown, consideration will be given to extending the response time. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, this response shall be submitted under oath or affirmation.

Dated at Rockville, Maryland
this 16th day of August 1993

NOTICE OF NONCONFORMANCE

Shur-Kut Supply Corporation (S-K)
Morton, Pennsylvania

Docket No. 99901174
EA 91-162

Based on the results of an NRC inspection conducted on June 18 through 20, 1990, it was found that certain of your activities were not performed in accordance with NRC requirements.

Criterion VII, "Control of Purchased Material, Equipment, and Services," of 10 CFR 50, Appendix B, states, in part, "Measures shall be established to assure that purchased material .... whether purchased directly or through contractors and subcontractors, conform to the procurement documents."

Criterion V, "Instructions, Procedures and Drawings," of 10 CFR 50, Appendix B, states, in part, "activities affecting quality .... shall be accomplished in accordance with ... instructions procedures, or drawings."

Contrary to the above, measures established to ensure that purchased materials conformed to the procurement documents were inadequate in that the following Philadelphia Electric Company (PECo) Purchase Orders (POs), invoking 10 CFR Part 21 and 10 CFR Part 50, Appendix B, were filled by S-K with parts that did not conform to the PO requirements for dimension and/or chemistry (90-01-01):

BW 345278 delivered on January 11, 1989
BW 610310 delivered on March 9, 1989
BW 611364 delivered on June 29, 1989
BW 611365 delivered on June 29, 1989
BW 611211 delivered on July 19, 1989

Please provide a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555 with copies to the Director, Office of Enforcement and the Chief, Vendor Inspection Branch, Division of Reactor Inspection and Licensee Performance, within 30 days of the date of the letter transmitting this Notice of Nonconformance. This reply should be marked as a "Reply to a Notice of Nonconformance" and should include for each nonconformance: (1) a description of the steps that have been or will be taken to correct these items; (2) a description of the steps that have been or will be taken to prevent recurrence; and (3) the dates your corrective actions and preventive measures were or will be completed.

Dated at Rockville, Maryland
this 16th day of August 1993

SYNOPSIS

In November 1990, the Nuclear Regulatory Commission (NRC) requested an investigation of Shur-Kut Supply Corporation (S-K) to determine if company officials knowingly executed false certificates of conformance (COCs) to represent commercial grade fasteners as nuclear grade fasteners.

The Office of Investigations (OI) investigation determined that the general manager of S-K knowingly and intentionally prepared false COCs to certify what he knew to be commercial grade items as nuclear grade items. S-K issued COCs from approximately September 1987 until September 1989 falsely representing products as meeting American Society of Testing Material (ASTM), American Society of Mechanical Engineers (ASME), and/or American Nuclear Standards Institute (ANSI) standards in response to Philadelphia Electric Company (PECO) purchase orders which had imposed 10 CFR 50, Appendix B, and 10 CFR 21 requirements. The general manager admitted that he provided commercial grade fasteners to PECO without substantiation that they could meet the technical specifications included in the procurement documents. Further, he failed to inform PECO about these deviations as required by 10 CFR Part 21.21.

In approximately June 1989, S-K's general manager met with PECO officials to discuss PECO's rejection of some fasteners provided to them by S-K. Following this meeting, S-K hired a consultant to revise the company's nuclear sales program. Testing documentation on hand at S-K appears to substantiate appropriate specifications for nuclear grade fasteners provided to PECO, beginning in about November 1989. In-house testing by PECO since that time has determined that, with the exception of some items on one purchase order, fasteners provided by S-K have met appropriate specifications.

56 FR 40664

§ 60.8 Deliberate misconduct.

(a) Any licensee or any employee of a licensee; and any contractor (including a supplier or consultant), subcontractor, or any employee of a contractor or subcontractor, of any licensee, who knowingly provides to any licensee, contractor, or subcontractor, components, equipment, materials, or other goods or services, that relate to a licensee's activities subject to this part: may not:

(1) Engage in deliberate misconduct that causes or, but for detection, would have caused, a licensee to be in violation of any rule, regulation, or order, or any term, condition, or limitation of any license, issued by the Commission, or

(2) Deliberately submit to the NRC, a licensee, or a licensee's contractor or subcontractor, information that the person submitting the information knows to be incomplete or inaccurate in some respect material to the NRC.

56 FR 40664

(b) A person who violates paragraph (a)(1) or (a)(2) of this section may be subject to enforcement action in accordance with the procedures in 10 CFR part 2, subpart B.

(c) For purposes of paragraph (a)(1) of this section, deliberate misconduct by a person means an intentional act or omission that the person knows:

(1) Would cause a licensee to be in violation of any rule, regulation, or order, or any term, condition, or limitation, of any license issued by the Commission, or

(2) Constitutes a violation of a requirement, procedure, instruction, contract, purchase order or policy of a licensee, contractor, or subcontractor.

II.A. MATERIALS LICENSEES, CIVIL PENALTIES AND ORDERS

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION II
101 MARIETTA STREET, N.W.
ATLANTA, GEORGIA 30323

MAY 24 1993

Docket No. 030-30936
License No. 45-16546-04
EA 93-089

Atec Associates of Virginia
ATTN: Mr. Gerald B. McCoy
Branch Manager
4603 Eisenhower Avenue
Alexandria, Virginia 22304-7313

Gentlemen:

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY - $375 (NRC INSPECTION REPORT NO. 45-16546-04/93-01)

This refers to the Nuclear Regulatory Commission (NRC) inspection conducted by Mr. H. Bermudez on April 15, 1993, at the facility of Atec Associates of Virginia, located in Alexandria, Virginia. The inspection included a review of the facts and circumstances related to the failure to maintain immediate control of a moisture/density gauge which contained licensed material. The report documenting this inspection was sent to you by letter dated April 30, 1993. As a result of this inspection, violations of NRC requirements were identified. An enforcement conference was held on May 14, 1993, in the NRC Region II office to discuss the violations, their cause, and your corrective actions to preclude recurrence. A list of enforcement conference attendees is provided with this letter (Enclosure 2). Also enclosed is a copy of the letter you provided at the enforcement conference (Enclosure 3).

The Violation in Part I in the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice) (Enclosure 1) involved the failure to place licensed material under constant surveillance and immediate control while not in storage. On April 9, 1993, a licensee technician using the moisture/density gauge which contained licensed material, left the gauge unattended for a short period of time next to a stone pan at a road construction site. While unattended, a backhoe struck the stone pan causing the stone pan to move and damage the gauge.

Although the source was retracted in the safe position and not damaged in this case, the violation associated with the gauge in Part I of the Notice is considered significant because of its safety implications. The NRC expects licensee personnel responsible for the safety and security of gauges containing licensed radioactive material to be constantly aware of the location of the gauge so as to preclude its being exposed to any hazards that could damage the gauge and cause unnecessary radiation exposure. Therefore, this violation has been categorized at Severity Level III in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy) 10 CFR Part 2, Appendix C.

The NRC recognizes that immediate corrective actions were taken at the time of the accident that included notification of local authorities, notifying the Radiation Safety Officer who responded to the scene, and securing the gauge after determining there was no radiation hazard associated with the event.

To emphasize the importance of ensuring that gauges containing licensed radioactive material are controlled in accordance with regulatory requirements and license conditions, I have been authorized to issue the enclosed Notice of Violation and Proposed Imposition of Civil Penalty in the amount of $375 for the Severity Level III violation set forth in Part I of the enclosed Notice. The base civil penalty for a Severity Level III violation is $500. The escalation and mitigation factors in the Policy were considered as discussed below.

Neither escalation nor mitigation was warranted for the factor of identification because the violation is considered to be self-disclosing. Mitigation of 25 percent was warranted for good immediate corrective action that included immediate initiation of recovery activities. Additional mitigation was not applied because long term corrective actions could have been more comprehensive. For example, your corrective actions did not include the development of a formal audit program designed to ensure technicians are complying with regulatory requirements. Neither escalation nor mitigation was applied for the factor of licensee performance based on the results of two previous inspections conducted by the NRC. The other adjustment factors in the Policy were considered and no further adjustment to the base civil penalty is considered appropriate. Therefore, based on the above, the base civil penalty has been decreased by 25 percent.

The violation in Part II in the enclosed Notice was identified by the NRC during the follow up inspection conducted on April 15, 1993. The violation is categorized at Severity Level IV and involves the failure to block and brace a package of licensed materials during transportation. This violation indicates a laxness and inattention to detail. The inspection report documenting the inspection conducted on April 15, 1993, identified two additional violations involving the transportation of a package of licensed materials with an unlabeled and unmarked cover over the overpack and the failure to maintain shipping papers readily visible while transporting a package of licensed materials. During the enforcement conference, you indicated that these violations may not have occurred as indicated in the inspection report and that you would discuss them with you staff and provide NRC additional information. In your letter of May 20, 1993 and in a telephone conversation with Mr. Douglas M. Collins of the Region II office on May 24, 1993, you stated that you disagreed with the violations. You acknowledged that the gauge was covered at the job site and that the shipping papers were not visible to anyone entering the drivers's compartment while the gauge was at the job site. However, your position was that during transport of the gauge the labels and markings were clearly visible and the shipping papers were

within reach of the driver and visible to anyone entering the driver's compartment. The NRC is continuing to evaluate the information provided by you; therefore, the apparent violations are not being included in the enclosed Notice. We will advise you at a later date of our final action on this matter.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. In your response, you should document the specific actions taken and any additional actions you plan to prevent recurrence. After reviewing your response to this Notice, including your proposed corrective actions and the results of future inspections, the NRC will determine whether further NRC enforcement action is necessary to ensure compliance with NRC regulatory requirements.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter and its enclosures will be placed in the NRC Public Document Room.

The responses directed by this letter and the enclosed Notice are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, Pub. L. No. 96-511.

Should you have any questions concerning this letter, please contact us.

Sincerely,

Stewart D. Ebneter
Regional Administrator

Enclosures:
1. Notice of Violation and Proposed Imposition of Civil Penalty
2. Enforcement Conference Attendees
3. Licensee ltr to NRC, dtd 5/12/93

cc w/encls:
Commonwealth of Virginia

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

Atec Associates of Virginia
Alexandria, Virginia

Docket No. 030-30936
License No. 45-16546-04
EA 93-089

During an NRC inspection conducted on April 15, 1993, violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C, the Nuclear Regulatory Commission proposes to impose a civil penalty pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (Act), 42 U.S.C. 2282, and 10 CFR 2.205. The particular violation and associated civil penalty are set forth below:

I. Violation Assessed a Civil Penalty

10 CFR 20.207(a) requires that licensed materials stored in an unrestricted area be secured against unauthorized removal from the place of storage. 10 CFR 20.207(b) requires that materials not in storage be under the constant surveillance and immediate control of the licensee. As defined in 10 CFR 20.3(a)(17), an unrestricted area is any area access to which is not controlled by the licensee for purposes of protection of individuals from exposure to radiation and radioactive materials.

Contrary to the above, on April 9, 1993, licensed materials consisting of approximately 10 millicuries of cesium-137 and 50 millicuries of americium-241 contained in a moisture/density gauge located at a road construction site in Fairfax County, Virginia, an unrestricted area, was not secured against unauthorized removal, and was neither under constant surveillance, nor under the immediate control of the licensee. Consequently, while unattended, the gauge was damaged as a result of being struck by construction equipment.

This is a Severity Level III violation (Supplement IV).
Civil Penalty - $375

II. Violation Not Assessed a Civil Penalty

10 CFR 71.5(a) requires that a licensee who transports licensed material outside of the confines of its plant or other place of use, or who delivers licensed material to a carrier for transport, comply with the applicable requirements of the regulations appropriate to the mode of transport of the Department of Transportation (DOT) in 49 CFR Parts 170 through 189.

49 CFR 177.842 requires, in part, that packages of radioactive material be so blocked and braced that they cannot change position during conditions normally incident to transportation.

Contrary to the above, on April 15, 1993, the licensee transported a package containing cesium-137 and americium-241 contained in a moisture/density gauge outside the confines of its plant, and the package was not blocked and braced such that it could not change position during conditions normally incident to transportation.

This is a Severity Level IV violation (Supplement V).

Pursuant to the provisions of 10 CFR 2.201, Atec Associates of Virginia (Licensee) is hereby required to submit a written statement or explanation to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, within 30 days of the date of this Notice of Violation and Proposed Imposition of Civil Penalty (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each alleged violation: (1) admission or denial of the alleged violation, (2) the reasons for the violation if admitted, and if denied, the reasons why, (3) the corrective steps that have been taken and the results achieved, (4) the corrective steps that will be taken to avoid further violations, and (5) the date when full compliance will be achieved. If an adequate reply is not received within the time specified in this Notice, an Order or a Demand for Information may be issued as to why the license should not be modified, suspended, or revoked or why such other action as may be proper should not be taken. Consideration may be given to extending the response time for good cause shown. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, this response shall be submitted under oath or affirmation.

Within the same time as provided for the response required above under 10 CFR 2.201, the Licensee may pay the civil penalty by letter addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, with a check, draft, money order, or electronic transfer payable to the Treasurer of the United States in the amount of the civil penalty proposed above, or the cumulative amount of the civil penalties if more than one civil penalty is proposed, or may protest imposition of the civil penalty in whole or in part, by a written answer addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission. Should the Licensee fail to answer within the time specified, an order imposing the civil penalty will be issued. Should the Licensee elect to file an answer in accordance with 10 CFR 2.205 protesting the civil penalty, in whole or in part, such answer should be clearly marked as an "Answer to a Notice of Violation" and may: (1) deny the violation listed in this Notice in whole or in part, (2) demonstrate extenuating circumstances, (3) show error in this Notice, or (4) show other reasons why the penalty should not be imposed. In addition to protesting the civil penalty in whole or in part, such answer may request remission or mitigation of the penalty.

In requesting mitigation of the proposed penalty, the factors addressed in Section VI.B.2 of 10 CFR Part 2, Appendix C, should be addressed. Any written answer in accordance with 10 CFR 2.205 should be set forth separately from the statement or explanation in reply pursuant to 10 CFR 2.201, but may incorporate parts of the 10 CFR 2.201 reply by specific reference (e.g.,

citing page and paragraph numbers) to avoid repetition. The attention of the Licensee is directed to the other provisions of 10 CFR 2.205, regarding the procedure for imposing a civil penalty.

Upon failure to pay any civil penalty due which subsequently has been determined in accordance with the applicable provisions of 10 CFR 2.205, this matter may be referred to the Attorney General, and the penalty, unless compromised, remitted, or mitigated, may be collected by civil action pursuant to Section 234c of the Act, 42 U.S.C. 2282c.

The response noted above (Reply to Notice of Violation, letter with payment of civil penalty, and Answer to a Notice of Violation) should be addressed to: Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555 with a copy to the Regional Administrator, U.S. Nuclear Regulatory Commission, Region II.

Dated at Atlanta, Georgia
this 24th day of May 1993

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION II
101 MARIETTA STREET, N.W.
ATLANTA, GEORGIA 30323

APR 8 1993

Docket No. 70-27
License No. SNM-42
EA 93-012

Babcock and Wilcox Company
ATTN: Mr. J. A. Conner
Vice President and General Manager
Naval Nuclear Fuel Division
Post Office Box 785
Lynchburg, Virginia 24505-0785

Gentlemen:

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTIES - $37,500 (NRC INSPECTION REPORT NOS. 70-27/92-24 AND 70-27/93-03)

This refers to the Nuclear Regulatory Commission (NRC) inspections conducted by Mr. M. Elliott on December 1, 1992 - January 15, 1993, and January 16 - February 5, 1993, at the Babcock and Wilcox Company's Naval Nuclear Fuel Division (NNFD) located in Lynchburg, Virginia. The first referenced inspection included a review of the facts and circumstances related to multiple examples of the failure to use Raschig rings as nuclear criticality safety controls and multiple examples of the failure to conduct audits and correct audit findings. The second referenced inspection included a review of the facts and circumstances related to multiple examples of the failure to establish nuclear criticality safety limits and controls for activities involving special nuclear material, and the failure to ensure that nuclear criticality safety audit findings were promptly corrected. The reports documenting these inspections were sent to you by letters dated February 12 and February 25, 1993, respectively. As a result of these inspections, violations of NRC requirements were identified. An enforcement conference was held on March 12, 1993, in the NRC Region II office to discuss the violations, their cause, and your corrective actions to preclude recurrence. A summary of this conference was sent to you by letter dated March 18, 1993.

The seven violations in Part I.A of the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice) relate to the failure to use Raschig rings for nuclear criticality safety controls as prescribed by the national standards incorporated in your license. The violation in Part I.B of the Notice involves five examples of conducting licensed activities involving special nuclear material without establishing nuclear safety criticality limits and controls or conducting operations at variance with the nuclear safety criticality limits and controls that ensure safe operations. The violation in Part I.C of the Notice involved six examples of

the nuclear criticality safety audit program not being conducted in compliance with regulatory requirements. The majority of these violations were identified by the NRC during routine inspection activity.

The violations in Part I.A of the enclosed Notice are of concern because of the safety implications associated with the proper use of Raschig rings in nuclear criticality safety controls. The failure to ensure the adequate application and use of the Raschig rings is considered to be a significant safety concern. On December 18, 1992, you were issued a Confirmation of Action Letter that limited your uranium scrap recovery operations pending verification of the Raschig ring volume in tanks being utilized in that operation. Furthermore, the length of time that this situation existed indicates a potentially significant lack of attention to licensed responsibilities involving systems important to safety. The significance of this problem lies in its potential for a nuclear criticality accident that existed because one of the primary criticality safety controls was degraded.

Violation I.C relating to your audit program is of particular concern to the NRC because most of the examples in Violations I.A and I.B were initially identified by your nuclear criticality safety staff as audit findings that had gone uncorrected for a significant period of time. Furthermore, it was only after the NRC reviewed the audit findings and discussed their significance with your staff that the decision was made to shut down the affected operations until the appropriate nuclear criticality safety evaluations could be performed. This indicates a lack of management oversight of the nuclear criticality safety audit program. The lack of management attention to this important audit program, particularly in view of the serious deficiencies that were identified by the audit staff, is a serious safety concern.

When viewed collectively, these violations constitute a breakdown in your system for establishing and maintaining nuclear criticality safety controls. Therefore, in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy) 10 CFR Part 2, Appendix C, the above violations have been evaluated in the aggregate as a Severity Level III problem.

Notwithstanding the corrective actions that have been taken or planned to prevent recurrence, in order to emphasize the importance of appropriate management attention to, and oversight of, the nuclear criticality safety program to ensure that operational activities are conducted safely and in accordance with requirements, I have been authorized, after consultation with the Director, Office of Enforcement, and the Deputy Executive Director for Nuclear Materials Safety, Safeguards, and Operations Support, to issue the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice) in the amount of $37,500 for the violations in Part I of the Notice. The base value of a civil penalty for a Severity Level III problem in $12,500. The escalation and mitigation factors in the Enforcement Policy were considered.

Escalation of 50 percent was warranted for the factor of identification because the majority of the violations were identified by the NRC or by your staff as a result of questions raised by the NRC during inspection activities. Mitigation of 50 percent was applied for the factor of corrective action. Once the magnitude of the problem related to the Raschig rings was understood by your staff, immediate action was taken to shut down all operations in the uranium recovery facility and completely replace all Raschig rings with new rings. Further, your corrective action related to the implementation of new administrative controls related to the audit program appears to outline a program that, if appropriately implemented, should be effective. Neither escalation nor mitigation was warranted for licensee performance because mitigation for your generally good recent enforcement history and the overall general improvements in your operations was offset by your poor performance in oversight of the nuclear criticality safety program which did not receive the appropriate level of management attention. Escalation of 100 percent was warranted for the factor of prior opportunity to identify because the corrective actions that resulted from the escalated enforcement action (EA 88-225) issued on November 18, 1988, should have led you to identify the problem with the Raschig rings. In addition, your audit program identified the problems related to Raschig rings and NCS limits and controls, but because of the ineffectiveness of the audit program followup, the problems were not corrected. Escalation of 100 percent was warranted for duration because of the significant length of time some of the violations existed. The other adjustment factors in the Enforcement Policy were considered and no further adjustment to the base civil penalty is considered appropriate. Therefore, based on the above, the base civil penalty has been increased by 200 percent.

The violation in Part II of the Notice involved the failure of supervisory personnel to thoroughly explain the requirements of a Radiation Work Permit (RWP) to operators and to post a copy of the RWP in the area. This violation has been categorized at Severity Level IV.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. In your response, you should document the specific actions taken and any additional actions you plan to prevent recurrence. After reviewing your response to this Notice, including your proposed corrective actions and the results of future inspections, the NRC will determine whether further NRC enforcement action is necessary to ensure compliance with NRC regulatory requirements.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter and its enclosure will be placed in the NRC Public Document Room.

The responses directed by this letter and the enclosed Notice are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, Pub. L. No. 96-511.

Should you have any questions concerning this letter, please contact us.

Sincerely,

Stewart D. Ebneter
Regional Administrator

Enclosure:
Notice of Violation and Proposed
Imposition of Civil Penalty

cc w/encl:
A. F. Olsen
Licensing Officer
Babcock and Wilcox Company
Naval Nuclear Fuel Division
P. O. Box 785
Lynchburg, VA 24505

Commonwealth of Virginia

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

Babcock and Wilcox Company
Naval Nuclear Fuel Division
Lynchburg, Virginia

Docket No. 70-27
License No. SNM-42
EA 93-012

During NRC inspections conducted on December 1, 1992 through February 5, 1993, violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C, the Nuclear Regulatory Commission proposes to impose a civil penalty pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (Act), 42 U.S.C. 2282, and 10 CFR 2.205. The particular violations and associated civil penalty are set forth below:

I. Violations Assessed a Civil Penalty

A. On February 13, 1978, the nuclear criticality safety function authorized the handling of uranium solutions in the uranium recovery facility (URF) up to a maximum uranium concentration of 400 grams uranium per liter [facility limit] provided that the Raschig rings were maintained in accordance with ANSI-N16.4-1971 (1971 Standard) which was the predecessor of ANSI/ANS 8.5-1979. Special Nuclear Materials (SNM) License No. SNM-42 was renewed on May 31, 1984, and the requirements set forth below became effective.

License Condition No. 9 of License No. SNM-42 requires that licensed material be used in accordance with statements, representations, and conditions contained in Sections I through IV of the application (License Application) dated February 22, 1982, and supplements thereto.

Section III, Chapter 2 Paragraph 2.4 of the License Application specifies that "The Raschig rings will be used in accordance with Raschig ring standard (ANSI/ANS-85-1979)" (sic).

Section 6.5.1 of American National Standards Institute/American Nuclear Society 8.5 dated 1979 (1979 Standard) requires inspections of Raschig rings used for primary criticality control, at intervals not exceeding 13 months, be performed as described in Sections 6.1 through 6.4 of the Standard.

Section III, Chapter 1, Paragraph 1.2 of the License Application requires activities at Naval Nuclear Fuel Division (NNFD) involving special nuclear material to be conducted according to limits and controls established by Nuclear Criticality Safety (NCS) and approved by the Nuclear Licensing Board.

1. Section 5.5 of the 1971 and 1979 Standards requires the maximum solution concentration for a vessel to be based on Section 7 of the 1971 and 1979 Standards which specify, in part, that the

maximum permissible concentration of homogeneous solutions of fissile materials in vessels packed with 32 glass volume percentage of borosilicate-glass Raschig rings is 400 grams of uranium per liter (gU/l).

Contrary to the above, activities involving special nuclear material was not conducted in accordance with the limits and controls established by NCS and approved by the Nuclear Licensing Board. Specifically, measurements made between December 16, 1992, and January 5, 1993, in the URF determined the glass volume fraction to be less than 32 percent in nine vessels where borosilicate Raschig rings were used as a nuclear criticality safety control. This condition may have existed since 1978 in that measurements made between November 1, 1978, and April 19, 1979, determined that the glass volume fraction in four of 12 vessels tested was less than 32 percent, while the facility was operated with an authorized facility limit of 400 gU/l.

2. Section 6.3.3 of the 1979 Standard requires the determination of the loss of glass volume in the tank in addition to the apparent volume decrease due to settling and breakage through examination of control Raschig rings from representative regions of the tank.

   Contrary to the above, between May 31, 1984, and January 29, 1993, the loss of glass volume was not determined every 13 months for Raschig ring-filled vessels where Raschig rings were used as primary nuclear criticality safety controls.

3. Section 5.1 of the 1979 Standard requires that there shall be provision for the installation and removal of all the Raschig ring samples required for inspection during the anticipated life of the vessel's Raschig ring charge and that there shall be assurance that Raschig rings removed for inspections were not replacements added as the result of some previous inspection.

   Contrary to the above, between May 31, 1984, and January 29, 1993, provisions were not established to assure that Raschig ring inspection samples removed from vessels where they were used as the primary nuclear criticality safety control, were not replacements added as the result of some previous inspection.

4. Section 6.2.1 of the 1971 and 1979 Standards requires appropriate fissile material balances to be made for vessels using Raschig rings as the primary nuclear criticality safety control.

Contrary to the above, between 1979 and January 29, 1993, appropriate fissile material balances were not made on vessels containing Raschig rings used for primary nuclear criticality safety controls.

5. Section 6.2.2 of the 1971 and 1979 Standards requires the Raschig rings to be removed from representative regions of each Raschig ring-filled vessel and any solids deposited on their surface to be analyzed for uranium.

   Contrary to the above, between 1979 and January 29, 1993, the quantity of uranium in solids deposited on Raschig rings from representative regions of all Raschig ring-filled vessels was not analyzed as required every 13 months for vessels containing Raschig rings used for primary nuclear criticality safety controls.

6. Section 6.2.3 of the 1971 and 1979 Standards requires the determination of the presence of significant quantities of non-fissile solids, including glass corrosion products in Raschig ring-filled vessels.

   Contrary to the above, between 1979 and January 29, 1993, determination of the presence of non-fissile solids was not performed every 13 months for vessels containing Raschig rings used for primary nuclear criticality safety controls.

7. Section 6.3.2 of the 1971 and 1979 Standards requires the licensee to perform qualitative tests on Raschig rings that are used in environments where agitation is no more than that caused by mixing the solution with an air sparge at a rate of approximately 1 scfm/ft^2 of sectional area. The required tests shall consist first of visual inspection of the Raschig rings for chipped edges, crazing, cracks, and scratches, all of which may affect the mechanical strength. An additional examination shall be simple drop tests on the used Raschig rings followed by a comparison of the observed breakage rate with that of unused Raschig rings under the same test conditions.

   Contrary to the above, between 1979 and 1993, drop tests on used Raschig rings to determine the extent of deterioration of Raschig ring strength were not performed every 13 months for vessels containing Raschig rirgs used for primary nuclear criticality safety controls.

B. License Condition No. 9 of SNM-42 requires that licensed material be used in accordance with statements, representations, and conditions contained in Section I through IV of the application dated February 22, 1982, and supplements thereto.

Section III, Chapter 1, Paragraph 1.2 of the License Application requires activities at NNFD involving special nuclear material to be conducted according to limits and controls established by NCS and approved by the Nuclear Licensing Board. These limits and controls are provided to operating areas in nuclear criticality safety procedures and in nuclear criticality safety postings.

Section II, Paragraph 6.0 of the License Application requires activities to be conducted in accordance with approved written procedures.

Section II, Paragraph 6.3 of the License Application requires nuclear criticality safety procedures and postings be established for operations involving licensed material. These procedures and postings are to be generated by NCS and reviewed and approved by the operating departments.

Nuclear Criticality Safety Procedure NCS-700, "General Nuclear Criticality Safety Requirements," Revision 1, dated June 11, 1991, requires, in part, any operation involving the storing, moving, or processing of SNM to have: an approved operating procedure, an approved nuclear safety procedure, and an appropriate nuclear safety posting.

Contrary to the above, the licensee conducted activities involving SNM either without establishing or at variance with NCS limits and controls in that:

1. For periods beginning at various times from approximately 1968 through 1983, to January 21, 1993, SNM was used or stored in or on the following work areas, storage stands and equipment in core assembly operations without NCS limits and controls being established and provided in approved NCS procedures and postings. These include: Area 11 A1G Unit Cell Assembly Stands beginning in 1972, D2W Inspection Gauge beginning in 1983, Numerous Up-Ending Carts beginning in 1969, A1G Unit Cell Length Inspection Stand beginning in 1972, Area 5 S3G Vertical Storage Rack/Pit beginning in 1968, Area 1 S3G Power Unit Assembly Stand/Pit beginning in 1968, Area 4 A1W-3 and AFR (S6W) Fuel Cell Assembly Stand (Raised Floor) beginning in 1968, and Core Unit Assembly Stands beginning in 1973.

2. From approximately March 1991 to January 21, 1993, a drum counter and a segmented gamma scanner were used to determine

quantities of SNM in containers and NCS limits and controls had not been established for the use of SNM with the equipment.

3. From approximately 1970 to January 21, 1993, SNM was stored in shipping containers and NCS limits and controls had not been established and provided in approved NCS procedures and postings.

4. From approximately 1975 to January 21, 1993, SNM was used and transported on up-ender carts in the water volume test area and NCS limits and controls had not been established and provided in approved NCS procedures and postings.

5. From approximately June 1991 to January 22, 1993, uranium metal contained in waste from the Research and Test Reactor Fuel Elements (RTRFE) facility was routinely stored on a storage rack which was posted with NCS postings prohibiting the storage of uranium metal on the rack.

C. License Condition No. 9 of License No. SNM-42 requires that licensed material be used in accordance with statements, representations, and conditions contained in Section I through IV of the application dated February 22, 1982, and supplements thereto.

Section II, Paragraph 6.0 requires activities involving licensed materials be conducted in accordance with written and approved procedures.

Section II, Paragraph 7.4 of the License Application requires the licensee to perform a nuclear criticality safety audit of selected plant activities involving SNM every quarter (every 90 days plus or minus 10 days). These audits shall be conducted by Nuclear Criticality Safety Engineers. The entire plant (where SNM is processed or stored) is to be audited once every two quarters and follow-up audits will be conducted by NCS during subsequent quarterly audits.

Paragraph 7.4 also specifies that the section manager of the area in which a violation or deficiency is identified shall be required to respond in writing to the report, addressing the findings and outlining corrective actions already taken, the steps planned to complete the corrective action, and actions to prevent recurrence, if appropriate.

Procedure NCSE-03, "Nuclear Criticality Safety Audits," Paragraph F.2 states, in part, "The audit shall be conducted in accordance with the audit plan....Immediate action shall

be taken by the auditing engineer to reduce or eliminate any high or extreme risk identified during the audit." Paragraph E.2 of procedure NCSE-03 provides definitions for the levels of assessed risk. Paragraph G states in part that the results of an audit shall be documented a report; the report is forwarded to the Department Manager(s) and Section Manager(s) of areas where findings are identified; and a written response, signed by the appropriate Section Manager, shall be requested. Paragraph H.1 requires that the response be reviewed by the Manager, NCS for acceptability. The review "shall consider appropriateness of the corrective actions taken and/or planned and the timeliness of these actions." Paragraph K requires that "Follow-up audits to provide verification of any corrective actions for previously identified audit items shall be performed each quarter."

Procedure SS-02-02-01, Rev 0, dated February 26, 1992, describes the charter and membership of the NNFD Safety Review Committee. The procedure also outlines the activities of the committee which include: assessment of the adequacy and effectiveness of the safety programs, and review and evaluation of trends in findings of audits and assessments.

Contrary to the above, between June 1990 and February 1993 the NCS audit program was not conducted in compliance with regulatory requirements in that:

1. Immediate action to reduce or eliminate high risk findings was not taken in that: one high risk finding identified in April 1991, one high risk finding identified in December 1991, one high risk finding identified in March 1992, and one high risk finding identified in September 1992 were not reduced or eliminated for 22, 15, 11, and 5 months respectively.

2. Each area of the plant was not audited at least every two quarters in that: the Main bays of the Naval Reactor (NR) Clad Shop and the Supercompactor were not audited between December 16, 1991, and December 23, 1992, vaults and the A bays of the NR Clad shop were not audited between March 20 and December 23, 1992, and the Conversion area and the Laundry were not audited between December 16, 1991, and September 30, 1992.

3. As of December 21, 1992, follow-up audits to provide verification of corrective actions for approximately 140 of 203 audit items identified since June 1989 were not performed.

4. Previously identified audit items were not included in audit plans developed for the second quarter 1992 and the third quarter 1992 audits, and follow-up audits were not performed for these items.

5. Audits were not conducted in accordance with internally developed audit plans in that: the fourth quarter 1991 audit did not followup on previous audit findings as directed by the audit plan, and the first quarter 1992 audit did not audit all areas as directed by the audit plan.

6. The responses to first quarter 1992 audit finding No. 3 and third quarter 1992 audit observation No. 10 were not signed by the appropriate section manager.

These violations represent a Severity Level III problem (Supplement VI). Civil Penalty - $37,500

II. Violation Not Assessed a Civil Penalty

Section II. Paragraph 6.4 of the License Application requires Radiation Work Permits (RWP) to be issued for non-routine activities involving licensed materials which are not covered by operating procedures. RWP requirements are developed by the appropriate disciplines within the Safety and Safeguards Department after reviewing the scope of the work activities.

Radiation Protection Manual Procedure RP-06, "Radiation Work Permit," Revision 2, dated May 22, 1992, requires area and/or worker supervision to thoroughly explain the requirements of the RWP to all operators and have them sign the RWP Instruction Form, RP-06, Form 4; post a copy of the RWP in the area while work is being performed; and to monitor all work being performed under the RWP to assure that all requirements are being met.

Contrary to the above, on February 4, 1993, supervision of the Uranium Recovery Facility failed to thoroughly explain the requirements of the RWP number 93-022 to operators and failed to post a copy of the RWP in the area while non-routine work was being performed which was not covered by an operating procedure.

This is a Severity Level IV violation (Supplement VI).

Pursuant to the provisions of 10 CFR 2.201, Babcock and Wilcox Company, Naval Nuclear Fuel Division (NNFD) (Licensee) is hereby required to submit a written statement or explanation to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, within 30 days of the date of this Notice of Violation and Proposed Imposition of Civil Penalty (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each alleged violation: (1) admission or denial of the alleged violation, (2) the reasons for the violation if admitted, and if denied, the reasons why, (3) the corrective steps that have been taken and the results achieved, (4) the corrective steps that will be taken to avoid further violations, and (5) the date when full compliance will be achieved. If an adequate reply is not received within the time specified in this Notice, an order or a Demand for Information may be issued as to why the license should not be modified, suspended, or revoked or why such other action as may be proper should not be taken. Consideration may be given to extending the response time for good cause shown. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, this response shall be submitted under oath or affirmation.

Within the same time as provided for the response required above under 10 CFR 2.201, the Licensee may pay the civil penalty by letter addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, with a check, draft, money order, or electronic transfer payable to the Treasurer of the United States in the amount of the civil penalty proposed above, or the cumulative amount of the civil penalties if more than one civil penalty is proposed, or may protest imposition of the civil penalty in whole or in part, by a written answer addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission. Should the Licensee fail to answer within the time specified, an order imposing the civil penalty will be issued. Should the Licensee elect to file an answer in accordance with 10 CFR 2.205 protesting the civil penalty, in whole or in part, such answer should be clearly marked as an "Answer to a Notice of Violation" and may: (1) deny the violation listed in this Notice in whole or in part, (2) demonstrate extenuating circumstances, (3) show error in this Notice, or (4) show other reasons why the penalty should not be imposed. In addition to protesting the civil penalty in whole or in part, such answer may request remission or mitigation of the penalty.

In requesting mitigation of the proposed penalty, the factors addressed in Section VI.B.2 of 10 CFR Part 2, Appendix C, should be addressed. Any written answer in accordance with 10 CFR 2.205 should be set forth separately from the statement or explanation in reply pursuant to 10 CFR 2.201, but may incorporate parts of the 10 CFR 2.201 reply by specific reference (e.g., citing page and paragraph numbers) to avoid repetition. The attention of the Licensee is directed to the other provisions of 10 CFR 2.205, regarding the procedure for imposing a civil penalty.

Upon failure to pay any civil penalty due which subsequently has been determined in accordance with the applicable provisions of 10 CFR 2.205, this

matter may be referred to the Attorney General, and the penalty, unless compromised, remitted, or mitigated, may be collected by civil action pursuant to Section 234c of the Act, 42 U.S.C. 2282c.

The response noted above (Reply to Notice of Violation, letter with payment of civil penalty, and Answer to a Notice of Violation) should be addressed to: Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555 with a copy to the Regional Administrator, U.S. Nuclear Regulatory Commission, Region II, and a copy to the NRC Resident Inspector at NNFD.

Dated at Atlanta, Georgia
this 6th day of April 1993

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

AUG 2 0 1993

Docket No. 70-27
License No. SNM-42
EA 93-012

Babcock and Wilcox Company
ATTN: Mr. J. A. Conner
Vice President and General Manager
Naval Nuclear Fuel Division
Post Office Box 785
Lynchburg, Virginia 24505-0785

Gentlemen:

SUBJECT: ORDER IMPOSING CIVIL MONETARY PENALTY - $37,500

This refers to your letters dated May 6, 1993, in response to the Notice of Violation and Proposed Imposition of Civil Penalty (Notice) sent to you by our letter dated April 6, 1993. Our letter and Notice described ten violations, identified during inspections conducted on December 1, 1992 - January 15, 1993, and January 16 - February 5, 1993, at the Babcock and Wilcox Company's Naval Nuclear Fuel Division (NNFD) located in Lynchburg, Virginia.

To emphasize the importance of appropriate management attention to, and oversight of, the nuclear criticality safety program in order to ensure that operational activities are conducted safely and in accordance with requirements, a civil penalty of $37,500 was proposed.

In your responses, you disagreed with the severity level assessed the violations and with the application of the escalation and mitigation factors. You also indicated that two of the violations were incorrect and expressed the concern that the problems cited in the Notice of Violation do not justify a civil penalty of $37,500 when compared to problems at other fuel facilities assessed civil penalties.

After consideration of your responses, we have concluded for the reasons given in the Appendix attached to the enclosed Order Imposing Civil Monetary Penalty that a sufficient basis was not provided to change the categorization of the severity level of the violation, or for mitigation of the assessed civil penalty. Accordingly, we hereby serve the enclosed Order on Babcock and

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Wilcox Company's Naval Nuclear Fuel Division imposing a civil monetary penalty in the amount of $37,500. We will review the effectiveness of your corrective actions during a subsequent inspection.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice", a copy of this letter and the enclosure will be placed in the NRC's Public Document Room.

Sincerely,

James Lieberman, Director
Office of Enforcement

Enclosure:
Order Imposing Civil Monetary
Penalty w/Appendix

cc w/encl:
A. F. Olsen
Licensing Officer
Babcock and Wilcox Company
Naval Nuclear Fuel Division
P. O. Box 785
Lynchburg, VA 24505

Commonwealth of Virginia

UNITED STATES
NUCLEAR REGULATORY COMMISSION

In the Matter of	)	
	)	Docket No. 70-27
BABCOCK & WILCOX	)	License No. SNM-42
Lynchburg, Virginia	)	EA 93-012

ORDER IMPOSING CIVIL MONETARY PENALTY

I

Babcock and Wilcox Company, Naval Nuclear Fuel Division (NNFD or Licensee) is the holder of Special Nuclear Material (SNM) License No. SNM-42 issued by the Nuclear Regulatory Commission (NRC or Commission) on May 31, 1984. The license authorizes the Licensee to fabricate nuclear fuel components for the Naval Reactor Program, research and university reactor components, and compact reactor fuels. The license also authorizes the licensee to perform recovery/disposal operations of scrap fuel generated by the NNFD or other organizations in accordance with the conditions specified therein. The license, originally issued on August 27, 1956, was last renewed on May 31, 1984, with an expiration date of August 31, 1989. The license is currently under timely renewal.

II

An inspection of the Licensee's activities was conducted on December 1, 1992 - January 15, 1993, and January 16 - February 5, 1993. The results of this inspection indicated that the Licensee had not conducted its activities in full compliance with NRC requirements. A written Notice of Violation and Proposed

Imposition of Civil Penalty (Notice) was served upon the Licensee by letter dated April 6, 1993. The Notice stated the nature of the violations, the NRC requirements that had been violated, and the amount of the civil penalty proposed for the violations. The Licensee responded to the Notice by letters dated May 6, 1993. In its response, the Licensee admitted all the violations in Section I.A except Violation I.A.1., which was denied. In addition, the licensee noted an inaccuracy in the recitation of this violation. The Licensee admitted Violation I.B with the exception of example 5 (five), which the Licensee denied. The Licensee also noted an incorrect statement in that example. The Licensee admitted Violation I.C and the violations cited in Section II. The Licensee disagreed with the NRC staff's assessment of the safety significance of the violations and the application of the escalation and mitigation factors. The Licensee also was of the view that the problems cited in the Notice of Violation did not justify a civil penalty of $37,500 when compared to problems at other fuel facilities which have been assessed civil penalties.

III

After consideration of the Licensee's responses and the statements of fact, explanation, and argument for mitigation contained therein, as well as all information concerning these matters available to date, the NRC staff has determined, as set

forth in the Appendix to this Order, that the violations occurred as stated and that the penalty proposed for the violation designated in the Notice should be imposed.

IV

In view of the foregoing and pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (Act), 42 U.S.C. 2282, and 10 CFR 2.205, IT IS HEREBY ORDERED THAT:

The Licensee pay a civil penalty in the amount of $37,500 within 30 days of the date of this Order, by check, draft, money order, or electronic transfer, payable to the Treasurer of the United States and mailed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555.

V

The Licensee may request a hearing within 30 days of the date of this Order. A request for a hearing should be clearly marked as a "Request for an Enforcement Hearing" and shall be addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555. Copies also shall be sent to the Assistant General Counsel for Hearings and Enforcement at the same address and to

the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555. Copies also shall be sent to the Assistant General Counsel for Hearings and Enforcement at the same address and to the Regional Administrator, NRC Region II, 101 Marietta Street N.W., Suite 2900, Atlanta, Georgia 30323.

If a hearing is requested, the Commission will issue an Order designating the time and place of the hearing. If the Licensee fails to request a hearing within 30 days of the date of this Order, the provisions of this Order shall be effective without further proceedings. If payment has not been made by that time, the matter may be referred to the Attorney General for collection.

In the event the Licensee requests a hearing as provided above, the issues to be considered at such hearing shall be:

(a) whether the Licensee was in violation of the requirements set forth in Violation I.A.1 and example 5 of Violation I.B as set forth in the Notice, and

(b) whether, on the basis of Violation I.A.1 and example 5 of Violation I.B, and the other violations in the Notice, which the Licensee has admitted, this Order should be sustained.

FOR THE NUCLEAR REGULATORY COMMISSION

James Lieberman, Director
Office of Enforcement

Dated at Rockville, Maryland
this 20th day of August 1993

APPENDIX

EVALUATIONS AND CONCLUSION

On April 6, 1 , a Notice of Violation and Proposed Imposition of Civil Penalty (Notice) was issued for violations identified during an NRC inspection. Babcock and Wilcox NNFD responded in two letters dated May 6, 1993 that contained respectively an Answer and a Reply to the Notice. The licensee denied violation I.A.1 and example 5 of violation I.B. In addition, the licensee disagreed with the NRC's characterization of the safety significance of the violations as reflected in the categorization of the violations as a Severity Level III problem, the application of the escalation and mitigation factors, and the amount of the proposed civil penalty.

The NRC's evaluation and conclusions regarding the licensee's responses are as follows:

I. Restatement of Violation I.A.1

On February 13, 1978, the nuclear criticality safety function authorized the handling of uranium solutions in the uranium recovery facility (URF) up to a maximum uranium concentration of 400 grams uranium per liter [facility limit] provided that the Raschig rings were maintained in accordance with ANSI-N16.4-1971 (1971 Standard) which was the predecessor of ANSI/ANS 8.5-1979. Special Nuclear Materials (SNM) License No SNM-42 was renewed on May 31, 1984, and the requirements set forth below became effective.

License Condition No. 9 of License No. SNM-42 requires that licensed material be used in accordance with the statements, representations, and conditions contained in Sections I through IV of the application (License Application) dated February 22, 1982, and supplements thereto.

Section III, Chapter 2, Paragraph 2.4 of the License Application specifies that "The Raschig rings will be used in accordance with Raschig ring standard (ANSI/ANS-85-1979)" (sic).

Section 6.5.1 of American National Standards Institute/American Nuclear Society 8.5 dated 1979 (1979 Standard) requires inspections of Raschig rings used for primary criticality control, at intervals not exceeding 13 months, to be performed as described in Sections 6.1 through 6.4 of the Standard.

Section III, Chapter 1, Paragraph 1.2 of the License Application requires activities at Naval Nuclear Fuel

Division (NNFD) involving special nuclear material to be conducted according to limits and controls established by Nuclear Criticality Safety (NCS) and approved by the Nuclear Licensing Board.

1. Section 5.5 of the 1971 and 1979 Standards requires the maximum solution concentration for a vessel to be based on Section 7 of the 1971 and 1979 Standards which specify, in part, that the maximum permissible concentration of homogeneous solutions of fissile materials in vessels packed with 32 glass volume percentage of borosilicate-glass Raschig rings is 400 grams of uranium per liter (gU/l).

   Contrary to the above, activities involving special nuclear material were not conducted in accordance with the limits and controls established by NCS and approved by the Nuclear Licensing Board. Specifically, measurements made between December 16, 1992, and January 5, 1993, in the URF determined the glass volume fraction to be less than 32 percent in nine vessels where borosilicate Raschig rings were used as a nuclear criticality safety control. This condition may have existed since 1978 in that measurements made between November 1, 1978, and April 19, 1979, determined that the glass volume fraction in four of 12 vessels tested was less than 32 percent, while the facility was operated with an authorized facility limit of 400 gU/l.

Summary of Licensee's Response

The licensee stated that violation I.A.1 is incorrect and is not supported by the 1978 test results. The licensee contended that the measurement results from 1978 should have been rounded to the nearest whole number so that all tanks save one tested in 1978 contained glass volume fractions of at least 32%. The licensee also claimed that the one tank for which 1978 test results indicated glass volume fractions of 28.87% probably contained at least 32% glass after 1978 because the 1993 test results of this vessel indicated 32% glass volume fraction. The licensee also contended that although procedures were not in place to show technical compliance with the ANSI Standard, controls and other practices were in place to assure that other characteristics about the Raschig rings were maintained. Although volume fractions were not determined at 13 month intervals and volumes were less than required, the licensee is of the view that the overall program for maintaining Raschig rings did assure safe conditions.

NRC Evaluation of Licensee's Response

The NRC does not agree with the licensee's statement that the percent volume fractions should be rounded up. Normal scientific practice allows for the rounding of numbers as noted in the licensee's response, but such a practice is not acceptable in cases such as this where the glass volume fraction must meet a minimum standard of 32% in order for the licensee to be in compliance with a nuclear criticality safety limit. It is a fact admitted by the licensee that all the fractions referenced were less than 32% prior to rounding up. The licensee's conclusion that the one tank that tested at 28.87% in 1978 and greater than 32% in 1993 could be valid, but the licensee did not demonstrate whether the 32% was in effect during the intervening years or whether there were additions of Raschig rings during this time to increase a substandard volume fraction. The information provided by the licensee in the response did not include information demonstrating that the tanks met the requirement at all times nor did it provide any basis for disputing the fact that the licensee failed to conduct operations in accordance with Nuclear Criticality Safety, Nuclear Licensing Board and license requirements regarding the use of Raschig ring filled vessels. The licensee implies that this is a technical violation, since other characteristics concerning the Raschig rings were maintained. The NRC disagrees with this statement. Compliance with the ANSI standard was required by the licensee's NCS evaluations and all NCS evaluations performed for the affected operations assumed the ANSI standard requirements regarding the Raschig ring filled vessels were being maintained. The percent volume fraction is a key item in compliance, since the criticality safety limits used by the licensee assumed a certain minimum volume fraction to be present.

II. Restatement of Example 5 of Violation I.B

License Condition No. 9 of SNM-42 requires that licensed material be used in accordance with statements, representations, and conditions contained in Section I through IV of the application dated February 22, 1982, and supplements thereto.

Section III, Chapter 1, Paragraph 1.2 of the License Application requires activities at NNFD involving special nuclear material to be conducted according to limits and controls established by NCS and approved by the Nuclear Licensing Board. These limits and controls are provided to operating areas in nuclear criticality safety procedures and in nuclear criticality safety postings.

Section II, Paragraph 6.0 of the License Application requires activities to be conducted in accordance with approved written procedures.

Section II, Paragraph 6.3 of the License Application requires nuclear criticality safety procedures and postings to be established for operations involving licensed material. These procedures and postings are to be generated by NCS and reviewed and approved by the operating departments.

Nuclear Criticality Safety Procedure NCS-700, "General Nuclear Criticality Safety Requirements," Revision 1, dated June 11, 1991, requires, in part, any operation involving the storing, moving, or processing of SNM to have: an approved operating procedure, an approved nuclear safety procedure, and an appropriate nuclear safety posting.

Contrary to the above, the licensee conducted activities involving SNM either without establishing or at variance with NCS limits and controls in that:

5. From approximately June 1991 to January 22, 1993, uranium metal contained in waste from the Research and Test Reactor Fuel Elements (RTRFE) facility was routinely stored on a storage rack which was posted with NCS postings prohibiting the storage of uranium metal on the rack.

Summary of Licensee's Response

The licensee disagreed with this violation based on its interpretation of the intent of the NCS posting in question. The licensee stated: "Although the sign posted on the rack did prohibit uranium metal from being placed on the rack, it was not intended that the prohibition would apply to small amounts of uranium metal dust from boxline cleanouts." The licensee indicated that dust was the only type metal placed on the rack. The licensee further indicated that the intent of the posting was understood by licensee personnel. The licensee also indicated that the licensee auditor who identified this item was confused over the intent of the sign.

NRC Evaluation of Licensee's Response

The licensee argues that the violation should not stand since licensee personnel understood the intent of the posting, i.e., the posting prohibition was not meant to apply to the storing of uranium dust from boxline cleanouts. The NRC does not agree with this argument for two reasons.

First, the requirement necessarily states that NCS limits and controls provided in work areas in the form of NCS procedures and postings must be followed. Compliance with this requirement is not, and cannot be dependent on the individual understanding of licensee personnel as to the intent of the control or posting. The licensee recognized this in its NNFD Policy Statement - Nuclear Criticality Safety, dated March 1991, signed by the Vice President and General Manager which requires licensee staff to strictly comply with all nuclear criticality safety limits and controls. Second, the fact that at least one member of the licensee's staff, i.e., the auditor who identified this item, was not clear on the intent of the posting undercuts the licensee's contention that its employees understood the intent of the posting.

III. Summary of Licensee's Request for Mitigation

The licensee contended that the problems cited in the Notice do not justify a civil penalty of $37,500 when compared to problems at other fuel facilities which have been assessed civil penalties. The licensee also disagreed with the NRC's characterization of the safety significance of the individual problems. The licensee asserted its belief that no limits and controls were violated and that unsafe conditions did not exist. The licensee indicated that the safety margins required by the license were met although the Raschig rings were not maintained as required. The licensee also asserted that affected operations were not shut down to perform NCS evaluations but only to perform tests required by the ANSI standard. The licensee indicated that contrary to NRC's statements, management was involved in and attentive to the NCS program which resulted in a decrease in NCS audit findings from 1990 through 1992. The licensee stated that most of the audit findings which were violations were not identified as violations and therefore did not attract appropriate management attention.

The licensee further argued that the NRC incorrectly applied the escalation and mitigation factors. The licensee indicated that the violations described in the Notice were licensee identified as a result of the internal NCS audit program and that 50 percent escalation based on this factor was incorrect. The licensee indicated mitigation for past performance should be applied because only two Severity Level IV violations had been identified in the area of nuclear criticality safety over the past four years and no violations were identified during the last two years and that the NRC inappropriately used currently identified problems in its assessment of past performance. The licensee also indicated that escalation of the civil penalty

by 100 percent for prior opportunity to identify was not appropriate because the problems had been identified by licensee audits. Furthermore, the licensee disagreed with the assertion that corrective actions for a 1988 enforcement case (EA 88-225) should have directly lead to identification of the current problems. The licensee also disagreed with the 100 percent escalation for duration because, in the licensee's view, use of this factor is reserved for violations involving "particularly safety significant violations" or where a "significant regulatory message is warranted," none of which applied to the instant case.

NRC Evaluation of Licensee's Request for Mitigation

The NRC continues to view the violations collectively as a significant regulatory concern. The significance was not based upon an actual criticality safety occurrence, but on the potential for one and weaknesses in the system for establishing and maintaining criticality safety controls. The violations, when viewed together, represent significant failures by the licensee to establish and maintain nuclear criticality safety controls for certain critical plant operations. In addition, the licensee permitted the nuclear criticality safety audit function to operate contrary to internal procedures and in a manner in which safety findings were not promptly closed. The licensee admitted that the findings were not properly categorized so that appropriate management attention would be given to them. This represents a significant failure in the nuclear criticality safety program and cause for NRC concern. The violations were thus collectively categorized as a Severity Level III problem in accordance with the Enforcement Policy, 10 CFR Part 2, Appendix C, Section IV. This application of the Enforcement Policy is consistent with that utilized for escalated enforcement cases with other NRC licensees.

The NRC disagrees with the licensee's contention that controls were sufficient for Raschig ring use although not in full compliance. The nuclear criticality safety function approved the facility limit of 400 grams of uranium per liter based on the provision that the borosilicate-glass Raschig rings, including percent volume, were maintained in accordance with the ANSI standard. Based on the evidence available, this was not done. The licensee failed to establish a program to assure the required nuclear criticality safety controls (i.e., percent volume of Raschig rings) were implemented and maintained. When the nuclear criticality safety audit function identified that data did not exist to demonstrate that tanks contained a sufficient volume of Raschig rings, no action was taken to correct the situation until the NRC pointed out the license requirement.

After finally measuring the Raschig ring volume in January 1993, the licensee was able to demonstrate, based on data used in the establishment of the ANSI standard, that a margin of safety had been maintained. This did not eliminate the fact that from approximately 1978 until 1993, the licensee operated Raschig ring filled tanks without knowing the volume occupied by the rings, and thus without knowing whether the safety margin implicit in the ANSI standard was in place.

The licensee contended that the NNFD staff did not shut down affected operations to perform nuclear criticality safety evaluations to correct the Raschig ring issues in Violation I.A. The activities identified in example 1 of violation I.B, however, were discontinued when the licensee could not locate the nuclear criticality safety evaluations and after NRC discussion with the licensee. The fourth paragraph in NRC's letter dated April 6, 1993, does incorrectly imply that operations were shut down in regard to the Raschig rings to perform evaluations. This error, however, does not negate the NRC conclusion that licensee management did not provide adequate attention to establishing compliance for the Raschig ring volumes. The licensee did not shut down operations to determine compliance until after discussions with the NRC.

Involvement by licensee management in the nuclear criticality safety program was not clearly evident to the NRC. This observation is based on the above statements as well as the extended period of time audit findings remained open. The licensee admits that part of the problem was due to improperly characterized audit findings not reaching management's attention. The licensee correctly states that the number of audit findings decreased from 1990 to 1992, but, of equal significance was the length of time audit findings remained open. During a nuclear criticality safety assessment performed by the NRC in 1990, it was noted that audit findings were remaining open for an extended period of time. The licensee took some action to correct that situation, but it was not sufficient to prevent repeated failures to correct audit findings which were observed during the subject inspections.

The NRC acknowledges that licensee personnel identified certain issues during nuclear criticality safety audits, but these were not recognized by the licensee as violations of license conditions requiring prompt action to assure safety and compliance. For example, the NRC had to identify to licensee management on December 16, 1992, that they were committed in the license application to follow the specific ANSI Standard for Raschig rings, and that an inability to

demonstrate compliance was a violation of the conditions of the license. This was followed by a Confirmation of Action Letter on December 18, 1992. Also, the failure to post certain equipment was identified after an extended period of time to be symptomatic of the failure to have nuclear criticality safety evaluations on file. Further evidence that indicated that the licensee did not recognize these as violations is supported by the licensee's May 6, 1993, answer to the violations, in which the licensee indicated that most of the audit findings were not recognized as violations. Since the licensee did not realize that these were violations of their license conditions and take corrective action in a timely manner until the NRC raised the issue, the licensee was not given credit for identification. Therefore, in considering the factor of identification, escalation of 50 percent was warranted because the majority of the violations were identified by the NRC or by the licensee's staff as a result of questions raised by the NRC. The discussion of this factor in Section VI.B.1(a) of the NRC Enforcement Policy indicates that the purpose of this factor is to encourage licensees to monitor, supervise, and audit activities in order to assure safety and compliance. Mitigation for this factor would be inappropriate and unsupported by the facts in this case.

With respect to licensee performance, poor performance in oversight of the nuclear criticality safety program was discussed above. Further, the discussion of the licensee performance factor in Section VI.B.1(c) of the Enforcement Policy does not limit consideration to only enforcement history. Prior performance, as defined in the Enforcement Policy, also includes the licensee's overall performance in regulated activities such as those that would be analogous to areas reviewed in the Systematic Assessment of Licensee Performance (SALP) evaluations for power reactors. In applying this factor, neither escalation nor mitigation was warranted because an offset was considered appropriate in balancing generally good recent enforcement history and overall general improvements in operations with poor performance in oversight of the Nuclear Criticality Safety program. For example, in 1990, the NRC identified 27 weaknesses in the Nuclear Criticality Safety program and issued two Severity Level IV violations in the Nuclear Criticality Safety area. Also, in 1992, other weaknesses were identified in the Nuclear Criticality Safety area regarding internal notification, maintenance of equipment and monitoring of criticality alarm warning system for operability. The staff also considered the enforcement action taken in connection with EA 91-159 issued on December 6, 1991, following an enforcement conference conducted on November 25, 1991. As a result of that enforcement action,

a Severity Level IV violation was issued for the failure to conduct an adequate evaluation of the response of the radiation detectors in the nuclear criticality monitoring system. This generally poor performance in oversight of the Nuclear Criticality Safety program was viewed as a contravening data point that offset any mitigation for your overall recent good improvements in operations.

The NRC disagrees with the licensee's conclusions that escalation of 100 percent for prior opportunity was incorrectly applied. The licensee contended the NRC was incorrect in stating that corrective actions for a 1988 enforcement action would have led them to identify the Raschig ring problem. The 1988 enforcement action was for the failure to establish adequate controls to implement the double contingency principle associated with unfavorable geometry containers, which included some containers in and around the uranium recovery facility. The NRC concluded that since the corrective actions included a review of the controls associated with those containers, the licensee should have reviewed controls for all such unfavorable geometry containers including any containing Raschig rings. This would have led to discovery of the Raschig ring problem. Of more significance to NRC's decision to escalate, were the indications of problems identified by the audit program, which were not recognized as a violation sooner. The licensee's multiple opportunities to identify and correct the violations were taken into consideration and resulted in escalation of the civil penalty for this factor.

As stated in Section VI.B.2(f) of the Enforcement Policy, the duration factor is normally applied in cases involving particularly safety significant violations or where a significant regulatory message is warranted. The NRC considers the licensee's failure to (1) implement a significant license condition pertaining to nuclear criticality safety (NCS), (2) conduct activities involving SNM in accordance with NCS limits and controls, and (3) provide an appropriate level of management attention toward the NCS audit program to collectively be a significant regulatory concern. In addition, the licensee was either aware or clearly should have been aware of most of those violations which existed for a significant length of time. Therefore, the NRC concluded that escalation of the civil penalty by 100 percent was warranted to provide a significant regulatory message to the licensee that emphasizes the importance of appropriate management attention to, and oversight of, the NCS control program.

NRC Conclusion

The NRC has concluded that the violations in question (Violation I.A.1 and example 5 of Violation I.B) occurred as stated and neither an adequate basis for a reduction of the severity level nor for mitigation of the civil penalty was provided by the licensee. Consequently, the proposed civil penalty in the amount of $37,500 should be imposed by Order.

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PENNSYLVANIA 19406-1415

August 9, 1993

Docket Nos. 030-01942
030-00245
070-01450
License Nos. 20-12009-01
20-12009-03
SNM-1439
EA 93-186

Ms. Ruth Blodgett, Senior Vice President
Berkshire Health Systems, Inc.
725 North Street
Pittsfield, Massachusetts 01201

Dear Ms. Blodgett:

Subject: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTIES - $7,500
(NRC Inspection Report Nos. 030-01942/93-001; 030-00245/93-001; and 70-01450/93-001)

This letter refers to the NRC inspection conducted on June 29 and 30, 1993, at your facility located in Pittsfield, Massachusetts, of activities authorized by NRC License Nos. 20-12009-01; 20-12009-03; and SNM-1439. The inspection report was sent to you on July 20, 1993. During the inspection, thirteen apparent violations of NRC requirements were identified, including two violations of Quality Management (QM) Program requirements. On July 27, 1993, an enforcement conference was conducted with Mr. Thomas Romeo and another member of your staff, as well as a consultant, to discuss the apparent violations, their causes and your corrective actions. A copy of the enforcement conference report is enclosed (Enclosure 2). Two of the apparent violations presented in the July 20, 1993 report are not being cited, based on information provided at the enforcement conference, as described in the enforcement conference report.

The eleven violations that are being cited are described in the enclosed Notice of Violation and Proposed Imposition of Civil Penalties (Notice) (Enclosure 1). One of the violations involved four examples of a violation of your medical Quality Management (QM) Program. This violation involved the failure to prepare a written directive prior to the administration of iodine-131, phosphorus-32, and cesium-137 to patients, as well as one example of not having a written

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directive signed by an authorized user and not having all of the required information in the directive. Although this violation did not result in any misadministration of radioactive materials to patients at the facility, this violation is of particular concern because such violations create the potential for a misadministration.

The other ten violations being cited include: (1) failure to provide training in the requirements of the QM Program to supervised individuals; (2) failure of the Radiation Safety Officer (RSO) to brief management annually concerning the byproduct material program; (3) failure of management to conduct an annual review of the radiation safety program; (4) failure to include pertinent data in the individuals' radiation exposure records; (5) failure to establish a required quorum for a Radiation Safety Committee (RSC) meeting in that the required management representative was not present at the meetings; (6) failure to test the dose calibrator for linearity over its entire range of use (a repetitive violation previously cited during an NRC inspection in 1990); (7) failure to measure available ventilation rates in the areas where radioactive gas is used; (8) failure to post clearance time in the room where radioactive gas is used; (9) failure to perform a radiation survey of contiguous areas after implanting byproduct material; and (10) failure of the RSO to ensure that the xenon collection system was checked after every use. The large number of these violations, as well as the multiple examples and duration of some of them, collectively represent a breakdown in the control of licensed activities

The NRC is concerned that there appears to have been a failure to devote sufficient time to radiation safety program activities, that contributed to these violations, and that represent a significant lack of management attention to, and oversight of, licensed activities at the facility. In addition, the NRC is also concerned that the reviews performed by the Radiation Safety Committee (RSC) at your facility failed to identify the violations. The NRC license issued to Berkshire Health Systems, Inc. entrusts responsibility for radiation safety to the RSC and the RSO, and requires effective oversight of the licensed programs by the management of the hospital. Therefore, incumbent upon each NRC licensee is the responsibility of management in general, and the RSC and RSO in particular, to protect the public health and safety by ensuring that all requirements of the NRC license are met and that any potential violations of NRC requirements are identified and expeditiously corrected. The violation of QM program requirements involving the failure to prepare written directives is of significant regulatory concern to the NRC since each of the specific QM program requirements provides a safety barrier that, if not adhered to, could result in a misadministration. Therefore, in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy) 10 CFR Part 2, Appendix C, this violation is classified at Severity Level III and is set forth in Section I of the enclosed Notice. The ten other violations that collectively represent a breakdown in the control of licensed activities are also categorized in the aggregate as a Severity Level III problem, and are set forth in Section II of the enclosed Notice.

The NRC recognizes that prior to the recent inspection, the management of Berkshire Health Systems, Inc. recognized that concerns existed with the overall management of the radiation safety program, and had negotiated with a consultant to have a complete review performed of the radiation safety program. The NRC also recognized that subsequent to the NRC inspection, prompt and comprehensive corrective actions were taken or planned to correct the violations and effect improvements in the control and implementation of the radiation safety program. These actions, which were described at the enforcement conference, include, but are not limited to: (1) development of a plan, including a formalized checklist, for performing annual audits at the facility; the instruction of your staff in the requirements of the QM program and the posting of the policy regarding written directives and patient verification prior to each administration of therapeutic and diagnostic doses of iodine-131 in the nuclear medicine department; providing a special training session for the hospital administration and members of the Radiation Safety Committee on the regulations governing the use of byproduct materials at your facility; and the completion of your consultant's comprehensive audit of the radiation safety program including the QM program in August 1993.

Notwithstanding those actions, to emphasize the importance of (1) adequate implementation of the QM program, and (2) aggressive management oversight of the radiation safety program, so as to ensure that licensed activities are conducted safely and in accordance with requirements, and violations, when they exist, are promptly identified and corrected, I have been authorized to issue the enclosed Notice of Violation and Proposed Imposition of Civil Penalties (Notice) in the amount of $7,500 for the violations set forth in Sections I and II of the enclosed Notice.

With respect to the violation of the QM program requirements, the base civil penalty amount for this Severity Level III violation is $2,500. A basis exists for 50% escalation of the penalty because the violation was identified by the NRC, and 100% escalation of the penalty because the violation involved multiple examples. However, a basis also exists for 50% mitigation of the civil penalty on the basis of your prompt and comprehensive corrective actions. Therefore, on balance, 100% escalation of the base civil penalty is warranted. The other escalation/mitigation factors were considered and no further adjustment is warranted.

With respect to the remaining violations that were classified in the aggregate at Severity Level III, the base civil penalty amount of $2,500 has been escalated by 50% because the violations were identified by the NRC, and mitigated by 50% because of your prompt and comprehensive corrective actions. Therefore, on balance, no adjustment to the civil penalty for this Severity Level III problem is warranted. The other escalation/mitigation factors were considered and no further adjustment is considered appropriate.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. In your response, you should document the specific actions taken and any additional actions you plan to prevent recurrence. In this response, please address how you plan to enhance management oversight to ensure compliance with the requirements. After reviewing your response to this Notice, including your proposed corrective actions and the results of future inspections, the NRC will determine whether further

NRC enforcement action is necessary to ensure compliance with NRC regulatory requirements.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter and its enclosures will be placed in the NRC Public Document Room.

The responses directed by this letter and the enclosed Notice are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, Pub. L. No. 96-511.

Sincerely,

Thomas T. Martin
Regional Administrator

Enclosures:
1. Notice of Violation and Proposed Imposition of Civil Penalties
2. Enforcement Conference Report

cc w/encls:
Public Document Room (PDR)
Nuclear Safety Information Center (NSIC)
Commonwealth of Massachusetts (2)

ENCLOSURE 1

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTIES

Berkshire Health Systems, Inc.
Pittsfield, Massachusetts

Docket Nos. 030-01942
030-00245
070-01450
License Nos. 20-12009-01
20-12009-03
SNM-1439
EA No. 93-186

During an NRC inspection conducted on June 29 and 30, 1993, violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C, the Nuclear Regulatory Commission proposes to impose civil penalties pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (Act), 42 U.S.C. 2282, and 10 CFR 2.205. The particular violations and associated civil penalties are set forth below:

I. Violation of the Quality Management Program Requirements

10 CFR 35.32(a)(1)(i) and (iii-v), requires, in part, that prior to administration, a written directive be prepared for: any teletherapy radiation dose; any administration of quantities greater than 30 microcuries of either sodium iodide I-125 or I-131; any therapeutic administration of a radiopharmaceutical, other than sodium iodine-125 or iodine-131; or any brachytherapy radiation dose.

10 CFR 35.2 defines written directive as an order in writing for a specific patient, dated and signed by an authorized user prior to the administration of a radiopharmaceutical or radiation, except for brachytherapy, containing the following information:

i. For teletherapy: the total dose, dose per fraction, treatment site, and overall treatment period;

ii. For any administration of quantities greater than 30 microcuries of sodium iodide I-125 or I-131: the dosage.

iii. For a therapeutic administration of a radiopharmaceutical other than sodium iodide I-125 or I-131: the radiopharmaceutical, dosage, and route of administration;

iv. For brachytherapy:

1. Prior to implantation: the radioisotope, number of sources, and source strengths, and

2 After implantation but prior to completion of the procedure: the radioisotope, treatment site, and total source strength and exposure time (or, equivalently, the total dose).

Contrary to the above, on multiple occasions prior to administration of a radiopharmaceutical or radiation dose, the licensee either did not prepare a written directive, or the written directives did not contain the required information for administration of: teletherapy radiation dose, quantities greater than 30 microcuries of sodium iodide I-125 or I-131, therapy dosage of a radiopharmaceutical other than sodium iodide I-125 or I-131, and brachytherapy radiation dose, as evidenced by the following examples:

a. On February 10, 1993, the licensee administered a therapeutic dosage of 4.2 millicuries of phosphorus-32 to a patient, and as of June 30, 1993, the written directive had not been prepared;

b. On April 13, 1992, the licensee administered a dosage of 148.7 millicuries of sodium iodine-131 to a patient, and as of June 30, 1993, the written directive had not been prepared;

c. On November 12, 1992, the licensee administered a teletherapy radiation dose to a patient, and as of June 30, 1993, the written directive did not include the signature of the authorized user or the overall treatment period; and

d. On May 17, 1993, the licensee implanted five cesium-137 sources of total nominal activity of 75 millicuries into a patient, and as of June, 30, 1993, the written directive had not been prepared.

This is a Severity Level III violation (Supplement VI).

Civil Penalty - $5,000

II. Violations Representative of a Breakdown in Control of Licensed Activities

A. 10 CFR 35.25(a)(1) requires, in part, that a licensee that permits the use of byproduct material by an individual under the supervision of an authorized user shall instruct the supervised individual in the licensee's written quality management program.

Contrary to the above, as of June 30, 1993, the licensee had not instructed certain of its supervised individuals in the licensee's quality management program. Specifically, the nuclear medicine technologists, who administer iodine-131 dosages under the supervision of an authorized user, were not trained in the licensee's quality management program.

B. 10 CFR 35.21(a) requires that the licensee, through the Radiation Safety Officer, ensure that radiation safety activities are being performed in accordance with approved procedures.

The licensee's procedure for checking the operation of the reusable collection system is described in the licensee's letter, dated December 23, 1991, and was approved by Condition No. 14 of NRC License No. 20-12009-01.

The licensee's letter, dated December 23, 1991, states, in Item No. 6, that the reusable collection system will be checked after every use.

Contrary to the above, on August 31, 1992, the licensee, through its Radiation Safety Officer, failed to ensure that radiation safety activities were being performed in accordance with the above approved procedure. Specifically, the licensee used the reusable collection system to administer a 15 millicurie dosage of xenon-133 to a patient on August 31, 1992, and as of June 30, 1993, the licensee had not checked the operation of the collection system before using it again on three subsequent occasions to administer dosages of xenon-133 to patients.

C. Condition 14 of License No. 20-12009-01 requires that licensed materials be possessed and used in accordance with statements, representations and procedures contained in an application dated June 24, 1991.

Item 1.b. of ATT [Attachment] 10.2 (ALARA program) of the June 21, 1991 application requires, in part, that management perform a formal annual review of the radiation safety program.

Contrary to the above, between June 24, 1991, and June 30, 1993, the licensee's management did not perform a formal annual review of its radiation safety program.

D. 10 CFR 35.21(b)(3) requires that the Radiation Safety Officer brief management once each year on the byproduct material program.

Contrary to the above, as of June 30, 1993, the Radiation Safety Officer had never briefed management on the byproduct material program.

E. 10 CFR 35.205(e) requires, in part, that a licensee measure each six months the ventilation rates available in areas of use of radioactive gas.

Contrary to the above, the licensee used radioactive xenon-133 gas in the scanning room and did not measure the ventilation rates therein from March 1992 to June 30, 1993.

F. 10 CFR 20.401(a) requires that each licensee maintain records showing radiation exposures on Form NRC-5, in accordance with the instructions contained in that form, or on clear and legible records containing all the information required by Form NRC-5.

Contrary to the above, as of June 30, 1993, the licensee did not maintain exposure records containing the required information. Specifically, radiation exposure records of several individuals did not include their respective dates of birth and identification numbers.

G. 10 CFR 35.22(a)(3) requires that to establish a quorum and to conduct business, at least one-half of the Radiation Safety Committee's membership must be present, including the Radiation Safety Officer and the management's representative.

Contrary to the above, on August 26, 1992, the licensee's Radiation Safety Committee met and conducted business and the management's representative was not present.

H. 10 CFR 35.50(b)(3) requires, in part, that a licensee test each dose calibrator for linearity over the range of its use between the highest dosage that will be administered to a patient and 10 microcuries.

Contrary to the above, the licensee's dose calibrator linearity test performed on February 18, 1992 covered only the range between 99.4 millicuries and 19.5 microcuries and the highest dosage that the licensee measured on April 13, 1992 was 102.7 millicuries.

This is a repetitive violation.

I. 10 CFR 35.205(d) requires, in part, that a licensee post the safety measures to be instituted in case of a spill of a radioactive gas at the area of use and the calculated time needed after a spill to reduce the concentration to the occupational limit listed in 10 CFR Part 20, Appendix B.

Contrary to the above, from August 31, 1992 to April 21, 1993, the licensee used radioactive xenon-133 gas in the nuclear medicine scanning room and the licensee did not post the calculated time needed after a spill to reduce the concentration to the occupational limit listed in 10 CFR Part 20, Appendix B.

J. 10 CFR 35.415(a)(4) requires, in part, that a licensee, promptly after implanting brachytherapy sources, survey the dose rates in contiguous restricted and unrestricted areas with a radiation measurement survey instrument to demonstrate compliance with the requirements of 10 CFR Part 20.

Contrary to the above, on May 15, 1993, the licensee implanted cesium-137 brachytherapy sources and did not survey the dose rates in restricted and unrestricted areas contiguous to the room of the implanted patient to demonstrate compliance with the requirements of 10 CFR Part 20. Specifically, the dose rates in the room adjacent to the patient's room were not measured.

These violations are classified in the aggregate as a Severity Level III problem (Supplements IV and VI).

Civil Penalty - $2,500

Pursuant to the provisions of 10 CFR 2.201, Berkshire Health Systems, Inc. (Licensee) is hereby required to submit a written statement or explanation to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, within 30 days of the date of this Notice of Violation and Proposed Imposition of Civil Penalties (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each alleged violation: (1) admission or denial of the alleged violation, (2) the reasons for the violation if admitted, and if denied, the reasons why, (3) the corrective steps that have been taken and the results achieved, (4) the corrective steps that will be taken to avoid further violations, and (5) the date when full compliance will be achieved. If an adequate reply is not received within the time specified in this Notice, an order or a Demand for Information may be issued to show cause why the license should not be modified, suspended, or revoked or why such other action as may be proper

should not be taken. Consideration may be given to extending the response time for good cause shown. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, this response shall be submitted under oath or affirmation.

Within the same time as provided for the response required above under 10 CFR 2.201, the Licensee may pay the civil penalties by letter addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, with a check, draft, money order, or electronic transfer payable to the Treasurer of the United States in the amount of the civil penalty proposed above, or the cumulative amount of the civil penalties if more than one civil penalty is proposed, or may protest imposition of the civil penalties in whole or in part, by a written answer addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission. Should the Licensee fail to answer within the time specified, an order imposing the civil penalties will be issued. Should the Licensee elect to file an answer in accordance with 10 CFR 2.205 protesting the civil penalties, in whole or in part, such answer should be clearly marked as an "Answer to a Notice of Violation" and may: (1) deny the violation(s) listed in this Notice, in whole or in part, (2) demonstrate extenuating circumstances, (3) show error in this Notice, or (4) show other reasons why the penalties should not be imposed. In addition to protesting the civil penalties in whole or in part, such answer may request remission or mitigation of the penalties.

In requesting mitigation of the proposed penalties, the factors addressed in Section VI.B.2 of 10 CFR Part 2, Appendix C, should be addressed. Any written answer in accordance with 10 CFR 2.205 should be set forth separately from the statement or explanation in reply pursuant to 10 CFR 2.201, but may incorporate parts of the 10 CFR 2.201 reply by specific reference (e.g., citing page and paragraph numbers) to avoid repetition. The attention of the Licensee is directed to the other provisions of 10 CFR 2.205, regarding the procedure for imposing civil penalties.

Upon failure to pay any civil penalties due which subsequently have been determined in accordance with the applicable provisions of 10 CFR 2.205, this matter may be referred to the Attorney General, and the penalties, unless compromised, remitted, or mitigated, may be collected by civil action pursuant to Section 234c of the Act, 42 U.S.C. 2282c.

The response noted above (Reply to Notice of Violation, letter with payment of civil penalties, and Answer to a Notice of Violation) should be addressed to: Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555 with a copy to the Regional Administrator, U.S. Nuclear Regulatory Commission, Region I.

Dated at King of Prussia, Pennsylvania
this 9th day of August 1993

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PENNSYLVANIA 19406-1415

NOV 20 1992

Docket No. 9999-0001
New York License No. 2467-3128
EA 92-203

Mr. Stanley Liebert, President
Capital Materials Testing, Inc.
2712 Route 9
Ballston Spa, New York 12020

Dear Mr. Liebert:

Subject: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY - $ 7,500
(NRC Inspection Reports No. 9999-0001/92-026)

This letter refers to the NRC inspection conducted on October 6-7, 1992, at a field site located in Pittsfield, Massachusetts, and continued in the Region I office on October 14 and 16, 1992, to review records of training of radiographers. The inspection consisted of a review of activities authorized by an NRC general license granted to you pursuant to 10 CFR 150.20(a) since you possess a specific license from the State of New York, an NRC agreement state. The inspection report was sent to you on October 30, 1992. During the inspections, five apparent violations of NRC requirements were identified. On November 10, 1992, an enforcement conference was conducted with you, a member of your staff, and your consultant, to discuss the violations, their causes and your corrective actions. A copy of the Enforcement Conference Report is enclosed.

The violations, which are described in the enclosed Notice, include: (1) the failure to perform an adequate survey of the entire circumference of a radiography device, as well as the guide tube, after the completion of a radiography activity, to ensure that the radioactive source had returned to its shielded position; (2) the failure to secure the radioactive source, as required, in the shielded position each time it was returned to that position; (3) failure to perform an adequate survey of the area before conducting radiography; (4) failure to adequately post, with the appropriate caution signs, a radiation area and high radiation area that existed at the field site in Pittsfield, Massachusetts; and (5) the failure to maintain shipping papers in the proper location in the transport vehicle.

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Of particular concern to the NRC was your failure to perform an adequate survey after completion of a radiography activity, that could have resulted in the failure to detect a source if the source was not fully retracted into the radiographic exposure device. This violation of an important radiography requirement is described in Section I of the enclosed Notice. Your failure to perform an adequate survey is particularly significant given the fact that the failure of a source to fully retract to the shielded position can result in significant exposures to workers or members of the public. Therefore, the violation is classified at Severity Level III in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C (1992) (Enforcement Policy).

The NRC recognizes that actions have been taken or planned by you to correct the violations. These actions, which were described at the enforcement conference, included issuance of a memorandum, dated November 6, 1992, from your Manager of Nondestructive Testing to all radiographers and radiographer's assistants, which described the violations identified during the NRC inspection, and emphasized the importance of adherence to requirements. The NRC also recognizes that prior to the inspection, you had retained a consultant to act as Radiation Safety Officer and audit your licensed activities, as a result of several violations identified by the State of New York in August 1992.

Notwithstanding those actions, to emphasize (1) the importance of appropriate management attention to your regulatory responsibilities to ensure that all personnel strictly adhere to all regulatory requirements in the future, and (2) the need for ensuring that all corrective actions, both taken and planned, are properly implemented and are long-lasting, I have been authorized to issue the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice) in the amount of $7,500 for the violation set forth in Section I of the enclosed Notice.

The base civil penalty amount for a Severity Level III violation is $5,000. The escalation and mitigation factors set forth in the enforcement policy were considered, and on balance, the base civil penalty amount for the violation set forth in Section I has been increased by 50% to $7,500 because (1) the violation was identified by the NRC, and therefore, 50% escalation of the civil penalty on this factor is warranted; and (2) your corrective actions, as described herein, although acceptable, were not considered prompt or extensive, and therefore, no adjustment of the civil penalty on this factor is warranted. The other factors were considered and no further adjustment was warranted.

The other four violations identified during the inspection are described in Section II of the enclosed Notice and are classified individually at Severity Level IV.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. In your response, you should document the specific actions taken and any additional actions you plan to prevent recurrence. After reviewing your response to this Notice, including your proposed corrective actions, and the results of future inspections, the NRC will determine whether further enforcement action is necessary to ensure compliance with NRC regulatory requirements.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter and the enclosures will be placed in the NRC Public Document Room.

The responses directed by this letter and the enclosed Notice are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, Pub. L. 96-511.

Sincerely,

Thomas T. Martin
Regional Administrator

Enclosures:
1. Notice of Violation and Proposed Imposition of Civil Penalty
2. Enforcement Conference Report

cc w/encls:
Public Document Room (PDR)
Nuclear Safety Information Center (NSIC)
Commonwealth of Massachusetts
State of New York

ENCLOSURE 1

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

Capital Materials Testing, Inc.
Ballston Spa, New York 12020

Docket No. 9999-0001
New York License No. 2467-3128
EA 92-203

During an NRC inspection conducted on October 6, 7, 14, and 16, 1992, violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C (1992), the Nuclear Regulatory Commission proposes to impose a civil penalty pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (Act), 42 U.S.C. 2282, and 10 CFR 2.205. The particular violations and associated civil penalty are set forth below:

I. VIOLATION ASSESSED A CIVIL PENALTY

10 CFR 34.43(b) requires, in part, the licensee to ensure that a survey with a calibrated and operable radiation survey instrument is made after each radiographic exposure to determine that the sealed source has been returned to its shielded position. The survey must include the entire circumference of the radiographic exposure device and any source guide tube.

Contrary to the above, on October 6, 1992, at a temporary job site at a gas pipeline installation for Berkshire Gas of Pittsfield, Massachusetts, a licensee radiographer's assistant did not perform an adequate survey after each radiographic exposure to determine that the sealed source has been returned to its shielded position, in that although the radiographer's assistant walked toward the exposure device with the survey instrument, the survey did not include the entire circumference of the radiographic exposure device and the source guide tube.

This violation is classified at Severity Level III (Supplement VI).

Civil Penalty - $7,500

II. VIOLATION NOT ASSESSED A CIVIL PENALTY

A. 10 CFR 34.22(a) requires, in part, that, during radiographic operations, the sealed source assembly be secured in the shielded position each time the source is returned to that position.

Contrary to the above, on October 6, 1992, at a temporary job site at a gas pipeline installation for Berkshire Gas of Pittsfield, Massachusetts, a licensee radiographer's assistant did not secure the sealed source assembly in the shielded position after returning the source to the shielded position at the termination of a radiographic exposure.

This is a Severity Level IV violation (Supplement VI).

B. 10 CFR 20.201(b) requires that each licensee make such surveys as may be necessary to comply with the requirements of Part 20 and that are reasonable under the circumstances to evaluate the extent of radiation hazards that may be present. As defined in 10 CFR 20.201(a), "survey" means an evaluation of the radiation hazards incident to the production, use, release, disposal, or presence of radioactive materials or other sources of radiation under a specific set of conditions.

Contrary to the above, on October 6, 1992, at a temporary job site at a gas pipeline installation for Berkshire Gas of Pittsfield, Massachusetts, the licensee did not make an adequate survey to assure compliance with 10 CFR Part 20.105(b)(1) which limits radiation levels in unrestricted areas. Specifically, the inspectors did not observe any survey being performed in the area that they were watching, which included more than one-half of the unrestricted area.

This is a Severity Level IV violation (Supplement IV).

C. 10 CFR 34.42 requires, notwithstanding any provisions in 10 CFR 20.204(c), that areas in which radiography is being performed be conspicuously posted as required by 10 CFR 20.203(b) and (c)(1).

10 CFR 20.203(b) requires that each radiation area shall be conspicuously posted with a sign or signs bearing the radiation caution symbol and the words "CAUTION RADIATION AREA."

10 CFR 20.203(c)(1) requires that each high radiation area shall be conspicuously posted with a sign or signs bearing the radiation caution symbol and the words "CAUTION HIGH RADIATION AREA."

Contrary to the above, on October 6, 1992, during radiography performed at a gas pipeline installation for Berkshire Gas of Pittsfield, Massachusetts, the licensee did not conspicuously post the radiation area and did not post the high radiation area in which industrial radiography was being performed. Specifically, the high radiation area was not posted at all, and the radiation area was not posted adequately in that although it was posted with two cones, the cones were not visible from most approaches to the site.

This is a Severity Level IV violation (Supplement VI).

D. 10 CFR 71.5 in part, requires each licensee who transports licensed material outside of the confines of the plant or other place of use or who delivers licensed material to a carrier for transport shall comply with the requirements of the regulations appropriate to the mode of transport of the Department of Transportation in 49 CFR Parts 170-189. 49 CFR 177.817(e)(2)(ii) which requires that when the driver is not at the vehicle's controls, the shipping papers shall be: (A) In a holder which is mounted to the inside of the door on the driver's side of the vehicle; or (B) on the driver's seat in the vehicle.

Contrary to the above, on October 6, 1992, at a temporary job site at a gas pipeline installation for Berkshire Gas of Pittsfield, Massachusetts, shipping papers for an iridium-192 radiography device were not in a holder mounted to the inside of the door on the driver's side of the vehicle or on the driver's seat in the vehicle. Specifically, the shipping papers were taped to the wall inside the rear cabin of the vehicle.

This is a Severity Level IV violation (Supplement V).

Pursuant to the provisions of 10 CFR 2.201, Capital Materials Testing, Inc. is hereby required to submit a written statement or explanation to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, within 30 days of the date of this Notice of Violation and Proposed Imposition of Civil Penalty (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each alleged violation: (1) admission or denial of the alleged violation, (2) the reasons for the violation if admitted, and if denied, the reasons why, (3) the corrective steps that have been taken and the results achieved, (4) the corrective steps that will be taken to avoid further violations, and (5) the date when full compliance will be achieved. If an adequate reply is not received within the time specified in this Notice, an order or a demand for information may be issued as to why the license should not be modified, suspended, or revoked or why such other action as may be proper should not be taken. Consideration may be given to extending the response time for good cause shown. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, this response shall be submitted under oath or affirmation.

Within the same time as provided for the response required above under 10 CFR 2.201, the Licensee may pay the civil penalty by letter addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, with a check, draft, money order, or electronic transfer payable to the Treasurer of the United States in the amount of the civil penalty, or may protest imposition of the civil penalty in whole or in part, by a written answer addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission. Should the Licensee fail to answer within the time specified, an order imposing the civil penalty will be issued. Should the Licensee elect to file an answer in accordance with 10 CFR 2.205 protesting the civil penalty, in whole or in part, such answer should be clearly marked as an "Answer to a Notice of Violation" and may: (1) deny the violations listed in this Notice, in whole or in part, (2) demonstrate extenuating circumstances, (3) show error in this Notice, or (4) show other reasons why the penalty should not be imposed. In addition to protesting the civil penalty in whole or in part, such answer may request remission or mitigation of the penalty.

In requesting mitigation of the proposed penalty, the factors addressed in Section V.B of 10 CFR Part 2, Appendix C (1992), should be addressed. Any written answer in accordance with 10 CFR 2.205 should be set forth separately from the statement or explanation in reply pursuant to 10 CFR 2.201, but may incorporate parts of the 10 CFR 2.201 reply by specific reference (e.g., citing page and paragraph numbers) to avoid repetition. The attention of the Licensee is directed to the other provisions of 10 CFR 2.205, regarding the procedure for imposing civil penalties.

Upon failure to pay any civil penalty due which subsequently has been determined in accordance with the applicable provisions of 10 CFR 2.205, this matter may be referred to the Attorney General, and the penalty, unless compromised, remitted, or mitigated, may be collected by civil action pursuant to Section 234c of the Act, 42 U.S.C. 2282(c).

The response noted above (Reply to Notice of Violation, letter with payment of civil penalty, and Answer to a Notice of Violation) should be addressed to: Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555 with a copy to the Regional Administrator, U.S. Nuclear Regulatory Commission, Region I, 475 Allendale Road, King of Prussia, Pennsylvania 19406.

Dated at King of Prussia, Pennsylvania
this 20th day of November 1992

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

FEB 0 3 1993

Docket No. 9999-0001
License No. 2467-3128
EA 92-203

Capital Materials Testing, Inc.
ATTN: Mr. Stanley Liebert, President
2712 Route 9
Ballston Spa, New York 12020

Dear Mr. Liebert:

SUBJECT: ORDER IMPOSING A CIVIL MONETARY PENALTY - $7,500
(Inspection Report No. 9999-0001/92-026)

This refers to your letter dated December 9, 1992, in response to the Notice of Violation and Proposed Imposition of Civil Penalty (Notice) sent to you by the NRC letter, dated November 20, 1992. The NRC letter and Notice described five violations identified at a field site in Pittsfield, Massachusetts, during an NRC inspection conducted on October 6-7, 1992. To emphasize (1) the importance of appropriate management attention to your regulatory responsibilities to ensure that all personnel strictly adhere to all regulatory requirements in the future, and (2) the need for ensuring that all corrective actions, both taken and planned, are properly implemented and are long-lasting, a civil penalty in the amount of $7,500 was proposed.

In your response, you did not deny the violations set forth in the Notice, but you requested remission of the civil penalty, for the reasons set forth in your response, as summarized in the Appendix to the enclosed Order. After consideration of your response, we have concluded for the reasons given in the Appendix attached to the enclosed Order Imposing Civil Monetary Penalty, that an adequate basis was not provided for mitigation of the penalty. Accordingly, we hereby serve the enclosed Order on Capital Materials Testing, Inc., imposing a civil monetary penalty in the amount of $7,500. We will review the effectiveness of your corrective actions during a subsequent inspection.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice", a copy of this letter and the enclosures will be placed in the NRC's Public Document Room.

Sincerely,

Hugh L. Thompson

Hugh L. Thompson
Deputy Executive Director for
Nuclear Materials Safety, Safeguards
and Operations Support

Enclosures: As Stated

cc w/encls:
Public Document Room (PDR)
Nuclear Safety Information Center (NSIC)
Ms. Donna Ross, Div. of Policy Analysis
and Planning, State of New York Energy Office
Robert Hallisey, Commonwealth of Massachusetts
Dept. of Public Health

UNITED STATES
NUCLEAR REGULATORY COMMISSION

In the Matter of	)	
	)	
Capital Materials Testing, Inc.	)	Docket No. 9999-0001
Ballston Spa, New York 12020	)	License No. 2467-3128
	)	EA 92-203

ORDER IMPOSING CIVIL MONETARY PENALTY

I

Capital Materials Testing, Inc. (Licensee) is the holder of a Byproduct Material License issued by the State of New York which authorizes the Licensee to use byproduct materials in industrial radiography and replacement of sources in accordance with the conditions specified therein. On October 6-7, 1992, the New York State Licensee was working at a field site in Pittsfield, Massachusetts under NRC jurisdiction subject to the reciprocity requirements set forth in 10 CFR 150.20 and 10 CFR Part 34, Subpart B.

II

An inspection of the Licensee's activities was conducted on October 6-7, 1992. The results of the inspection indicated that CMT had not conducted its activities in full compliance with NRC requirements. A written Notice of Violation and Proposed Imposition of Civil Penalty (Notice) was served upon the Licensee by letter dated November 20, 1992. The Notice stated the nature of the violations, the provisions of the NRC's requirements that the Licensee had violated, and the amount of the civil penalty proposed

for the violations. The Licensee responded to the Notice in a letter, dated December 9, 1992. In its response, the Licensee did not deny the violations, but requested remission of the civil penalty.

III

After consideration of the Licensee's response and the statements of fact, explanation, and argument for mitigation contained therein, the NRC staff has determined, as set forth in the Appendix to this Order, that the violations occurred as stated and that the penalty proposed for Violation I designated in the Notice should be imposed.

IV

In view of the foregoing, and pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (Act), 42 U.S.C. 2282, and 10 CFR 2.205, IT IS HEREBY ORDERED THAT:

The Licensee pay a civil penalty in the amount of $7,500 within 30 days of the date of this Order, by check, draft, money order, or electronic transfer, payable to the Treasurer of the United States and mailed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555.

The Licensee may request a hearing within 30 days of the date of this Order. A request for a hearing should be clearly marked as a "Request for an Enforcement Hearing" and shall be addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555. Copies also shall be sent to the Assistant General Counsel for Hearings and Enforcement at the same address and to the Regional Administrator, NRC Region I, 475 Allendale Road, King of Prussia, Pennsylvania 19406.

If a hearing is requested, the Commission will issue an Order designating the time and place of the hearing. If the Licensee fails to request a hearing within 30 days of the date of this Order, the provisions of this Order shall be effective without further proceedings. If payment has not been made by that time, the matter may be referred to the Attorney General for collection.

In the event the Licensee requests a hearing as provided above, the issue to be considered at such hearing shall be whether, on the

basis of Violation I set forth in the Notice, this Order should be sustained.

FOR THE NUCLEAR REGULATORY COMMISSION

Hugh L. Thompson
Deputy Executive Director for Nuclear
Materials Safety, Safeguards
and Operations Support

Dated at Rockville, Maryland
this 3rd day of February 1993

APPENDIX

EVALUATIONS AND CONCLUSION

On November 20, 1992, a Notice of Violation and Proposed Imposition of Civil Penalty (Notice) was issued to Capital Materials Testing (CMT), Inc. for five violations identified during an NRC inspection on October 6-7, 1992, at a field site in Pittsfield, Massachusetts. CMT responded to the Notice on December 9, 1992. CMT did not deny the violations, but requested full mitigation of the civil penalty. The NRC's evaluations and conclusions regarding CMT's requests are as follows:

1. Restatement of Violation Assessed a Civil Penalty

   10 CFR 34.43(b) requires, in part, the licensee to ensure that a survey with a calibrated and operable radiation survey instrument is made after each radiographic exposure to determine that the sealed source has been returned to its shielded position. The survey must include the entire circumference of the radiographic exposure device and any source guide tube.

   Contrary to the above, on October 6, 1992, at a temporary job site at a gas pipeline installation for Berkshire Gas of Pittsfield, Massachusetts, a licensee radiographer's assistant did not perform an adequate survey after each radiographic exposure to determine that the sealed source has been returned to its shielded position, in that although the radiographer's assistant walked toward the exposure device with the survey instrument, the survey did not include the entire circumference of the radiographic exposure device and the source guide tube.

   This violation is classified at Severity Level III (Supplement VI).

   Civil Penalty - $7,500

2. Summary of Licensee Response

   CMT, in its response, does not deny the violation, but does request remission of the penalty on the basis that CMT, a State of New York (Agreement State) licensee, had never been cited for failure to survey; the magnitude of the fine would be detrimental, financially, to CMT; CMT took corrective actions which included voluntary initiation of an audit; and the violation was an inconsistent and isolated interaction of radiation safety procedures.

3. NRC Evaluation of Licensee Response

The NRC has evaluated CMT's response, and based upon that evaluation, the NRC has concluded that CMT did not provide an adequate basis for mitigation of the civil penalty.

With respect to CMT's contentions that it had never been cited for the failure to survey, and the violation was an inconsistent and isolated infraction of a radiation safety procedure, the NRC notes that these considerations, in themselves, do not provide a basis for mitigation of the penalty. CMT is responsible for the acts of its employees. Performing proper surveys after use of a radiography device is fundamental to radiation safety; the failure by other NRC licensee personnel to do so has resulted, at times, in significant radiological exposures to radiography personnel. While CMT may not have been cited for such a violation in the past by the NRC, this was the first NRC inspection conducted of CMT. Therefore, these licensee contentions do not provide a basis for mitigation of the civil penalty.

With respect to CMT's contention that the civil penalty would be financially detrimental, CMT provided no details to support that contention, and therefore mitigation is not warranted.

With respect to CMT's corrective action, the NRC notes that while those actions were acceptable, they were not of a prompt and comprehensive nature because while the licensee was aware of the findings of the NRC inspection on October 7, 1992, it did not issue a memorandum to its employees describing the violation and corrective action until November 6, 1992. Therefore, those actions do not provide a basis for any mitigation of the penalty.

4. NRC Conclusion

The NRC has concluded that CMT has not provided an adequate basis for mitigation of the civil penalty. Consequently, the proposed civil penalty in the amount of $7,500 should be imposed.

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

APR 26 1993

Docket No. 9999-0001
License No. 2467-3128
EA 92-203

Capital Materials Testing, Inc.
ATTN: Mr. Stanley Liebert
President
2712 Route 9
Ballston Spa, New York 12020

Dear Mr. Liebert:

SUBJECT: ORDER MODIFYING AN ORDER IMPOSING A CIVIL MONETARY PENALTY - $5,000

This letter confirms your telephone conversation with Ms. Patricia A. Santiago and Mr. Eugene Holler, NRC, on April 8, 1993, in reference to your letter dated March 25, 1993, in response to NRC letters dated February 26, 1993 and March 13, 1993. As discussed with you, NRC has reviewed the information and statements you submitted in your March 25, 1993, letter regarding your corrective actions to Violation I in the Notice of Violation and Proposed Imposition of Civil Penalty - $7,500 (Notice, and information from your December 9, 1992 response to the Notice in which you did not deny the violations set forth in the Notice, but requested remission of the civil penalty. After consideration of your response, the NRC staff has determined that the $7500 civil penalty be mitigated by 50 percent of the $5,000 base civil penalty for a Severity Level III violation, based on your prompt and extensive corrective actions. In addition, the staff concluded that no additional basis is provided for further mitigation of the penalty for the reasons given in the Appendix attached to the February 3, 1993 Order Imposing Civil Monetary Penalty. Accordingly, I hereby serve the enclosed Order Modifying an Order Imposing a Civil Monetary Penalty on Capital Materials Testing, Inc. (CMT), imposing a civil monetary penalty in the amount of $5,000 for Violation I of the Notice.

Further, based on the March 25, 1993, financial information submitted, the NRC staff is prepared to accept payments over time, including interest in accordance with the Enforcement Policy. A payment schedule has been developed and is enclosed in the form of a Promissory Note in Payment of the Civil Penalty (Note). This Note must either be signed in duplicate and returned within 10 days to the Director, Office of Enforcement,

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

U. S. Nuclear Regulatory Commission, Mail Stop 7H5, Washington, D. C. 20555 or you must notify us within 10 days of the date of this letter, if you request that we proceed with your February 24, 1993 request for a hearing. The only issue to be considered at such a hearing shall be whether, on the basis of Violation I set forth in the Notice, the Order should be sustained. Failure to take either of these approaches, may result in this case being referred to the Department of Justice.

We have also enclosed a copy of the NRC Enforcement Policy which contains the examples of violations and the severity level at which they are categorized. As discussed with you on April 8, 1993, Violation I described in the Notice issued to CMT was classified at Severity Level III consistent with example C.8. set forth in Supplement VI of the NRC Enforcement Policy.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice", a copy of this letter and the enclosures will be placed in the NRC's Public Document Room.

Sincerely,

Hugh L. Thompson, Jr.
Deputy Executive Director for
Nuclear Materials Safety,
Safeguards and Operations Support

Enclosures: As Stated

cc w/encls:
Public Document Room (PDR)
Nuclear Safety Information Center (NSIC)
Ms. Donna Ross, Div. of Policy Analysis
and Planning, State of New York Energy Office
Robert Hallisey, Commonwealth of Massachusetts
Dept. of Public Health

UNITED STATES
NUCLEAR REGULATORY COMMISSION

In the Matter of	)	
	)	
Capital Materials Testing, Inc.	)	Docket No. 9999-0001
Ballston Spa, New York 12020	)	License No. 2467-3128
	)	EA 92-203

ORDER MODIFYING ORDER IMPOSING CIVIL MONETARY PENALTY

I

Capital Materials Testing, Inc. (Licensee) is the holder of a Byproduct Material License issued by the State of New York which authorizes the Licensee to use byproduct materials in industrial radiography and replacement of sources in accordance with the conditions specified therein. On October 6-7, 1992, the New York State Licensee was working at a field site in Pittsfield, Massachusetts under NRC jurisdiction subject to the reciprocity requirements set forth in 10 CFR 150.20.

II

An NRC inspection of the Licensee's activities was conducted on October 6-7, 1992. The results of the inspection indicated that the Licensee had not conducted its activities in full compliance with NRC requirements. A written Notice of Violation and Proposed Imposition of Civil Penalty (Notice) was served upon the Licensee by letter dated November 20, 1992. The Notice stated the nature of the violations, the provisions of the NRC's requirements that the Licensee had violated, and the amount of the civil penalty proposed for the violations. The Licensee responded to the Notice in a letter, dated December 9, 1992.

III

Upon review of the facts of this case, including the information submitted in the licensee's March 25, 1993 letter, I find that the Licensee's prompt and extensive corrective actions support a $2,500 reduction of the $7,500 civil penalty imposed in the February 3, 1993 Order, based on mitigation consistent with the NRC Enforcement Policy.

IV

In view of the foregoing, and pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (Act), 42 U.S.C. 2282, and 10 CFR 2.205, IT IS HEREBY ORDERED THAT:

The NRC February 3, 1993 Order Imposing a Civil Monetary Penalty in the amount of $7,500 be modified to the amount of $5,000.

V

The Licensee may request that the NRC proceed with the Licensee's February 24, 1993 request for a hearing within 10 days of the date of this Order. If the Licensee requests that the NRC proceed with its hearing request, the Commission will issue an Order designating the time and place of the hearing. If the

In its response, the Licensee did not deny the violations, but requested remission of the civil penalty.

After consideration of the Licensee's response and the statements of fact, explanation, and argument for mitigation contained therein, the NRC staff determined that the violations occurred as stated and that the penalty proposed for Violation I designated in the Notice should be imposed. Accordingly, NRC issued an Order Imposing a Civil Monetary Penalty to the licensee on February 3, 1993. The licensee responded in a letter dated February 24, 1993 and requested a hearing. In correspondence dated February 26, 1993 and March 13, 1993, the NRC confirmed telephone conversations between Mr. Stanley Liebert, Licensee President, and NRC representatives in which the Licensee requested delay in processing of the Licensee's February 24, 1993 hearing request until after NRC reviewed additional information the Licensee was to submit for consideration. On March 25, 1993, the Licensee submitted the additional information. The information specified the corrective actions taken by the Licensee following the October 6-7, 1992 NRC inspection and provided financial information to support the Licensee's assertion concerning its ability to pay.

Licensee does not request the NRC to proceed with its request for hearing within 10 days of the date of this Order, the provisions of this Order shall be effective without further proceedings. If full payment has not been made by that time, or if either arrangements for payment over time are not completed by that time, the matter may be referred to the Attorney General for collection.

In the event the Licensee requests proceeding with a hearing as provided above, the issue to be considered at such hearing shall be whether, on the basis of Violation I, admitted by the Licensee, this Order should be sustained.

FOR THE NUCLEAR REGULATORY COMMISSION

Hugh L. Thompson, Jr.
Deputy Executive Director for Nuclear
Materials Safety, Safeguards
and Operations Support

Dated at Rockville, Maryland
this 26th day of April 1993

Promissory Note in Payment of Civil Penalty

Docket No. 9999-0001
License No. 2467-3128
EA 92-203

1. Obligation - For value received, Capital Materials Testing, Inc., (hereafter referred to as the Maker) promises to pay to the order of the Treasurer of the United States the principal sum of $5,000 dollars, with interest accruing from June 1, 1993 at the rate of 4.00 percent per year. This note is being given for the purpose of paying off an amount which constitutes the sum of the principal due and all unpaid interest and other charges owed to the United States on the civil penalty ($5,000) debt, which has been assigned the control number captioned above. The Maker further acknowledges and admits the validity and amount of that preexisting debt, which the principal sum stated in this note is intended to repay. The Maker further acknowledges that execution of this note constitutes a waiver of the right to contest the amount of the civil penalty and the underlying violations on which the civil penalty is based under Section 234c of the Atomic Energy Act of 1954, as amended, 42 U.S.C. section 2282c.

2. Installments - This note is to be paid in monthly installments starting June 1, 1993, plus interest on the unpaid principal balance, payable to the Treasurer of the United States, within 30 days of the "Payment Date" specified in the amortization schedule. Payments begin on June 1, 1993, and continue until either the principal sum and all interest and other charges assessed under the provisions of this note have been fully paid, or this note is considered to be in default. Payments will be mailed to the following address:

U.S. Nuclear Regulatory Commission
Division of Accounting and Finance
License Fee & Debt Collection Branch
Mail Stop MNBB 4503
Washington, D.C. 20555

Page four of this note is the schedule of monthly installments, without administrative charges and late payment penalties.

3. Administrative Charges - Administrative charges to cover the costs incurred by the United States in handling and processing past-due amounts will be assessed at the rate of $10.00 per month for each payment more than thirty (30) days past due.

4. Late Payment Penalties - Late payment penalties will be assessed on any amount more than ninety (90) days past due, at the rate of six (6) percent per year.

5. Payment Crediting - The payments that the Maker makes under this note will be credited as of the date received by the U.S. Nuclear Regulatory Commission first to outstanding penalties and

administrative charges; second to accrued interest; and third to the outstanding principal of the civil penalty.

6. Default, Acceleration, and Other Remedies - If any installment shall remain unpaid for a period of thirty (30) days or more, this note shall, at the option of the United States, be considered to be in default. In the event of default, the full amount of the principal sum, together with any accrued interest, late payment penalties and administrative charges assessed under this note, less any payments actually received by the United States from the Maker, shall be due and payable in full immediately without the need for further demands or notices to the Maker. Furthermore, in the event of default, the Maker agrees that the United States may exercise any collection options legally available to it, including, but not limited to: referring to a private debt collection agency, filing adverse credit reports to local and national credit reporting bureaus, referring the Maker's account for legal actions, and suspending or revoking any licenses or other privilege which the U.S. Nuclear Regulatory Commission has granted to the Maker.

7. Default Costs and Fees - In the event of default, the Maker agrees to pay all reasonable collection costs, court costs, and attorney's fees incurred by the United States as a result of the default and of any appropriate collection actions taken by the United States.

8. ~~Confess Judgment Provisions - The Maker, if permitted by~~ Controlling Law (as specified in paragraph 9), does hereby authorize and empower a United States Attorney, any of his assistants, or any attorney of any court of record, State or Federal, to appear for the Maker and to enter and confess judgment against the Maker for the entire amount of this obligation, with interest, less payments actually made, at any time after the same becomes due and payable, as herein provided, in any court of record, Federal or State; to waive the issuance and service of process upon the Maker in any suit on the obligation; to waive any venue requirement in such suit; to release all errors which may intervene in entering upon such judgment or in issuing any execution thereon; and to consent to immediate execution on said judgment. The Maker does hereby ratify and confirm all that said attorney may do by virtue hereof.

9. Controlling Law - Except where controlled by Federal law, all disputes concerning this note shall be controlled by the law of the jurisdiction in which the Maker resides at the time this note is signed.

10. Changes - The provision of this note may not be changed except by a written agreement which specifies the agreed-upon changes and which is signed by the Maker and an authorized representative of the United States.

11. Legal Effect - This note shall not be legally binding upon the Maker or the United States until it has been first signed by the Maker and then countersigned by an appropriate official of the United States in the spaces indicated below. The United States will promptly provide the Maker a copy of this note after it has been countersigned.

12. Signatures and Certifications - As the Maker, I do hereby certify that I have read and understood the terms of this note.

SIGNED: This 6 day of May, 1993.

Captive Motorsports Testing, Inc

Maker's Signature

Stanley P. Liebert

Printed Name

2381 Rt 9

Street Address

Mechanicville, N.Y. 12118

Pres.

14 1579595

Taxpayer Identification Number

518-899-6055

Telephone Number

I am an authorizing official of the ~~maker and do~~ New York certify that the Maker is incorporated in the State of Wisconsin at the time this note is signed and that the signature above is that of an individual authorized to enter into a promissory note for the Maker.

SIGNED:

Capital Mortgage Investors Inc

Signature | Printed Name | Street Address

2381 Rt 9
Melrose, N.Y. 12118

President

As authorized representative of the United States, I hereby agree to the payment of this debt owed by the Maker to the United States under the terms of the installment agreement evidenced by this note.

COUNTERSIGNED:

Director, Division of Accounting & Finance

Representative's Representative's Title and Agency | Representative's Signature | Lee Hiller Name

Date countersigned: July 12, 1993
U. S. Nuclear Regulatory Commission

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION IV
611 RYAN PLAZA DRIVE, SUITE 400
ARLINGTON, TEXAS 76011-8064

JUN 11 1993

Docket No. 030-32333
License No. 11-27393-01
EA 93-121

Cassia Memorial Hospital
ATTN: Richard Packer, Administrator
2303 Park Avenue
Burley, Idaho 83318

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY - $2,500 (NRC INSPECTION REPORT NO. 030-32333/93-01)

This refers to the inspection conducted on March 18 and May 4, 1993 at Cassia Memorial Hospital, Burley, Idaho. A report describing the results of this inspection was issued on May 18, 1993. On May 27, 1993, Mr. Brian Hickenlooper of your staff and other hospital representatives participated in an enforcement conference with the NRC in Boise, Idaho to discuss the hospital's failure to establish and maintain a Quality Management Program as required by 10 CFR 35.32 and 10 additional violations of requirements. A list of the participants in that enforcement conference is enclosed (Enclosure 2).

The NRC determined in March 1993 that Cassia Memorial Hospital (Cassia) had not submitted a Quality Management Program (QMP). A Confirmatory Action Letter was issued to you on March 12, 1993, to document your commitment to ensure immediate compliance with 10 CFR 35.32 and to develop and submit to the NRC a written QMP within 30 days. The May 4, 1993 inspection confirmed that you established and implemented a written QMP in late March.

As discussed during the enforcement conference, 10 CFR Part 35 was revised in January 1992 to require NRC medical licensees to establish and maintain written QMPs to provide high confidence that byproduct material or radiation from byproduct material would be administered as directed by an authorized user. The rule requires, in part, that a written directive be prepared prior to the administration to patients of iodine-131 in quantities greater than 30 microcuries. The March 18, 1993 inspection confirmed that Cassia had not established and maintained a written QMP as required by the rule and that Cassia had performed one procedure -- on January 27, 1993 -- without using a written directive as required.

As discussed during the enforcement conference, 10 CFR 35.21(a) requires the licensee, through its radiation safety officer, to ensure that radiation safety activities are being performed in accordance with regulatory requirements in the daily operation of the byproduct material program. Cassia representatives indicated during the enforcement conference that the hospital had relied on a contracted consulting service to perform various required activities and keep the hospital abreast of current requirements. Nonetheless, Cassia, as the licensee, is responsible through its radiation safety officer and radiation safety committee to ensure that all requirements

are met. Cassia's failure to establish a written QMP and failure to meet a number of other NRC requirements indicate that Cassia failed to recognize its responsibility.

The remaining violations include: a failure of the hospital's radiation safety committee to meet during one calendar quarter in 1992; a failure to verify the qualifications of a visiting authorized user prior to his using licensed material; a failure to perform all required geometry tests of the dose calibrator; a failure to calibrate a survey instrument annually; a failure to leak-test a sealed calibration source; a failure to establish "trigger levels" for daily and weekly contamination surveys; a failure to use the appropriate units in recording the results of surveys; and a failure of the radiation safety officer to sign records of dose calibrator tests, leak tests, and source inventory records.

A substantial failure to implement a QMP alone may be classified at Severity Level III, in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy) 10 CFR Part 2, Appendix C. In this case, the NRC recognizes that Cassia performed only one procedure that required a written QMP. However, the NRC views the combination of failing to establish a written QMP and the remaining violations as representative of a potentially significant lack of attention toward licensed responsibilities. Therefore, all of the violations are being considered collectively as a Severity Level III problem.

The NRC acknowledges that you took prompt action to restore compliance with the QMP requirement following the identification of this problem in early March and took prompt action to correct the remaining violations following the May 4, 1993 inspection. In addition, you provided information during the enforcement conference indicating that responsible officials, including the radiation safety officer, will take a more active role in ensuring that requirements are met and that the radiation safety committee will review all quality issues and record-keeping issues at its quarterly meetings.

These deficiencies demonstrate the need for increased and improved management attention to the radiation safety program to assure that licensed activities are conducted safely and in accordance with NRC regulatory requirements. To emphasize this need, and the need for lasting corrective action to assure that the violations do not recur, I have been authorized to issue the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice) in the amount of $2,500 for the Severity Level III problem described above and in the Notice. The base value of a civil penalty for a Severity Level III problem is $2,500. The civil penalty adjustment factors in the Enforcement Policy were considered but resulted in no net adjustment. While the NRC considered Cassia's corrective actions worthy of mitigation, this was offset by escalation because the violations were identified by the NRC through its inspections. The other adjustment factors were considered and no further adjustment to the base civil penalty was considered appropriate.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. In your

response, you should document the specific actions taken and any additional actions you plan to prevent recurrence. You should also describe the actions taken or planned to improve the management oversight over your radiation safety program by the radiation safety officer and hospital administration. After reviewing your response to this Notice, including your proposed corrective actions, and the results of future inspections, the NRC will determine whether further NRC enforcement action is necessary to ensure compliance with NRC regulatory requirements.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter and its enclosure will be placed in the NRC Public Document Room. The responses directed by this letter and the enclosed Notice are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, Pub. L. No. 96-511.

Sincerely,

for James L. Milhoan
Regional Administrator

Enclosures:
1) Notice of Violation and Proposed Imposition of Civil Penalty
2) List of enforcement conference participants

cc w/Enclosures: State of Idaho

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

Cassia Memorial Hospital
Burley, Idaho

Docket No. 030-32333
License No. 11-27393-01
EA 93-121

During an NRC inspection conducted on March 18 and May 4, 1993, violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C, the Nuclear Regulatory Commission proposes to impose a civil penalty pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (Act), 42 U.S.C. 2282, and 10 CFR 2.205. The particular violations and associated civil penalty are set forth below:

A. 10 CFR 35.32(a), which became effective on January 27, 1992, states, in part, that a licensee shall establish and maintain a written quality management program to provide high confidence that byproduct material or radiation from byproduct material will be administered as directed by the authorized user. The quality management program must include written policies and procedures to meet the specific objective that, prior to administration, a written directive is prepared for any administration of quantities greater than 30 microcuries of either sodium iodide I-125 or I-131.

10 CFR 35.2 specifies, in part, that a written directive means an order in writing for a specific patient, dated and signed by an authorized user prior to the administration of a radiopharmaceutical. For the administration of quantities greater than 30 microcuries of either sodium iodide I-125 or I-131, the written directive must include the dosage.

10 CFR 35.32(f)(2) requires that a licensee submit to the appropriate NRC Regional Office in accordance with 10 CFR 30.6 by January 27, 1992, a written certification that the quality management program has been implemented along with a copy of the program.

Contrary to the above, as of March 18, 1993, the licensee had not established, maintained, nor submitted to NRC a written quality management program. Additionally, on January 7, 1993, the licensee administered 20 millicuries of sodium iodide I-131 to a patient, and a written directive was not prepared by an authorized user prior to administration of the radiopharmaceutical.

B. 10 CFR 35.21(a) requires, in part, that a licensee, through the Radiation Safety Officer, shall ensure that radiation safety activities are being performed in accordance with approved procedures and regulatory requirements in the daily operation of the licensee's byproduct material program.

Contrary to the above, the licensee did not ensure through its Radiation Safety Officer that radiation safety activities were performed in accordance with approved procedures and regulatory requirements in the daily operation of the licensee's byproduct material program. Specifically, the licensee failed to perform the following activities in accordance with regulatory requirements:

1. 10 CFR 35.22(a)(2) requires that the Radiation Safety Committee meet at least quarterly.

   Contrary to the above, the licensee's Radiation Safety Committee did not meet between May 21, 1991, and October 29, 1991, a period in excess of one calendar quarter.

2. 10 CFR 35.27(a)(2) provides, in part, that a licensee may permit any visiting authorized user to use licensed material for medical use under the terms and conditions of the licensee's license for 60 days each year if the licensee has a copy of a license issued by the Commission or an Agreement State or a permit issued by a Commission or Agreement State broad licensee that identifies the visiting authorized user by name as the authorized user for medical use.

   Contrary to the above, during December 1992 and April 1993, the licensee permitted a visiting authorized user to use licensed material for medical use under the terms and conditions of the licensee's license, and the licensee did not have a copy of a license issued by the Commission or an Agreement State or a permit issued by a Commission or Agreement State broad licensee that identified the visiting user by name as the authorized user for medical use.

3. 10 CFR 35.50(b)(4) requires, in part, that a licensee test each dose calibrator for geometry dependence upon installation over the range of volumes and volume configurations for which it will be used.

   Contrary to the above, the licensee's test for geometry dependence, conducted in May 1992, was not performed for all volume configurations for which the instrument was used. Specifically, the licensee's geometry test was performed only for a vial configuration although the licensee routinely assays syringes containing radiopharmaceuticals.

4. 10 CFR 35.50(e), (e)(2), (e)3 and (e)4 require, in part, that a licensee retain records of accuracy tests, geometry tests, and linearity tests of the dose calibrator for 3 years unless directed otherwise, and

that the records include the signature of the Radiation Safety Officer.

Contrary to the above, as of May 4, 1993, the licensee's records of the accuracy tests, geometry tests, and linearity tests of its dose calibrator did not include the signature of the Radiation Safety Officer.

5. 10 CFR 35.51(a) requires that a licensee calibrate the survey instruments used to show compliance with 10 CFR Part 35 before first use, annually, and following repair.

Contrary to the above, the licensee used a Ludlum Model 14C survey instrument to show compliance with 10 CFR Part 35 and, during that time, this instrument had not been calibrated annually. Specifically, this instrument had not been calibrated between May 10, 1990, and June 6, 1992.

6. 10 CFR 35.59(b)(2) requires, in part, that a licensee in possession of a sealed source test the source for leakage at intervals not to exceed 6 months or at other intervals approved by the Commission or an Agreement State.

Contrary to the above, the licensee did not test a sealed source containing approximately 169 microcuries of cesium-137 for leakage between February 1991 and June 1992, an interval in excess of 6 months, and no other interval was approved by the Commission or an Agreement State.

7. 10 CFR 35.59(d) requires that a licensee retain records of leakage test results for 5 years; and that the records contain the model number, and serial number if assigned, of each source tested; the identify of each source radionuclide and its estimated activity; the measured activity of each test sample expressed in microcuries; a description of the method used to measure each test sample; the date of the test; and the signature of the Radiation Safety Officer.

Contrary to the above, as of May 4, 1993, the licensee's records of leakage test results conducted between May 21, 1991, and March 16, 1993, did not contain the signature of the Radiation Safety Officer.

8. 10 CFR 35.59(g) requires, in part, that a licensee retain for 5 years records of quarterly physical inventories of sealed sources and brachytherapy

sources in its possession, and that the records contain the model number of each source, and serial number if one has been assigned, the identity of each source radionuclide and its nominal activity, the location of each source, and the signature of the Radiation Safety Officer.

Contrary to the above, as of May 4, 1993, the licensee's records of physical inventories of its sealed calibration sources conducted between April 23, 1991, and March 16, 1993, did not contain the signature of the Radiation Safety Officer.

9. 10 CFR 35.70(d) requires, in part, that a licensee establish radiation dose trigger levels for the daily and weekly surveys of areas where radiopharmaceuticals are routinely prepared for use or administered and areas where radiopharmaceuticals or radiopharmaceutical waste is stored.

Contrary to the above, as of May 4, 1993, the licensee had not established radiation dose trigger levels for its daily and weekly surveys of the nuclear medicine hot lab and imaging areas where radiopharmaceuticals were prepared, administered, stored, and held as waste.

10. 10 CFR 35.70(h) requires, in part, that a licensee retain a record of each survey for 3 years. The record must include the detected dose rate at several points in each area expressed in millirem per hour or the removable contamination in each area expressed in disintegrations per minute per 100 square centimeters.

Contrary to the above, as of May 4, 1993, the licensee's records of surveys did not express removable contamination in each area in disintegrations per minute per 100 square centimeters. These records expressed removable contamination in counts per minute.

These violations represent a Severity Level III problem (Supplement VI). Civil Penalty - $2,500

Pursuant to the provisions of 10 CFR 2.201, Cassia Memorial Hospital (Licensee) is hereby required to submit a written statement or explanation to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, within 30 days of the date of this Notice of Violation and Proposed Imposition of Civil Penalty (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each alleged violation: (1) admission or denial of the alleged violation, (2) the reasons for the violation if admitted, and if denied, the reasons why, (3) the corrective

steps that have been taken and the results achieved, (4) the corrective steps that will be taken to avoid further violations, and (5) the date when full compliance will be achieved. If an adequate reply is not received within the time specified in this Notice, an order or a Demand for Information may be issued to show cause why the license should not be modified, suspended, or revoked or why such other action as may be proper should not be taken. Consideration may be given to extending the response time for good cause shown. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, this response shall be submitted under oath or affirmation.

Within the same time as provided for the response required above under 10 CFR 2.201, the Licensee may pay the civil penalty by letter addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, with a check, draft, money order, or electronic transfer payable to the Treasurer of the United States in the amount of the civil penalty proposed above, or the cumulative amount of the civil penalties if more than one civil penalty is proposed, or may protest imposition of the civil penalty in whole or in part, by a written answer addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission. Should the Licensee fail to answer within the time specified, an order imposing the civil penalty will be issued. Should the Licensee elect to file an answer in accordance with 10 CFR 2.205 protesting the civil penalty, in whole or in part, such answer should be clearly marked as an "Answer to a Notice of Violation" and may: (1) deny the violation(s) listed in this Notice, in whole or in part, (2) demonstrate extenuating circumstances, (3) show error in this Notice, or (4) show other reasons why the penalty should not be imposed. In addition to protesting the civil penalty in whole or in part, such answer may request remission or mitigation of the penalty.

In requesting mitigation of the proposed penalty, the factors addressed in Section VI.B.2 of 10 CFR Part 2, Appendix C, should be addressed. Any written answer in accordance with 10 CFR 2.205 should be set forth separately from the statement or explanation in reply pursuant to 10 CFR 2.201, but may incorporate parts of the 10 CFR 2.201 reply by specific reference (e.g., citing page and paragraph numbers) to avoid repetition. The attention of the Licensee is directed to the other provisions of 10 CFR 2.205, regarding the procedure for imposing a civil penalty.

Upon failure to pay any civil penalty due which subsequently has been determined in accordance with the applicable provisions of 10 CFR 2.205, this matter may be referred to the Attorney General, and the penalty, unless compromised, remitted, or mitigated, may be collected by civil action pursuant to Section 234c of the Act, 42 U.S.C. 2282c.

The responses noted above (Reply to Notice of Violation, letter with payment of civil penalty, and Answer to a Notice of Violation) should be addressed to: Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555 with a copy to the Regional Administrator, U.S. Nuclear Regulatory Commission, Region IV, 611 Ryan Plaza Drive, Suite 400, Arlington, Texas, 76011.

Dated at Arlington, Texas
this 11th day of June 1993

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION V

1450 MARIA LANE
WALNUT CREEK, CALIFORNIA 94596-5368

MAR 31 1993

Docket No. 030-11883
License No. 53-16929-01
EA 93-40

Castle Medical Center
640 Ulukahiki Street
Kailua, Hawaii 96734

Attention: John Monge
Vice President, Business Outpatient Services

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTIES ($7,500) (NRC Inspection Report No. 030-11883/93-02)

This refers to the inspection conducted on February 9-11, 19, and 22, 1993, at your facility in Kailua, Hawaii. The results of the inspection were reported in NRC Inspection Report No. 030-11883/93-01, dated March 4, 1993. The inspectors identified nineteen apparent violations of NRC requirements. The violations, their causes, and your corrective actions were discussed with you during an Enforcement Conference on March 19, 1993. The results of the Enforcement Conference were documented in NRC Inspection Report 93-02, and are enclosed. As noted in Report 93-02, you contested several of the violations, and after further consideration, we have decided that citations in some areas are inappropriate, and in others that aggregation is appropriate, leading to our final citation of nine violations.

The nine violations are described in the enclosed Notice of Violation and Proposed Imposition of Civil Penalties (Notice). The violations involve a failure to effectively establish and maintain your Quality Management Program (QMP), a failure to provide adequate instruction to supervised individuals, and a breakdown in your management control system designed to provide adequate oversight of your radiation safety program.

The QMP violation (Violation A) includes three examples of failure to establish and maintain a written QMP: 1) failure on many occasions to prepare a written directive prior to administration of a radiopharmaceutical, 2) failure to make a record of each recordable event (such as failures to prepare written directives) which includes the relevant facts and corrective actions taken, and 3) failure to provide instruction to personnel in the written QMP. In addition, audits performed by your consultant did not determine whether there was compliance with all aspects of the QMP. The root cause of Violation A appears to be either that your consultant failed to identify defects in or the lack of written directives, or that management failed to heed the consultant's findings. Essentially, your activities were conducted without the formality intended by the QM rule.

The examples in Violation A demonstrate a significant failure to effectively implement and maintain the QMP. Therefore, in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions" (Enforcement Policy), 10 CFR Part 2, Appendix C, this violation has been categorized at Severity Level III.

Violations B through I include: 1) failure to perform daily constancy checks for the loaner dose calibrator, and upon installation of the loaner dose calibrator, failure to perform accuracy, linearity, and geometry tests, 2) failure to perform daily surveys, 3) failure to verify proper instrument operation with a dedicated check source each day of use, 4) failure to perform ventilation rate checks at six month intervals, 5) failure to perform surveys to evaluate the proper placement of dosimetry, 6) failure of nuclear medicine personnel to monitor their hands, 7) failure to implement safety measures for an inpatient therapy, and 8) failure to provide annual refresher training.

Individually, Violations B through I are not significant safety concerns, but collectively, they represent a significant breakdown in your Radiation Safety Program. The root causes of the programmatic breakdown appear to be inadequate training of nuclear medicine technologists, and insufficient management oversight of the use of radioactive material. Most of these violations might have been prevented had management observed work practices to verify proper implementation of the Radiation Safety Program and the QMP. Therefore, in accordance with the Enforcement Policy, these violations are classified in the aggregate as a Severity Level III problem.

The NRC staff recognizes that after the inspectors identified the violations, you took immediate corrective action for the violations involving the QMP. These corrective actions included training all authorized users in the requirements of the QMP, and implementing policies and procedures to ensure that there is a written directive prior to the administration of radiopharmaceuticals greater than 30 microcuries of iodine-125 or iodine-131, or of therapy treatments other than those involving iodine-125 or iodine-131. Additional corrective actions for violations not related to the QMP included posting of warning signs, enhancements of the computer program associated with the Nuclear Medicine Information System, training on the specific causes of the violations listed in Inspection Report 93-01, and the removal of non-certified technologists from nuclear medicine duties until the completion of a formal qualification program is completed.

However, to emphasize the need for effective management oversight of your QMP and Radiation Safety Program, I have been authorized, after consultation with the Director, Office of Enforcement, to issue the enclosed Notice of Violation and Proposed Imposition of Civil Penalties (Notice) in the amount of $7,500 for the Severity Level III violation (Violation A) and the Severity Level III problem (Violations B through I). The base value of a civil penalty for a Severity Level III violation or problem is $2,500. The escalation and mitigation factors in the Enforcement Policy were considered.

Both base civil penalties were escalated 50% based on the NRC Inspectors' identification of the violations. Both base civil penalties were mitigated 50% for prompt corrective action, as evidenced by your removal from nuclear medicine duties the two non-certified technologists, your training of the authorized users in the requirements of the QMP, and your implementation of the requirements of the QMP prior to the administration of therapeutic radiopharmaceuticals.

The base civil penalty for the programmatic breakdown (Violations B through I) was escalated 100% because there was prior opportunity to identify the violations. Specifically, the contents of NRC Information Notice (IN) 90-71, "Effective Use of Radiation Safety Committees to Exercise Control Over Medical Use Programs", and IN 91-71, "Training and Supervision of Individuals Supervised By an Authorized User", should have enabled you to prevent or promptly correct most if not all of the violations. Licensees are expected to review Information Notices for applicability to their licensed programs, and to consider actions, as appropriate, to preclude situations similar to the ones described in the Information Notices. It also appears that your consultant may have identified at least some of the violations, but your corrective actions were either incomplete or totally lacking in some cases.

The other adjustment factors in the Policy were considered but no further adjustment to the base civil penalties is considered appropriate. Based on the above, the base civil penalty for Violations B through I was escalated 100%.

Two violations, the failure to perform daily constancy checks as required by 10 CFR 35.50(b)(1), and the failure to perform daily radiation surveys as required by 10 CFR 35.70(a), are considered repeat violations from the NRC inspection performed on May 8, 1991. This repetitiveness is a matter of concern because licensee corrective actions for previously identified problems are expected to prevent recurrence. Failure to prevent recurrence indicates that management is not adequately monitoring the licensee's program.

Three additional violations are not being cited because the criteria specified in Section VII.B of the Enforcement Policy (10 CFR Part 2, Appendix C) were satisfied: the administration to humans of a radiopharmaceutical with an assayed molybdenum concentration of greater than 0.15 microcuries of molybdenum per millicurie of technetium-99m in violation of 10 CFR 35.204(a), the failure to remove or obliterate radiation labels as required by 10 CFR 35.92(a)(3), and the failure to specify the correct model number on records of sealed source inventories as required by 10 CFR 35.59(g).

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. In your response, you should document the specific actions taken and any additional actions you plan to prevent recurrence. After reviewing your response to this Notice, including your proposed corrective actions and the results of future

inspections, the NRC will determine whether further NRC enforcement action is necessary to ensure compliance with NRC regulatory requirements.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter and its enclosure will be placed in the NRC Public Document Room.

The responses directed by this letter and the enclosed Notice are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, Pub. L. No. 96-511.

Sincerely,

FOR John B. Martin
Regional Administrator

Enclosure:
Notice of Violation and
Proposed Imposition of Civil Penalties
NRC Enforcement Conference Report 93-02

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTIES

Castle Medical Center
Kailua, Hawaii

Docket No. 030-11883
License No. 53-16929-01
EA No. 93-40

During an NRC inspection conducted on February 9-11, 19, and 22, 1993, violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C, the Nuclear Regulatory Commission proposes to impose civil penalties pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (Act), 42 U.S.C. 2282, and 10 CFR 2.205. The particular violations and associated civil penalties are set forth below:

A. 10 CFR 35.32 requires that a licensee establish and maintain a written Quality Management Program (QMP) to provide high confidence that byproduct material or radiation from byproduct material will be administered as directed by the authorized user.

1. 10 CFR 35.32(a) requires in part that prior to administration, a written directive be prepared for administration of quantities greater than 30 microcuries of either sodium iodide I-125 or I-131 or any therapeutic radiopharmaceutical, other than sodium iodide I-125 or I-131.

   As defined in 10 CFR 35.2, a written directive means an order in writing for a specific patient, dated, and signed by an authorized user prior to the administration of a radiopharmaceutical which includes the dosage and route of administration.

   Contrary to the above, between January 27, 1992, and February 9, 1993, the licensee administered greater than 30 microcuries of iodine-131 on 14 occasions and therapeutic administrations of phosphorus-32 on 4 occasions, without first preparing a written directive which included the signature of the authorized user, the route of administration, and the amount to be administered, prior to administering the radiopharmaceutical to the patient.

2. 10 CFR 35.32(c) requires in part that the licensee evaluate and respond, within 30 days after discovery of the recordable event, to each recordable event by: (1) assembling the relevant facts, including the cause; (2) identifying what, if any, corrective action is required to prevent recurrence; and (3) retaining a record, in an auditable form, for three years, of the relevant facts and what corrective action, if any, was taken.

   Recordable events as defined in 10 CFR 35.2 include administration of a radiopharmaceutical without a written directive and administration of a radiopharmaceutical where a written directive is

required without daily recording of each administered radiopharmaceutical dose in the appropriate record.

Contrary to the above, records of recordable events identified and evaluated by the annual audit of the QMP performed on December 16, 1992, did not include the relevant facts and the corrective action taken.

3. 10 CFR 35.25(a)(1) requires in part that the licensee instruct supervised individuals in the licensee's written QMP.

Contrary to the above, between January 27, 1992, and January 1993, the licensee did not instruct a nuclear medicine technologist, a supervised individual, in the licensee's written QMP.

This is a Severity Level III violation (Supplement VI).
Civil Penalty - $2,500.

B. 10 CFR 35.50(b) requires, in part, that a licensee check each dose calibrator for constancy with a dedicated check source at the beginning of each day of use and that the licensee test the dose calibrator for accuracy, linearity, and geometry upon installation.

Contrary to the above, on September 14 and 15, 1992, the licensee installed a loaner dose calibrator and did not check the dose calibrator for constancy or test the dose calibrator for accuracy, linearity, and geometry. The dose calibrator was used to measure patient doses of radiopharmaceuticals on those days.

C. 10 CFR 35.70(a) requires that a licensee survey with a radiation detection survey instrument at the end of each day of use all areas where radiopharmaceuticals are routinely prepared for use or administered.

Contrary to the above, on at least five occasions from May 8, 1991, until February 9, 1993, the licensee did not survey with a radiation detection instrument at the end of the day areas where radiopharmaceuticals were routinely prepared for use and administered. Specifically, on March 3, July 9, 12, 14, and September 28, 1992, no survey was performed at the end of the day when the on-call technologist performed nuclear medicine duties, i.e., preparing or administering radiopharmaceuticals.

D. 10 CFR 35.51(c) requires, in part, that a licensee check each survey instrument for proper operation with the dedicated check source each day of use.

Contrary to the above, as of February 9, 1993, the licensee did not check its Xetex and Victoreen Model 293 with pancake probe survey meters with a dedicated check source on days when the instruments were used.

E. 10 CFR 35.205(e) requires, in part, that a licensee measure each six months the ventilation rates available in areas of use of radioactive gas.

Contrary to the above, the licensee used radioactive xenon-133 gas in the imaging room but did not measure the ventilation rates therein from September 1991, to July 22, 1992, a period of 10 months.

F. 10 CFR 20.201(b) requires that each licensee make such surveys as may be necessary to comply with the requirements of Part 20 and which are reasonable under the circumstances to evaluate the extent of radiation hazards that may be present. As defined in 10 CFR 20.201(a), "survey" means an evaluation of the radiation hazards incident to the production, use, release, disposal, or presence of radioactive materials or other sources of radiation under a specific set of conditions.

Contrary to the above, the licensee did not make surveys to assure compliance with 10 CFR 20.202(a)(1), which requires the use of personnel monitoring equipment for those individuals who are likely to receive a dose in any calendar quarter in excess of 25 percent of the applicable value specified in 10 CFR 20.101. Specifically, between May 8, 1991, and February 9, 1993, the licensee did not adequately evaluate the proper placement of finger dosimetry for nuclear medicine technologists.

G. License Condition 15 requires in part that the licensee possess and use licensed material in accordance with the statements, representations, and procedures contained in the application dated March 10, 1992.

Attachment 8.1, "Personnel Training Program," of the application dated March 10, 1992, requires in part that nuclear medicine technologists receive annual refresher training from the authorized user or radiation safety consultant.

Contrary to the above, a nuclear medicine technologist did not receive annual refresher training from the authorized user or radiation safety consultant during 1991 and 1992.

H. License Condition 15 requires in part that the licensee possess and use licensed material in accordance with the statements, representations, and procedures contained in the application dated March 10, 1992.

Attachment 10.4, "Rules for Safe Use of Radiopharmaceuticals," of the application dated March 10, 1992, requires licensee personnel to monitor their hands after each procedure or prior to leaving the area.

Contrary to the above, between May 8, 1991, and February 9, 1993, licensee personnel failed on several occasions to monitor their hands after each procedure or prior to leaving the area.

I. License Condition 15 requires in part that the licensee possess and use licensed material in accordance with the statements, representations, and procedures contained in the application dated March 10, 1992.

Attachment 10.14 "Radiation Safety Procedures for Radiopharmaceutical Therapy", of the application dated March 10, 1992, requires the licensee to prepare the patient's room, order disposable table service, inform the housekeeping service that personnel should stay out of the room until otherwise notified, mark a visitors "safe line" on the floor as far from the patient as possible, supply the nurses with film badges, TLD's or pocket dosimeters, pick up waste for transfer to decay in storage, and decontaminate the room prior to release for general occupancy.

Contrary to the above, on April 7, 1992, the licensee performed an inpatient radiopharmaceutical therapy using phosphorus-32 without preparing the patient's room, ordering disposable table service, informing the housekeeping service that personnel should stay out of the room until otherwise notified, marking a visitors "safe line" on the floor, supplying the nurses with film badges, TLD's or pocket dosimeters, picking up waste for transfer to decay in storage, or verifying that the room was decontaminated prior to release for general occupancy.

Violations B through I above constitute a Severity Level III problem (Supplement VI).
Civil Penalty - $5,000.

Pursuant to the provisions of 10 CFR 2.201, Castle Medical Center (Licensee) is hereby required to submit a written statement or explanation to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, within 30 days of the date of this Notice of Violation and Proposed Imposition of Civil Penalties (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each alleged violation: (1) admission or denial of the alleged violation, (2) the reasons for the violation if admitted, and if denied, the reasons why, (3) the corrective steps that have been taken and the results achieved, (4) the corrective steps that will be taken to avoid further violations, and (5) the date when full compliance will be achieved. If an adequate reply is not received within the time specified in this Notice, an order or a Demand for Information may be issued to show cause why the license should not be modified, suspended, or revoked or why such other action as may be proper should not be taken. Consideration may be given to extending the response time for good cause shown. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, this response shall be submitted under oath or affirmation.

Within the same time as provided for the response required above under 10 CFR 2.201, the Licensee may pay the civil penalties by letter addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, with a check, draft, money order, or electronic transfer payable to the Treasurer of the United States in the amount of the civil penalty proposed above, or the

cumulative amount of the civil penalties if more than one civil penalty is proposed, or may protest imposition of the civil penalties in whole or in part, by a written answer addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission. Should the Licensee fail to answer within the time specified, an order imposing the civil penalties will be issued. Should the Licensee elect to file an answer in accordance with 10 CFR 2.205 protesting the civil penalties, in whole or in part, such answer should be clearly marked as an "Answer to a Notice of Violation" and may: (1) deny the violation(s) listed in this Notice, in whole or in part, (2) demonstrate extenuating circumstances, (3) show error in this Notice, or (4) show other reasons why the penalties should not be imposed. In addition to protesting the civil penalties in whole or in part, such answer may request remission or mitigation of the penalties.

In requesting mitigation of the proposed penalties, the factors addressed in Section VI.B.2 of 10 CFR Part 2, Appendix C, should be addressed. Any written answer in accordance with 10 CFR 2.205 should be set forth separately from the statement or explanation in reply pursuant to 10 CFR 2.201, but may incorporate parts of the 10 CFR 2.201 reply by specific reference (e.g., citing page and paragraph numbers) to avoid repetition. The attention of the Licensee is directed to the other provisions of 10 CFR 2.205, regarding the procedure for imposing a civil penalties.

Upon failure to pay any civil penalties due which subsequently has been determined in accordance with the applicable provisions of 10 CFR 2.205, this matter may be referred to the Attorney General, and the penalties, unless compromised, remitted, or mitigated, may be collected by civil action pursuant to Section 234c of the Act, 42 U.S.C. 2282c.

The response noted above (Reply to Notice of Violation, letter with payment of civil penalties, and Answer to a Notice of Violation) should be addressed to: Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555 with a copy to the Regional Administrator, U.S. Nuclear Regulatory Commission, Region V.

Dated at Walnut Creek, California
this 31st day of March, 1993

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

JUL 02 1993

Docket No. 030-11883
License No. 53-16929-01
EA 93-040

Castle Medical Center
ATTN: John Monge
Vice President
Business Outpatient Services
640 Ulukahiki Street
Kailua, Hawaii 96734-4498

SUBJECT: ORDER IMPOSING CIVIL MONETARY PENALTIES - $7,500

This refers to your two letters dated April 30, 1993, in response to the Notice of Violation and Proposed Imposition of Civil Penalties (Notice) sent to you by our letter dated March 31, 1993. Our letter and Notice described nine violations identified by the NRC during an unannounced inspection conducted on February 9-11, 19, and 22, 1993.

To emphasize the need for effective management oversight of your Quality Management Program (QMP) and Radiation Safety Program, civil penalties of $7,500 were proposed.

In your response you denied Violations A.1, A..2, A.3, and F, and a portion of Violation D. You also argued that Violation E should not have been cited. You admitted Violations B, C, G, H, and I as documented in the Notice. Additionally, you requested remission of the civil penalties.

Based on your response, we have withdrawn the portion of Violation D relating to the failure to source check the Victoreen pancake probe. Violation D remains a violation, however, because there was a failure to source check the Xetex survey meter, as admitted in your response. After consideration of the remaining responses, we have concluded for the reasons given in the Appendix attached to the enclosed Order Imposing Civil Monetary Penalties, that withdrawal of the violations or remission of the civil penalties is not warranted. Accordingly, we hereby serve the enclosed Order on Castle Medical Center imposing civil monetary penalties in the amount of $7,500.

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Your responses to two of the violations appear to contain inaccurate information. In response to Violation A.1, you indicated that written directives have contained all necessary information since December 16, 1992 whereas, according to the Chief Technologist, on December 21, 1992, a nine millicurie phosphorous 32 dosage was administered before the written directive was dated and signed by the authorized user. In response to Violation A.2, you stated that the annual review of the quality management (QM) program indicated only one administration where no written directive was found, and that the written directive for that administration was later found. However, the consultant's report of the annual review of the QM program dated January 7, 1993, indicates that there were two written directives missing, not one. Providing inaccurate information may be a further symptom of the lack of sufficient management attention to assure compliance with NRC requirements. In addition, providing inaccurate information to NRC is, in and of itself, a violation of 10 CFR 30.9 and may be the subject of further escalated enforcement action. Therefore, in order to determine whether inaccurate information was provided and whether further enforcement action is warranted, please provide to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, within 30 days of the date of this letter, the following information, in writing and under oath or affirmation:

A. A response, based on a thorough review of your April 30, 1993, letters, identifying any information in those letters that is either incomplete or inaccurate.

B. In regard to all inaccurate information that was provided: (1) indicate how the inaccuracy occurred; (2) describe actions taken or planned to assure that, in the future, information and records provided to, or maintained for, the NRC are complete and accurate in all material respects; and (3) state why the NRC should have confidence that, in the future, you will comply with the requirement in 10 CFR 30.9 to provide NRC with information that is complete and accurate in all material respects.

In your response to Violation B, you stated that if the dose calibrator is not operational, you will use individual dosages ordered from the radiopharmacy. Such action would violate 10 CFR 35.53(a) and (b), which require in part that the Licensee measure the activity of each radiopharmaceutical dosage before medical use.

In your response to Violation G, you state that a self-paced training program has been established for all nuclear medicine technologists and that the review of all procedures by the technologists will be documented annually. However, your

response did not indicate how the results of a self-paced training program will be verified by management.

In your response to Violation I, you state that Castle Medical Center has a policy of not performing in-patient therapy procedures and that therapy doses will not be administered to in-patients until they are discharged. However, your response did not indicate how you plan to prevent the failure to implement your procedures for in-patient therapy given a situation similar to that in Violation I.

Information regarding the deficiencies identified in your responses, as noted above, should be mailed to the Director, Office of Enforcement, at the above address, with a copy to the Regional Administrator, Region V, 1450 Maria Lane, Walnut Creek, California 94596-5368.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice", a copy of this letter and the enclosures will be placed in the NRC's Public Document Room.

Sincerely,

/Hugh L. Thompson, Jr.

Hugh L. Thompson, Jr.
Deputy Executive Director for
Nuclear Materials Safety, Safeguards
and Operations Support

Enclosures: As Stated

UNITED STATES
NUCLEAR REGULATORY COMMISSION

In the Matter of	)	
	)	Docket No. 030-11883
Castle Medical Center	)	License No. 53-16929-01
Kailua, Hawaii	)	EA 93-040

ORDER IMPOSING CIVIL MONETARY PENALTIES

I

Castle Medical Center is the holder of Materials License No. 53-6929-01, first issued by the Nuclear Regulatory Commission (NRC or Commission) on June 4, 1976, and most recently renewed on March 5, 1993. The license authorizes the medical use of radioactive materials in accordance with the conditions specified therein and in 10 CFR 35.100, 35.200, and 35.300.

II

An inspection of the Licensee's activities was conducted on February 9-11, 19, and 22, 1993. The results of this inspection indicated that the Licensee had not conducted its activities in full compliance with NRC requirements. A written Notice of Violation and Proposed Imposition of Civil Penalties (Notice) was served upon the Licensee by letter dated March 31, 1993. The Notice states the nature of the violations, the provisions of the NRC's requirements that the Licensee had violated, and the amount of the civil penalties proposed for the violations.

The Licensee responded to the Notice in two letters dated April 30, 1993. In its response, the Licensee agreed that violations B, C, G, H, and I occurred as documented in the

Notice. For reasons described in the Appendix to this Order, the Licensee denied Violations A.1, A.2, A.3, and F; denied a portion of Violation D; and argued that Violation E should not have been cited. In addition, the Licensee requested remission of the civil penalties.

III

After consideration of the Licensee's response and the statements of fact, explanation, and argument for mitigation contained therein, the NRC staff has determined, as set forth in the Appendix to this Order, that Violation D should be modified to delete one example as provided in the Appendix, that the remaining violations occurred as stated, and that the penalties proposed for the violations designated in the Notice should be imposed.

IV

In view of the foregoing and pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (Act), 42 U.S.C. 2282, and 10 CFR 2.205, IT IS HEREBY ORDERED THAT:

The Licensee pay civil penalties in the amount of $7,500 within 30 days of the date of this Order, by check, draft, money order, or electronic transfer, payable to the

Treasurer of the United States and mailed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555.

V

The Licensee may request a hearing within 30 days of the date of this Order. A request for a hearing should be clearly marked as a "Request for an Enforcement Hearing" and shall be addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, with a copy to the Commission's Document Control Desk, Washington, D.C. 20555. Copies also shall be sent to the Assistant General Counsel for Hearings and Enforcement at the same address and to the Regional Administrator, NRC Region V, 1450 Maria Lane, Walnut Creek, California 94596-5368.

If a hearing is requested, the Commission will issue an Order designating the time and place of the hearing. If the Licensee fails to request a hearing within 30 days of the date of this Order, the provisions of this Order shall be effective without further proceedings. If payment has not been made by that time, the matter may be referred to the Attorney General for collection.

In the event the Licensee requests a hearing as provided above, the issues to be considered at such hearing shall be:

(a) whether the Licensee was in compliance with the requirements specified in Violations A.1, A.2, A.3, and F, as set forth in the Notice referenced in Section II above, and Violation D as modified in the Appendix, and

(b) whether, on the basis of such violations and the additional violations set forth in the Notice that the Licensee admitted, this Order should be sustained.

FOR THE NUCLEAR REGULATORY COMMISSION

Hugh L. Thompson, Jr.
Deputy Executive Director for
Nuclear Materials Safety, Safeguards
and Operations Support

Dated at Rockville, Maryland
this 2nd day of July 1993

APPENDIX

EVALUATIONS AND CONCLUSIONS

On March 31, 1993, a Notice of Violation and Proposed Imposition of Civil Penalties (Notice) was issued for violations identified during an NRC inspection conducted on February 9-11, 19, and 22, 1993. Castle Medical Center (Licensee or CMC) responded to the Notice in two letters dated April 30, 1993. The Licensee denied Violations A.1, A.2, A.3, and F, and a portion of Violation D; argued that Violation E should not be cited; and requested remission of the civil penalties. The NRC's evaluation and conclusion of the Licensee's requests are as follows:

Restatement of Violation A.1

A. 10 CFR 35.32 requires that a Licensee establish and maintain a written Quality Management Program (QMP) to provide high confidence that byproduct material or radiation from byproduct material will be administered as directed by the authorized user.

1. 10 CFR 35.32(a) requires in part that prior to administration, a written directive be prepared for administration of quantities greater than 30 microcuries of either sodium iodide I-125 or I-131 or any therapeutic radiopharmaceutical, other than sodium iodide I-125 or I-131.

As defined in 10 CFR 35.2, a written directive means an order in writing for a specific patient, dated, and signed by an authorized user prior to the administration of a radiopharmaceutical which includes dosage and route of administration.

Contrary to the above, between January 27, 1992, and February 9, 1993, the Licensee administered greater than 30 microcuries of iodine-131 on 14 occasions and therapeutic administrations of phosphorus-32 on 4 occasions, without first preparing a written directive which included the signature of the authorized user, the route of administration, and the amount to be administered, prior to administering the radiopharmaceutical to the patient.

Summary of Licensee's Response

The Licensee denies the violation, arguing that it complied with its interpretation of the requirement between January 27 and December 16, 1992. CMC states that prior to December 16, 1992, it adequately implemented the QMP by having the authorized user sign either the Patient Consent Form or the written directive form (described in the QMP) prior to administration of a radiopharmaceutical, and provided

representative copies of the completed forms. The Licensee states that, after December 16, 1992, the Licensee interpreted the QMP to require signature of the written directive form by the authorized user prior to administration, and that after December 16, 1992, no radiopharmaceuticals requiring a written directive were administered without the authorized user first signing the written directive form.

NRC Evaluation of the Licensee's Response

Although the Licensee claims that it misinterpreted the requirement, that fact does not nullify the violation. Further, the requirement is clear and leaves no room for misinterpretation. 10 CFR 35.2 defines written directive as an order in writing that is dated and signed by an authorized user prior to the administration of a radiopharmaceutical, which includes, for iodine-131, the dosage, and for phosphorous 32, the radiopharmaceutical, dosage and route of administration.

Moreover, Section 3 of the Licensee's revised QMP submitted on March 10, 1992 states that:

> Prior to administration of a dosage of greater than 30 microcuries of sodium iodide I-131 and any therapeutic radiopharmaceutical, a written directive shall be signed and dated by an authorized user. The written directive shall contain the following information: a) The name of the patient, b) The date of the request, c) The radiopharmaceutical, d) The dosage, e) The route of administration, and f) The signature of the authorized user.

While the patient consent form could comply with the requirement for a written directive if all information and signatures were added prior to each administration, nine of fourteen patient consent forms did not include the amount of iodine-131 to be administered. Also, of the four patient consent forms used for phosphorus-32 therapy, two forms were signed by the referring physician instead of the authorized user, one of the two forms did not include the route of administration and the other form did not include the amount of phosphorus-32 to be administered, and two forms could not be located for the inspectors' review.

The Licensee enclosed two forms to show that it satisfied the intent of the QMP because the authorized user signed at least one of the forms. The patient consent form was signed by the authorized user; however, the amount of iodine-131 to be administered was omitted; further, the written directive

form was completed by the technologist during or immediately after administration. It was not until after the administration that the technologist obtained the authorized user's signature on the written directive form.

Finally, the Licensee states that "[S]ince December 16, 1992, written directives containing all the necessary information and signed in advance have been used for therapy administrations." However, according to the Chief Technologist, a nine millicurie phosphorus 32 dosage was administered to a patient on December 21, 1992, before the patient consent form or the written directive form were dated and signed by an authorized user.

Restatement of Violation A.2

10 CFR 35.32(c) requires in part that the Licensee evaluate and respond, within 30 days after discovery of the recordable event, to each recordable event by: (1) assembling the relevant facts, including the cause; (2) identifying what, if any, corrective action is required to prevent recurrence; and (3) retaining a record, in an auditable form, for three years, of the relevant facts and what corrective action, if any, was taken.

Recordable events as defined in 10 CFR 35.2 include administration of a radiopharmaceutical without a written directive and administration of a radiopharmaceutical where a written directive is required without daily recording of each administered radiopharmaceutical dose in the appropriate record.

Contrary to the above, records of recordable events identified and evaluated by the annual audit of the QMP performed on December 16, 1992, did not include the relevant facts and the corrective action taken.

Summary of Licensee's Response

The Licensee denies the violation, arguing that the annual review of the QMP identified one administration where no written directive was found, and that the written directive for that administration was later found and thus did not constitute a recordable event. CMC also argues that under its interpretation of the regulations prior to December 16, 1992, the lack of the countersignature on the written directive when the physician had signed the patient consent form did not constitute a recordable event.

NRC's Evaluation of Licensee's Response

The audit performed by the consultant on December 16, 1992, identified problems that fall under the definition of recordable event in 10 CFR 35.2, including: (1) a patient treatment omitted from the radiopharmaceutical dosage log and (2) written directives not found for two patient treatments. The Licensee's claim that it misinterpreted the rule does not change the fact that these problems were identified and that they are, by definition, recordable events.

The regulation requires that the Licensee retain a record of the relevant facts and corrective action for each recordable event, which the Licensee did not do. Although the Licensee claims that it later found one of the written directives, the violation still occurred as stated, because a record of the relevant facts and the corrective action was not retained for the other recordable events identified in the audit report.

Restatement of Violation A.3

10 CFR 35.25(a)(1) requires in part that the Licensee instruct supervised individuals in the Licensee's written QMP.

Contrary to the above, between January 27, 1992, and January 1993, the Licensee did not instruct a nuclear medicine technologist, a supervised individual, in the Licensee's written QMP.

Summary of Licensee's Response

The Licensee denies the violation, arguing that the technologist is the Director of Radiology and that he participated in discussions regarding the QMP at Radiation Safety Committee (RSC) meetings conducted on March 2 and September 28, 1992, when selected items of the QMP were discussed, and therefore he got the required training because, as the Director of Radiology, he is capable of assessing his own training needs in specific program areas.

NRC's Evaluation of Licensee's Response

During the Enforcement Conference, the Radiation Safety Officer (RSO) stated that an overview of the QMP was discussed during the Radiation Safety Committee meetings, but that it did not include specific requirements associated with the QMP. See NRC Enforcement Conference Report 93-02, dated March 31, 1993 at page 2, paragraph 2. Therefore,

attendance at the RSC meetings did not fulfill the training requirement.

The NRC inspection report further documents the fact that the training requirement was not fulfilled. Specifically, the Director of Radiology stated to the NRC inspector that he had not received any QMP training until January 1993 and that, until that time, he was unaware of any requirement to complete a written directive prior to the administration of a therapy dose. Moreover, on December 14, 1992, the Director of Radiology administered 14.9 millicuries of iodine-131 to a patient even though the authorized user had not specified, on the patient consent form or on the written directive form, the amount of iodine-131 to be administered.

Summary of Licensee's request for Mitigation of Civil Penalty Assessed for Violations A.1, A.2, and A.3

The Licensee disagrees that Violations A.1, A.2, and A.3 demonstrate a significant failure to effectively implement and maintain the QMP, stating that the violations merely document CMC's changing interpretation of the regulations in an effort to meet the intent of the QMP, and its effort to make the record keeping requirements fit with the Licensee's existing record keeping requirements. The Licensee contends that the intent of the QMP was met, as evidenced by the fact that there were no misadministrations between January 27, 1992 and February 9, 1993. Accordingly, CMC continues, the violations should have been classified as Severity Level IV.

The Licensee also disagrees with the staff's escalation of the civil penalty based on the NRC's identification of the problems, arguing that CMC identified the need for the authorized user's signature on the written directive, as documented in the minutes of the RSC meeting of December 16, 1992. Additionally, the Licensee contends that the discrepancies identified in the annual evaluation of the QMP were not considered as recordable events due to CMC's interpretation of the regulations in effect at that time.

NRC's Evaluation of Licensee's Request for Mitigation of Civil Penalty Assessed for Violations A.1, A.2, and A.3

In accordance with the NRC Enforcement Policy, 10 CFR Part 2, Appendix C, Supplement VI.C.6, a substantial failure to implement the QMP is an example of a Severity Level III problem regardless of whether or not a misadministration occurred. A review of the QMP requirements in 10 CFR 35.25 and 35.32 clearly shows that the three key elements of any quality management program must be: (1) administration of therapy treatments in accordance with a written directive as

defined in 10 CFR 35.2, (2) training of individuals in the requirements of the QMP, and (3) appropriate response to recordable events. The licensee had violations in all three areas. Therefore, Violations A.1, A.2, and A.3, when considered in the aggregate, represent a substantial failure to implement the QMP.

The 50% escalation for NRC identification of the violation is warranted because the Licensee failed to identify: 1) that the referring physician instead of the authorized user had signed the patient consent form (written directive) on two occasions, 2) that the amount of iodine-131 to be administered was not specified on the patient consent form (written directive) on nine occasions, 3) that the amount of phosphorus-32 to be administered was not specified on the patient consent form (written directive) on one occasion, 4) that the route of administration for phosphorus-32 was not specified on the patient consent form (written directive) on one occasion, 5) that it had not retained a record of the relevant facts and corrective action for recordable events, and 6) that the Director of Radiology had not been trained in the QMP as required.

NRC Conclusion

The NRC staff concludes that Violations A.1, A.2, and A.3 occurred as stated and that neither an adequate basis for a reduction of the severity level nor for mitigation of the civil penalty was provided by the Licensee. Consequently, the proposed civil penalty in the amount of $2,500 should be imposed.

Violations B through I

The Licensee denies Violation F and a portion of Violation D, and argues that Violation E should not have been cited because the criteria in Section VII.B of the Enforcement Policy were satisfied. The Licensee admits the remaining violations.

Restatement of Violation D

10 CFR 35.51(c) requires, in part, that a Licensee check each survey instrument for proper operation with the dedicated check source each day of use.

Contrary to the above, as of February 9, 1993, the Licensee did not check its Xetex and Victoreen Model 293 with pancake probe survey meters with a dedicated check source on days when the instruments were used.

Summary of Licensee's Response

The Licensee admits that it failed to check the Xetex survey meter with a dedicated check source, but disagrees that the violation occurred with the Victoreen Model 493 survey meter, stating that the inspector misunderstood the certified nuclear medicine technologist when she stated she did not use the Victoreen survey meter and pancake probe for daily surveys to mean that she did not source check the meter before use.

NRC's Evaluation of Licensee's Response

Based on the Licensee's explanation, the portion of Violation D relating to the failure to source check the Victoreen pancake probe is withdrawn. Violation D should still be cited, however, because the Licensee did fail to source check the Xetex survey meter before use.

Restatement of Violation E

10 CFR 35.205(e) requires, in part, that a Licensee measure each six months the ventilation rates available in areas of use of radioactive gas.

Contrary to the above, the Licensee used radioactive xenon-133 gas in the imaging room but did not measure the ventilation rates therein from September 1991, to July 22, 1992, a period of 10 months.

Summary of Licensee's Response

The Licensee indicated that this violation should not have been cited because it was identified by its consultant during an audit performed on June 24, 1992.

NRC's Evaluation of Licensee's Response

In specified circumstances, Section VII.B(2) of the Enforcement Policy allows, but does not require, the NRC staff to refrain from issuing a Notice of Violation for licensee identified Severity Level IV violations. In this case, however, the Licensee performed four more xenon studies after the Licensee was aware that the surveillance test was past due. It is within the discretion of the NRC staff to cite this violation, and the staff has chosen to do so because the violation is indicative of the pattern of inadequate management attention to assure compliance with NRC requirements.

Restatement of Violation F

10 CFR 20.201(b) requires that each Licensee make such surveys as may be necessary to comply with the requirements of Part 20 and which are reasonable under the circumstances to evaluate the extent of radiation hazards that may be present. As defined in 10 CFR 20.201(a), "survey" means an evaluation of the radiation hazards incident to the production, use, release, disposal, or presence of radioactive materials or other sources of radiation under a specific set of conditions.

Contrary to the above, the Licensee did not make surveys to assure compliance with 10 CFR 20.202(a)(1), which requires the use of personnel monitoring equipment for those individuals who are likely to receive a dose in any calendar quarter in excess of 25 percent of the applicable value specified in 10 CFR 20.101. Specifically, between May 8, 1991, and February 9, 1993, the Licensee did not adequately evaluate the proper placement of finger dosimetry for nuclear medicine technologists.

Summary of Licensee's Response

The Licensee denies the violation, contending that an evaluation was made of the proper placement of the ring dosimeter in that the technologist wore the dosimeter on a finger, rather than on the wrist, and that the work performed by the technologist is so varied that it is pointless to evaluate which finger of which hand should be monitored.

To support its position, CMC references NCRP Report No. 57, "Instrumentation and Monitoring Methods for Radiation Protection, 1978," Section 4.2.2.3, and Regulatory Guide 10.8, "Guide for the Preparation of Applications for Medical Use Programs," Appendix I, regarding the criteria for placement of extremity dosimeters.

CMC contends that NCRP 57 supports the view that dosimeters can be worn on any finger rather than on a specific finger of a specific hand, and that Regulatory Guide 10.8 provides no specific guidance on this issue. CMC adds that based on a review of exposure records for 1991 and 1992, no monitoring was required because the technologist's extremity doses were 6.4% and 5.8%, respectively, of the limits specified in 10 CFR 20.101.

NRC's Evaluation of Licensee's Response

While NCRP guidance does not take precedent over NRC requirements, NCRP 57, Section 4.2.2.3, "Partial Body Exposure" does state in part:

> Where sealed or unsealed radioactive sources are handled, it may be particularly important to determine the dose to the hands. Extremity dosimeters should be worn **as near to the point of maximum exposure as possible** (on a finger or the wrist) and should not be shielded from radiation by the extremity. (Emphasis added).

The Licensee's contention that it is acceptable to place the extremity dosimeter on either hand conflicts with the recommendation to place dosimeters "as near to the point of maximum exposure as possible."

Regulatory Guide 10.8, Appendix I, does not specify how dosimeters are to be worn. However, Appendix I does indicate that dosimeters should be worn as prescribed by the Radiation Safety Officer (RSO). As documented in the inspection report, the RSO stated that he had never evaluated which of the technologist's hands was likely to receive the highest dose.

The inspection report indicates that the technologist's method of drawing and injecting doses brought the left hand, where she wore the dosimeter, in proximity to shielded volumes of Tc-99m, and brought the right hand in proximity to unshielded volumes. The Licensee cannot use the dosimeter readings from the left hand to argue that no monitoring is required because the dose to the right hand, which was not measured, may be significantly greater based on the inspector's observation of the technologist's work habits.

Summary of Licensee's request for Mitigation of Civil Penalty Assessed for Violations B through I

The Licensee admits six of the eight violations, but argues that individually these violations would be considered minor. CMC also disagrees that the violations collectively represent a programmatic breakdown in the Radiation Safety Program, and adds that the violations were identified as a result of an extremely detailed, three-day inspection.

CMC disagrees with the escalation of the penalty based on two NRC Information Notices (INs). CMC challenges the relevance of IN 90-71, "Effective Use of Radiation Safety

Committees [RSCs] to Exercise Control Over Medical Use Programs," because, according to the Licensee, the six purposes of the RSC described in the discussion section of IN 90-71, including RSC review of the radiation safety program, were fulfilled at CMC, as documented in the RSC meeting minutes.

CMC also challenges the applicability of IN 91-71, "Training and Supervision of Individuals Supervised by an Authorized User," arguing that the significant incidents cited therein were caused in part by training problems which were of much greater significance than those at CMC. Specifically, while conceding that three of the six admitted violations were caused by training deficiencies, CMC contends that a training program was in place and that attention to the training of facility personnel is documented in the RSC meeting minutes.

Finally, CMC argues that the proposed civil penalty is not consistent with the enforcement actions described in IN 90-71, or with a recent unspecified enforcement action in Hawaii.

NRC's Evaluation of Licensee's Request for Mitigation of Civil Penalty Assessed for Violations B through I

The NRC Enforcement Policy, Section IV.A, states in part that a group of violations may be evaluated in the aggregate and assigned a single, increased severity level, thereby resulting in a Severity Level III problem, if the violations have the same underlying cause or programmatic deficiencies, or if the violations contributed to or were unavoidable consequences of the underlying problem. The NRC staff concluded that all of the violations stem from the same root cause, namely, a pattern of lack of attention by the RSO and management above the RSO to compliance with NRC regulatory requirements. Thus aggregation was warranted.

As to the relevance of IN 90-71, this notice indicates that the RSC should review the functions of the RSO to ensure that the RSO does not have other duties that prevent adequate attention to the safety program, and that the RSO has not delegated substantial responsibilities to other staff members or to consultants. As documented in the inspection report, the oversight of the Radiation Safety Program was primarily limited to administrative reviews of the program by the consultant. Further, CMC personnel conceded during the Enforcement Conference that the Radiation Safety Program had not received enough management attention.

Contrary to CMC's contention that its RSC fulfilled the six purposes of RSCs outlined in IN 90-71, the RSC failed to identify radiation safety problems; initiate, recommend or provide corrective actions; and verify implementation of corrective actions (Purpose One of IN 90-71). While the Licensee may have identified some problems, it failed to implement timely, lasting corrective action, as documented in NRC Inspection Report No. 93-01, Section 3. Specifically, the Licensee failed to implement corrective actions concerning: 1) the failure to perform ventilation room checks, 2) the failure to obtain dose calibrator records for a "loaner" dose calibrator, 3) the failure to implement the Quality Management Program by using written directives, by evaluating recordable events, and by training personnel in the provisions of the QMP, 4) the failure to provide and document annual radiation safety refresher training, 5) the failure to perform required surveys (repeat violation), and 6) the failure to perform required dose calibrator constancy checks (repeat violation).

As to the relevance of IN 91-71, this Notice was written specifically to remind licensees of the importance of providing adequate instruction and supervision to individuals, such as technologists, who work under the supervision of an authorized user. This notice also highlights the need for adequate training of individuals such as part-time, cross-trained, or temporary technologists. As documented in the inspection report, the Licensee's primary technologist is a Certified Nuclear Medicine Technologist (CNMT), and two other, non-certified technologists fill in for her when she is not available. Violation B was caused by a non-certified technologist's lack of familiarity with the operation of the dose calibrator, resulting in his use of a loaner dose calibrator from the radiopharmacy and his lack of familiarity with the requirement for performing dose calibrator tests upon installation of the dose calibrator. Violation C occurred because the non-certified technologists did not understand the requirement for performing surveys at the end of each day of use of radiopharmaceuticals. Violation D occurred because the technologists assumed that if the instrument did not have an installed source, the source check did not have to be performed. Violation H occurred because the technologist assumed that removing gloves prior to leaving the area meant that there was no need to monitor her hands. Violation I occurred because the staff wrongly thought that the requirement applied to the use of iodine-131 for inpatient therapy and not for phosphorus-32 inpatient therapy.

Licensees are expected to be pro-active in identifying and correcting their own violations and are required to maintain compliance with NRC regulatory requirements at all times. Therefore, the degree of detail of an NRC inspection or the length of time devoted to it have no bearing on the consideration of any resulting enforcement action. Further, in this case, the inspection was extended due to the number and nature of the violations that were being identified.

It is also inappropriate to compare the monetary amount of civil penalties assessed among different licensees because the effect of the Enforcement Policy's mitigating and escalating factors on the final monetary amount is case specific. Further, the total monetary amount was higher in this case because there were two separate Severity Level III problems and, in accordance with the Enforcement Policy, a separate civil penalty was assessed for each problem.

NRC Conclusion

The NRC has concluded that Violations B through I occurred as stated and that neither an adequate basis for a reduction of the severity level nor for mitigation of the civil penalty was provided by the Licensee. Consequently, the proposed civil penalty for Violations B through I in the amount of $5,000 should be imposed.

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION IV
611 RYAN PLAZA DRIVE, SUITE 400
ARLINGTON, TEXAS 76011-8064

JUL - 8 1993

Docket No. 030-02392
License No. 25-02337-03
EA 93-164

Columbus Hospital
ATTN: Mr. William J. Downer, President
500 15th Avenue South
P.O. Box 5013
Great Falls, Montana 59403

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY - $2,500 (NRC INSPECTION REPORT NO. 030-02392/93-01)

This refers to the inspection conducted on April 28, 1993, at Columbus Hospital, Great Falls, Montana. A report describing the results of this inspection was issued on June 11, 1993. On June 30, 1993, Mr. Boatman, Executive Vice President, and other hospital representatives participated in an enforcement conference with the NRC in the NRC's Arlington, Texas office to discuss the hospital's failure to adhere to its written Quality Management Program as required by 10 CFR 35.32. A list of the participants in that enforcement conference is enclosed (Enclosure 2). The conference was open to public observation in accordance with the terms of a pilot program begun by the NRC in July 1992.

As discussed during the enforcement conference, 10 CFR Part 35 was revised in January 1992 to require NRC medical licensees to establish and maintain written Quality Management Programs (QMPs) to provide high confidence that byproduct material or radiation from byproduct material would be administered as directed by an authorized user. The rule requires, in part, that a written directive be prepared and signed by an authorized user prior to the administration to patients of iodine-131 in quantities greater than 30 microcuries and prior to the therapeutic administration of any other radiopharmaceutical.

With respect to the use of iodine-131, the written QMP developed by Columbus Hospital (Columbus) and submitted to the NRC in January 1992 conformed to the above regulation. It requires the **Authorized User** (emphasis added) to provide a signed written directive before the human use of iodine-131 in quantities greater than 30 microcuries and requires that the existence of a written directive be verified when completing Form A, "Administration of I-131/I-125."

The violations in Section I of the enclosed Notice of Violation and Proposed Imposition of Civil Penalty include: 1) a failure on the part of Columbus personnel to adhere to its QMP on 18 occasions in that iodine-131 in quantities greater than 30 microcuries was administered to patients without the authorized user providing a signed, written directive and without properly verifying that a written directive had been prepared; and 2) a failure of Columbus's QMP to require written directives for the therapeutic

administration of phosphorous-32, which Columbus had administered to patients on two occasions.

The first violation appears to have occurred because Columbus personnel involved in administering these radiopharmaceuticals believed that a request from a referring physician, i.e., a request to have a particular procedure performed on a patient, constituted a written directive. As discussed during the enforcement conference, such a request does not meet the intent of the regulation because it does not come from an authorized user and does not specify the quantity of radioisotope to be administered. The second violation appears to have occurred because the hospital's QMP was developed without recognition of the fact that phosphorous-32 would be administered to patients.

Thus, Columbus's QMP and its implementation failed to meet the primary objective of the regulation: to provide high confidence that these radioisotopes would be administered as directed by an authorized user. While the NRC considers these violations a significant regulatory concern, we acknowledge that in no case does it appear that these violations affected, or resulted in errors in, the treatment of patients who were administered radioisotopes. The NRC also notes that the hospital's QMP was being properly implemented with regard to brachytherapy. Nonetheless, in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy) 10 CFR Part 2, Appendix C, the NRC considers the violations representative of a substantial failure to implement a QMP and are classified as a Severity Level III problem.

Columbus officials informed the NRC at the enforcement conference that it had temporarily suspended the administration of radioisotopes requiring the use of prior written directives and that it was in the process of revising its procedures and QMP to assure complete compliance with 10 CFR 35.32(a).

To emphasize the importance of maintaining compliance with this important regulatory requirement, I have been authorized to issue the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice) in the amount of $2,500 for the Severity Level III problem described above and in the Notice. The base value of a civil penalty for a Severity Level III problem is $2,500. The civil penalty adjustment factors in the Enforcement Policy were considered but resulted in no net adjustment. While the NRC considered Columbus's good regulatory performance worthy of mitigation, this was offset by escalation based on these violations having been identified by the NRC through its inspections. The other adjustment factors were considered and no further adjustment to the base civil penalty was considered appropriate.

In addition to the violations that were assessed a civil penalty, the enclosed Notice addresses in Section II a failure of Columbus to review its QMP in accordance with the requirements of 10 CFR 35.32(b). This was not identified as an apparent violation in the inspection report, but was discussed during the enforcement conference. This violation, while important, has been classified at Severity Level IV and is not being assessed a civil penalty.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. In your response, you should document the specific actions taken and any additional actions you plan to prevent recurrence. After reviewing your response to this Notice, including your proposed corrective actions, and the results of future inspections, the NRC will determine whether further NRC enforcement action is necessary to ensure compliance with NRC regulatory requirements.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter and its enclosure will be placed in the NRC Public Document Room. The responses directed by this letter and the enclosed Notice are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, Pub. L. No. 96-511.

Sincerely,

James L. Milhoan

James L. Milhoan
Regional Administrator

Enclosures:
1) Notice of Violation and Proposed Imposition of Civil Penalty
2) List of enforcement conference participants

cc w/Enclosures: State of Montana

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

Columbus Hospital
Great Falls, Montana

Docket No. 030-02392
License No. 25-02337-03
EA 93-164

During an NRC inspection conducted on April 28, 1993, violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C, the Nuclear Regulatory Commission proposes to impose a civil penalty pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (Act), 42 U.S.C. 2282, and 10 CFR 2.205. The particular violations and associated civil penalty are set forth below:

I. Violations Assessed a Civil Penalty

A. 10 CFR 35.32(a), which became effective on January 27, 1992, requires, in part, that each licensee establish and maintain a written quality management program to provide high confidence that byproduct material or radiation from byproduct material will be administered as directed by the authorized user. The quality management program must include written policies and procedures to meet the objectives that: (1) prior to administration, a written directive is prepared for any administration of quantities greater than 30 microcuries of sodium iodide I-125 or I-131 and any therapeutic administration of a radiopharmaceutical other than sodium iodide I-125 or I-131; (2) prior to administration, the patient's identity is verified by more than one method as the individual named in the written directive; (3) each administration is in accordance with the written directive; and (5) any unintended deviation from the written directive is identified and evaluated, and appropriate action is taken.

10 CFR 35.2, "Definitions," defines a written directive, in part, as an order in writing for a specific patient, dated and signed by an authorized user prior to administration of a radiopharmaceutical and specifies, in part, that for the administration of quantities greater than 30 microcuries of either sodium iodide I-125 or I-131 or any therapeutic administration of a radiopharmaceutical other than sodium iodide I-125 or I-131, the written directive must include the dosage. For therapeutic administration of a radiopharmaceutical other than sodium iodide I-125 or I-131, the written directive must include the route of administration.

Contrary to the above, between January 27, 1992, and April 28, 1993:

1. The licensee failed to establish and maintain a quality management program that ensured that a written directive was prepared prior to (1) the administration of sodium iodide I-131 in quantities greater than 30 microcuries and (2) the therapeutic administration of a radiopharmaceutical other than sodium iodide I-125 or I-131. Specifically, an authorized user failed to prepare a written directive for 18 doses of sodium iodide I-131 administered to patients in quantities ranging from 30 microcuries to 30 millicuries. In addition, the authorized user failed to prepare a written directive for 2 therapeutic administrations of P-32 in quantities of 4.4 and 4.7 millicuries.

2. The licensee failed to develop written policies and procedures for therapeutic administrations of radiopharmaceuticals other than sodium iodide I-125 or I-131, i.e., P-32, to meet the objectives that (1) the patient's identity was verified by more than one method as the individual named in the written directive, (2) each administration was in accordance with the written directive, and (3) any unintended deviation from the written directive was identified and evaluated, and appropriate action taken.

B. 10 CFR 35.25(a)(2) requires, in part, that a licensee that permits the receipt, possession, use or transfer of byproduct material by an individual under the supervision of an authorized user shall require the supervised individual to follow the written quality management procedures established by the licensee.

The licensee's Quality Management Program, dated January 24, 1992, contains a written policy and procedure for administration of I-125 or I-131 which specifies that before the human use of either radioactive I-125 or I-131, in quantities greater than 30 microcuries, the authorized user must provide a signed written directive for the use of these isotopes. The procedure accompanying the Quality Management Program, as described in Form A of the program, also specifies that prior to administration of I-125 or I-131, the individual administering the dose must verify that a written directive has been made for the administration.

Contrary to the above, between January 27, 1992, and April 28, 1993, an individual working under the supervision of an authorized user failed to verify that a written directive was made prior to administering 18 doses of sodium iodide I-131 in quantities ranging from 30 microcuries to 30 millicuries.

These violations represent a Severity Level III problem (Supplement VI).
Civil Penalty - $2,500

II. Violation Not Assessed a Civil Penalty

10 CFR 35.32(b) requires, in part, that a licensee develop procedures for and conduct a review of the QM program including, since the last review, an evaluation of: (1) a representative sample of patient administrations, (2) all recordable events, and (3) all misadministrations to verify compliance with all aspects of the QM program at intervals no greater than 12 months.

Contrary to the above, between January 27, 1992, and April 28, 1993, the licensee failed to conduct a review of that portion of its QM program which applied to the use of radiopharmaceuticals subject to the QM Rule.

This is a Severity Level IV violation (Supplement VI).

Pursuant to the provisions of 10 CFR 2.201, Columbus Hospital (Licensee) is hereby required to submit a written statement or explanation to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, within 30 days of the date of this Notice of Violation and Proposed Imposition of Civil Penalty (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each alleged violation: (1) admission or denial of the alleged violation, (2) the reasons for the violation if admitted, and if denied, the reasons why, (3) the corrective steps that have been taken and the results achieved, (4) the corrective steps that will be taken to avoid further violations, and (5) the date when full compliance will be achieved.

If an adequate reply is not received within the time specified in this Notice, an order or a Demand for Information may be issued to show cause why the license should not be modified, suspended, or revoked or why such other action as may be proper should not be taken. Consideration may be given to extending the response time for good cause shown. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, this response shall be submitted under oath or affirmation.

Within the same time as provided for the response required above under 10 CFR 2.201, the Licensee may pay the civil penalty by letter addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, with a check, draft, money order, or electronic transfer payable to the Treasurer of the United States in the amount of the civil penalty proposed above, or the cumulative amount of the civil penalties if more than one civil penalty is proposed, or may protest imposition of the civil penalty, in whole or in part, by a written answer addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission. Should the Licensee fail to answer within the time specified, an order imposing the civil penalty will be issued. Should the Licensee elect to file an answer in accordance with 10 CFR 2.205 protesting the civil penalty, in whole or in part, such answer should be clearly marked as an "Answer to a Notice of Violation" and may: (1) deny the violations listed in this Notice, in whole or in part, (2) demonstrate extenuating circumstances, (3) show error in this Notice, or (4) show other reasons why the penalty should not be imposed. In addition to protesting the civil penalty, in whole or in part, such answer may request remission or mitigation of the penalty.

In requesting mitigation of the proposed penalty, the factors addressed in Section VI.B.2 of 10 CFR Part 2, Appendix C should be addressed. Any written answer in accordance with 10 CFR 2.205 should be set forth separately from the statement or explanation in reply pursuant to 10 CFR 2.201, but may incorporate parts of the 10 CFR 2.201 reply by specific reference (e.g., citing page and paragraph numbers) to avoid repetition. The attention of the Licensee is directed to the other provisions of 10 CFR 2.205, regarding the procedure for imposing a civil penalty.

Upon failure to pay any civil penalty due which subsequently has been determined in accordance with the applicable provisions of 10 CFR 2.205, this matter may be referred to the Attorney General, and the penalty, unless compromised, remitted, or mitigated, may be collected by civil action pursuant to Section 234c of the Act, 42 U.S.C. 2282c.

The responses noted above (Reply to Notice of Violation, letter with payment of civil penalty, and Answer to a Notice of Violation) should be addressed to: Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555 with a copy to the Regional Administrator, U.S. Nuclear Regulatory Commission, Region IV, 611 Ryan Plaza Drive, Suite 400, Arlington, Texas 76011.

Dated at Arlington, Texas
this 8th day of July 1993

Enclosure 2

ENFORCEMENT CONFERENCE ATTENDANCE

LICENSEE: Columbus Hospital, Great Falls, Montana

TIME/DATE: 1 p.m. CDT, June 30, 1993

MEETING LOCATION: NRC Region 4, Arlington, Texas

EA NUMBER: 93-164

Columbus Hospital representatives

Daniel W. Boatman, Executive Vice President
James C. Mailander, Radiologist/Chairman of Dept.
Rod Wimmer, Radiation Safety Officer

NRC Region 4 representatives

James L. Milhoan, Regional Administrator
William L. Brown, Regional Counsel
Dwight D. Chamberlain, Deputy Director, Div. of Radiation Safety & Safeguards
Charles L. Cain, Chief, Nuclear Materials Inspection Section, DRSS
Linda L. Kasner, Senior Radiation Specialist, NMIS, DRSS
Gary F. Sanborn, Regional Enforcement Officer
Carol J. Gordon, Secretary, Office of the Regional Administrator

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
799 ROOSEVELT ROAD
GLEN ELLYN, ILLINOIS 60137

MAR 10 1993

Docket No. 030-12231
License No. 13-17124-01
EA 93-022

Community Hospital South
ATTN: Kathy Clark
Administrator
1402 East County Line Road South
Indianapolis, Indiana 46227

Dear Ms. Clark:

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY - $6,875
(NRC INSPECTION REPORT NO. 030-12231/92001)

This refers to the routine safety inspection at Community Hospital South, conducted on November 17, 1992, and authorized by NRC License No. 13-17124-01. A copy of the report documenting this inspection was mailed to you on February 12, 1993. Significant violations of NRC requirements were identified during the inspection, and on February 18, 1993, an enforcement conference was held in the Region III office.

The violations are fully described in the enclosed Notice of Violation (Notice). Examples of the violations are the failures to: perform the annual review of the radiation safety program and quarterly reviews of the ALARA program (As Low As Reasonably Achievable); provide required training; calculate the amount of time needed to reduce the concentration of xenon-133 after a spill; have correct instrumentation; and perform area surveys at the end of the day. These violations, taken collectively, represent a significant breakdown in the control of NRC licensed activities at Community Hospital South. Therefore, in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy) 10 CFR Part 2, Appendix C, the violations are classified in the aggregate as a Severity Level III problem.

The root causes of the violations were discussed during the enforcement conference. The major factor contributing to the violations appeared to be a lack of management support and oversight of the NRC licensed program. The discussions at the enforcement conference led to the addition of two violations (failure to ensure that xenon-133 procedures were performed in a room at negative pressure, and the failure to leak test a cesium-137 sealed source at required intervals). Two apparent violations

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were reconsidered based on the enforcement conference discussions. One apparent violation concerned the failure to provide training to nuclear medicine personnel upon assuming their duties. That violation was deleted because your consulting medical physicist provided evidence demonstrating that the required training had been performed. The second apparent violation, the failure to appoint a replacement Radiation Safety Officer (RSO), was not cited because the RSO named on the license remained on your medical staff and was at your facility on a weekly basis. However, his duties were essentially assumed by your consulting medical physicist, who is the RSO at other NRC licensed facilities associated with Community Hospital South.

The NRC license issued to Community Hospital South entrusts responsibility for radiation safety to the management of the hospital. Incumbent upon each NRC licensee is the responsibility to protect the public health and safety, including the health and safety of the employees, by assuring that all requirements of the NRC license are met and any potential violation of NRC requirements is identified and expeditiously corrected. Your failure to recognize and correct the named RSO's limited involvement in the radiation safety program, especially after his relocation to another facility on or about October 1, 1992, is a significant concern to the NRC because the RSO is expected to be your technical expert on the conditions of the NRC license and NRC regulations. Moreover, several of the violations were identified to you by your consulting medical physicist and corrective measures were not implemented. To have allowed these violations to occur and go uncorrected for an extended period demonstrates ineffective or insufficient management oversight of the radiation safety program by those individuals responsible for radiation safety, in particular members of management and the Radiation Safety Committee.

To emphasize the need for effective management and oversight of NRC licensed activities, I am issuing the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice) in the amount of $6,875 for the Severity Level III problem.

The base value of a civil penalty for a Severity Level III problem is $2,500. In summary the base civil penalty was increased 175 percent. The base civil penalty was initially escalated 50 percent because all of the violations were identified by the NRC. The base civil penalty was escalated 25 percent because you corrected some issues but not others. (For example, xenon-133 procedures continued and the room ventilation study was not made. Also, your proposed corrective actions did not include measures to ensure management involvement in radiation safety.) The base civil penalty was increased an additional 100 percent for the prior opportunities you had to identify some of the violations. As examples, prior to the NRC inspection your consulting medical physicist reported to you that the Radiation Safety Committee was

not meeting at the required intervals and certain training had not been conducted. Nevertheless, you took no action to correct those problems. The remaining factors in the enforcement policy were also considered and no further adjustment to the base civil penalty was considered appropriate.

It is fortuitous that your consulting medical physicist assumed many, if not all, of the responsibilities of your RSO and at times chaired your Radiation Safety Committee. More stringent enforcement action may have been considered except for this intervention.

You are required to document your response to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. In your response, please ensure that you describe the actions, including any internal or external audits, you have taken to strengthen the management and oversight of your NRC licensed program.

After reviewing your response to this Notice, including your proposed corrective actions and the results of future inspections, the NRC will determine whether further NRC enforcement action is necessary to ensure compliance with NRC regulatory requirements.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter and its enclosure will be placed in the NRC Public Document Room.

The responses directed by this letter and the enclosed Notice are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, Public Law No. 96-511.

Sincerely,

A. Bert Davis
Regional Administrator

Enclosure:
Notice of Violation and Proposed
Imposition of Civil Penalty

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

Community Hospital South
Indianapolis, Indiana

Docket No. 030-12231
License No. 34-16241-01
EA 93-022

During an NRC inspection conducted on November 17, 1992, violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C, the Nuclear Regulatory Commission proposes to impose a civil penalty pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (Act), 42 U.S.C. 2282, and 10 CFR 2.205. The particular violations and associated civil penalty are set forth below:

A. 10 CFR 35.13(e) requires that a licensee apply for and must receive a license amendment before it adds to or changes the areas of use or address or addresses of use identified in the application or on the license.

Contrary to the above, on or about April 1, 1992, the licensee changed the area where byproduct material is used for lung ventilation studies from Imaging Room No. 1 to an adjacent room, and, as of that date, the licensee had not applied for a license amendment authorizing the change.

B. 10 CFR 35.205(b) requires that a licensee administer radioactive gases only in rooms that are at negative pressure compared to surrounding rooms.

Contrary to the above, from about April 1 to November 17, 1992, the licensee administered radioactive xenon-133 gas in the new "Raytheon Room," which was not at negative pressure compared to surrounding rooms.

C. 10 CFR 35.205(c) requires, in part, that before receiving, using, or storing a radioactive gas, the licensee shall calculate the amount of time needed after a spill to reduce the concentration in the room to the occupational limit listed in 10 CFR Part 20 Appendix B.

Contrary to the above, from about April 1 to November 17, 1992, the licensee used radioactive xenon-133 gas in the new "Raytheon Room" and the licensee did not calculate the amount of time needed after a spill to reduce the concentration therein to the occupational limit listed in 10 CFR Part 20, Appendix B.

D. 10 CFR 35.205(d) requires, in part, that a licensee post the safety measures to be instituted in case of a spill of a radioactive gas at the area of use and the calculated time needed after a spill to reduce the concentration to the

occupational limit listed in 10 CFR Part 20, Appendix B.

Contrary to the above, from about April 1 to November 17, 1992, the licensee used radioactive xenon-133 gas in the new "Raytheon Room" and the licensee did not post the safety measures to be instituted in case of a spill of xenon-133 gas and the calculated time needed after a spill to reduce the concentration to the occupational limit listed in 10 CFR Part 20, Appendix B.

E. 10 CFR 35.205(e) requires, in part, that a licensee measure each six months the ventilation rates available in areas of use of radioactive gas.

Contrary to the above,

1. The licensee used radioactive xenon-133 gas in Room No. 1 and did not measure the ventilation rates therein each six months from July 31, 1991 to November 17, 1992.

2. The licensee used radioactive xenon-133 gas in the new "Raytheon Room" and did not measure the ventilation rates therein each six months from about April 1 to November 17, 1992.

F. 10 CFR 35.22(a)(2) requires that the Radiation Safety Committee meet at least quarterly.

Contrary to the above, the licensee's Radiation Safety Committee did not meet at least quarterly. Specifically, the Radiation Safety Committee did not meet between January 17, 1991 and July 31, 1991, between July 31, 1991 and January 31, 1992, and between January 31, 1992, and July 23, 1992, periods in excess of one calendar quarter.

G. 10 CFR 35.22(a)(3) requires that to establish a quorum and conduct business, at least one half of the Radiation Safety Committee's membership must be present, including the Radiation Safety Officer and the management's representative.

Contrary to the above, on July 23, 1992, and November 12, 1992, the licensee's Radiation Safety Committee met, conducted business, and the Radiation Safety Officer was not present.

H. 10 CFR 35.20(c) requires, in part, that the licensee's ALARA program must include a review of summaries of the types and quantities of byproduct material used.

10 CFR 35.22(a) requires, in part, that the licensee's Radiation Safety Committee meet at least quarterly and the minutes of each Radiation Safety Committee meeting must include the ALARA program reviews described in 10 CFR 35.20(c).

Contrary to the above, from January 17, 1991, to November 12, 1992, the Radiation Safety Committee did not review and the minutes of the Radiation Safety Committee meetings did not include a review of the ALARA program described in 10 CFR 35.20(c). Specifically, the summaries of the types and quantities of byproduct material used were not reviewed.

I. 10 CFR 35.22(b)(6) requires that, to oversee the use of licensed material, the Radiation Safety Committee must review annually, with the assistance of the Radiation Safety Officer, the licensee's radiation safety program.

Contrary to the above, from about February 15, 1990, to November 17, 1992, the licensee, through its Radiation Safety Committee, did not review, with the assistance of the Radiation Safety Officer, the licensee's radiation safety program annually.

J. 10 CFR 35.21(a) requires that the licensee, through the Radiation Safety Officer, ensure that radiation safety activities are performed in accordance with approved procedures. The licensee's procedures are described in the licensee's application dated February 29, 1988, and were approved by License Condition No. 13.

1. The licensee's application dated February 29, 1988, states in Item 8 that the licensee will establish and implement the model training program that was published in Appendix A, of Regulatory Guide 10.8, Revision 2.

   Appendix A of Regulatory Guide 10.8, Revision 2, "Model Training Program," requires, in part, that the licensee instruct personnel, including ancillary personnel, in specified subjects at the following intervals: (1) before assuming duties with, or in the vicinity of, radioactive material, (2) during annual refresher training, and (3) whenever there is a significant change in duties, regulations, or the terms of the license.

   Contrary to the above, as of November 17, 1992, the licensee, through its Radiation Safety Officer, failed to ensure that radiation safety activities were being performed in accordance with the above procedure. Specifically, annual refresher training for ancillary personnel had not been provided since February 1990.

2. The licensee's application dated February 29, 1988, states in Item No. 10.12 that the licensee will establish and implement the model procedure for area surveys that was published in Appendix N of Regulatory Guide 10.8, Revision 2.

   Appendix N of Regulatory Guide 10.8, Revision 2, "Model Procedure for Area Surveys," requires the licensee's

Radiation Safety Officer review and sign the records for area and contamination surveys at least monthly and also promptly in those cases in which action levels were exceeded.

Contrary to the above, from January 2 to November 17, 1992, the licensee, through its Radiation Safety Officer, failed to ensure that radiation safety activities were performed in accordance with the above procedure. Specifically, the Radiation Safety Officer did not review or sign records of area surveys and contamination surveys as required.

K. 10 CFR 35.220 requires that a licensee authorized to use byproduct material for imaging and localization possess a portable radiation detection survey instrument capable of detecting dose rates over the range of 0.1 millirem per hour to 100 millirem per hour, and a portable radiation measurement survey instrument capable of measuring dose rates over the range 1 millirem per hour to 1000 millirem per hour.

Contrary to the above, as of November 17, 1992, the licensee did not possess a portable radiation detection survey instrument capable of detecting dose rates over the range of 0.1 millirem per hour to 100 millirem per hour.

L. 10 CFR 35.70(a) requires that a licensee survey with a radiation detection survey instrument at the end of each day of use all areas where radiopharmaceuticals are routinely prepared for use or administered.

Contrary to the above, on numerous occasions from about January 2 to November 17, 1992, the licensee did not survey with a radiation detection instrument at the end of the day the nuclear medicine "hot" lab and imaging room, areas where radiopharmaceuticals are routinely prepared for use or administered.

M. 10 CFR 35.59(b)(2) requires, in part, that a licensee in possession of a sealed source test the source for leakage at intervals not to exceed six months or at other intervals approved by the Commission or an Agreement State.

Contrary to the above, the licensee did not test a sealed source containing nominally 224 microcuries of cesium-137 for leakage between January 17, 1991, and November 17, 1992, an interval in excess of six months, and no other interval was approved by the Commission or an Agreement State.

N. 10 CFR 35.50(e) requires, in part, that a licensee retain records of dose calibrator tests for accuracy, linearity and geometrical dependence and the records must include the signature of the Radiation Safety Officer.

Contrary to the above, from about February 17, 1989, to November 17, 1992, the licensee's records of dose calibrator tests for accuracy, linearity and geometrical dependence did not include the signature of the Radiation Safety Officer.

O. 10 CFR 35.59(d) requires that a licensee retain records of leakage test results for five years; and that the records contain the model number, and serial number if assigned, of each source tested; the identity of each source radionuclide and its estimated activity; the measured activity of each test sample expressed in microcuries; a description of the method used to measure each test sample; the date of the test; and the signature of the Radiation Safety Officer.

Contrary to the above, from about February 17, 1989, to November 17, 1992, the licensee's records of leakage test results did not contain the signature of the Radiation Safety Officer.

P. 10 CFR 35.59(g) requires, in part, that a licensee retain for five years records of quarterly physical inventories of sealed sources in its possession, and that the records contain the model number of each source, and serial number if one has been assigned, the identity of each source radionuclide and its nominal activity, the location of each source, and the signature of the Radiation Safety Officer.

Contrary to the above, from about February 17, 1989, to November 17, 1992, the licensee's records of physical inventories of its sealed source did not include the signature of the Radiation Safety Officer.

Q. 10 CFR 35.22(a)(4) requires that the minutes of each Radiation Safety Committee meeting include: (i) The date of the meeting; (ii) Members present; (iii) Members absent; (iv) Summary of deliberations and discussions; (v) Recommended actions and the numerical results of all ballots; and (vi) ALARA program reviews described in Section 35.20(c).

Contrary to the above, the minutes for the meetings of the Radiation Safety Committee held from January 17, 1991, to November 17, 1992 did not include members absent from the meeting.

R. 10 CFR 35.92(b) requires that a licensee retain for three years a record of each disposal of byproduct material permitted under 10 CFR 35.92(a), and that the record include the date of the disposal, the date on which the byproduct material was placed in storage, the radionuclides disposed, the survey instrument used, the background dose rate, the dose rate measured at the surface of each waste container, and the name of the individual who performed the disposal.

Contrary to the above, from January 2, 1992, to November 17, 1992, the licensee's records of disposal of byproduct material permitted under 10 CFR 35.92(a) did not include the date on which the byproduct material was placed in storage and the background dose rate.

S. 10 CFR 35.70(h) requires, in part, that a licensee retain records of each contamination survey required by 10 CFR 35.70. The records must include, in part, the removable contamination in each area expressed in disintegrations per minute per 100 square centimeters.

Contrary to the above, from January 2, 1992 to November 17, 1992, the licensee failed to retain records of surveys required by 10 CFR 35.70 that included the removable contamination in each area expressed in disintegrations per minute per 100 square centimeters. Specifically, removable contamination was expressed in counts per minute.

This is a Severity Level III problem (Supplements IV and VI). Cumulative Civil Penalty - $6,875.

Pursuant to the provisions of 10 CFR 2.201, Community Hospital South (Licensee) is hereby required to submit a written statement of explanation to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, within 30 days of the date of this Notice of Violation and Proposed Imposition of Civil Penalty (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each alleged violation: (1) admission or denial of the alleged violation, (2) the reasons for the violation if admitted, and if denied, the reasons why, (3) the corrective steps that have been taken and the results achieved, (4) the corrective steps that will be taken to avoid further violations, and (5) the date when full compliance is achieved. If an adequate reply is not received within the time specified in this Notice, an order may be issued to show cause why the license should not be modified, suspended, or revoked or why such other actions as may be proper should not be taken. Consideration may be given to extending the response time for good cause shown. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, this response shall be submitted under oath or affirmation.

Within the same time as provided for the response required under 10 CFR 2.201, the Licensee may pay the civil penalty by letter addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission with a check, draft, money order, or electronic transfer payable to the Treasurer of the United States in the amount of the civil penalty proposed above, or may protest imposition of the civil penalty in whole or in part, by a written answer addressed to the Director, Office of Enforcement, U. S. Nuclear Regulatory Commission. Should the Licensee fail to answer within the time specified, an order imposing the civil penalty will be issued. Should the Licensee elect to file an answer in accordance with 10 CFR 2.205 protesting the civil penalty, in whole

or in part, such answer should be clearly marked as an "Answer to a Notice of Violation" and may: (1) deny the violations listed in this Notice in whole or in part, (2) demonstrate extenuating circumstances, (3) show error in this Notice, or (4) show other reasons why the penalty should not be imposed. In addition to protesting the civil penalty in whole or in part, such answer may request remission or mitigation of the penalty.

In requesting mitigation of the proposed penalty, the factors addressed in Section V.B of 10 CFR Part 2, Appendix C (1991), should be addressed. Any written answer in accordance with 10 CFR 2.205 should be set forth separately from the statement or explanation in reply pursuant to 10 CFR 2.201, but may incorporate parts of the 10 CFR 2.201 reply by specific reference (e.g., citing page and paragraph numbers) to avoid repetition. The attention of the Licensee is directed to the other provisions of 10 CFR 2.205, regarding the procedure for imposing a civil penalty.

Upon failure to pay any civil penalty due which subsequently has been determined in accordance with the applicable provisions of 10 CFR 2.205, this matter may be referred to the Attorney General, and the penalty, unless compromised, remitted, or mitigated, may be collected by civil action pursuant to Section 234c of the Act, 42 U.S.C. 2282c.

The responses noted above (Reply to Notice of Violation, letter with payment of civil penalty, and Answer to a Notice of Violation) should be addressed to: Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555 with a copy to the Regional Administrator, U.S. Nuclear Regulatory Commission, Region III, 799 Roosevelt Road, Glen Ellyn, Illinois 60137.

FOR THE NUCLEAR REGULATORY COMMISSION

A. Bert Davis
Regional Administrator

Dated at Glen Ellyn, Illinois
this 10th day of March 1993

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

AUG 11 1993

Docket No. 030-12231
License No. 13-17124-01
EA 93-022

Community Hospital South
ATTN: Kathy A. Clark, Administrator
1402 East County Line Road South
Indianapolis, Indiana 46227

Dear Ms. Clark:

SUBJECT: ORDER IMPOSING CIVIL MONETARY PENALTY - $5,625

This refers to your letter dated April 5, 1993, in response to the Notice of Violation and Proposed Imposition of Civil Penalty (Notice) sent to you by our letter dated March 10, 1993. Our letter and Notice described 20 violations identified by the NRC during a routine safety inspection conducted at Community Hospital South on November 17, 1992.

To emphasize the need for effective management and oversight of NRC licensed activities, a civil penalty of $6,875 was proposed.

In your response you denied Violations I and K, admitted Violations N and S with mitigating circumstances, fully admitted the remaining violations, and requested remission of the civil penalty.

After considering your response, we have concluded for the reasons given in the Appendix attached to the enclosed Order Imposing Civil Monetary Penalty that, notwithstanding your admission of Violations M, O, and P, they are withdrawn. Withdrawal of Violations M, O, and P does not affect the overall Severity Level III problem or the amount of the civil monetary penalty assessed for the problem. As to the remaining issues, you did not provide an adequate basis for modifying or withdrawing any of the other violations or reducing the Severity Level. However, we have concluded that escalation of the base civil penalty based on Prior Opportunity to Identify should be reduced from 100 percent to 50 percent, which results in a reduction of the proposed civil penalty by $1,250. The reasons for these conclusions are more fully set forth in the Appendix to

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the enclosed Order. Accordingly, we hereby serve the enclosed Order Imposing Civil Monetary Penalty on Community Hospital South, Indianapolis, Indiana (Licensee) imposing a civil monetary penalty in the amount of $5,625. We expect that you have now improved your management controls and effectiveness of your Radiation Safety Officer. We will review the effectiveness of your corrective actions during a subsequent inspection.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter and the enclosures will be placed in the NRC's Public Document Room.

Sincerely,

Hugh L. Thompson, Jr.
Deputy Executive Director for
Nuclear Materials Safety, Safeguards
and Operations Support

Enclosures:
1. Order Imposing Civil Monetary Penalty
2. Appendix - Evaluations and Conclusion

UNITED STATES
NUCLEAR REGULATORY COMMISSION

In the Matter of	)	
	)	Docket No. 030-12231
COMMUNITY HOSPITAL SOUTH	)	License No. 13-17124-01
Indianapolis, Indiana	)	EA 93-022

ORDER IMPOSING CIVIL MONETARY PENALTY

I

Community Hospital South, Indianapolis, Indiana (Licensee) is the holder of Byproduct License No. 13-17124-01 first issued by the Nuclear Regulatory Commission (NRC or Commission) on October 7, 1976, and renewed in its entirety on March 31, 1988. The license expired on June 30, 1993, and is currently under timely renewal. The license authorizes the Licensee to use any radiopharmaceutical identified in 10 CFR 35.100, to use any radiopharmaceutical identified in 10 CFR 35.200 except technetium-99m generators, any radiopharmaceutical for therapy identified in 10 CFR 35.300, and any brachytherapy source identified in 10 CFR 35.400, in accordance with the conditions specified therein.

II

An inspection of the Licensee's activities was conducted on November 17, 1992. The results of the inspection indicated that the Licensee had not conducted its activities in full compliance with NRC requirements. A written Notice of Violation and Proposed Imposition of Civil Penalty (Notice) was served upon the Licensee by letter dated March 10, 1993. The Notice stated the

nature of the violations, the provision of the NRC's requirements that the Licensee had violated, and the amount of the civil penalty proposed for the violations. The Licensee responded to the Notice by letter dated April 5, 1993. In its response, the Licensee denied Violations I and K, admitted Violations N and S with mitigating circumstances, admitted fully the remainder of the violations, and requested remission of the civil penalty.

III

After consideration of the Licensee's response and the statements of fact, explanation, and argument for mitigation contained therein, the NRC staff has determined, as set forth in the Appendix to this Order, that with the exception of Violations M, O, and P, which are withdrawn, the violations occurred as stated; that the penalty proposed for the remaining violations designated in the Notice should be mitigated by $1,250 based on reconsideration of the application of the factor in the Enforcement Policy for Prior Opportunity to Identify; and that a civil penalty of $5,625 should be imposed.

IV

In view of the foregoing and pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (Act), 42 U. S. C. 2282, and 10 CFR 2.205, IT IS HEREBY ORDERED THAT:

The Licensee pay a civil penalty in the amount of $5,625 within 30 days of the date of this Order, by check, draft, electronic transfer, or money order, payable to the Treasurer of the United States and mailed to the Director, Office of Enforcement, U. S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555.

V

The Licensee may request a hearing within 30 days of the date of this Order. A request for a hearing should be clearly marked as a "Request for an Enforcement Hearing" and shall be addressed to the Director, Office of Enforcement, U. S. Nuclear Regulatory Commission, Washington, D.C. 20555, with a copy to the Commission's Document Control Desk, Washington, D. C. 20555. Copies also shall be sent to the Assistant General Counsel for Hearings and Enforcement at the same address and to the Regional Administrator, NRC Region III, 799 Roosevelt Road, Glen Ellyn, Illinois 60137.

If a hearing is requested, the Commission will issue an Order designating the time and place of the hearing. If the Licensee fails to request a hearing within 30 days of the date of this Order, the provisions of this Order shall be effective without further proceedings. If payment has not been made by that time,

the matter may be referred to the Attorney General for collection.

In the event the Licensee requests a hearing as provided above, the issues to be considered at such hearing shall be:

(a) whether the Licensee was in violation of the Commission's requirements as set forth in Violations I and K in the Notice referenced in Section II above, and

(b) whether, on the basis of such violations and the additional violations set forth in the Notice of Violation as modified in Section III above that the Licensee admitted, this Order should be sustained.

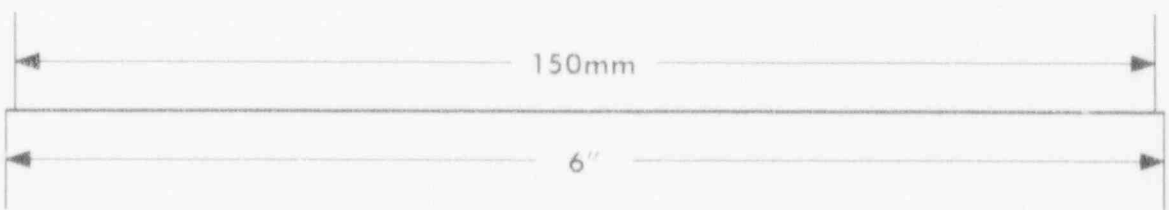
FOR THE NUCLEAR REGULATORY COMMISSION

Hugh L. Thompson, Jr.
Deputy Executive Director
for Nuclear Materials Safety, Safeguards
and Operations Support

Dated at Rockville, Maryland
this 11th day of August 1993

2

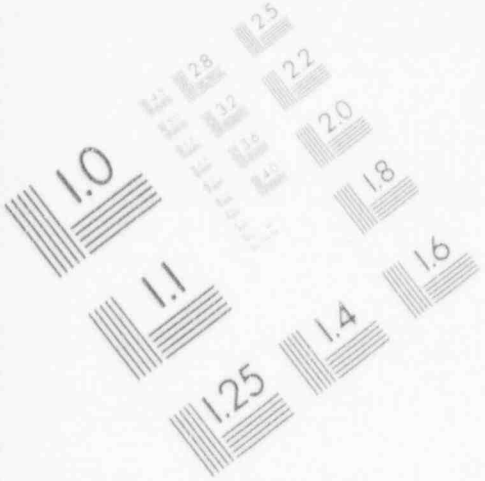
IMAGE EVALUATION TEST TARGET (MT-3)

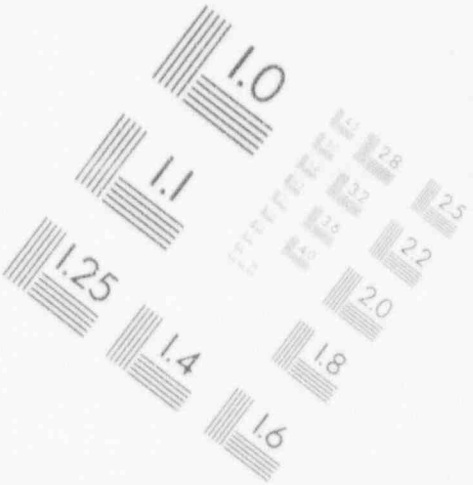


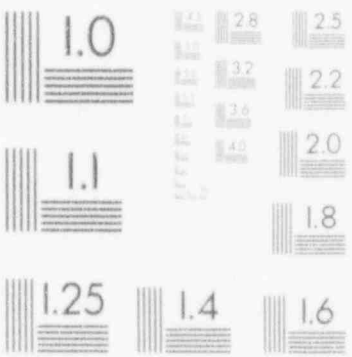
PHOTOGRAPHIC SCIENCES CORPORATION
770 BASKET ROAD
P.O. BOX 338
WEBSTER, NEW YORK 14580
(716) 265-1600

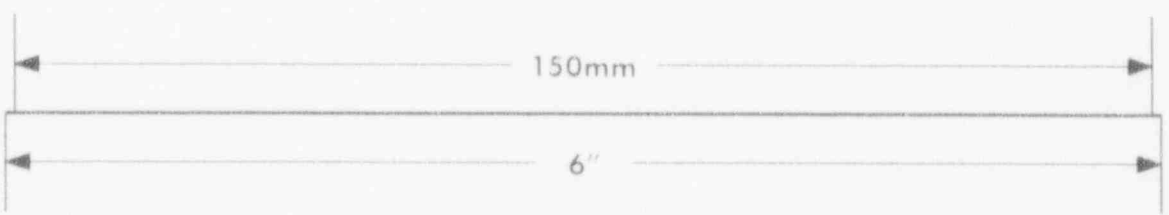
2

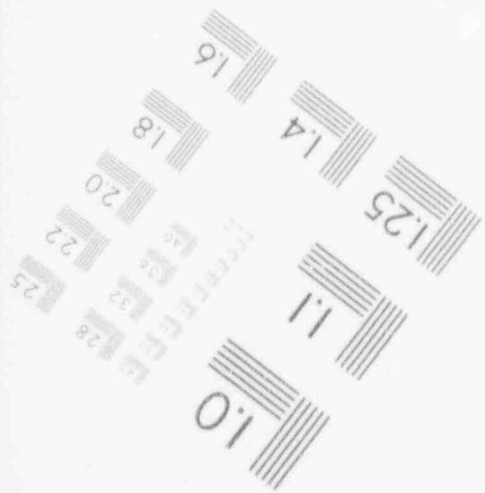
IMAGE EVALUATION TEST TARGET (MT-3)

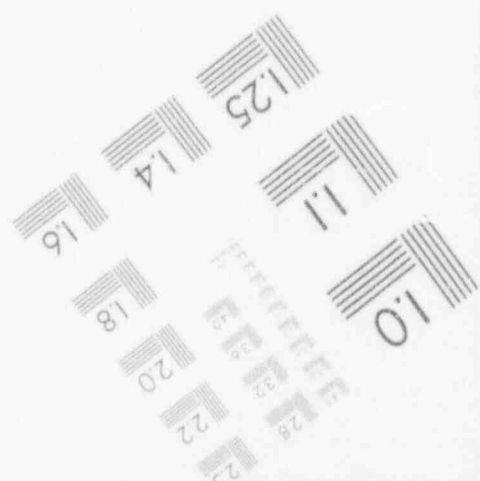












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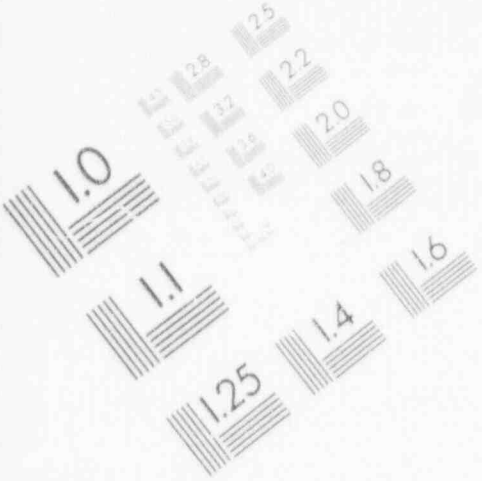
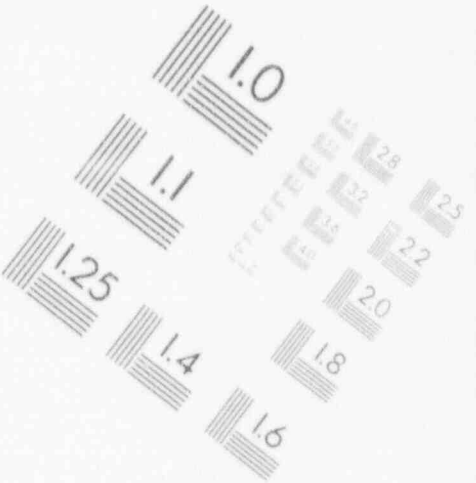
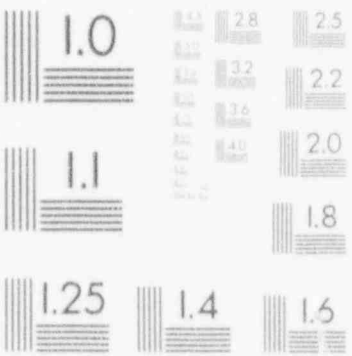
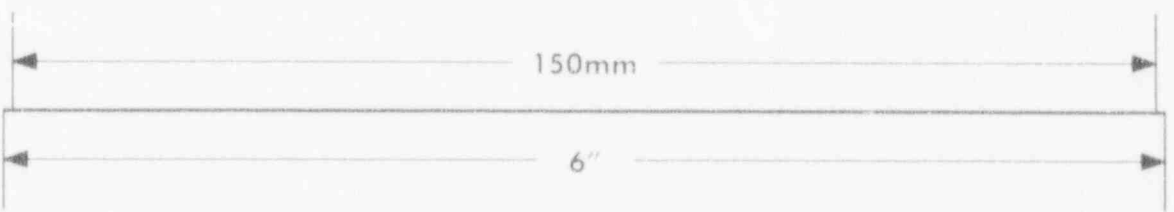
2

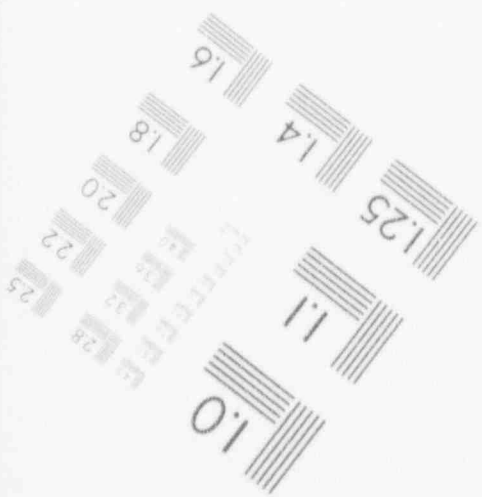
IMAGE EVALUATION TEST TARGET (MT-3)

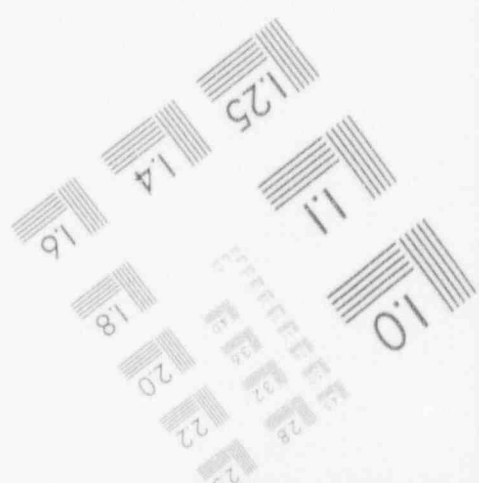












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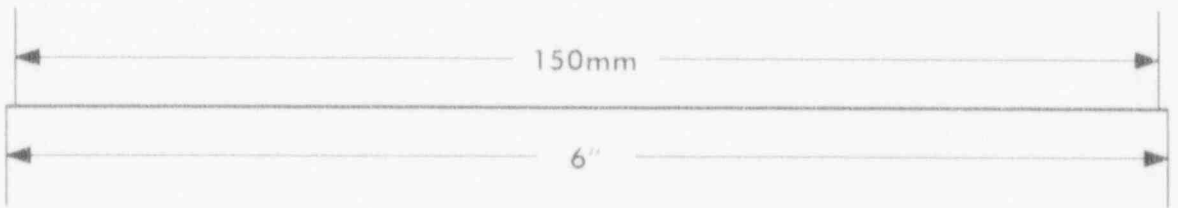
2

IMAGE EVALUATION TEST TARGET (MT-3)



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APPENDIX
EVALUATION AND CONCLUSIONS

On March 10, 1993, a Notice of Violation and Proposed Imposition of Civil Penalty (Notice) was issued for violations identified during an NRC inspection on November 17, 1992, at Community Hospital South, Indianapolis, Indiana (Licensee). Community Hospital South responded to the Notice by letter dated April 5, 1993. In its response, the Licensee denied Violations I and K, admitted Violations N and S with mitigating circumstances, and admitted the remaining violations. In addition, the Licensee believes the NRC's assessment of the civil penalty adjustment factors was based on incorrect information. The Licensee disagreed with the NRC position (set forth in the March 10, 1993, letter transmitting the Notice) on escalating the amount of the base civil penalty for identification (50 percent) and for prior opportunity to identify (100 percent). The Licensee states that extenuating circumstances exist. Further, the Licensee requested remission of the civil penalty because of prior good performance. The NRC's evaluation and conclusions regarding the Licensee's request are as follows:

I. Violations Assessed Civil Penalties

A. Restatement of Violation I.

10 CFR 35.22(b)(6) requires that, to oversee the use of licensed material, the Radiation Safety Committee must review annually, with the assistance of the Radiation Safety Officer, the licensee's radiation safety program.

Contrary to the above, from about February 15, 1990, to November 17, 1992, the licensee, through its Radiation Safety Committee, did not review, with the assistance of the Radiation Safety Officer, the licensee's radiation safety program annually.

Restatement of Licensee's Response to Violation I.

The annual review of the operations was performed. The personnel exposure assays and the consulting physicist/lab reviews were reviewed at every meeting. The construction of the report was delegated by the Radiation Safety Officer to the Consultant.

NRC's Evaluation of Licensee's Response to Violation I.

The Licensee's response refers to certain activities that were reviewed at each Radiation Safety Committee meeting. However, review of these activities does not constitute an "annual review of the radiation safety program." 10 CFR 35.22(b)(6) distinguishes the annual review of the radiation safety program from the other

reviews delineated in 10 CFR 35.22(b)(1) through 35.22(b)(5). Several of the required reviews are part of the routine business of the Radiation Safety Committee (e.g. recommendations for maintaining individual and collective doses as low as reasonably achievable (10 CFR 35.22(b)(1)), approval of specified individuals (10 CFR 35.22(b)(2)), and approval of minor changes in radiation safety procedures (10 CFR 35.22(b)(3))). Other reviews are required at quarterly intervals (e.g. a review of a summary of the occupational radiation dose records (10 CFR 35.22(b)(4)), and a review of all incidents involving byproduct material (10 CFR 35.22(b)(5))). However, in addition to these reviews, the Radiation Safety Committee is also required by 35.22(b)(6) to review the radiation safety program annually.

The annual review of the Licensee's radiation safety program by the Radiation Safety Committee is described in Regulatory Guide 10.8, Appendix F, "Model Radiation Safety Committee Charter and Radiation Safety Officer Delegation of Authority." The Licensee committed to Appendix F in Section 10.1 of the application dated February 29, 1988. Additionally, Appendix F is referenced in Condition 15.A of the NRC License. Responsibility No. 7 of Appendix F of Regulatory Guide 10.8 indicates that, "The Committee shall...review at least annually the RSO's summary report of the entire radiation safety program to determine that all activities are being conducted safely, in accordance with NRC regulations and the conditions of the license, and consistent with the ALARA program and philosophy. The review must include an examination of records, reports from the RSO, results of NRC inspections, written safety procedures, and the adequacy of the management control system."

The Licensee's response does not indicate that the Committee reviewed the RSO's summary report of the entire radiation safety program to determine that all activities were being conducted safely and in accordance with NRC regulations and the conditions of the license and the ALARA program and philosophy. The Licensee's response also does not indicate that the Radiation Safety Committee made a determination of the adequacy of the radiation safety program on an annual basis.

All of the reviews required by 10 CFR 35.22(b) are conducted for the purpose of maintaining individual and collective occupational doses as low as reasonably

achievable (ALARA). To oversee the use of licensed material, the Committee must complete each of these six reviews at the times and occasions indicated by 10 CFR 35.22(b). If the Committee does not complete each of these six reviews, then the Committee has failed to oversee the use of licensed material. Conducting the other reviews required by 10 CFR 35.22(b)(1) through 35.22(b)(5) does not substitute for the annual review required by 10 CFR 35.22(b)(6).

The Licensee's response indicated that the RSO delegated many of the RSO's regulatory responsibilities to the consultant, including documenting the Radiation Safety Committee's annual review. NRC Information Notice No. 90-71, "Effective Use of Radiation Safety Committees to Exercise Control Over Medical Use Programs," describes the responsibilities of the Radiation Safety Committee that includes the annual review of the radiation safety program, responsibilities of the RSO, and use of consultants. If the Radiation Safety Committee does not possess the necessary experience or training to perform the required annual review, then the Licensee may seek qualified assistance from outside consultants. However, it is the Licensee's responsibility to ensure that the review, even if performed by a consultant, and corrective actions meet the regulatory requirements.

Conclusion

The NRC has concluded that the information provided in the Licensee's response does not provide a basis to find that the annual review was performed as required; therefore, the violation occurred as stated.

B. Restatement of Violation K.

10 CFR 35.220 requires that a Licensee authorized to use byproduct material for imaging and localization studies possess a portable radiation detection survey instrument capable of detecting dose rates over the range of 0.1 millirem per hour to 100 millirem per hour, and a portable radiation measurement survey instrument capable of measuring dose rates over the range 1 millirem per hour to 1000 millirem per hour.

Contrary to the above, as of November 17, 1992, the licensee did not possess a portable radiation detection survey instrument capable of detecting dose rates over the range of 0.1 millirem per hour to 100 millirem per hour.

Restatement of Licensee's Response to Violation K.

The survey instruments possessed did not meet the intent of 10 CFR 35.220. The instruments, Victoreen CDV-700 and Victoreen 740F, were identified in various communications with the NRC. Because the range was covered and the NRC had approved amendments listing those instruments, the Licensee stated it believed it was in full compliance.

However, the Licensee stated that immediately following the November 17 inspection, it obtained a survey meter from Community Hospital East that covered the range up to 100 millirem per hour. It also purchased a Ludlum Model 14-C that covered the required range. This instrument had been budgeted for prior to the site survey and was received, calibrated and placed into service on December 12, 1992.

NRC's Evaluation of Licensee's Response to Violation K.

The Licensee admits that the survey instruments described in its written correspondence with the NRC did not meet the intent of 10 CFR 35.220. In addition, that correspondence (including the Licensee's renewal application of February 29, 1988) merely lists the survey instruments as "additional equipment" and does not request the staff to approve them for any particular purpose. In reviewing the license, the staff did not approve the instruments as satisfying the requirements of 10 CFR 35.220. Regardless of the Licensee's renewal application submitted to the NRC (dated February 29, 1988) and its assertion of tacit approval of the instrumentation in its possession at the time of submission of the license renewal, 10 CFR 35.999 (effective April 1, 1987) provides, in part, that at the time of license renewal and thereafter the amendments to 10 CFR Part 35 shall apply. Therefore, effective April 1, 1987, the Licensee was required to comply with any new requirements found in amended 10 CFR Part 35, in addition to the conditions of the existing license. 10 CFR 35.220 (effective April 1, 1987) required that the Licensee possess a portable radiation detection survey instrument capable of detecting dose rates over the range of 0.1 millirem per hour to 100 millirem per hour. The detection survey instrument possessed by the Licensee at the time of the inspection on November 17, 1992, was only capable of measuring dose rates over the range 0.1 millirem per hour to 50 millirems per hour.

The NRC notes that prior to the NRC inspection, the Licensee had budgeted for the purchase of a portable radiation detection survey instrument capable of detecting dose rates over the range of 0.1 millirem per hour to 100 millirem per hour; however, the Licensee had delayed that purchase for almost one year. The violation was identified by the Licensee's consultant (as described below). Therefore, once the Licensee identified the problem, the Licensee should have corrected the problem by obtaining the instrument on a timely basis. Further, the inspector found it necessary on several occasions during the inspection to remind the Licensee to obtain the required instrumentation. During the inspection, the Licensee borrowed an appropriate survey instrument until one could be purchased.

Conclusion

The NRC has concluded that the information provided in the Licensee's response does not provide a basis to find that the Licensee possessed the required survey instrumentation; therefore, the violation occurred as stated.

C. Restatement of Violation N.

10 CFR 35.50(e) requires, in part, that a licensee retain records of dose calibrator tests for accuracy, linearity and geometrical dependence and the records must include the signature of the Radiation Safety Officer.

Contrary to the above, from about February 17, 1989, to November 17, 1992, the licensee's records of dose calibrator tests for accuracy, linearity and geometrical dependence did not include the signature of the Radiation Safety Officer.

Restatement of Licensee's Response to Violation N.

Violation admitted with mitigating circumstances. The tests were performed and the results were reviewed by the Radiation Safety Committee. The consulting physicist was authorized by the Radiation Safety Officer to perform the review.

NRC's Evaluation of Licensee's Response to Violation N.

The Licensee admitted the violation because the Radiation Safety Officer did not sign the records of

dose calibrator quality assurance tests. The NRC recognizes the Radiation Safety Officer as the individual who is responsible for ensuring the safe use of licensed material for the institution. Although certain tasks may be delegated, the Radiation Safety Officer may not delegate responsibility for certain matters specifically assigned by regulation (including the obligation to sign records imposed by 10 CFR 35.50(e)) to another individual. The signature of the Radiation Safety Officer is an indication of acknowledgement of the test results on behalf of the Licensee. Lack of the Radiation Safety Officer's signature is an indication that dose calibrator quality assurance test results were not directly within the knowledge of the Licensee.

Conclusion

The NRC has concluded that the information provided in the Licensee's response does not provide a basis to find that the Radiation Safety Officer signed the records as required; therefore, the violation occurred as stated.

D. Restatement of Violation 5.

10 CFR 35.70(h) requires, in part, that a licensee retain records of each contamination survey required by 10 CFR 35.70. The records must include, in part, the removable contamination in each area expressed in disintegrations per minute per 100 square centimeters.

Contrary to the above, from January 2, 1992 to November 17, 1992, the licensee failed to retain records of surveys required by 10 CFR 35.70 that included the removable contamination in each area expressed in disintegrations per minute per 100 square centimeters. Specifically, removable contamination was expressed in counts per minute.

Restatement of Licensee's Response to Violation 5.

The Licensee admitted the violation with mitigating circumstances. The counting efficiency of the Licensee's well counter had been determined and trigger levels established. However, the data from the well counter was stored as counts per minute (cpm) on the well counter tape.

NRC's Evaluation of Licensee's Response to Violation S.

Notwithstanding the Licensee's description of its method of counting samples and the form in which the data were recorded, the Licensee did not deny that the data in the records were in incorrect units. In summary, the Licensee admitted the violation.

Conclusion

The NRC has concluded that the information provided in the Licensee's response does not provide a basis to find that it recorded removable contamination results in disintegrations per minute per 100 square centimeters; therefore, the violation occurred as stated.

E. NRC Withdrawal of Violations M, O, and P.

Violation M was for the Licensee's failure to test a sealed source containing 224 microcuries of cesium-137 for leakage at required six month intervals, with no other interval approved by the Commission or an Agreement State. This failure also resulted in Violation O and P because the Licensee had no records of leakage test results and physical inventories containing the signature of the Radiation Safety Officer.

The Licensee stated that at the time of the last NRC inspection on February 16, 1989, the inspector advised it to discontinue doing leak tests on its source because the activity level was below the requirement. This was questioned by the physicist and documented in the Radiation Safety Committee meeting minutes. However, the Licensee stopped doing leak tests on this source based on this advice, and discontinued the preparation of any records for those tests.

Although the Licensee unconditionally admitted Violation M and O, the staff has considered the Licensee's claim that an NRC inspector had advised the Licensee that leak tests were not necessary. Additionally, the staff has reviewed the Licensee's contention that the physical inventory was not signed by the Radiation Safety Officer because the source was below the activity that required a leak test. The staff did provide such advice for leak tests during the February 16, 1989, inspection. In view of that advice, which was erroneous because 10 CFR 35.59(b)(2) was in effect at the time of that inspection, the Licensee

discontinued the leak test of its sealed source and preparation of records for those tests as required by 10 CFR 35.59(d). Additionally, the Licensee's Radiation Safety Officer discontinued signing records of physical inventories for this source as required by 10 CFR 35.59(g). While it appears that the Licensee was in violation of 10 CFR 35.59(b)(2) and 35.59(d) from January 17, 1991 through November 17, 1992, and 10 CFR 35.59(g) from February 17, 1989 through November 17, 1992, the Licensee did act in good faith based upon the advice of an NRC inspector.

Subsequent to the inspection, the NRC inspector was in contact with the Licensee's consulting medical physicist. The consultant performed the required leak test and removable radioactivity was not detected. However, the record of that leak test was not signed by the Licensee's Radiation Safety Officer because he had delegated to the consulting medical physicist the authority to sign that record. As stated above with reference to records of dose calibrator tests, the Radiation Safety Officer cannot delegate such authority.

Conclusion

The evidence supports the Licensee's position that during a February 16, 1989, inspection, the NRC inspector provided erroneous advice and the Licensee in good faith discontinued performing the leakage test for its sealed source and preparation of records for those tests. Additionally, the Licensee's Radiation Safety Officer discontinued signing records of leak tests and physical inventories. Therefore, in the staff's discretion, Violations M, O, and P are withdrawn. However, as explained in Section II below, this does not affect either the scope of the Severity Level III problem or the amount of the civil monetary penalty assessed to the problem.

II. Summary of Licensee's Request for Mitigation

The Licensee requests remission of the proposed civil penalty because according to the Licensee, the asserted bases for the increase of the base civil penalty are factually incorrect and extenuating circumstances exist. Acknowledging that violations did occur, the Licensee asserts that it was acting to perform the duties, in substance, expected of it. The Licensee also asserts that it acted promptly to correct the violations.

The Licensee states that it is not fair or desirable to penalize the hospital under the civil penalty adjustment factors of Identification and Prior Opportunity to Identify. The Licensee contends that the NRC inappropriately escalated the civil penalty because not all of the violations were identified by the NRC, the Licensee took corrective action, and the Licensee's medical physicist diligently reviewed and reported on compliance matters. Therefore, any increase in the amount of the civil penalty would discourage a licensee from finding and correcting issues and would be in direct opposition to the NRC's enforcement philosophy of encouraging licensees to identify issues.

The Licensee argues that in most instances, the goals of the NRC's regulations have been accomplished and that the hospital and its employees, especially the consulting physicist, have acted responsibly. The Licensee states that in a few instances there was ignorance of the requirement; however, in most circumstances there was a genuine effort to comply. Therefore, as a result of positive licensee performance, the Licensee requests mitigation by at least 50 percent and as much as 100 percent of the base civil penalty.

The Licensee opposes the 25 percent escalation based on the Corrective Action factor. The Licensee argues that xenon-133 procedures were immediately terminated when the Licensee was informed by the NRC inspector on November 17, 1992, of the apparent violation. Additionally, the Licensee believes that the promptness with which it corrected all the violations that involved use of radioactive materials should be considered a mitigating factor. Therefore, as a result of prompt and immediate corrective action, the Licensee requests the base civil penalty be reduced by 50 percent . Additionally, the Licensee took exception to a statement in NRC's letter of March 10, 1993, transmitting the Notice of Violation and Proposed Imposition of Civil Penalty that the proposed corrective actions did not include measures to ensure management involvement in radiation safety.

In conclusion, the Licensee states that mitigation of 100 percent of the civil penalty amount is justified as a result of reducing the base civil penalty by 50 percent under licensee performance and 50 percent under corrective action.

NRC Evaluation of Licensee's Request for Mitigation

The Licensee is correct that the NRC Enforcement Policy (Policy) encourages licensees to monitor, supervise and audit activities in order to assure safety and compliance. However, this is only one goal of the Policy. The purpose

of the Policy is to ensure compliance, obtain prompt correction of violations, deter future violations and encourage improvement in the performance of a licensee.

The findings of the November 17, 1992, inspection and the discussions with the Licensee's representatives during the February 18, 1993, enforcement conference clearly indicated that the Licensee's Radiation Safety Officer (RSO) was not ensuring that radiation safety activities were performed in accordance with approved procedures and regulatory requirements in the daily operation of the Licensee's byproduct material program, as required by 10 CFR 35.21(a). This was clearly the root cause of all the violations.

Furthermore, the RSO permitted the consulting medical physicist to assume his (the RSO's) duties. The Licensee is still responsible for the radiation safety program, as required by the license, if the licensee employs a consultant to assist the RSO. In this instance, the consulting medical physicist identified some violations in the radiation safety program and communicated those violations to Licensee management; however, few if any corrective actions were initiated by the RSO or Licensee management. The fact that previously identified violations went uncorrected demonstrates the lack of managerial attention to radiation safety; and, in the aggregate, the violations represent a significant breakdown in the control of NRC licensed activities at Community Hospital South. Therefore, the violations were appropriately categorized as a Severity Level III problem in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy) 10 CFR Part 2, Appendix C. The staff's withdrawal of Violations M, O, and P does not negate the above facts or conclusions. Accordingly, the remaining violations represent a Severity Level III problem, and the staff's withdrawal of Violations M, O, and P is not a basis for reduction of the proposed civil penalty.

The Licensee contends that the NRC was inconsistent in applying the civil penalty adjustment factors and the Licensee was penalized because the consulting medical physicist diligently reviewed and reported on compliance matters. However, while the consulting medical physicist identified four violations to management, Licensee management was unresponsive and permitted these four violations to continue uncorrected.

The Licensee believes that it should receive credit for the findings of the consultant medical physicist and that, therefore, the civil penalty adjustment factors of Identification and Prior Opportunity to Identify were

misapplied. The NRC disagrees that the Identification factor was misapplied. The Licensee is correct that the cover letter enclosing the Notice of Violation and Proposed Imposition of Civil Penalty incorrectly states that the NRC identified all the violations. In escalating the base civil penalty by 50 percent under the Identification factor, the NRC recognizes that the Licensee's consultant identified four of the violations prior to the NRC inspection (i.e. Radiation Safety Committee did not meet quarterly, ventilation rates were not measured in rooms of xenon-133 usage, need for proper survey instrumentation, and the lack of annual refresher training for ancillary personnel). However, the remaining 13 of the 17 violations (not counting Violations M, O, and P) were identified by the NRC. The NRC Enforcement Policy states, in part, "The purposes of this [Identification] factor is to encourage licensees to monitor, supervise, and audit activities in order to assure safety and compliance." NRC expects licensees to be pro-active in auditing their programs and instituting corrective action when violations are identified. In this case, the NRC identified the majority of the violations as a result of the Licensee's failure to effectively audit their program. Accordingly, 50 percent mitigation under the Identification factor is warranted.

In escalating the base civil penalty by 100 percent under the Prior Opportunity to Identify factor, the NRC considered the fact that the Licensee's consulting medical physicist provided periodic written reports to management that addressed four of the violations; however, management did not correct two of those violations (i.e. ventilation rates were not measured in rooms of xenon-133 usage, and the need for proper survey instrumentation). Additionally, Licensee management failed to plan and take effective corrective steps to correct the remaining violations (i.e. Radiation Safety Committee did not meet quarterly and the lack of annual refresher training for ancillary personnel) within a reasonable time after identification. Moreover, the NRC issued a Notice of Violation to the Licensee dated February 16, 1989, identifying five violations. Two of the violations (i.e. annual refresher training for ancillary personnel was not conducted, and ventilation rates were not measured in rooms of xenon-133 usage) were repeat violations identified during the November 17, 1992, inspection. The License should have identified these violations sooner as a result of the consultant's audit findings, and taken effective and lasting corrective steps within a reasonable time. Therefore, the Licensee had prior opportunity to identify and correct violations which, in part, contributed to the breakdown in the control of licensed activities and represent a lack of attention or carelessness toward

licensed responsibilities. However, since you only had a prior opportunity to identify some of the violations contributing to the breakdown in control of your program, the NRC staff has reconsidered its position and finds that, on balance, escalation of 50 percent, as opposed to 100 percent, is appropriate based on the Prior Opportunity to Identify factor.

The Licensee argues that escalation of the base civil penalty by 25 percent for corrective action is not appropriate since the example cited in the Notice describing the continued use of xenon-133 and the failure to perform room ventilation studies is incorrect. The NRC acknowledges that the Licensee discontinued performing xenon-133 studies in the unauthorized location ("Raytheon Room") upon identification of the violation by the NRC. On November 17, 1992, the Licensee changed locations where xenon-133 was administered and resumed the use of xenon-133 for patient studies in the original authorized location (Room 1). However, the Licensee failed to resume the performance of measurements of ventilation rates in Room 1 until February 1993. Therefore, the same violation for failure to perform measurements of ventilation rates continued in Room 1 after NRC identification of the initial problem in the "Raytheon Room". Additionally, the Licensee did not take immediate actions upon discovery of other violations (i.e., need for proper survey instrumentation and the lack of annual refresher training for ancillary personnel) to restore safety and compliance with the requirements. Once the consultant identified the failure to possess proper survey instrumentation, the Licensee did not purchase the instrumentation for almost a year. In addition, up to the time of the enforcement conference, the annual refresher training for ancillary personnel had not been conducted. In regards to these violations, the Licensee did not take prompt, extensive, or lasting corrective action upon their discovery to restore safety and compliance.

Addressing the Licensee's request for mitigation up to 100 percent for good past performance, the NRC Enforcement Policy provides in pertinent part, "License Performance .... Notwithstanding good performance, mitigation of the civil penalty based on this factor is not normally warranted where the current violation reflects a substantial decline in performance that has occurred over the time since the last NRC inspection ...." Even if the Licensee's past performance had been good, this guidance negates the Licensee's request for mitigation. Moreover, the Licensee's past performance has not been good such as to warrant mitigation under this factor. Five violations were identified during the last inspection on February 16, 1989.

Two of those violations had not been corrected at the time of the November 17, 1992, inspection. Those violations were: (1) annual refresher training was not conducted for employees involved with radiation safety; and (2) ventilation rates in rooms where xenon-133 was used were not done at six month intervals. Furthermore, the corrective action for a third violation from the February 16, 1989, inspection was not effective. While the Licensee did appoint a nursing representative to serve on the Radiation Safety Committee, the Licensee did not ensure the attendance of that person. As a result, the nursing representative did not attend any meetings of the Radiation Safety Committee following the appointment. Therefore, no mitigation for good past performance is warranted.

Conclusion on Mitigation

The NRC staff has concluded that the information provided in the Licensee's response provides an adequate basis for partial mitigation of the civil penalty. Accordingly, a reduction of the civil penalty in the amount of $1,250 is warranted.

III. NRC Conclusion

The information provided by the Licensee in its Reply and Answer to a Notice of Violation, dated April 5, 1993, described extenuating circumstances for Violations M, O, and P contending that an NRC inspector told the Licensee to discontinue the activities associated with those violations. Such advice was provided to the Licensee regarding Violations M and O. The information provided was erroneous, but the Licensee apparently acted in good faith and discontinued the regulatory actions associated with Violations M, O, and P. Consequently, Violations M, O, and P have been withdrawn. As explained above, withdrawal of Violations M, O, and P does not affect the overall Severity Level III problem associated with the breakdown of the management oversight of licensed activities. However, based on reconsideration of the factor for Prior Opportunity to Identify, a reduction of $1,250 in the amount of the proposed civil penalty is warranted.

In summary, the Licensee's Reply and Answer to a Notice of Violation, including the extenuating circumstances surrounding Violations M, O, and P, did not provide an adequate basis for reduction of the severity level. However, a reduction of $1,250 in amount of the proposed civil penalty is warranted. Consequently, a civil penalty in the amount of $5,625 should be imposed.

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PENNSYLVANIA 19406-1415

SEP 17 1992

Docket No. 030-05373
License Nos. 29-09814-01
EA 92-136

Mr. H. J. Soni, President
Eastern Testing and Inspection, Inc.
139 Crown Point Road
Thorofare, New Jersey 08086

Dear Mr. Soni:

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY - $7,500 (NRC Inspection Report No. 030-05373/92-001)

This letter refers to the NRC inspection conducted on June 17, and July 7 and 8, 1992, at the above address in Thorofare, New Jersey, and at a field site in Carney's Point, New Jersey, of activities authorized by the NRC License No. 29-09814-01. The inspection report was sent to you on July 28, 1992. During the inspection, nine apparent violations of NRC requirements were identified. On August 6, 1992, an enforcement conference was conducted with you and Mr. J. Badiali of your staff to discuss the apparent violations, their causes and your corrective action. Based upon the discussions at the enforcement conference, one of the apparent violations, involving the failure to control access to a potential high radiation area, has been changed to a failure to post the area with signs during radiographic operations. A copy of the enforcement conference report was sent to you on August 14, 1992.

The violations are described in the enclosed Notice of Violation and Proposed Imposition of Civil Penalty. The violations consist of the failures to: (1) perform audits at the required quarterly frequency for three of the five individuals authorized to perform radiography (one of the individuals had, in fact, never been audited, and another individual had not been audited since March 1991); (2) calibrate pocket dosimeters and alarm rate meters at intervals not to exceed one year, as required; (3) update the Operating and Emergency Procedure Manual to provide instructions concerning the use of the alarm ratemeters; (4) post a high radiation area that existed above the side walls of the permanent radiographic cell at the Thorofare facility; (5) survey the entire circumference of an iridium-192 exposure device after each exposure while it was being used at the field site in Carney's Point; (6) properly block and brace radiographic exposure devices while in transport to and from field sites; (7) register with the NRC as a user of an NRC approved package; and (8) transport a cobalt-60 exposure device, when you moved from your previous facility in Pennsauken, New Jersey, to Thorofare in 1989, in a package approved by the DOT or the NRC.

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

The NRC is concerned with the nature and number of these violations, particularly given the fact that the Radiation Safety Officer (RSO) at the facility was aware of the actions needed to ensure compliance with requirements, but did not take those necessary actions in a timely manner. For example, with respect to the violations involving the failure to calibrate the pocket dosimeters, the failure to audit radiographers at the required frequency, and the failure to brace materials while in transport, the RSO indicated that he understood the need for action to comply with the requirements, but just did not get to completing those actions. Further, with respect to the violation involving the movement of a radiographic device in an unauthorized container, the RSO indicated that he understood the requirement for an approved container, but believed that the container fabricated for the transport was safe enough. These failures to ensure that the licensed activities were conducted in accordance with NRC requirements constitute careless disregard on the part of the RSO and therefore are considered willful within the context of the NRC enforcement policy.

The NRC license issued to Eastern Testing and Inspection Inc. entrusts responsibility for radiation safety to the management of the company, including the RSO; therefore, the NRC expects effective oversight and implementation of its licensed programs by both management and the RSO. Incumbent upon each NRC licensee is the responsibility of management in general, and the RSO in particular, to protect the public health and safety by ensuring that all requirements of the NRC license are met and any potential violations of NRC requirements are identified and expeditiously corrected. Given the number and the nature of the violations, the fact that some of them involved multiple examples over an extended duration, the careless disregard by the RSO in not ensuring the required actions were taken in a timely manner, and management's failure to identify and correct these problems, the violations are classified in the aggregate as a Severity Level III problem in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C (Enforcement Policy).

The NRC recognizes that subsequent to this recent inspection, actions were taken or planned to correct the violations and effect improvements in the control and implementation of the radiation safety program. These actions, which were described at the enforcement conference, included: (1) correction of the audit and calibration violations prior to any further conduct of radiography; (2) submittal of operating manual changes and personnel training to resolve the survey and procedure violations; (3) registering as a user of NRC-approved transportation containers; and (4) verbal commitment by you, as the President of Eastern Testing and Inspection, to back up the RSO in ensuring that regulatory requirements are implemented.

Notwithstanding those actions, the NRC remains concerned that while the radiation safety program improved following the NRC issuance of a civil penalty in 1987 for other violations of NRC requirements, these recent findings indicate that once again there has been a significant deterioration in the attention to, and oversight of, your radiation safety program. Therefore, to emphasize the importance of adequate attention to, and oversight of, the radiation safety program, so as to ensure that (1) licensed activities are conducted safely and in accordance with requirements, and (2) violations, when they exist, are promptly identified and corrected, I have been authorized, in consultation with the Director, Office of Enforcement, to issue the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice) in the amount of $7,500 for the Severity Level III problem set forth in the enclosed Notice.

The base civil penalty amount for a Severity Level III problem is $5,000. The escalation and mitigation factors set forth in the enforcement policy were considered, and on balance, a 50% increase of the base civil penalty amount was deemed appropriate because: (1) the violations were identified by the NRC, and therefore, 50 percent escalation of the base civil penalty on this factor is warranted; (2) your corrective actions, as described herein, although acceptable, do not warrant any mitigation of the civil penalty in that the actions were, in part, initiated in response to an NRC Confirmatory Action Letter issued on June 18, 1992, and your actions to prevent recurrence are not viewed as extensive in that your reliance on the presence and recollection of program managers to assure timely implementation of required activities is not consistent with the programmatic controls routinely administered within the radiography industry; and (3) although your past performance includes a total of four minor violations being identified during the last two NRC inspections in 1991 and 1990, no mitigation of the base civil penalty on this factor is warranted since the current violations reflect a decline in performance that has occurred over the time since the last NRC inspection. The other escalation/mitigation factors were considered and no further adjustment was warranted.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. In your response, you should document the specific actions taken and any additional actions you plan to prevent recurrence. In addition, you are hereby required pursuant to Sections 161c, 182, and 186 of the Atomic Energy Act of 1954, as amended, 10 C.F.R. 2.204 and 10 C.F.R. 30.32(b), to provide in writing, under oath or affirmation, a statement as to your basis for your having assurance that those individuals responsible for the violations described in the Notice will comply with NRC requirements in the future.

Finally, we note that an Order was issued to Eastern Testing and Inspection on August 31, 1992, for failure to pay an annual fee. If you decide not to request a hearing or pay the annual license fee and therefore consent to have your license terminated, your response may include a statement as to why this civil penalty should not be imposed.

After reviewing your response to this Notice, including your proposed corrective actions, and the results of future inspections, the NRC will determine whether further enforcement action is necessary to ensure compliance with NRC regulatory requirements.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter and the enclosures will be placed in the NRC Public Document Room.

The responses directed by this letter and the enclosed Notice are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, Pub. L. 96-511.

Sincerely,

Thomas T. Martin
Regional Administrator

Enclosure: Notice of Violation and Proposed Imposition of Civil Penalty

cc w/encl:
Public Document Room (PDR)
Nuclear Safety Information Center (NSIC)
State of New Jersey

ENCLOSURE

Notice of Violation
and
Proposed Imposition of Civil Penalty

Eastern Testing and Inspection, Inc.
Thorofare, New Jersey 08086

Docket No. 030-05373
License No. 29-09814-01
EA 92-136

During an NRC inspection conducted on June 17, and July 7-8, 1992, violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C, the Nuclear Regulatory Commission proposes to impose a civil penalty pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (Act), 42 U.S.C. 2282, and 10 CFR 2.205. The particular violations and associated civil penalty are set forth below:

A. 10 CFR 34.43(b) requires that a physical radiation survey be made after each radiographic exposure to determine that the sealed source has been returned to its shielded position. The entire circumference of the radiographic exposure device must be surveyed.

Contrary to the above, on July 7, 1992, a survey performed by a radiographer employed by the licensee after a radiographic exposure at a field site located in Carney's Point New Jersey, did not include the entire circumference of the iridium-192 camera which contained a 10 curie sealed source. Specifically, the radiographer only surveyed the length of the guide tube up to the camera-guide tube connection. The radiographer also indicated that was his routine practice.

B. 10 CFR 34.33(c) requires that pocket dosimeters be checked at intervals not to exceed one year for correct response to radiation.

Contrary to the above, from April 1991 to June 17, 1992, an interval exceeding one year, pocket dosimeters used by the licensee's personnel who performed radiographic operations had not been checked for correct response to radiation.

C. 10 CFR 34.33(f)(4) requires that alarm ratemeters be calibrated at periods not to exceed one year for correct response to radiation.

Contrary to the above, from January 1991 to June 17, 1992, a period in excess on one year, alarm ratemeters used by the licensee's personnel who performed field radiographic operations had not been calibrated for correct response to radiation.

D. 10 CFR 34.32(e) requires that Operating and Emergency Procedures include instructions in personnel monitoring and the use of personnel monitoring equipment.

Contrary to the above, as of June 17, 1992, Operating and Emergency Procedures Manuals issued to the licensee's radiography personnel did not contain instructions with regard to the use of certain personnel monitoring equipment, namely, alarm ratemeters.

E. 10 CFR 34.11(d)(1) requires, in part, that an applicant have an inspection program that includes observation of the performance of each radiographer and radiographer's assistant during an actual radiographic operation at intervals not to exceed three months.

Condition 17 of License No. 29-09814-01 incorporates the inspection program containing requirements stated in 10 CFR 34.11(d)(1) as submitted in the licensee's letter, dated January 12, 1987, into License No. 29-09814-01. Section 4.b of the letter, dated January 12, 1987, requires that internal inspections on each individual involved in radiography activities be done on a quarterly basis.

Contrary to the above, as of June 17, 1992, the licensee's inspection program had not included the observation of the performance of certain radiography personnel at intervals not to exceed three months. Specifically, one radiographer had not been audited since January 20, 1992; another radiographer, the Company's Executive Vice President, had not been audited since March 15, 1991; and a third radiographer, the company's President, had never been audited.

F. 10 CFR 34.42 requires that, notwithstanding any provisions in 10 CFR 20.204(c), areas in which radiography is being performed must be conspicuously posted as required by 10 CFR 20.203(c)(1).

10 CFR 20.203(c)(1) requires that each high radiation area shall be conspicuously posted with a sign or signs bearing the radiation caution symbol and the words "CAUTION HIGH RADIATION AREA."

Contrary to the above, as of July 8, 1992, the licensee had not posted the area above its permanent radiography cell No. 2, in which industrial radiography was periodically performed, as a high radiation area, with the required signs.

G. 10 CFR 71.12 grants a general license to a Commission licensee for transport of radioactive material in NRC-approved packages provided that: (1) the licensee has a quality assurance program, whose description has been submitted to and approved by the Commission as satisfying the provisions of 10 CFR Part 71, subpart H; (2) the licensee has a copy of the certificate of compliance or other approval for the package; and (3) the shipper has registered in writing with the NRC as a user of the specific Department of Transportation (DOT) specification package.

Contrary to the above, the licensee admitted that it had transported a Gamma Industries Model Gammatron 200A exposure device, containing 53 curies of cobalt-60, but that as of June 17, 1992, the licensee did not have a current copy of the certificate of compliance or other approval for that device and had not registered with the NRC as a user of the DOT specification package used to transport greater than 7 curie quantities of cobalt-60 in a special form.

H. 10 CFR 71.5(a) requires, in part, that no licensee shall transport any licensed material outside the confines of its plant or other place of use, or deliver any licensed material to a carrier for transport, unless the licensee complies with applicable requirements of the regulations appropriate to the mode of transport of the Department of Transportation (DOT) in 49 CFR Parts 170-189.

1. 49 CFR 173.416 specifies, in part, the types of packages authorized for shipment of radioactive material in quantities exceeding the activity of special form radioactive material as listed in 49 CFR 173.435, and includes the requirement that the package or container be approved or authorized by the NRC or DOT.

   49 CFR 173.435 establishes this value to be 7 curies for cobalt-60 in special form (the maximum A_1 quantity).

   Contrary to the above, in or about November 1989, approximately 70 curies of cobalt-60 contained in a Technical Operations 500 exposure device (Serial No. 2198) was packaged by the licensee and shipped in a steel shipping container (not authorized by 49 CFR 173.416) and transported from Pennsauken, New Jersey to Thorofare, New Jersey, and that package (container) was not approved or authorized by the NRC or the DOT.

2. 49 CFR 177.842(d) requires that packages must be so blocked and braced that they cannot change position during conditions normally incident to transportation.

Contrary to the above, from March 1992 through June 17, 1992, the licensee's Type B transportation containers (containing Gamma Industries Model Gamma Century SA exposure devices loaded with iridium-192 sealed sources for transport to and from temporary job sites) had not been routinely blocked and braced so they could not change position during conditions normally incident to transportation.

These violations are classified in the aggregate as a Severity Level III problem (Supplement VI).

Civil Penalty - $7,500

Pursuant to the provisions of 10 CFR 2.201, Eastern Testing and Inspection, Inc. (Licensee) is hereby required to submit a written statement or explanation to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, within 30 days of the date of this Notice of Violation and Proposed Imposition of Civil Penalty (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each alleged violation: (1) admission or denial of the alleged violation, (2) the reasons for the violation if admitted, and if denied, the reasons why, (3) the corrective steps that have been taken and the results achieved, (4) the corrective steps that will be taken to avoid further violations, and (5) the date when full compliance will be achieved. If an adequate reply is not received within the time specified in this Notice, an order or a demand for information may be issued as to why the license should not be modified, suspended, or revoked or why such other action as may be proper should not be taken. Consideration may be given to extending the response time for good cause shown. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, this response shall be submitted under oath or affirmation.

Within the same time as provided for the response required above under 10 CFR 2.201, the Licensee may pay the civil penalty by letter addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, with a check, draft, money order, or electronic transfer payable to the Treasurer of the United States in the amount of the civil penalty proposed above, or may protest imposition of the civil penalty in whole or in part, by a written answer addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission. Should the Licensee fail to answer within the time specified, an order imposing the civil penalty will be issued. Should the Licensee elect to file an answer in accordance with 10 CFR 2.205 protesting the civil penalty, in whole or in part, such answer should be clearly marked as an "Answer to a Notice of Violation" and may: (1) deny the violation(s) listed in this Notice, in whole or in part, (2) demonstrate extenuating circumstances, (3) show error in this Notice, or (4) show other reasons why the penalty should not be imposed. In addition to protesting the civil penalty in whole or in part, such answer may request remission or mitigation of the penalty.

In requesting mitigation of the proposed penalty, the factors addressed in Section VI.B of 10 CFR Part 2, Appendix C (1992), should be addressed. Any written answer in accordance with 10 CFR 2.205 should be set forth separately from the statement or explanation in reply pursuant to 10 CFR 2.201, but may incorporate parts of the 10 CFR 2.201 reply by specific reference (e.g., citing page and paragraph numbers) to avoid repetition. The attention of the Licensee is directed to the other provisions of 10 CFR 2.205, regarding the procedure for imposing a civil penalty.

Upon failure to pay any civil penalty due which subsequently has been determined in accordance with the applicable provisions of 10 CFR 2.205, this matter may be referred to the Attorney General, and the penalty, unless compromised, remitted, or mitigated, may be collected by civil action pursuant to Section 234 of the Act, 42 U.S.C. 2282(c).

The response noted above (Reply to Notice of Violation, letter with payment of civil penalty, and Answer to a Notice of Violation) should be addressed to: Director, Office of Enforcement, U. S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555 with a copy to the Regional Administrator, U. S. Nuclear Regulatory Commission, Region I, 475 Allendale Road, King of Prussia, Pennsylvania 19406.

Dated at King of Prussia, Pennsylvania
this 17th day of September 1992

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

JAN 25 1993

Docket No. 030-05373
License Nos. 29-09814-01
EA 92-136

Mr. H. J. Soni, President
Eastern Testing and Inspection, Inc.
139 Crown Point Road
Thorofare, New Jersey 08086

Dear Mr. Soni:

SUBJECT: ORDER IMPOSING A CIVIL MONETARY PENALTY - $7,500
(Inspection Report No. 030-05373/92-001)

This refers to your two letters, dated October 16 and 26, 1992, respectively, in response to the Notice of Violation and Proposed Imposition of Civil Penalty (Notice) sent to you by the NRC letter, dated September 17, 1992. The NRC letter and Notice described nine violations identified at your facility and at a field site in Carney's Point, New Jersey, during an NRC inspection conducted on June 17, and July 7 and 8, 1992. To emphasize the importance of adequate attention to, and oversight of, the radiation safety program, so as to ensure that (1) licensed activities are conducted safely and in accordance with requirements, and (2) violations, when they exist, are promptly identified and corrected, a civil penalty in the amount of $7,500 was proposed.

In your response, you did not deny the violations set forth in the Notice, but you requested full mitigation of the civil penalty, for the reasons set forth in your response, as summarized in the Appendix to the enclosed Order. After consideration of your response, we have concluded, for the reasons given in the Appendix attached to the enclosed Order Imposing Civil Monetary Penalty, that an adequate basis was not provided for mitigation of the penalty. Accordingly, we hereby serve the enclosed Order on Eastern Testing and Inspection, Inc., imposing a civil monetary penalty in the amount of $7,500. We will review the effectiveness of your corrective actions during a subsequent inspection.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice", a copy of this letter and the enclosures will be placed in the NRC's Public Document Room.

Sincerely,

James Lieberman, Director
Office of Enforcement

Enclosures: As Stated

cc w/encls:
Public Document Room (PDR)
Nuclear Safety Information Center (NSIC)
State of New Jersey

UNITED STATES
NUCLEAR REGULATORY COMMISSION

In the Matter of	)	
	)	
EASTERN TESTING AND INSPECTION, INC.	)	Docket No. 030-05373
	)	License No. 29-09814-01
Thorofare, New Jersey	)	EA 92-136

ORDER IMPOSING CIVIL MONETARY PENALTY

I

Eastern Testing and Inspection, Inc. (Licensee) is the holder of Byproduct Material License No. 29-09814-01, issued by the Nuclear Regulatory Commission (NRC or Commission), which authorizes the Licensee to use byproduct materials for use in industrial radiography and replacement of sources in accordance with the conditions specified therein. The license was issued on February 2, 1964, was last renewed on February 20, 1987, and remains active under the timely renewal application submitted on February 3, 1992.

II

An inspection of the Licensee's activities was conducted on June 17, and July 7 and 8, 1992. The results of the inspection indicated that the Licensee had not conducted its activities in full compliance with NRC requirements. A written Notice of Violation and Proposed Imposition of Civil Penalty (Notice) was served upon the Licensee by letter dated September 17, 1992. The Notice stated the nature of the violations, the provisions of the NRC's requirements that the Licensee had violated, and the amount of the civil penalty proposed for the violations. The Licensee

responded to the Notice in two letters, dated October 16 and 26, 1992, respectively. In its responses, the Licensee did not deny the violations, but requested full mitigation of the civil penalty.

III

After consideration of the Licensee's responses and the statements of fact, explanation, and argument for mitigation contained therein, the NRC staff has determined, as set forth in the Appendix to this Order, that the violations occurred as stated and that the penalty proposed for the violations designated in the Notice should be imposed.

IV

In view of the foregoing, and pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (Act), 42 U.S.C. 2282, and 10 CFR 2.205, IT IS HEREBY ORDERED THAT:

The Licensee pay a civil penalty in the amount of $7,500 within 30 days of the date of this Order, by check, draft, money order, or electronic transfer, payable to the Treasurer of the United States and mailed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555.

V

The Licensee may request a hearing within 30 days of the date of this Order. A request for a hearing should be clearly marked as a "Request for an Enforcement Hearing" and shall be addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555. Copies also shall be sent to the Assistant General Counsel for Hearings and Enforcement at the same address and to the Regional Administrator, NRC Region I, 475 Allendale Road, King of Prussia, Pennsylvania 19406.

If a hearing is requested, the Commission will issue an Order designating the time and place of the hearing. If the Licensee fails to request a hearing within 30 days of the date of this Order, the provisions of this Order shall be final and effective without further proceedings. If payment has not been made by that time, the matter may be referred to the Attorney General for collection.

In the event the Licensee requests a hearing as provided above, the issues to be considered at such hearing shall be whether, on

the basis of the violations set forth in the Notice, this Order should be sustained.

FOR THE NUCLEAR REGULATORY COMMISSION

James Lieberman, Director
Office of Enforcement

Dated at Rockville, Maryland
this 25th day of January 1993

APPENDIX

EVALUATIONS AND CONCLUSION

On September 17, 1992, a Notice of Violation and Proposed Imposition of Civil Penalty (Notice) was issued for nine violations identified during an NRC inspection on June 17, and July 7 and 8, 1992 at the Eastern Testing and Inspection, Inc. (Licensee or ETI) facility in Thorofare, New Jersey, and at a field site in Carney's Point, New Jersey. The Licensee responded to the Notice in a reply dated October 16, 1992 and an answer dated October 26, 1992 (collectively "responses"). The Licensee did not deny the violations, but requested full mitigation of the civil penalty. The NRC's evaluations and conclusions regarding the Licensee's requests are as follows:

1. Summary of Licensee Answer

The Licensee, in its answer, requests remission/mitigation of the proposed imposition of penalties, claiming that there are areas where extenuating circumstances played a very relevant part in causing some of the violations. The Licensee states that it has a very good Radiation Safety Program, and has consistently had acceptable NRC inspections over many years. While the Licensee acknowledged the NRC concern over the violations, the Licensee contends that the NRC statement that the RSO and ETI management acted in careless disregard is totally unjustified. The Licensee states that attention to safety has always been extremely important to the RSO and ETI management.

The Licensee also states that it has been licensed since 1964, and has always endeavored to conduct activities in accordance with NRC regulations; does not have a history of disregard for public safety; and does not have a history of not calibrating instruments in a timely manner. The Licensee also claims that the open enforcement conference was extremely damaging to its reputation, in that it had numerous inquiries from customers questioning the safety program, and has lost a major customer, coincidentally, who also was concerned about the news releases. The Licensee also states that the NRC's decision to classify the violation in the aggregate at Severity Level III is extreme in that the Licensee does not feel it endangered public health and safety.

2. NRC Evaluation of Licensee Responses

The NRC has evaluated the licensee responses, and based upon that evaluation, the NRC has concluded that (1) some of the violations did occur as a result of careless disregard by the RSO; (2) the violations collectively did constitute a lack of management attention to, and control of, the radiation safety program, and were appropriately classified

in the aggregate at Severity Level III; and (3) the licensee did not provide an adequate basis for mitigation of the civil penalty.

With respect to the licensee contention that the violations did not involve careless disregard on the part of the RSO and ETI management, the NRC concluded that the RSO, and not ETI management, acted with careless disregard. As stated in the Notice, the RSO indicated at the enforcement conference that he understood the need for action to comply with the requirements, but just did not get around to completing those actions. Further, the RSO stated, with regard to the violation involving the movement of a radiographic device in an unauthorized container, that he understood the requirement for an authorized container, but believed that the container fabricated for transport was safe enough. Thus, the failures here to ensure that licensed activities were conducted in accordance with NRC requirements, when the RSO was fully aware of the NRC requirements, constitutes careless disregard on the part of the RSO and therefore are considered willful within the context of the NRC Enforcement Policy.

With respect to the licensee contention that the classification of violations at Severity Level III was extreme, and that such classification was inappropriate since they did not endanger the public health and safety, the NRC also disagrees with this licensee contention. A total of nine violations were identified during the inspection. Some of the violations involved multiple examples that existed over an extended duration which were not identified and corrected by management or the RSO. Some of the violations resulted from careless disregard on the part of the RSO, as already described herein. On this basis, the NRC concludes that the violations demonstrated a lack of adequate attention to, and oversight of, the Radiation Safety Program by management and the RSO, and, therefore, were appropriately classified in the aggregate at Severity Level III. This conclusion is consistent with NRC action taken in the past in cases similar to this one. Although there may not have been an actual endangerment of the public resulting from these violations, such violations can create the potential for unnecessary exposures to workers and members of the pub

The licensee contends that the NRC should mitigate the civil penalty on the basis that (1) the Severity Level III classification was inappropriate, and a lower severity level would not result in a civil penalty, and (2) it lost a major customer as a result of the enforcement conference. The NRC arrived at the proposed civil penalty by applying

escalation/mitigation factors as required by the NRC Enforcement Policy. The explanation of the bases for the civil penalty was described in the Notice. The licensee's bases for requesting mitigation in no way relate to or impact the application of the escalating/mitigating factors. Therefore, since the NRC maintains that the violations were appropriately classified at Severity Level III, as already described herein, the licensee argument does not provide a basis for mitigation of the civil penalty.

3. NRC Conclusion

The NRC concludes that the licensee has not provided an adequate basis for mitigation of the civil penalty. Consequently, the proposed civil penalty in the amount of $7,500 should be imposed.

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

JUN 24 1993

Docket No. 030-05373
License No. 29-09814-01
EA 92-136

Eastern Testing and Inspection, Inc.
ATTN: Mr. H. J. Soni, President
139 Crown Point Road
Thorofare, New Jersey 08086

Dear Mr. Soni:

SUBJECT: PROMISSORY NOTE IN PAYMENT OF CIVIL PENALTY (NOTE)

This is in reference to the June 22, 1993, telephone conversation between yourself, Messers D. Soni, J. Badiali, Eastern Testing and Inspection, Inc. (ETI), and Ms. P. Santiago and Mr. E. Holler, NRC concerning a proposed settlement of an Order Imposing a Civil Monetary Penalty dated January 25, 1993. On February 17, 1993, you requested a hearing. However, on March 16, 1993, you requested the hearing be placed in abeyance pending submittal of additional information.

As discussed with you during telephone conversations, June 17 and 22, 1993, the NRC staff reviewed the information and statements you submitted in your letters dated April 13, 1993, May 10, 1993, and June 15, 1993, regarding your ability to pay, financial status, impact of the enforcement action on your business, and other additional information you considered relevant to the Order Imposing a Civil Monetary Penalty - $7,500 issued January 25, 1993 to ETI. After consideration of your financial status, the NRC staff proposed that the $7,500 civil penalty be reduced to $5,000 and payment of the civil penalty be completed over a 5 year period. In addition, the NRC staff concluded that no additional basis was provided for further reduction of the penalty for the reasons given in the Appendix attached to the January 25, 1993 Order Imposing Civil Monetary Penalty.

During the telephone conversation on June 22, 1993, you indicated you did not want the NRC staff to proceed with your request for hearing and agreed to payment of a $5,000 civil penalty over time as proposed by the NRC staff based on consideration of your corporation's ability to pay. Therefore, I am enclosing a Note that you should sign and return in duplicate prior to July 1, 1993, to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Mail Stop 7H5, Washington, D. C. 20555. Following return of the signed Note, an Order confirming this action will be issued.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice", a copy of this letter will be placed in the NRC's Public Document Room.

If you have any questions, please contact Ms. Patricia A. Santiago at 301-504-2741.

Sincerely,

James Lieberman, Director
Office of Enforcement

Enclosure: As stated

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

JUL 13 1993

Docket No. 030-05373
License No. 29-09814-01
EA 92-136

Eastern Testing and Inspection, Inc.
ATTN: Mr. H. J. Soni, President
139 Crown Point Road
Thorofare, New Jersey 08086

Dear Mr. Soni:

SUBJECT: ORDER MODIFYING AN ORDER IMPOSING A CIVIL MONETARY PENALTY - $5,000 and PROMISSORY NOTE IN PAYMENT OF CIVIL PENALTY (NOTE)

This acknowledges receipt of the signed copy of the Promissory Note in Payment of the Civil Penalty (Note) dated June 29, 1993, in response to the NRC letter dated June 24, 1993. Based on the April 13, 1993 and May 10, 1993, financial information submitted by ETI, the NRC staff, as provided for in the NRC Enforcement Policy, 10 CFR Part 2, Appendix C, accepts payment of a reduced civil monetary penalty over time with interest in accordance with the payment schedule forwarded with the June 24, 1993 NRC letter. Accordingly, I hereby serve the enclosed Order Modifying an Order Imposing a Civil Monetary Penalty on Eastern Testing and Inspection, Inc. imposing a civil monetary penalty in the amount of $5,000, payable in accordance with the Note, for violations cited in the Notice of Violation and Proposed Imposition of Civil Penalty issued September 17, 1992, to ETI. A countersigned copy of the Note is also enclosed.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice", a copy of this letter and the enclosures will be placed in the NRC's Public Document Room.

Sincerely,

James Lieberman, Director
Office of Enforcement

Enclosures: As Stated

UNITED STATES
NUCLEAR REGULATORY COMMISSION

In the Matter of	)	
	)	
EASTERN TESTING and	)	Docket No. 030-05373
INSPECTION, INC.	)	License No. 29-09814-01
Thorofare, New Jersey	)	EA 92-136

ORDER MODIFYING ORDER IMPOSING CIVIL MONETARY PENALTY

I

Eastern Testing and Inspection, Inc. (Licensee) is the holder of Byproduct Material License No. 29-09814-01 issued by the Nuclear Regulatory Commission (NRC or Commission) which authorizes the Licensee to use byproduct materials for use in industrial radiography and replacement of sources in accordance with the conditions specified therein. The license was issued on February 2, 1964, was last renewed on February 20, 1987, and remains active under the timely renewal application submitted on February 3, 1992.

II

As a result of a June 17, and July 7 and 8, 1992, NRC inspection of the Licensee's activities, a written Notice of Violation and Proposed Imposition of Civil Penalty (Notice) in the amount of Seven Thousand Five Hundred Dollars was served upon the Licensee by NRC letter dated September 17, 1992. The Licensee responded to the Notice in two letters, dated October 16 and 26, 1992, respectively. In its response, the Licensee did not deny the violations, but requested full mitigation of the civil penalty.

After consideration of the Licensee's response and the statements of fact, explanation, and argument for mitigation contained therein, the NRC staff determined that the violations occurred as stated and that the penalty proposed for violation designated in the Notice should be imposed. Accordingly, NRC issued an Order Imposing a Civil Monetary Penalty to the licensee on January 25, 1993.

III

The licensee responded in a letter dated February 17, 1993 and requested a hearing. By letter dated March 17, 1993, the NRC confirmed a telephone conversation between Mr. H. J. Soni, Licensee President, and NRC representatives in which the Licensee requested delay in processing of its February 17, 1993 hearing request until after NRC reviewed additional information the Licensee was to submit for consideration. In correspondence dated April 13, 1993, May 10, 1993 and June 15, 1993, the Licensee submitted the additional information. These letters provided financial information to support the Licensee's assertion concerning its ability to pay, and additional information the Licensee considered relevant to the violations. During a June 22, 1993 telephone conversation between the NRC staff and Messrs. H. Soni, D. Soni, and J. Badiali, Esq., the NRC staff, as provided for in the NRC Enforcement Policy, proposed a $5,000 civil penalty based on the licensee's demonstrated

financial difficulty. The Licensee agreed to payment of the $5,000 penalty, with interest, over five years and indicated that it did not wish the NRC staff to proceed with the request for hearing. The Licensee signed a Promissory Note on June 29, 1993, for Payment of the Civil Penalty in response to an NRC letter dated June 24, 1993.

Upon review of the facts of this case, including the information submitted in the licensee's April 13, 1993, May 10, 1993, and June 15, 1993, letters, I find that the financial information provided on the Licensee's assertion of adverse financial impact and its ability to pay support a $2,500 reduction of the $7,500 civil penalty imposed in the January 25, 1993 Order. This is consistent with the NRC Enforcement Policy and, therefore, on July 12, 1993, I countersigned and, thereby, accepted the Promissory Note in payment for the Civil Monetary Penalty.

IV

In view of the foregoing, and pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (Act), 42 U.S.C. 2282, and 10 CFR 2.205, IT IS HEREBY ORDERED THAT:

The Order Imposing a Civil Monetary Penalty dated January 25, 1993, is modified to change Section IV as follows:

The Licensee pay a civil penalty of $5,000 in accordance with the procedures and payment installments provided in the attached Promissory Note executed by the Licensee's President on June 29, 1993, and countersigned by the Director, Office of Enforcement on July 12, 1993.

The Licensee's execution of the Promissory Note, as stated therein, constitutes a waiver of its rights to contest the amount of the civil penalty or the underlying violations on which the civil penalty is based.

FOR THE NUCLEAR REGULATORY COMMISSION

James Lieberman, Director
Office of Enforcement

Dated at Rockville, Maryland
this 13th day of July 1993

Promissory Note in Payment of Civil Penalty

Docket No. 030-05373
License No. 29-09814-01
EA 92-136

1. Obligation - For value received, Eastern Testing and Inspection, Inc., (hereafter referred to as the Maker) promises to pay to the order of the Treasurer of the United States the principal sum of $5,000 dollars, with interest accruing from July 1, 1993 at the rate of 4.00 percent per year. This note is being given for the purpose of paying off an amount which constitutes the sum of the principal due and all unpaid interest and other charges owed to the United States on a civil penalty ($5,000) debt, which has been assigned the control number captioned above. The Maker further acknowledges and admits the validity and amount of that preexisting debt, which the principal sum stated in this note is intended to repay. The Maker further acknowledges that execution of this note constitutes a waiver of the right to contest the amount of the civil penalty and the underlying violations on which the civil penalty is based under Section 234c of the Atomic Energy Act of 1954, as amended, 42 U.S.C. section 2282c.

2. Installments - This note is to be paid in monthly installments starting July 1, 1993, plus interest and administrative charges on the unpaid principal balance, payable to the Treasurer of the United States within 30 days of the "Payment Date" specified in the amortization schedule. Payments begin on July 1, 1993, and continue until either the principal sum and all interest and other charges assessed under the provisions of this note have been fully paid, or this note is considered to be in default. Payments will be mailed to the following address:

U.S. Nuclear Regulatory Commission
Division of Accounting and Finance
License Fee & Debt Collection Branch
Mail Stop MNBB 4503
Washington, D.C. 20555

Page five of this note is the schedule of monthly installments.

3. Late Payment Penalties - Late payment penalties will be assessed on any amount more than ninety (90) days past due, at the rate of six (6) percent per year.

4. Late Payment Administrative Charges - Administrative charges to cover the costs incurred by the United States in handling and processing past-due amounts will be assessed at the rate of $10.00 per month for each payment more than thirty (30) days past due.

5. Payment Crediting - The payments that the Maker makes under this note will be credited as of the date received by the U.S. Nuclear Regulatory Commission first to outstanding penalties and administrative charges; second to accrued interest; and third to the outstanding principal of the civil penalty.

6. Default, Acceleration, and Other Remedies - If any installment shall remain unpaid for a period of thirty (30) days or more, this note shall, at the option of the United States, be considered to be in default. In the event of default, the full amount of the principal sum, together with any accrued interest, late payment penalties and administrative charges assessed under this note, less any payments actually received by the United States from the Maker, shall be due and payable in full immediately without the need for further demands or notices to the Maker. Furthermore, in the event of default, the Maker agrees that the United States may exercise any collection options legally available to it, including, but not limited to: referring to a private debt collection agency, filing adverse credit reports to local and national credit reporting bureaus, referring the Maker's account for legal actions, and suspending or revoking any licenses or other privilege which the U.S. Nuclear Regulatory Commission has granted to the Maker.

7. Default Costs and Fees - In the event of default, the Maker agrees to pay all reasonable collection costs, court costs, and attorney's fees incurred by the United States as a result of the default and of any appropriate collection actions taken by the United States.

8. Confess Judgment Provisions - The Maker, if permitted by Controlling Law (as specified in paragraph 9), does hereby authorize and empower a United States Attorney, any of his assistants, or any attorney of any court of record, State or Federal, to appear for the Maker and to enter and confess judgment against the Maker for the entire amount of this obligation, with interest, less payments actually made, at any time after the same becomes due and payable, as herein provided, in any court of record, Federal or State; to waive the issuance and service of process upon the Maker in any suit on the obligation; to waive any venue requirement in such suit; to release all errors which may intervene in entering upon such judgment or in issuing any execution thereon; and to consent to immediate execution on said judgment. The Maker does hereby ratify and confirm all that said attorney may do by virtue hereof.

9. Controlling Law - Except where controlled by Federal law, all disputes concerning this note shall be controlled by the law of the jurisdiction in which the Maker resides at the time this note is signed.

10. Changes - The provision of this note may not be changed except by a written agreement which specifies the agreed-upon changes and which is signed by the Maker and an authorized representative of the United States.

11. Legal Effect - This note shall not be legally binding upon the Maker or the United States until it has been first signed by the Maker and then countersigned by an appropriate official of the United States in the spaces indicated below. The United States will promptly provide the Maker a copy of this note after it has been countersigned.

12. Signatures and Certifications - As the Maker, I do hereby certify that I have read and understood the terms of this note.

SIGNED: This 29TH day of JUNE, 1993.

Maker's Signature	HIMAT J. SONI Printed Name	139 CROWNPOINT RD. THOROFARE, N.J. Street Address

22-1734091 Taxpayer Identification Number	609-845-1776 Telephone Number

I am an authorizing official of the Maker and do certify that the Maker is incorporated in the State of New Jersey at the time this note is signed and that the signature above is that of an individual authorized to enter into a promissory note for the Maker.

SIGNED:

Signature	Printed Name	Street Address
	J. JOSEPH BAOIALI	139 CROWN POINT RD. THOROFARE, N.J.

As authorized representative of the United States, I hereby agree to the payment of this debt owed by the Maker to the United States under the terms of the installment agreement evidenced by this note.

COUNTERSIGNED:

Representative's Signature	Representative's Name	Title and Agency
	JAMES LIEBERMAN	DIRECTOR, OFFICE OF ENFORCEMENT NRC

Date countersigned: July 12, 1993
U. S. Nuclear Regulatory Commission

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION V

1450 MARIA LANE
WALNUT CREEK, CALIFORNIA 94596-5368

August 18, 1993

Docket No.030-09518
License No. 46-10100-02
EA 93-181

Environmental Protection Agency
Region 10 Laboratory
7411 Beach Drive East
Port Orchard, Washington 98366

Attention: Mr. Michael Johnston, Laboratory Director

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY - $1000
(NRC INSPECTION REPORT NO. 030-09518/93-02)

This refers to the inspection conducted by Mr. Kent M. Prendergast on June 23 and July 9, 1993, of your Port Orchard, Washington Facility. The results of the inspection were reported in NRC Inspection Report No. 030-09518/93-01, dated July 16, 1993. Six violations of NRC requirements were identified by the NRC as a result of this inspection. The violations, their causes, and your corrective actions were discussed with you during an Enforcement Conference held on July 29, 1993. The results of the Enforcement Conference are documented in NRC Inspection Report No. 030-09518/93-02, which is enclosed.

On February 22, 1993, the Environmental Protection Agency (EPA) reported the loss of four gas chromatograph detector cells containing licensed materials. This NRC inspection was performed to determine the reason for the loss and the status of corrective actions to preclude any further loss of radioactive materials. As a result of this inspection several violations were identified. The violations included: (1) failure to properly inventory licensed radioactive materials; (2) failures to secure radioactive materials against unauthorized removal; (3) failures to ensure that radioactive materials are transferred only to individuals authorized to receive them; (4) failures to provide radiation safety training to individuals who may frequent the restricted area; (5) failures to perform leak tests of sealed sources; (6) and failure to perform necessary radiation surveys prior to the transport of radioactive materials.

The violations are described in the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice). The number of violations and the failure to alleviate the conditions that resulted in the loss of radioactive materials denote a breakdown in management control of your radiation safety program. Collectively, the violations identified in Section I of the Notice represent a significant lack of attention toward licensee responsibilities for the control of radioactive materials and are a cause for significant regulatory concern.

Therefore, in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions" (Enforcement Policy), 10 CFR Part 2, Appendix C, the violations described in Section I of the enclosed notice have been classified in the aggregate as a Severity Level III problem. The other violations in Section II of the attached Notice were not assessed a civil penalty due to their less serious nature. These violations have been categorized as Severity Level IV violations. Although these violations are of lower safety significance, they provide additional evidence that your management control system has not been effective in identifying and correcting violations of NRC requirements.

We recognized that subsequent to the inspection you took prompt action to improve your oversight of the radiation safety program as described in the enclosed enforcement conference report. However, to emphasize the need for effective management oversight regarding control of activities involving licensed radioactive materials, I have been authorized to issue the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice) in the amount of $1000 for the Severity Level III problem. The base value of a civil penalty for a Severity Level III problem is $500. The civil penalty adjustment factors in the Enforcement Policy were considered.

The base civil penalty for the Severity Level III problem was escalated 50% because it was identified by the NRC, reduced 50% for prompt and aggressive corrective action, and increased 100% for the prior opportunity to have identified and corrected the conditions that resulted in the loss of radioactive materials described in your January 22, 1993, letter. Specifically, you recognized in late 1992 that licensed material was unaccounted for yet you did not take prompt action to evaluate the effectiveness of your inventory or material control procedures. There was also prior opportunity to have identified and corrected the violation in that loss or accidental disposal of radioactive materials was discussed in NRC Information Notices (IN) 89-35, issued March 30, 1989, and (IN) 90-14, issued March 6, 1990. The other adjustment factors listed in the Enforcement Policy were also considered, but no further adjustments were deemed appropriate. Therefore, based on the above, the base civil penalty has been increased by 100 percent.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. In your response, you should document the specific actions taken and any additional actions you plan to prevent recurrence. After reviewing your response to this Notice, including your proposed corrective actions and the results of future inspections, the NRC will determine whether further NRC enforcement action is necessary to ensure compliance with NRC regulatory requirements.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter and its enclosure will be placed in the NRC Public Document Room.

The responses directed by this letter and the enclosed Notice are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, Pub. L. No. 96-511.

Sincerely,

Bobby H. Faulkenberry
Regional Administrator

Enclosures:
Notice of Violation and Proposed Imposition
of Civil Penalty
NRC Inspection Report 93-02

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

EPA Region 10
Port Orchard, Washington

Docket No. 030-09518
License No. 46-10100-02
EA 93-181

During an NRC inspection conducted on June 23 and July 9, 1993, violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C, the Nuclear Regulatory Commission proposes to impose a civil penalty pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (Act), 42 U.S.C. 2282, and 10 CFR 2.205. The particular violations and associated civil penalty are set forth below:

I. Violations assessed a civil Penalty

A. 10 CFR 30.41(a) and (b)(5) require in part that no licensee transfer byproduct material except to a person authorized to receive such byproduct material under the terms of a specific or general license issued by the Commission or Agreement State.

Contrary to the above, in late 1991, the licensee transferred 2 gas chromatographs containing approximately 540 mCi of byproduct material to the General Services Administration, an agency not authorized to receive such byproduct material under the terms of a specific or general license.

B. License Condition 14 requires the licensee to conduct a physical inventory every six months to account for all sources and/or devices received and possessed under the license.

Contrary to the above, inventories were not conducted every six months for the period January 15, 1991 to February 3, 1992, and for the period August 17, 1992 to June 23, 1993.

C. 10 CFR 20.207(a) requires that licensed materials stored in an unrestricted area be secured against unauthorized removal from the place of storage. 10 CFR 20.207(b) requires that licensed materials in an unrestricted area and not in storage be tended under constant surveillance and immediate control of the licensee. As defined in 10 CFR 20.3(a)(17), an unrestricted area is any area access to which is not controlled by the licensee for purposes of protecting individuals from exposure to radiation and radioactive materials.

Contrary to the above, on June 23, 1993, licensed material, a detector cell containing 15 mCi of nickel-63 in a gas chromatograph, was stored in an unrestricted area and the material was not secured against unauthorized removal and was not under constant surveillance and immediate control of the licensee.

D. 10 CFR 19.12 requires in part that all individuals working in or frequenting a restricted area be instructed in the precautions and procedures to minimize exposure to radioactive materials, in the purpose and functions of protective devices employed, and in the applicable provisions of the Commission's regulations and licenses.

Contrary to the above, as of June 23, 1993, individuals who were working in or had access to laboratory no. 11 and other designated areas where radioactive materials are used had not been instructed in the applicable provisions of the regulations and the conditions of the license.

The above violations are considered a Severity Level III Problem (Supplement IV and VI). Cumulative Civil Penalty-$1000.

II. Violations Not Assessed A civil Penalty.

A. License Condition 13A requires in part that the sources specified in Item 7.A be tested for leakage and/or contamination at intervals not to exceed 6 months.

Contrary to the above, the licensee failed to conduct leak tests at six month intervals for two sources specified in Item 7.A of the license. The sources identified as model M610-0163, serial numbers 0770 and 0785, were not leak tested for the period June 25, 1992 to June 23, 1993, a period exceeding 6 months.

This is a Severity Level IV Violation (Supplement VI).

B. 10 CFR 71.5(a) requires that a licensee who transports licensed material outside the confines of its plant or other place of use, or who delivers licensed material to a carrier for transport, comply with the applicable requirements of the regulations appropriate to the mode of transport of the Department of Transportation (DOT) in 49 CFR Parts 170 through 189.

49 CFR 173.421 excepts radioactive materials in certain limited quantities, defined therein, from the specification packaging, shipping paper and certification, marking, and labeling requirements of subpart H, 49 CFR Part 173.

49 CFR 173.421-1(c) provides in part that a "limited quantity" of radioactive material, may be shipped as excepted from specification packaging, shipping paper and certification, marking, and labeling requirements, provided the survey results for non-fixed (removable) radioactive surface contamination on the external surface of the package do not exceed the limits specified in Section 173.443(a).

Contrary to the above, gas chromatographs were shipped to the supplier on four occasions in 1992 and on one occasion in 1993, as "limited quantities" without performing the required surveys for removable contamination to demonstrate that the packages did not

exceed the limits specified in 173.443(a) and that they were free from contamination.

This is a Severity Level IV Violation (Supplement V).

Pursuant to the provisions of 10 CFR 2.201, EPA Region 10 is hereby required to submit a written statement or explanation to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, within 30 days of the date of this Notice of Violation and Proposed Imposition of Civil Penalty (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each alleged violation: (1) admission or denial of the alleged violation, (2) the reasons for the violation if admitted, and if denied, the reasons why, (3) the corrective steps that have been taken and the results achieved, (4) the corrective steps that will be taken to avoid further violations, and (5) the date when full compliance will be achieved. If an adequate reply is not received within the time specified in this Notice, an order or a Demand for Information may be issued to show cause why the license should not be modified, suspended, or revoked or why such other action as may be proper should not be taken. Consideration may be given to extending the response time for good cause shown. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, this response shall be submitted under oath or affirmation.

Within the same time as provided for the response required above under 10 CFR 2.201, the Licensee may pay the civil penalty by letter addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, with a check, draft, money order, or electronic transfer payable to the Treasurer of the United States in the amount of the civil penalty proposed above, or the cumulative amount of the civil penalties if more than one civil penalty is proposed, or may protest imposition of the civil penalty in whole or in part, by a written answer addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission. Should the Licensee fail to answer within the time specified, an order imposing the civil penalty will be issued. Should the Licensee elect to file an answer in accordance with 10 CFR 2.205 protesting the civil penalty, in whole or in part, such answer should be clearly marked as an "Answer to a Notice of Violation" and may: (1) deny the violation(s) listed in this Notice, in whole or in part, (2) demonstrate extenuating circumstances, (3) show error in this Notice, or (4) show other reasons why the penalty should not be imposed. In addition to protesting the civil penalty in whole or in part, such answer may request remission or mitigation of the penalty.

In requesting mitigation of the proposed penalty, the factors addressed in Section VI.B. of 10 CFR Part 2, Appendix C, should be addressed. Any written answer in accordance with 10 CFR 2.205 should be set forth separately from the statement or explanation in reply pursuant to 10 CFR 2.201, but may incorporate parts of the 10 CFR 2.201 reply by specific reference (e.g., citing page and paragraph numbers) to avoid repetition. The attention of the Licensee is directed to the other provisions of 10 CFR 2.205, regarding the procedure for imposing a civil penalty.

Upon failure to pay any civil penalty due which subsequently has been determined in accordance with the applicable provisions of 10 CFR 2.205, this matter may be referred to the Attorney General, and the penalty, unless compromised, remitted, or mitigated, may be collected by civil action pursuant to Section 234c of the Act, 42 U.S.C. 2282c.

The response noted above (Reply to Notice of Violation, letter with payment of civil penalty, and Answer to a Notice of Violation) should be addressed to: Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555 with a copy to the Regional Administrator, U.S. Nuclear Regulatory Commission, Region V.

Dated at Walnut Creek, California
This 18th day of August 1993

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION IV
611 RYAN PLAZA DRIVE, SUITE 400
ARLINGTON, TEXAS 76011-8064

JUN - 9 1993

Docket No. 150-00042
General License (10 CFR 150.20)
EA 93-073

Gray Wireline Service, Inc.
ATTN: Mr. Steve Gray, President
Post Office Box 854
Levelland, Texas 79336

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY - $1,500 (NRC INVESTIGATION REPORT NO. 4-92-038)

This refers to the investigation conducted by the NRC's Office of Investigations (OI) to determine whether Gray Wireline Services, Inc., violated NRC requirements regarding the payment of fees to the NRC and the accuracy of information provided to the NRC. The investigation, which was initiated in November 1992, determined that Gray Wireline Services, Inc., which holds a license issued by the State of Texas, an Agreement State, deliberately conducted licensed activities in the State of Montana in October and November of 1992 without paying the required $640 fee to the NRC and that you made false statements to an NRC representative when questioned about these activities.

On February 11, 1993, the NRC issued a Demand for Information to Gray Wireline Service, Inc., and requested that the NRC be provided with certain information to be used by the NRC in determining whether your privilege of performing licensed activities in NRC jurisdiction should be suspended or revoked or whether other enforcement action should be taken. You replied in a letter dated March 2, 1993, in which you: 1) pledged to furnish complete and accurate information to the NRC in the future; 2) pledged to possess and use radioactive material in accordance with all NRC radiation safety requirements; and 3) cited your company's good safety and compliance records in using radioactive materials.

The NRC's regulations in 10 CFR 30.9, which are applicable to Agreement State licensees working in NRC jurisdiction, require information provided to the NRC by licensees to be complete and accurate in all material respects. You deliberately violated this requirement when, on November 9, 1992, you told an NRC representative who telephoned you that Gray Wireline Service, Inc., had not used radioactive tracer materials in the State of Montana. You stated in your March 2, 1993, letter that you did this to save the reciprocity fee. The NRC must be able to rely on information provided by its licensees to make appropriate regulatory and safety judgments. We rely on information provided by Agreement State licensees to plan inspections in order to fulfill our responsibility to ensure that their activities are carried out in accordance with NRC requirements and with due regard for employee and public safety.

In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy) 10 CFR Part 2, Appendix C, a deliberate violation of this requirement by a licensee official is categorized at Severity Level I, the highest possible severity level. For your information, a copy of the NRC's Enforcement Policy is enclosed with this letter.

To emphasize the significance of intentionally providing false information to the NRC and the importance of ensuring that all future communications with the NRC are materially accurate, I have been authorized to issue the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice) in the amount of $1,500 for the Severity Level I violation described above and in the Notice.

The base value of a civil penalty for a Severity Level I violation is $1,000. The civil penalty adjustment factors in Section VI.B.2. of the Enforcement Policy were considered and resulted in an increase of $500, equal to 50 percent of the base value. This increase was made because this violation was discovered by the NRC through its investigative efforts (conversely, the Enforcement Policy provides that penalties may be reduced if violations are identified by licensees). While the remaining adjustment factors were considered, no further adjustments were considered appropriate.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. In your response, you should document the specific actions taken and any additional actions you plan to prevent recurrence. After reviewing your response to this Notice, including your proposed corrective actions and the results of future inspections, the NRC will determine whether further NRC enforcement action is necessary to ensure compliance with NRC regulatory requirements. You should be aware that if a similar violation occurs in the future, the NRC will consider suspending or revoking your authority to use the general license conferred under 10 CFR 150.20. You should also be aware of the regulation concerning deliberate misconduct, 10 CFR 30.10.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter and its enclosure will be placed in the NRC Public Document Room.

The responses directed by this letter and the enclosed Notice are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, Pub. L. No. 96-511.

Sincerely,

James L. Milhoan

James L. Milhoan
Regional Administrator

Enclosures: (See next page)

Enclosures:
1. Notice of Violation and Proposed Imposition of Civil Penalty
2. NRC Enforcement Policy

cc w/enclosure 1:
State of Texas Radiation Control Program Director

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

Gray Wireline Service, Inc.
Levelland, Texas

Docket 150-00042
General License (10 CFR 150.20)
EA 93-073

During an NRC investigation conducted between November 1992 and March 1993, a violation of NRC requirements was identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C, the Nuclear Regulatory Commission proposes to impose a civil penalty pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (Act), 42 U.S.C. 2282, and 10 CFR 2.205. The particular violation and associated civil penalty are set forth below:

> 10 CFR 30.9(a) requires, in part, that information provided to the NRC by a licensee be complete and accurate in all material respects.
>
> Contrary to the above, on November 9, 1992, the president of Gray Wireline Service, Inc., which holds a general license under 10 CFR 150.20, provided false information to an NRC representative. Specifically, the president told the NRC representative that Gray Wireline Service, Inc., had not used radioactive tracer materials in the NRC's jurisdiction, i.e., the State of Montana. This information was false because the company had used such materials in Montana in October and November of 1992 and was material because the company failed to pay associated fees and because the NRC had no opportunity to inspect the company's licensed activities in Montana.

This is a Severity Level I violation (Supplement VII).
Civil Penalty - $1,500

Pursuant to the provisions of 10 CFR 2.201, Gray Wireline Service, Inc. (Licensee) is hereby required to submit a written statement or explanation to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, within 30 days of the date of this Notice of Violation and Proposed Imposition of Civil Penalty (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each alleged violation: (1) admission or denial of the alleged violation, (2) the reasons for the violation if admitted, and if denied, the reasons why, (3) the corrective steps that have been taken and the results achieved, (4) the corrective steps that will be taken to avoid further violations, and (5) the date when full compliance will be achieved. If an adequate reply is not received within the time specified in this Notice, an order or a Demand for Information may be issued to show cause why the license should not be modified, suspended, or revoked or why such other action as may be proper should not be taken. Consideration may be given to extending the response time for good cause shown. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, this response shall be submitted under oath or affirmation.

Within the same time as provided for the response required above under 10 CFR 2.201, the Licensee may pay the civil penalty by letter addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, with a check, draft, money order, or electronic transfer payable to the Treasurer of the United States in the amount of the civil penalty proposed above or may protest imposition of the civil penalty in whole or in part, by a written answer addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission. Should the Licensee fail to answer within the time specified, an order imposing the civil penalty will be issued. Should the Licensee elect to file an answer in accordance with 10 CFR 2.205 protesting the civil penalty, in whole or in part, such answer should be clearly marked as an "Answer to a Notice of Violation" and may: (1) deny the violation listed in this Notice, in whole or in part, (2) demonstrate extenuating circumstances, (3) show error in this Notice, or (4) show other reasons why the penalty should not be imposed. In addition to protesting the civil penalty in whole or in part, such answer may request remission or mitigation of the penalty.

In requesting mitigation of the proposed penalty, the factors addressed in Section VI.B.2 of 10 CFR Part 2, Appendix C, should be addressed. Any written answer in accordance with 10 CFR 2.205 should be set forth separately from the statement or explanation in reply pursuant to 10 CFR 2.201, but may incorporate parts of the 10 CFR 2.201 reply by specific reference (e.g., citing page and paragraph numbers) to avoid repetition. The attention of the Licensee is directed to the other provisions of 10 CFR 2.205, regarding the procedure for imposing a civil penalty.

Upon failure to pay any civil penalty due which subsequently has been determined in accordance with the applicable provisions of 10 CFR 2.205, this matter may be referred to the Attorney General, and the penalty, unless compromised, remitted, or mitigated, may be collected by civil action pursuant to Section 234c of the Act, 42 U.S.C. 2282c.

The response noted above (Reply to Notice of Violation, letter with payment of civil penalty, and Answer to a Notice of Violation) should be addressed to: Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555 with a copy to the Regional Administrator, U.S. Nuclear Regulatory Commission, Region IV, 611 Ryan Plaza Drive, Suite 400, Arlington, Texas 76011.

Dated at Arlington, Texas
this 9th day of June 1993

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
799 ROOSEVELT ROAD
GLEN ELLYN, ILLINOIS 60137-5927

June 24, 1993

Docket No. 030-18236
License No. 48-11805-02
EA 93-141

Hazelton Wisconsin, Inc.
ATTN: Mr. Robert Conway
Corporate Vice President and General Manager
3301 Kineman Blvd
PO Box 7545
Madison, Wisconsin, 53707

Dear Mr. Conway

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY - $500
NRC INSPECTION REPORT NO. 030-18286/93001

This refers to the inspection conducted on May 20, 1993, at the Wisconsin Hazelton facilities at Madison, Wisconsin. A copy of the report documenting this inspection was mailed to you on June 11, 1993. Significant violations of NRC requirements were identified during the inspection, and on June 16, 1993, a telephone enforcement conference was held between you and Region III.

In May 1992, while conducting a semiannual leak test of sealed sources, your RSO determined that a 15 millicurie Ni-63 source had been accidently discarded to a local landfill in January 1992. Your attempts to locate and retrieve the source were unsuccessful. As a result, during your June 1992 Radiation Safety Committee (RSC) meeting, you developed corrective actions to preclude such accidental losses. One of the more significant of these corrective actions was to post a more prominent label on each of your 80 gas chromatographs alerting workers to the presence of radioactive sources and to contact the RSO prior to moving them. You ordered the new labels and received them in August but did not immediately place them on the gas chromatographs; you decided to wait until the next routine leak test was due in November. As a result, another source was accidently discarded in September 1992 and was not discovered until the November 1992 leak test.

The NRC is concerned about the loss of these radioactive sources. Such losses involve a potential hazard to the health and safety of the general public and represent a serious lack of control over licensed material. Of further concern is that you

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recognized the problem after the first loss and ordered better labels to alert the workers, but did not attach the new labels immediately. Doing so would probably have prevented the loss of the second source.

The root cause of the violation appeared to be a lack of training, understanding and knowledge by your staff. During the enforcement conference, you acknowledged that many of the workers were not aware that radioactive materials were present. One reason for this was that the labels on the sources were not prominent. A second reason was that the workers had not received much training. Also, your tracking system was not effective.

We acknowledge your corrective actions subsequent to the loss of the second source which included attaching the new labels. You also are now listing each user of the sources separately, and have spoken to each of them on an individual basis. You also indicated that you will provide a higher level of management involvement in keeping track of the sources.

The violation is described in Part I of the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice). It is significant because it represents a lack of attention to control of radioactive materials and a resultant potential hazard to the health and safety of the public. Therefore, in accordance with the "Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy) 10 CFR Part 2, Appendix C, the violation is classified at Severity Level III.

To emphasize the need for strict adherence to NRC regulations and especially to those for the control of radioactive material, I have been authorized to issue the enclosed Notice in the amount of $500. The base civil penalty for a Severity Level III violation is $500. The adjustment factors in the Enforcement Policy were considered and the base was mitigated 50% because you identified the violation and 100% because of your past good performance. However, the base was escalated 50% because of your ineffective and slow corrective actions to the first loss and 100% because of the multiple losses. Therefore, on balance, there was no change to the base.

Part II of the enclosed Notice pertains to your failure to conduct quarterly audits as required by your license. The requirement is that the radiation safety officer (RSO) or the assistant RSO make independent confirmatory surveys for removable contamination and ambient radiation levels at least quarterly. During the enforcement conference you acknowledged that this was not done between February 1992 and November 1992, and between January 1993 and May 1993.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your

response. In your response, you should document the specific actions taken and any additional actions you plan to prevent recurrence. After reviewing your response to this Notice, including your proposed corrective actions and the results of future inspections, the NRC will determine whether further NRC enforcement is necessary to ensure compliance with NRC regulatory requirements.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter and its enclosure will be placed in the NRC Public Document Room.

The responses directed by this letter and the enclosed Notice are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, Pub. L. No. 96-511.

Sincerely,

John B. Martin
Regional Administrator

Enclosure:
Notice of Violation and Proposed
Imposition of Civil Penalty

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

Hazelton Wisconsin, Inc.
Madison, Wisconsin

Docket No. 030-18286
License No. 48-11805-02
EA 93-141

During an NRC inspection conducted on May 20, 1993, violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions,", 10 CFR Part 2, Appendix C, the Nuclear Regulatory Commission proposes to impose a civil penalty pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (Act), 42 U.S.C. 2282, and 10 CFR 2.205. The particular violation and associated civil penalty are set forth below:

I. Violations Assessed a Civil Penalty

10 CFR 20.301 requires that no licensee shall dispose of licensed radioactive material except by certain specified authorized methods.

Contrary to the above, in January 1992 and September 1992, the licensee disposed of two sources of radioactive material, each containing approximately 15 millicuries of Ni-63, in the normal trash, a method not authorized by 10 CFR 20.301.

This is a Severity Level III violation (Supplement VI). Cumulative Civil Penalty - $500.

II. VIOLATION NOT ASSESSED A CIVIL PENALTY

Condition 28.B of License No. 48-11805-02 requires that licensed material be possessed and used in accordance with statements, representations and procedures contained in a letter dated October 20, 1989, and other reference documents.

Section 10.5.6, "Audits," of the referenced letter requires that independent confirmatory surveys for removable contamination and ambient radiation levels be conducted by the RSO or Assistant RSO in use and storage areas at least quarterly.

Contrary to the above, from approximately February 1992 through November 1992, and from January 1993 through May 1993, independent confirmatory surveys for removable contamination and ambient radiation levels were not conducted by the RSO or Assistant RSO in use area quarterly.

This is a Severity Level IV violation (Supplement VI)

Pursuant to the provisions of 10 CFR 2.201, Hazelton Wisconsin Inc., (Licensee) is hereby required to submit a written statement or explanation to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, within 30 days of the date of this Notice of Violation and Proposed Imposition of Civil Penalty (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each alleged violation: (1) admission or denial of the alleged violation, (2) the reasons for the violation if admitted, and if denied, the reasons why, (3) the corrective steps that have been taken and the results achieved, (4) the corrective steps that will be taken to avoid further violations, and (5) the date when full compliance will be achieved.
If an adequate reply is not received within the time specified in this Notice, an order or a Demand for Information may be issued to show cause why the license should not be modified, suspended, or revoked or why such other action as may be proper should not be taken. Consideration may be given to extending the response time for good cause shown. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, this response shall be submitted under oath or affirmation.

Within the same time as provided for the response required above under 10 CFR 2.201, the licensee may pay the civil penalty by letter addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, with a check, draft, money order, or electronic transfer payable to the Treasurer of the United States in the amount of the civil penalty proposed above, or the cumulative amount of the civil penalties if more than one civil penalty is proposed, or may protest imposition of the civil penalty in whole or in part, by a written answer addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission. Should the Licensee fail to answer within the time specified, an order imposing the civil penalty will be issued. Should the Licensee elect to file an answer in accordance with 10 CFR 2.205 protesting the civil penalty, in whole or in part, such answer should be clearly marked as an "Answer to a Notice of Violation" and may: (1) deny the violations listed in this Notice, in whole or in part, (2) demonstrate extenuating circumstances, (3) show error in this Notice, or (4) show other reasons why the penalty should not be imposed. In addition to protesting the civil penalty in whole or in part, such answer may request remission or mitigation of the penalty.

In requesting mitigation of the proposed penalty, the factors addressed in Section VI.B.2 of 10 CFR Part 2, Appendix C, should be addressed. Any written answer in accordance with 10 CFR 2.205 should be set forth separately from the statement or explanation in reply pursuant to 10 CFR 2.201, but may incorporate parts of the 10 CFR 2.201 reply by specific reference (e.g., citing page and paragraph numbers) to avoid repetition. The attention of the Licensee is directed to the other provisions of 10 CFR 2.205,

regarding the procedure for imposing a civil penalty.

Upon failure to pay any civil penalty due which subsequently has been determined in accordance with the applicable provisions of 10 CFR 2.205, this matter may be referred to the Attorney General, and the penalty, unless compromised, remitted, or mitigated, may be collected by civil action pursuant to Section 234c of the Act, 42 U.S.C. 2282c.

The response noted above (Reply to Notice of Violation, letter with payment of civil penalty, and Answer to a Notice of Violation) should be addressed to: Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555 with a copy to the Regional Administrator, U.S. Nuclear Regulatory Commission, Region III, 799 Roosevelt Road, Glen Ellyn, IL, 60137.

For the Nuclear Regulatory Commission

John B. Martin
Regional Administrator

Dated at Glen Ellyn, IL
this 24th day of June, 1993.

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
799 ROOSEVELT ROAD
GLEN ELLYN, ILLINOIS 60137-5927

June 9, 1993

Docket No. 030-02195
License No. 22-00519-03
EA 93-079

Mayo Foundation
ATTN: Sharon E. Dunemann
Chief Administrative Officer
Rochester, Minnesota 55905

Dear Ms. Dunemann:

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY - $6,000
(NRC INSPECTION REPORT NO. 030-02195/93001(DRSS))

This refers to the inspection conducted on April 2 through 7, 1993, at Mayo Foundation. The inspection included a review of the circumstances surrounding an incident on March 21-23, 1993, involving phosphorus-32 contamination. You reported the event to NRC Region III on April 1, 1993. The report documenting the inspection was sent to you by letter dated April 23, 1993. During the inspection violations of NRC requirements were identified. An enforcement conference was held on April 30, 1993, to discuss the violations, their causes, and your corrective actions.

On March 21, 1993, a researcher working alone in the Guggenheim Building unknowingly contaminated his hands when he opened a new vial containing 10 millicuries of phosphorus-32, and he spread phosphorus-32 within the laboratory and on his clothing. The contamination went undetected due to the researcher's failure to survey himself and the laboratory prior to leaving the work area. The researcher indicated that the survey meter located in the laboratory had low batteries and that he was in a hurry to leave. The researcher worked in the laboratory again that night, and again failed to survey. On March 22, 1993, the researcher continued to work with phosphorus-32, and again, he did not survey himself and the laboratory. In all three cases, he did not take the time to have the meter batteries changed or to use a meter from an adjacent laboratory. The authorized user had

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trained the researcher on the survey requirement, and the researcher indicated that he was aware of the requirement.

On March 23, 1993, the researcher used a meter from an adjacent laboratory, performed a survey, and discovered that his hands were contaminated. Contamination was spread within the laboratory, to a church, and to private automobiles, clothing and homes. The contamination also caused unnecessary exposure to the researcher's hands. By April 11, 1993, all potentially contaminated areas were surveyed, all areas were decontaminated, and all contaminated articles were collected and secured by the Radiation Safety Officer (RSO).

Two violations are described in Section I of the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice). The first violation involves the failure of the researcher to perform contamination surveys after using phosphorus-32 on March 21 and 22, 1993. This violation is willful in nature because the researcher had been trained on the survey requirement and was aware of the requirement, yet chose not to follow it. The fact that the researcher was in a hurry and the survey instrument had low batteries is no excuse. Clearly, the researcher should not have conducted the work unless he had a functional survey instrument and the time to conduct proper surveys. The researcher could have taken the time to change the batteries or could have used an instrument from an adjacent laboratory. This violation is the root cause of the contamination event. The safety consequences of the event were potentially significant in that the phosphorus-32 contamination was widespread, especially in the public domain.

The second violation involves inadequate off-site surveys performed by the health physics technician to detect the extent of the off-site contamination from the event. The Radiation Safety Office was informed of the event on March 23, 1993. On April 2, 1993, the RSO informed the NRC inspectors that the laboratory, homes, and vehicles had been surveyed and were either found to be clean or were decontaminated. Subsequently, the NRC inspectors identified contaminated church pews, many items of contaminated clothing, a contaminated vehicle, and several spots of contamination in the laboratory. The inspectors identified contamination in locations that, according to the RSO, had been surveyed and either had been decontaminated or had been found to be clean.

The violations described above represent a significant failure to control licensed material. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy) 10 CFR Part 2, Appendix C, these violations

normally would be categorized at Severity Level III. However, the Enforcement Policy, Section IV.C, provides that the severity level of a violation may be increased if the circumstances surrounding the matter involve willfulness. Therefore, the two violations are categorized in the aggregate as a Severity Level II problem.

Your corrective actions included retraining of the researcher and all other personnel who use phosphorus-32 to stress the importance of performing surveys, and identifying and cleaning up contaminated areas. However, as discussed at the enforcement conference, your surveys to assess the extent of contamination, in some cases, were not performed, were delayed, or were unreliable.

The NRC considers a willful violation of NRC requirements a very serious matter. To emphasize the importance the NRC places on the performance of necessary surveys and the unacceptability of willful violations, I have been authorized to issue the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice) in the amount of $6,000, assessed on the basis of Violation I.A. The base value of a civil penalty for a Severity Level II violation or problem is $4,000.

The civil penalty adjustment factors in the Enforcement Policy were considered. The base civil penalty was mitigated 50 percent for identification since you identified that the researcher failed to perform daily surveys. The base civil penalty was not mitigated for corrective actions because we had concerns in this area, as discussed above. The base civil penalty was escalated 100 percent for multiple occurrences in that the researcher failed to perform surveys on two consecutive days. Although your past performance has been good, no mitigation is warranted for this factor given the willful nature of the violation. The other adjustment factors in the Policy were considered and no further adjustment to the base civil penalty is considered appropriate. Therefore, based on the above, the base civil penalty has been increased by 50 percent.

Section II of the Notice contains violations which were not assessed a civil penalty. These involve failure to perform weekly surveys for removable contamination; failure of an individual to use a finger dosimeter when working with millicurie quantities of phosphorus-32; failure to conduct urinalysis of a radiation worker who used 10 millicuries of a beta emitting radioisotope; failure of an individual to wear a laboratory coat when working with phosphorus-32; and failure of an individual to receive radiation safety orientation training.

Although you identified Violations II.B, II.C, and II.E, your corrective action to prevent recurrence of those violations was not fully formulated at the time of the enforcement conference.

Therefore, we did not exercise discretion to treat these violations as non-cited violations under Section VII.B(2) of the Enforcement Policy. Specifically, the root cause of the three violations was your failure to track the researcher as a radiation worker, and your plans to ensure that all radiation workers were formally tracked and audited were incomplete at the time of the enforcement conference.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. In your response, you should document the specific actions taken and any additional actions you plan to prevent recurrence. In addition, in light of the willful action of the researcher involved in Violation I.A of the Notice, your response should address your basis for having confidence that this individual will, in the future, follow Commission requirements.

Please ensure that your response also addresses the following concerns that were documented in the inspection report and were further discussed at the enforcement conference: (1) your response to and evaluation of the contamination event was not aggressive, prompt, and thorough; (2) the authorized user failed to properly train and supervise his radiation workers; and (3) the scope and depth of quarterly laboratory audits conducted by the radiation safety staff technician appear to be inadequate.

After reviewing your response to this Notice, including your proposed corrective actions and the results of future inspections, the NRC will determine whether further NRC enforcement action is necessary to ensure compliance with NRC regulatory requirements.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter, its enclosure, and your responses will be placed in the NRC Public Document Room.

The responses directed by this letter and the enclosed Notice are not subject to the clearance procedures of the Office of

Management and Budget as required by the Paperwork Reduction Act of 1980, Public Law No. 96-511.

Sincerely,

for

John B. Martin
Regional Administrator

Enclosure:
Notice of Violation and Proposed
Imposition of Civil Penalty

cc/enclosure:
Richard Vetter, Ph.D., Radiation
Safety Officer, Mayo Foundation

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

Mayo Foundation
Rochester, Minnesota

Docket No. 030-02195
License No. 22-00519-03
EA 93-079

During an NRC inspection conducted on April 2-7, 1993, violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C, the Nuclear Regulatory Commission proposes to impose a civil penalty pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (Act), 42 U.S.C. 2282, and 10 CFR 2.205. The particular violations and associated civil penalty are set forth below:

I. Violations Assessed a Civil Penalty

A. License Condition No. 30 as contained in Amendment No. 43 dated June 4, 1992, states, in part, that the licensee shall conduct its program in accordance with the statements, representations and procedures contained in an application dated March 31, 1991, and a letter dated July 11, 1991.

The letter dated July 11, 1991, states, in part, in Item 6.b, "Phosphorus-32 Safety Instructions," that a daily meter survey is required if the laboratory possesses greater than 10 times the Annual Limit of Intake (ALI) (ten times 900 microcuries) or uses more than 10 microcuries of phosphorus-32 on that day.

Contrary to the above, on March 21 and 22, 1993, a daily meter survey was not performed and the laboratory (Guggenheim Building Room 319) possessed 10 millicuries of phosphorus-32, a quantity greater than 10 ALI and used more than 10 microcuries on those days.

B. License Condition No. 30 as contained in Amendment No. 43 dated June 4, 1992, states, in part, that the licensee shall conduct its program in accordance with the statements, representations and procedures contained in an application dated March 31, 1991, and a letter dated July 11, 1991.

The application dated March 31, 1991, states, in part, in Attachment 10.12, "Procedure for Area Surveys," that if major contamination (equal to or greater than 220 dpm/100 cm^2) is found of a beta emitter in an unrestricted area, decontamination by laboratory personnel and resurvey by Radiation Safety Office personnel within two working days are required.

10 CFR 20.201(b) requires that each licensee make such surveys as may be necessary to comply with the requirements of Part 20 and which are reasonable under the circumstances to evaluate the extent of radiation hazards that may be present. As defined in 10 CFR 20.201(a), "survey" means an evaluation of the radiation hazards incident to the production, use, release, disposal, or presence of radioactive materials or other sources of radiation under a specific set of conditions.

Contrary to the above:

1. From March 23, 1993, through April 3, 1993, the licensee did not perform adequate surveys to determine the presence of phosphorus-32 contamination in unrestricted areas including individuals' clothing, vehicles, homes, and a church, to assure that contamination limits in these unrestricted areas were not exceeded.

2. On March 25, 1993, major contamination (approximately 3,300 dpm) of phosphorus-32 (a beta emitter) was found by a laboratory person in his home (an unrestricted area) and a resurvey was not performed by Radiation Safety Office personnel until April 2, 1993, a period exceeding two days.

These violations represent a Severity Level II problem (Supplements IV and VI).

Civil Penalty - $6,000 (assessed for Violation I.A).

II. Violations Not Assessed a Civil Penalty

A. License Condition No. 30 as contained in Amendment No. 43 dated June 4, 1992, states, in part, that the licensee shall conduct its program in accordance with the statements, representations and procedures contained in an application dated March 31, 1991, and a letter dated July 11, 1991.

The letter dated July 11, 1991, states in Item 6.b, "Phosphorus-32 Safety Instructions," that a weekly survey for removable contamination is required if the laboratory possess greater than 10 ALI (10 times 900 microcuries) phosphorus-32 and uses more than 10 microcuries of phosphorus-32 at any one time.

Contrary to the above, weekly surveys for removable contamination were not performed in Guggenheim Building Room 319 during the weeks of January 18 through 22, 1993; January 25 through 29, 1993; and February 22

through 26, 1993, and the laboratory possessed greater than 10 ALI phosphorus-32 and used more that 10 microcuries of phosphorus-32 at any one time during those weeks.

This is a Severity Level IV violation (Supplement VI).

B. License Condition No. 30 as contained in Amendment No. 43 dated June 4, 1992, states, in part, that the licensee shall conduct its program in accordance with the statements, representations and procedures contained in an application dated March 31, 1991, and a letter dated July 11, 1991.

The letter dated July 11, 1991, states in Item 6.c, "Phosphorus-32 Safety Instructions," that finger dosimeters are required to be used by personnel working with millicurie quantities of phosphorus-32 unless previous measurements have shown exposure to be minimal.

Contrary to the above, an individual who routinely used millicurie quantities of phosphorus-32 from approximately September 1992 through March 23, 1993, failed to use a finger dosimeter when working with millicurie quantities of phosphorus-32 and the licensee did not have previous measurements that showed his exposure to be minimal.

This is a Severity Level IV violation (Supplement VI).

C. License Condition No. 30 as contained in Amendment No. 43 dated June 4, 1992, states, in part, that the licensee shall conduct its program in accordance with the statements, representations and procedures contained in an application dated March 31, 1991, and a letter dated July 11, 1991.

The application dated March 31, 1991, states in Attachment 10.16, Item III. A, that radiation workers who use a total of 10 millicuries of any beta emitting radioisotopes are required to have quarterly urinalysis.

Contrary to the above, a radiation worker who used at least 10 millicuries of phosphorus-32 during the fourth calendar quarter of 1992, did not have a quarterly urinalysis for that quarter.

This is a Severity Level IV violation (Supplement VI).

D. License Condition No. 30 as contained in Amendment No. 43 dated June 4, 1992, states, in part, that the

licensee shall conduct its program in accordance with the statements, representations and procedures contained in an application dated March 31, 1991, and a letter dated July 11, 1991.

The application dated March 31, 1991, states, in part, in Attachment 10.4, page 1, that laboratory rules be followed at all times when working with radioactive materials including wearing laboratory coats.

Contrary to the above, on March 21, 1993, an individual who worked with radioactive phosphorus-32 did not wear a laboratory coat when working with the material.

This is a Severity Level IV violation (Supplement VI).

E. License Condition No. 30 as contained in Amendment No. 43 dated June 4, 1992, states, in part, that the licensee shall conduct its program in accordance with the statements, representations and procedures contained in an application dated March 31, 1991, and a letter dated July 11, 1991.

The application dated March 31, 1991, states, in part, in Item 8, "Training for Individuals Working in or Frequenting Restricted Areas," that individuals using byproduct material will receive radiation safety orientation training upon employment.

Contrary to the above, as of April 3, 1993, an individual who used byproduct material routinely since approximately September 1992 did not receive radiation safety orientation training upon his employment in September 1992.

This is a Severity Level IV violation (Supplement VI).

Pursuant to the provisions of 10 CFR 2.201, Mayo Foundation (Licensee) is hereby required to submit a written statement of explanation to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, within 30 days of the date of this Notice of Violation and Proposed Imposition of Civil Penalty (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each alleged violation: (1) admission or denial of the alleged violation, (2) the reasons for the violation if admitted, and if denied, the reasons why, (3) the corrective steps that have been taken and the results achieved, (4) the corrective steps that will be taken to avoid further violations, and (5) the date when full compliance is achieved. If an adequate reply is not received within the time specified in this Notice, an order or a demand for information may be issued as to why the license should not be modified, suspended, or revoked or why such other actions as may be proper

should not be taken. Consideration may be given to extending the response time for good cause shown. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, this response shall be submitted under oath or affirmation.

Within the same time as provided for the response required under 10 CFR 2.201, the Licensee may pay the civil penalty by letter addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, with a check, draft, money order, or electronic transfer payable to the Treasurer of the United States in the amount of the civil penalty proposed above, or may protest imposition of the civil penalty in whole or in part, by a written answer addressed to the Director, Office of Enforcement, U. S. Nuclear Regulatory Commission. Should the Licensee fail to answer within the time specified, an order imposing the civil penalty will be issued. Should the Licensee elect to file an answer in accordance with 10 CFR 2.205 protesting the civil penalty, in whole or in part, such answer should be clearly marked as an "Answer to a Notice of Violation" and may: (1) deny the violation listed in this Notice in whole or in part, (2) demonstrate extenuating circumstances, (3) show error in this Notice, or (4) show other reasons why the penalty should not be imposed. In addition to protesting the civil penalty in whole or in part, such answer may request remission or mitigation of the penalty.

In requesting mitigation of the proposed penalty, the factors addressed in Section V.B of 10 CFR Part 2, Appendix C, should be addressed. Any written answer in accordance with 10 CFR 2.205 should be set forth separately from the statement or explanation in reply pursuant to 10 CFR 2.201, but may incorporate parts of the 10 CFR 2.201 reply by specific reference (e.g., citing page and paragraph numbers) to avoid repetition. The attention of the Licensee is directed to the other provisions of 10 CFR 2.205, regarding the procedure for imposing a civil penalty.

Upon failure to pay any civil penalty due which subsequently has been determined in accordance with the applicable provisions of 10 CFR 2.205, this matter may be referred to the Attorney General, and the penalty, unless compromised, remitted, or mitigated, may be collected by civil action pursuant to Section 234c of the Act, 42 U.S.C. 2282c.

The responses noted above (Reply to Notice of Violation, letter with payment of civil penalty, and Answer to a Notice of Violation) should be addressed to: Director, Office of

Enforcement, U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555 with a copy to the Regional Administrator, U.S. Nuclear Regulatory Commission, Region III, 799 Roosevelt Road, Glen Ellyn, Illinois 60137.

FOR THE NUCLEAR REGULATORY COMMISSION

for

John B. Martin
Regional Administrator

Dated at Glen Ellyn, Illinois
this 9th day of June 1993

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

AUG 24 1993

Docket No. 030-02195
License No. 22-00519-03
EA 93-079

Mayo Foundation
ATTN: Sharon E. Dunemann
Chief Administrative Officer
Rochester, Minnesota 55905

Dear Ms. Dunemann:

SUBJECT: ORDER IMPOSING CIVIL MONETARY PENALTY - $6,000

This refers to your letters dated June 30 and July 1, 1993, in response to the Notice of Violation and Proposed Imposition of Civil Penalty (Notice) sent to you by our letter dated June 9, 1993. Our letter and Notice describe seven violations identified during an NRC inspection conducted on April 2 through 7, 1993.

To emphasize the importance the NRC places on the performance of necessary surveys and the unacceptability of willful violations, a civil penalty of $6,000 was proposed.

In your responses, you object to the characterization of Violation I.A as willful, and request mitigation of the civil penalty.

After consideration of your responses, we have concluded, for the reasons given in the Appendix attached to the enclosed Order Imposing Civil Monetary Penalty, that Violation I.A was willful, and an adequate basis has not been provided for mitigation of the civil penalty. Accordingly, we hereby serve the enclosed Order on Mayo Foundation imposing a civil monetary penalty in the amount of $6,000. We will review the effectiveness of your corrective actions during a subsequent inspection.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter and the enclosure will be placed in the NRC's Public Document Room.

Sincerely,

James Lieberman, Director
Office of Enforcement

Enclosure: As stated

cc w/enclosure:
Richard Vetter, Ph.D, Radiation
Safety Officer, Mayo Foundation

UNITED STATES
NUCLEAR REGULATORY COMMISSION

In the Matter of	)	
	)	
MAYO FOUNDATION	)	Docket No. 030-02195
Rochester, Minnesota	)	License No. 22-00519-03
	)	EA 93-079

ORDER IMPOSING CIVIL MONETARY PENALTY

I

Mayo Foundation (Licensee) is the holder of Byproduct Material License No. 22-00519-03 issued by the Nuclear Regulatory Commission (NRC or Commission) on June 4, 1992. The license authorizes the Licensee to possess and use byproduct materials for medical diagnosis, therapy, and research on humans; and research and development, including animal studies and student instruction, in accordance with the conditions specified therein.

II

An inspection of the Licensee's activities was conducted on April 2 through 7, 1993. The results of this inspection indicated that the Licensee had not conducted its activities in full compliance with NRC requirements. A written Notice of Violation and Proposed Imposition of Civil Penalty (Notice) was served upon the Licensee by letter dated June 9, 1993. The Notice states the nature of the violations, the provisions of the NRC's requirements that the Licensee had violated, and the amount of the civil penalty proposed for the violations. The Licensee responded to the Notice by letters dated June 30 and July 1,

1993. In its responses, the Licensee objects to the characterization of Violation I.A as willful, and requests mitigation of the civil penalty.

III

After consideration of the Licensee's responses and the statements of fact, explanation, and argument for mitigation contained therein, the NRC staff has determined, as set forth in the Appendix to this Order, that the violation occurred as stated and that the penalty proposed for the violation designated in the Notice should be imposed.

IV

In view of the foregoing and pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (Act), 42 U.S.C. 2282, and 10 CFR 2.205, IT IS HEREBY ORDERED THAT:

The Licensee pay a civil penalty in the amount of $6,000 within 30 days of the date of this Order, by check, draft, money order, or electronic transfer, payable to the Treasurer of the United States and mailed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555.

V

The Licensee may request a hearing within 30 days of the date of this Order. A request for a hearing should be clearly marked as a "Request for an Enforcement Hearing" and shall be addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555. Copies also shall be sent to the Assistant General Counsel for Hearings and Enforcement at the same address and to the Regional Administrator, NRC Region III, 799 Roosevelt Road, Glen Ellyn, Illinois 60137.

If a hearing is requested, the Commission will issue an Order designating the time and place of the hearing. If the Licensee fails to request a hearing within 30 days of the date of this Order, the provisions of this Order shall be effective without further proceedings. If payment has not been made by that time, the matter may be referred to the Attorney General for collection.

In the event the Licensee requests a hearing as provided above, the issues to be considered at such hearing shall be:

Whether on the basis of Violations I.A and I.B admitted by the Licensee, this Order should be sustained.

FOR THE NUCLEAR REGULATORY COMMISSION

James Lieberman, Director
Office of Enforcement

Dated at Rockville, Maryland
this 24th day of August 1993

APPENDIX
EVALUATIONS AND CONCLUSIONS

On June 9, 1993, a Notice of Violation and Proposed Imposition of Civil Penalty (Notice) was issued for violations identified during an NRC inspection on April 2 through 7, 1993. Mayo Foundation (Licensee) responded to the Notice on June 30 and July 1, 1993. In its responses, the Licensee admits all of the violations, objects to the characterization of Violation I.A as willful, and requests mitigation of the civil penalty. The NRC's evaluation and conclusions regarding the licensee's requests are as follows:

Restatement of Violation I

A. License Condition No. 30 as contained in Amendment No. 43 dated June 4, 1992, states, in part, that the licensee shall conduct its program in accordance with the statements, representations and procedures contained in an application dated March 31, 1991, and a letter dated July 11, 1991.

The letter dated July 11, 1991, states, in part, in Item 6.b, "Phosphorus-32 Safety Instructions," that a daily meter survey is required if the laboratory possesses greater than 10 times the Annual Limit of Intake (ALI) (ten times 900 microcuries) or uses more than 10 microcuries of phosphorus-32 on that day.

Contrary to the above, on March 21 and 22, 1993, a daily meter survey was not performed and the laboratory (Guggenheim Building Room 319) possessed 10 millicuries of phosphorus-32, a quantity greater than 10 ALI and used more than 10 microcuries on those days.

B. License Condition No. 30 as contained in Amendment No. 43 dated June 4, 1992, states, in part, that the licensee shall conduct its program in accordance with the statements, representations and procedures contained in an application dated March 31, 1991, and a letter dated July 11, 1991.

The application dated March 31, 1991, states, in part, in Attachment 10.12, "Procedure for Area Surveys," that if major contamination (equal to or greater than 220 dpm/100cm^2) is found of a beta emitter in an unrestricted area, decontamination by laboratory personnel and resurvey by Radiation Safety Officer personnel within two working days are required.

10 CFR 20.201(b) requires that each licensee make such surveys as may be necessary to comply with the requirements of Part 20 and which are reasonable under the circumstances to evaluate the extent of radiation hazards that may be present. As defined in 10 CFR 20.201(a), "survey" means an evaluation of the radiation hazards incident to the

production, use, release, disposal, or presence of radioactive materials or other sources of radiation under a specific set of conditions.

Contrary to the above:

1. From March 23, 1993, through April 3, 1993, the licensee did not perform adequate surveys to determine the presence of phosphorus-32 contamination in unrestricted areas including individuals' clothing, vehicles, homes, and a church, to assure that contamination limits in these unrestricted areas were not exceeded.

2. On March 25, 1993, major contamination (approximately 3,300 dpm) of phosphorus-32 (a beta emitter) was found by a laboratory person in his home (an unrestricted area) and a resurvey was not performed by Radiation Safety Office personnel until April 2, 1993, a period exceeding two days.

Summary of Licensee's Response to Violation I

The Licensee admits Violation I.

Summary of Licensee's Request for Mitigation

The Licensee objects to the characterization that Violation I.A was willful in nature. The Licensee asserts that the term willful carries the strong connotation that the action (omission) was planned, deliberate, and intentional. The Licensee asserts that while the omission of a daily survey by this trainee was careless and negligent, it cannot be characterized as an omission that resulted from careful and thorough consideration, i.e., a deliberate decision, nor was the omission meant to deceive anyone.

The Licensee argues that the failure of the research trainee to conduct daily surveys should be characterized as an omission that resulted from a lack of thought and a lack of awareness of consequences, and that this omission does not differ in principle from many other violations that have resulted in enforcement actions where the violations were not considered willful in nature even though the licensee knew about the specific regulatory requirements associated with the violation.

In the Licensee's view, characterization of one type of violation as willful without informing licensees that such violations will be considered willful constitutes inconsistent, arbitrary, and capricious enforcement of regulatory requirements, which is unfair and injurious to the licensee.

The Licensee further asserts that characterization of a violation as willful on the basis that a trainee knew about a requirement

but failed to follow it, is a change in priority of importance that should be communicated to the regulated community prior to its implementation. The Licensee believes that "willfulness" is understood by the regulated community to be a deliberate action taken on the part of a licensee to avoid the implementation of a regulatory requirement or the failure to incorporate such a requirement into the licensee's safety program. The Licensee also asserts that characterization of the failure of an individual employee of a licensee to perform a specific safety requirement that has been incorporated into the licensee's safety program as willful is precedent setting and has not been communicated to licensees. Finally, the Licensee argues that the discussion of willful violations in 10 CFR Part 2 distinguishes between a person who is a licensee official, such as the Radiation Safety Officer, and a non-supervisory employee. According to the Licensee, the individual in question was a trainee who stood to gain no economic or other significant advantage as a result of this violation.

NRC Evaluation of Licensee's Request for Mitigation

The NRC's policy on willfulness has been formally communicated to this Licensee and the licensed community in general by the General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy) 10 CFR Part 2, Appendix C. Section IV.C of the policy states:

> [T]the severity level of a violation may be increased if the circumstances surrounding the matter involve careless disregard of requirements, deception, or other indications of willfulness. The term 'willfulness' as used in this policy embraces a spectrum of violations ranging from deliberate intent to violate or falsify to and including careless disregard for requirements.* In determining the specific severity level of a violation involving willfulness, consideration will be given to such factors as the position and responsibilities of the person involved in the violation (e.g., licensee official or non-supervisory employee), the significance of any underlying violation, the intent of the violator (i.e., careless disregard or deliberateness), and the economic or other advantage, if any, gained as a result of the violation. The relative weight given to each of these factors in arriving at the appropriate severity level will be dependent on the circumstances of the violation.

Violations I.A and I.B were categorized in the aggregate as a Severity Level II problem and a $6,000 civil penalty was assessed for Violation I.A. Violations I.A and I.B would normally have been categorized at Severity Level III; however, the severity level was increased to Severity Level II because of the willful nature of Violation I.A.

for Violation I.A. Violations I.A and I.B would normally have been categorized at Severity Level III; however, the severity level was increased to Severity Level II because of the willful nature of Violation I.A.

Violation I.A was willful, as that term is used in the Enforcement policy, because the researcher had been trained on the survey requirement and was aware of the requirement, yet chose not to follow it. Further, the researcher was performing post doctorate research and had previously used phosphorous-32 at another institution which indicates significant education and knowledge as to why such requirements exist and should be followed. On March 21, 1993, the researcher unknowingly contaminated his hands when he opened a new vial containing 10 millicuries of phosphorus-32, and he spread phosphorus-32 within the laboratory and on his clothing. The contamination went undetected due to the researcher's failure to survey himself and the laboratory prior to leaving the work area. The researcher indicated that the survey meter located in the laboratory had low batteries and that he was in a hurry to leave. The researcher worked in the laboratory again that night, and again failed to survey. On March 22, 1993, the researcher continued to work with phosphorus-32, and again, he did not survey himself and the laboratory. In all three cases, he did not take the time to have the meter batteries changed or to use a functioning meter from an adjacent laboratory. The authorized user had trained the researcher on the survey requirement, and the researcher indicated that he was aware of the requirement.

While the NRC staff agrees that the researcher's actions were not done for deception or monetary gain, those actions went well beyond mere forgetfulness or accidental omission; they demonstrated an unwillingness to comply with a known requirement. Moreover, if the researcher's actions had been based on deception or monetary gain, then direct enforcement action against the researcher under 10 CFR 30.10 would have been considered. The severity level of the problem was appropriately categorized at Severity Level II based on the willful nature of Violation I.A. In determining the severity level, the NRC staff weighed the significance of the underlying violation (including, in this case, the consequences), the advantage to the researcher (saving time), and the fact that the researcher was a non-supervisory employee. Moreover, if the surveys had been performed by the researcher, the offsite release would not have occurred.

Based on the above, the Licensee's argument that Violation I.A. was not willful does not provide an adequate basis for mitigation of the civil penalty. Additionally, the Licensee has provided no other basis for mitigation of the civil penalty.

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
799 ROOSEVELT ROAD
GLEN ELLYN, ILLINOIS 60137-5927

August 2, 1993

Docket No. 030-02049
License No. 21-04177-01
EA 93-179

Mercy Memorial Medical Center
ATTN: Mr. Robert P. Harrison
Chief Operating Officer
1234 Napier Avenue
St. Joseph, MI 49085

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTIES - $6,250
NRC INSPECTION REPORT No. 030-02049/93001

Dear Mr. Harrison:

This refers to the NRC inspection conducted between March 26 and April 7, 1993, at the Mercy-Memorial Medical Center in St. Joseph, Michigan. The inspection report was sent to you on May 10, 1993. During the inspection, apparent violations of NRC requirements were identified relating to your quality management and radiation safety training programs. These violations resulted in a misadministration when a patient received an inadvertent exposure (approximately 50 rads) to the buttocks, an area that was not intended for treatment. The violations also resulted in an unwarranted exposure to the nurse attending to the patient when she picked up the source in her bare hands and received approximately 15%-25% of the maximum allowable extremity dose. On July 20, 1993, an open enforcement conference was conducted with you and members of your staff to discuss the apparent violations, their causes, and your corrective actions. A copy of the Enforcement Conference Report was sent to you on July 26, 1993.

The NRC is concerned that the radiation safety and quality management programs were not implemented to ensure adequate safety and preclude events such as those that occurred. With respect to the unwarranted dose to the nurse, at the time of the inspection you had not evaluated the incident or calculated the exposure. Subsequently, at the request of the inspector, you performed the evaluation and determined that the exposure was about 15% of that allowed by the NRC regulations. With regard to that incident, it was fortuitous that the nurse did not receive a

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significantly higher dose, or that any other member of the hospital staff or the public was not exposed. It was also fortuitous that the nurse did not accidently dispose of the source in ordinary trash because she thought the object was a screw rather than a radioactive source.

During the conference you also stated that at times you deviated from the prescribed brachytherapy radiation plan without first providing written directives. Furthermore, in several instances the directives were not signed by the authorized user.

Violation I.A involved the failure to prepare the written directives, to establish a written quality management program to meet the specific objectives for brachytherapy uses, and to identify and evaluate the unintended irradiation to the patient. They are classified in the aggregate as a Severity Level III problem. Violation I.B involved the failure to assure that the radiation safety activities were being performed in accordance with approved procedures, and to provide required radiation training. They are also classified in the aggregate as a Severity Level III problem because the result was a substantial potential for an overexposure and an unwarranted exposure to the hand of the nurse. These severity level classifications are in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (NRC Enforcement Policy), 10 CFR Part 2, "Appendix C.

The NRC license issued to Mercy Memorial Medical Center entrusts responsibility for radiation safety to the management of the hospital, the Radiation Safety Committee (RSC), and the Radiation Safety Officer (RSO). Therefore, the NRC expects effective management control and oversight of this licensed program. Incumbent upon each NRC licensee is the responsibility to protect the public health and safety by ensuring that all requirements of the NRC license are met. The violations described in the enclosed Notice indicate a significant breakdown in the process by which management at the facility, and in particular, the RSC and RSO, ensure that the radiation safety program is properly implemented. This must be corrected.

The NRC recognizes that subsequent to the NRC inspection, actions were taken by you to correct the problems. However, to emphasize NRC's concern with the lack of adequate oversight of your program I have been authorized to issue the enclosed Notice of Violation and Proposed Imposition of Civil Penalties in the cumulative amount of $6,250 for the Severity Level III problems. The base civil penalty for each Severity Level III problem is $2,500. The escalation and mitigation factors in the NRC Enforcement Policy were considered, as discussed below.

Violation I.A was identified by the NRC and therefore was escalated 50%. Although your corrective actions were adequate to

improve the control and implementation of the quality management and radiation safety programs, these actions were not implemented until after the NRC discussed them with you and issued a Confirmatory Action Letter. Therefore, no mitigation of the base civil penalty was warranted. The other escalation and mitigation factors were considered and no further adjustment to the base civil penalty was warranted.

You identified Violation I.B concerning the training problem and therefore 50% mitigation is appropriate. Your corrective actions included training all nurses and requiring them to sign a document to that affect; conducting "dry runs" using dummy sources; committing to annual retraining; and posting pictures of various brachytherapy devices in prominent locations. These actions appear to be comprehensive and therefore 50% mitigation is also appropriate for this factor. However, these are offset by 100% escalation for duration because you confirmed at the enforcement conference that the training given to the nurses was inadequate because it had not addressed critical elements such as the size and appearance of radioactive sources. Furthermore, this deficiency had existed for a considerable length of time. Therefore, 100% escalation is appropriate for this factor. The other escalation and mitigation factors were considered and no further adjustment to the base civil penalty was warranted.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. In your response, you should document the specific actions taken and any additional actions you plan to prevent recurrence. After reviewing your response to this Notice, including your proposed corrective actions and the results of future inspection, the NRC will determine whether further enforcement action is necessary to ensure compliance with NRC regulatory requirements.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter and its enclosure will be placed in the NRC Public Document Room.

The responses directed by this letter and the enclosed Notice are not subject to the clearance procedures of the Office of

improve the control and implementation of the quality management and radiation safety programs, these actions were not implemented until after the NRC discussed them with you and issued a Confirmatory Action Letter. Therefore, no mitigation of the base civil penalty was warranted. The other escalation and mitigation factors were considered and no further adjustment to the base civil penalty was warranted.

You identified Violation I.B concerning the training problem and therefore 50% mitigation is appropriate. Your corrective actions included training all nurses and requiring them to sign a document to that affect; conducting "dry runs" using dummy sources; committing to annual retraining; and posting pictures of various brachytherapy devices in prominent locations. These actions appear to be comprehensive and therefore 50% mitigation is also appropriate for this factor. However, these are offset by 100% escalation for duration because you confirmed at the enforcement conference that the training given to the nurses was inadequate because it had not addressed critical elements such as the size and appearance of radioactive sources. Furthermore, this deficiency had existed for a considerable length of time. Therefore, 100% escalation is appropriate for this factor. The other escalation and mitigation factors were considered and no further adjustment to the base civil penalty was warranted.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. In your response, you should document the specific actions taken and any additional actions you plan to prevent recurrence. After reviewing your response to this Notice, including your proposed corrective actions and the results of future inspection, the NRC will determine whether further enforcement action is necessary to ensure compliance with NRC regulatory requirements.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter and its enclosure will be placed in the NRC Public Document Room.

The responses directed by this letter and the enclosed Notice are not subject to the clearance procedures of the Office of

Management and Budget as required by the Paperwork Reduction Act of 1980, Pub. L. No. 96-511.

Sincerely,

RJ Mueller for

John B. Martin
Regional Administrator

Enclosure:
Notice of Violation and Proposed Imposition
of Civil Penalties

cc/enclosure
DCD/DCB (RIDS)

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTIES

Mercy-Memorial Medical Center
St. Joseph, Michigan

Docket No. 030-02049
License No.21-04177-01
EA 93-179

During an NRC inspection conducted between March 26 and April 7, 1993, violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedures for NRC Enforcement Actions," 10 CFR Part 2, Appendix C, the Nuclear Regulatory Commission proposes to impose civil penalties pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (Act), 42 U.S.C. 2282, and 10 CFR 2.205. The particular violations and associated civil penalties are set forth below:

I. Violations Assessed a Civil Penalty

A. 10 CFR 35.32(a) requires, in part, that a licensee establish and maintain a written quality management program to provide high confidence that byproduct material or radiation from byproduct material will be administered as directed by the authorized user. The quality management program must include in part written policies and procedures to meet the specific objectives that (1) prior to administration a written directive is prepared for any brachytherapy dose, (2) final plans of treatment and related calculations for brachytherapy are in accordance with the written directive, (3) each administration is in accordance with the written directive, and that (4) any unintended deviation from the written directive is identified and evaluated, and appropriate action is taken. The licensee's written quality management program to address the specific objectives was submitted to NRC on January 2, 1992.

10 CFR 35.2 specifies, in part, that a written directive means an order in writing for a specific patient, dated and signed by an authorized user prior to administration of radiation. In addition, for brachytherapy uses the written directive must also include: (i) prior to implantation, the radioisotope, the number of sources, and the source strengths; and (ii) after implantation but prior to completion of the procedure, the radioisotope, treatment site, and total source strength and exposure time (or, equivalently, the total dose).

1. Contrary to the above, from January 27, 1992, to April 7, 1993, the licensee failed to establish and maintain a written quality management program to meet the specific objectives for brachytherapy uses. Specifically, the licensee's written

quality management program dated January 2, 1992, did not establish policies and procedures that (i) final plans of treatment and related calculations for brachytherapy are in accordance with the written directive, and that (ii) each brachytherapy administration is in accordance with the written directive.

2. Contrary to the above, from January 27, 1992 to April 7, 1993, the licensee failed to properly prepare written directives on several occasions. Specifically, the authorized user did not sign the written directives on July 7 and 21, and October 13, 1992. The written directives were not prepared prior to implantation of sources on March 3 and September 15, 1992. The actual source strengths and exposure time (or equivalently the total dose) were not recorded for written directives on March 3, July 7, and September 15, 1992. In these cases, the licensee's written directives failed to meet the specific objective.

3. Contrary to the above, on February 17, 1993, the licensee did not identify and evaluate an unintended deviation from the written directive, and take appropriate action. Specifically, the licensee did not identify that the radiation dose to the healthy tissue from the dislodged source was an unintended deviation from the written directive and the licensee did not take appropriate action to determine that a misadministration had occurred.

This is a Severity Level III problem (Supplement VI).
Civil Penalty - $3,750

B. 10 CFR 35.21(a) requires that the licensee, through the Radiation Safety Officer, ensure that radiation safety activities are being performed in accordance with approved procedures and regulatory requirements in the daily operation of the licensee's byproduct materials program. The licensee's procedures for safe use of brachytherapy sources are described in the licensee's application dated January 19, 1989, and were approved by License Condition No. 20.

The licensee's application dated January 19, 1989, states in Item No. 10.15 that the licensee will establish and implement "Procedures for Therapeutic Uses of Sealed Sources."

The licensee's "Procedures for Therapeutic Uses of

Sealed Sources," instructs nurses to "Never touch needles, capsules, or containers holding brachytherapy sources. If a source becomes dislodged, use long forceps and put it in the corner of the room or in the shielded container provided; contact the Radiation Safety Officer."

10 CFR 35.410 requires that a licensee provide radiation safety instruction to all personnel caring for a patient undergoing implant therapy. This instruction must describe: (1) Size and appearance of the brachytherapy sources; (2) Safe handling and shielding instructions in case of a dislodged source; (3) Procedures for patient control; (4) Procedures for visitor control; and (5) Procedures for notification of the Radiation Safety Officer if the patient dies or has a medical emergency.

1. Contrary to the above, on February 17, 1993, the licensee, through its Radiation Safety Officer, failed to ensure that radiation safety activities were being performed in accordance with approved procedures and regulatory requirements in the daily operation of the licensee's byproduct materials program. Specifically, the Radiation Safety Officer did not provide radiation safety oversight during a brachytherapy procedure in that a nurse caring for a patient undergoing brachytherapy at the licensee's facility discovered a dislodged brachytherapy source and removed it from the patient's bed with her bare hand. The nurse received an unwarranted radiation dose to the hand.

2. Contrary to the above, as of February 23, 1993, the licensee failed to provide the required radiation safety instruction to all personnel caring for patients undergoing implant therapy. Specifically, the licensee did not describe the size and appearance of brachytherapy sources to nurses that were caring for patients undergoing brachytherapy at the licensee's facility.

This is a Severity Level III problem (Supplement IV)
Civil Penalty - $2,500

II. Violations Not Assessed a Civil Penalty

10 CFR 35.21(b)(1) requires, in part, that the licensee's Radiation Safety Officer investigate accidents, misadministrations, and other deviations from approved

radiation safety practice and implement corrective actions as necessary.

10 CFR 20.201(b) requires that each licensee make such surveys as may be necessary to comply with the requirements of Part 20 and which are reasonable under the circumstances to evaluate the extent of radiation hazards that may be present. As defined in 10 CFR 20.201(a), "survey" means an evaluation of the radiation hazards incident to the production, use, release, disposal, or presence of radioactive materials or other sources of radiation under a specific set of conditions.

1. Contrary to the above, as of March 26, 1993, the licensee's Radiation Safety Officer did not investigate accidents, misadministrations, and other deviations from approved radiation safety practice and implement corrective actions as necessary. Specifically, the Radiation Safety Officer did not investigate the February 17, 1993, dislodged brachytherapy source event that led to a misadministration.

2. Contrary to the above, as of April 7, 1993, the licensee did not make evaluations to assure compliance with that part of 10 CFR 20.101 that limits the radiation dose to the extremities. Specifically, the licensee did not calculate or measure the radiation dose to the hand of the nurse who picked up a cesium-137 brachytherapy source containing 23 millicuries.

This is a Severity Level IV violation (Supplement VI).

Pursuant to the provisions of 10 CFR 2.201, Mercy-Memorial Medical Center is hereby required to submit a written statement of explanation to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, within 30 days of the date of this Notice of Violation and Proposed Imposition of Civil Penalties (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each alleged violation: (1) admission or denial of the alleged violation, (2) the reasons for the violation if admitted, and if denied, the reasons why, (3) the corrective steps that have been taken and the results achieved, (4) the corrective steps that will be taken to avoid further violations, and (5) the date when full compliance will be achieved.

If an adequate reply is not received within the time specified in this Notice, an order or a Demand for Information may be issued to show cause why the license should not be modified, suspended, or revoked or why such other action as may be proper should not be taken. Consideration may be given to extending the response

time for good cause shown. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, this response shall be submitted under oath or affirmation.

Within the same time as provided for the response required above under 10 CFR 2.201, the Licensee may pay the civil penalties by letter addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, with a check, draft, money order, or electronic transfer payable to the Treasurer of the United States in the amount of the civil penalty proposed above, or the cumulative amount of the civil penalties if more than one civil penalty is proposed, or may protest imposition of the civil penalties, in whole or in part, by a written answer addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission. Should the Licensee fail to answer within the time specified, an order imposing the civil penalties will be issued. Should the Licensee elect to file an answer in accordance with 10 CFR 2.205 protesting the civil penalties, in whole or in part, such answer should be clearly marked as an "Answer to a Notice of Violation" and may: (1) deny the violations listed in this Notice, in whole or in part, (2) demonstrate extenuating circumstances, (3) show error in this Notice, or (4) show other reasons why the penalties should not be imposed. In addition to protesting the civil penalties, in whole or in part, such answer may request remission or mitigation of the penalties.

In requesting mitigation of the proposed penalties, the factors addressed in Section VII.B.2 of 10 CFR Part 2, Appendix C should be addressed. Any written answer in accordance with 10 CFR 2.205 should be set forth separately from the statement or explanation in reply pursuant to 10 CFR 2.201, but may incorporate parts of the 10 CFR 2.201 reply by specific reference (e.g., citing page and paragraph numbers) to avoid repetition. The attention of the Licensee is directed to the other provisions of 10 CFR 2.205, regarding the procedure for imposing a civil penalties.

Upon failure to pay any civil penalties due which subsequently has been determined in accordance with the applicable provisions of 10 CFR 2.205, this matter may be referred to the Attorney General, and the penalties, unless compromised, remitted, or mitigated, may be collected by civil action pursuant to Section 234(c) of the Act, 42 U.S.C. 2282c.

The response noted above (Reply to Notice of Violation, letter with payment of civil penalties, and Answer to a Notice of Violation) should be addressed to: Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555 with a copy to the Regional Administrator, U.S. Nuclear Regulatory Commission, Region III.

Dated at Glen Ellyn, Illinois
this 2nd day of August 1993

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
799 ROOSEVELT ROAD
GLEN ELLYN, ILLINOIS 60137-5927

July 9, 1993

Docket No. 030-28875
License No. 48-24566-01
EA 93-150

Mobile Cardiovascular Testing
ATTN: Dennis Rakowski, Vice President,
Aurora Health Care
1218 West Kilbourn Avenue, Suite 220
Milwaukee, Wisconsin 53233

Dear Mr. Rakowski:

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY - $2,500
(NRC INSPECTION REPORT NO. 030-28875/93001)

This refers to the routine safety inspection conducted from May 26 to June 11, 1993 at the four facilities operated by Mobile Cardiovascular Testing, a subsidiary of Aurora Health Care. The facilities are located at the Metropolitan Imaging Center, the Family Health Plan Center, the New Town Diagnostic Center, and at your base facility, Mobile Cardiovascular Testing, all in Milwaukee, Wisconsin. The report documenting this inspection was mailed to you by letter, dated June 25, 1993. Significant violations of NRC requirements were identified during the inspection, and on June 29, 1993, an enforcement conference was held in the Region III office. Attending the enforcement conference were you, Mr. William L. Axelson, Deputy Director, Division of Radiation Safety and Safeguards, and other members of our respective staffs.

The inspection found 12 violations of NRC requirements that are fully described in the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice). These violations in the aggregate are indicative of a breakdown in the control of licensed activities that collectively represent a lack of attention toward licensed activities. Therefore, in accordance with the "Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy) 10 CFR Part 2, Appendix C, the violations are classified in the aggregate as a Severity Level III problem.

The root causes of the violations and the subsequent corrective actions were discussed during the enforcement conference. The significant factor contributing to the violations appeared to be a major expansion in your business during the past 1-2 years that

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placed major demands on your Radiation Safety Officer (RSO) in areas other than radiation safety. You also stated that management was not auditing the radiation safety function as it routinely does other areas of the company, such as the annual fiscal audit. The NRC recognizes that immediate corrective actions were taken, consisting of: developing a strategic recovery plan; authorizing the hiring of three more technicians to assist the RSO; retaining a technical consultant to audit your radiation safety program on a quarterly basis for the next two years; and retraining your technical staff.

As a holder of a license issued by the NRC, you are entrusted with the responsibility for radiation safety at each facility you operate. The NRC expects effective management oversight to ensure that all requirements of the NRC license are met. Therefore, to ensure that management effectively oversees the implementation of its NRC licensed program, I have decided to issue the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice) in the amount of $2,500 for the Severity Level III problem.

The base value of a civil penalty for a Severity Level III problem is $2,500. The civil penalty adjustment factors in the Enforcement Policy were considered. The civil penalty was initially escalated 50 percent because the NRC identified all of the violations. However, this was offset by 50 percent mitigation for your prompt and extensive corrective actions as previously described. The NRC noted that no violations were identified during the last NRC inspections (October 25, 1990, and April 3, 1986). However, mitigation of a civil penalty is not warranted where the current performance of a licensee reflects a substantial decline in its performance since the last NRC inspection. Therefore, an adjustment was not made to the base civil penalty for your past good performance. The remaining factors in the enforcement policy were also considered and no further adjustment to the base civil penalty is considered appropriate. On balance no adjustment was made to the amount of the base civil penalty.

You are required to document your response to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. In your response, please ensure that you describe the actions you have taken to strengthen the management oversight of your NRC licensed program. You should address the management of the program and any improvements needed in the procedures and practices to achieve and maintain compliance with NRC requirements and license conditions, including internal or external audits to assess the effectiveness of your program.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice,"

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter, its enclosure, and your response will be placed in the NRC Public Document Room.

The response directed by this letter and the enclosed Notice are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, Public Law No. 96-511.

Sincerely,

John B. Martin
Regional Administrator

Enclosure:
Notice of Violation and Proposed
Imposition of Civil Penalty

cc/enclosure
DCD/DCB (RIDS)

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

Mobile Cardiovascular Testing
Milwaukee, Wisconsin

Docket No. 030-28875
License No. 48-24566-01
EA 93-150

During an NRC inspection conducted from May 26 to June 11, 1993, violations of NRC requirements were identified. In accordance with the "Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C, the Nuclear Regulatory Commission proposes to impose a civil penalty pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (Act), 42 U.S.C. 2282, and 10 CFR 2.205. The particular violations and associated civil penalty are set forth below:

A. 10 CFR 20.207 (a) requires that licensed materials stored in an unrestricted area be secured against unauthorized removal from the place of storage. 10 CFR 20. 207 (b) requires that licensed materials not in an unrestricted area and not in storage be tended under constant surveillance and immediate control of the licensee. As defined in 10 CFR 20.3(a)(17), an unrestricted area is any area access to which is not controlled by the licensee for purposes of protection of individuals from exposure to radiation and radioactive materials.

Contrary to the above, on May 26, 1993, licensed material consisting of technetium-99(m) contamination on an imaging camera located in the hallway of Mobile Cardiovascular Testing, an unrestricted area, was not secured against unauthorized removal and was not under constant surveillance and immediate control of the licensee.

B. 10 CFR 35.59 (g) requires that a licensee in possession of a sealed source conduct a quarterly physical inventory of all such sources in its possession.

Contrary to the above, the licensee did not conduct a physical inventory of all sealed sources in its possession from January 1, 1992, to March 31, 1993, a period in excess of a calendar quarter.

C. 10 CFR 35.70 (f) requires that a licensee conduct weekly surveys for removable contamination of all areas where radiopharmaceuticals are routinely prepared for use, administered, or stored, as required by 10 CFR 35.70(e), so as to be able to detect contamination on each wipe sample of 2,000 disintegrations per minute.

Contrary to the above, on March 30, 1993, and May 7, 14, and 21, 1993, the licensee failed to conduct weekly surveys for contamination in areas at the main facility of Mobile

Cardiovascular Testing where radiopharmaceuticals were routinely prepared for use, administered, or stored in such a manner so as to be able to detect contamination on each wipe sample of 2,000 disintegrations per minute. Specifically, the equipment used to analyze the wipe samples was not sufficiently sensitive to detect 2,000 disintegrations per minute.

D. 10 CFR 35.50(e) and (e)(2) require, in part, that a licensee retain records of the annual accuracy tests of the dose calibrator and that records include the signature of the Radiation Safety Officer. 10 CFR 35.50(e) and (e)(3) further require, in part, that a licensee retain records of the quarterly dose calibrator linearity tests and that the records include the signature of the Radiation Safety Officer.

Contrary to the above:

1. The Radiation Safety Officer's signature was not included on the records of the annual accuracy tests of the dose calibrator performed on December 22, 1992, at the Family Health Plan Center, and performed on October 29, 1992, for the dose calibrators at the other facilities operated by the licensee (Mobile Cardiovascular Testing, Metropolitan Imaging Center, and New Town Diagnostic Center).

2. The Radiation Safety Officer's signature was not included on the records of the linearity tests of the dose calibrator performed on December 8, 1992, at the Family Health Plan Center, and performed on November 13, 1992, for the dose calibrator at the Metropolitan Imaging Center.

E. Condition 19 of License No.48-24566-01 requires that licensed material be possessed and used in accordance with statements, representations, and procedures contained in the application dated September 30, 1990, and incorporates the program described in Appendix A of NRC Regulatory Guide 10.8, "Guide for the Preparation of Applications for Medical Use Programs," Revision 2, dated August 1987.

1. Item 8 of the attachment to the application dated September 30, 1990, requires the licensee establish the model training program that was published in Appendix A of Regulatory Guide 10.8, Revision 2.

   Appendix A of Regulatory Guide 10.8, Revision 2, requires that personnel will be instructed before assuming duties with, or in the vicinity of, radioactive materials. Further, individuals will be

trained on the potential hazards associated with radioactive material in each area where the employees will work and the licensee's in-house work rules. Additionally, personnel will receive annual refresher training.

Contrary to the above,

a. Before assuming duties in March 1993, the licensee failed to instruct a secretary working in the vicinity of radioactive materials at Metropolitan Imaging Center on the potential hazards associated with radioactive material.

b. Since January 1993, the licensee failed to instruct a nuclear medicine technologist working at Metropolitan Imaging Center in all of the licensee's in-house work rules. Specifically, the technologist was not trained to check the survey meter for proper operation.

c. In 1992, the licensee failed to provide annual refresher training to all employed technical and ancillary personnel.

2. Item 9.3 of the attachment to the application dated September 30, 1990, requires the licensee develop a dose calibrator calibration procedure. The licensee's procedure is appended as Attachment 9.3 to the application. Attachment 9.3 requires that the licensee follow the calibration methods and frequencies for dose calibrators and defined in Regulatory Guide 10.8, Revision 2, Appendix C.

a. Item 5.f of Appendix C to Regulatory Guide 10.8 states, in part, that if the worst linearity deviation exceeds +/- 5 percent, the dose calibrator should be repaired or adjusted. If this cannot be done, the licensee is required to make a correction table or graph that will allow conversion from activity indicated by the dose calibrator to "true activity".

Contrary to the above, on December 8, 1992, linearity exceeded + 5 percent for a dose calibrator and the licensee failed to repair, adjust or make a correction table or graph to convert from activity indicated by the dose calibrator to "true activity". Specifically, the licensee's dose calibrator located at the Family Health Plan Center exceeded + 5 percent and was not repaired, adjusted or a correction table or

graph was created.

b. Item 1.b of Appendix C to Regulatory Guide 10.8 states, in part, that the linearity test of the dose calibrator shall be performed at least quarterly.

Contrary to the above,

(1) The licensee failed to test the linearity of the dose calibrator at Mobile Cardiovascular Testing from September 1, 1991, through March 31, 1993, a period exceeding one quarter.

(2) The licensee failed to test the linearity of the dose calibrators located at its facilities at Metropolitan Imaging Center, Family Health Plan Center, and New Town Diagnostic Center during the 1st quarter of 1993.

F. Item 10.4 of the attachment to the application dated September 30, 1990, requires the licensee establish the model safety rules for the use of radiopharmaceuticals that was published in Appendix I of Regulatory Guide 10.8, Revision 2.

1. Item 9 of Appendix I of Regulatory Guide 10.8, Revision 2, requires, in part, that radioactive waste be disposed of only in designated, labeled, and properly shield receptacles.

Contrary to the above, radioactive waste was not disposed of in designated, labeled, and properly shielded containers. Specifically, on May 26, 1993, the licensee disposed of radioactive wastes at Mobile Cardiovascular Testing and New Town Diagnostic Center in containers that were not labeled and properly shielded. Further, on May 27, 1993, the licensee disposed of radioactive waste at Metropolitan Imaging Center in a container that was not labeled and properly shielded.

2. Item 1 of Appendix I of Regulatory Guide 10.8, Revision 2, requires, in part, that laboratory coats or other protective clothing will be used at all times in areas where radioactive materials are used.

Contrary to the above, the licensee failed to ensure that laboratory coats or other protective clothing were used at all times in areas where radioactive materials

were used. Specifically, on May 26, 1993, a nuclear medicine technologist did not wear a laboratory coat or protective clothing while injecting patients with radiopharmaceuticals in the scan room at Mobile Cardiovascular Testing. Additionally, on May 27, 1993, a nuclear medicine technologist did not always wear a laboratory coat or protective clothing while injecting patients with radiopharmaceuticals at Metropolitan Imaging Center.

3. Item 7 of Appendix I of Regulatory Guide 10.8, Revision 2, requires, in part, that personnel monitoring devices be worn at all times while in areas where radioactive materials are used or stored. Item 8 of Regulatory Guide 10.8, Appendix I, further requires that a finger exposure monitor shall be worn during the preparation, assay, and injection of radiopharmaceuticals.

Contrary to the above, on May 27, 1993, the licensee failed to ensure that personnel monitoring devices were worn at all times while personnel were in areas where radioactive materials were used or stored. Further, the licensee failed to ensure that personnel wore a finger exposure monitor during the preparation, assay, and injection of radiopharmaceuticals. Specifically, the nuclear medicine technologist at Metropolitan Imaging Center did not wear a personnel monitor device while working in areas where radioactive materials were used and stored and did not wear a finger exposure monitor during the preparation, assay and injection of radiopharmaceuticals.

G. Item 10.12 of the attachment to the application dated September 30, 1990, requires the licensee establish the model procedure for area surveys that was published in Appendix N of Regulatory Guide 10.8, Revision 2.

1. Item 1.a. of Appendix N under the section titled, "Ambient Dose Rate Surveys," requires, in part, that the areas where radiopharmaceuticals are prepared and administered will be surveyed at the end of each day of use with a radiation detection survey meter.

Contrary to the above, on May 20, 21, 24, and 25, 1993, the licensee failed to survey at the end of the day the areas where radiopharmaceuticals were prepared and administered at Mobile Cardiovascular Testing.

2. Item 2 In Appendix N under the section titled, "Records," requires, in part, that the Radiation Safety Officer initial dose rate and contamination survey records at least monthly.

Contrary to the above, since May 4, 1992, the Radiation Safety Officer did not initial any dose rate or contamination survey records.

This is a Severity Level III problem (Supplement VI). Cumulative Civil Penalty - $2,500.

Pursuant to the provisions of 10 CFR 2.201, the Mobile Cardiovascular Testing (Licensee) is hereby required to submit a written statement of explanation to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, within 30 days of the date of this Notice of Violation and Proposed Imposition of Civil Penalty (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each alleged violation: (1) admission or denial of the alleged violation, (2) the reasons for the violation if admitted, and if denied, the reasons why, (3) the corrective steps that have been taken and the results achieved, (4) the corrective steps that will be taken to avoid further violations, and (5) the date when full compliance will be achieved. If an adequate reply is not received within the time specified in this Notice, an order or a demand for information may be issued as to why the license should not be modified, suspended, or revoked or why such other actions as may be proper should not be taken. Consideration may be given to extending the response time for good cause shown. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, this response shall be submitted under oath or affirmation.

Within the same time as provided for the response required under 10 CFR 2.201, the Licensee may pay the civil penalty by letter addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, with a check, draft, money order, or electronic transfer payable to the Treasurer of the United States in the amount of the civil penalty proposed above, or may protest imposition of the civil penalty in whole or in part, by a written answer addressed to the Director, Office of Enforcement, U. S. Nuclear Regulatory Commission. Should the Licensee fail to answer within the time specified, an order imposing the civil penalty will be issued. Should the Licensee elect to file an answer in accordance with 10 CFR 2.205 protesting the civil penalty, in whole or in part, such answer should be clearly marked as an "Answer to a Notice of Violation" and may: (1) deny the violations listed in this Notice in whole or in part, (2) demonstrate extenuating circumstances, (3) show error in this Notice, or (4) show other reasons why the penalty should not be imposed. In addition to protesting the civil penalty in whole or in part, such answer may request remission or mitigation of the penalty.

In requesting mitigation of the proposed penalty, the factors addressed in Section V.B of 10 CFR Part 2, Appendix C (1993), should be addressed. Any written answer in accordance with 10

CFR 2.205 should be set forth separately from the statement or explanation in reply pursuant to 10 CFR 2.201, but may incorporate parts of the 10 CFR 2.201 reply by specific reference (e.g., citing page and paragraph numbers) to avoid repetition. The attention of the Licensee is directed to the other provisions of 10 CFR 2.205, regarding the procedure for imposing a civil penalty.

Upon failure to pay any civil penalty due which subsequently has been determined in accordance with the applicable provisions of 10 CFR 2.205, this matter may be referred to the Attorney General, and the penalty, unless compromised, remitted, or mitigated, may be collected by civil action pursuant to Section 234c of the Act, 42 U.S.C. 2282c.

The responses noted above (Reply to Notice of Violation, letter with payment of civil penalty, and Answer to a Notice of Violation) should be addressed to: Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555 with a copy to the Regional Administrator, U.S. Nuclear Regulatory Commission, Region III, 799 Roosevelt Road, Glen Ellyn, Illinois 60137.

FOR THE NUCLEAR REGULATORY COMMISSION

John B. Martin
Regional Administrator

Dated at Glen Ellyn, Illinois
this 9th day of July 1993

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
799 ROOSEVELT ROAD
GLEN ELLYN, ILLINOIS 60137

January 22, 1993

Docket No. 030-20620
License No. 34-21409-01
EA 92-247

Pike Community Hospital
Attn: Richard Sobota
Administrator
100 Dawn Lane
Waverly, OH 45690

Dear Mr. Sobota:

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY - $3,750
(NRC INSPECTION REPORT NO. 030-20620/92001(DRSS))

This refers to the routine safety inspection at Pike Community Hospital conducted on September 29, 1992. The report documenting the inspection was sent to you by letter dated January 7, 1993, and on January 14, 1993, an open enforcement conference was conducted in the Region III office.

The NRC has determined that 16 violations of NRC requirements occurred under the Byproduct Material License issued to Pike Community Hospital. The violations, which are described in the enclosed Notice of Violation include failure to: assess personal contamination of a technologist; investigate spills and implement corrective actions; perform calculations to estimate the occupational dose from aerosols; review the ALARA program; review the radiation safety program by the Radiation Safety Committee; possess appropriate radiation detection survey equipment; maintain complete records of sealed source leak tests and inventories; conduct dose calibrator tests and maintain complete records; conduct area surveys at the end of the day and maintain appropriate records of daily and weekly surveys; and post NRC requirements.

These violations, taken collectively, represent a significant breakdown in the control of licensed activities at Pike Community Hospital. Therefore, in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy) 10 CFR Part 2, Appendix C, the violations are classified in the aggregate as a Severity Level III problem.

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

The root cause of the violations appears to be a lack of management attention to the radiation safety program by your administration, the Radiation Safety Committee, and the Radiation Safety Officer.

We acknowledge your broad corrective actions presented at the enforcement conference. These include revising your contractual arrangement with your radiology group, providing for increased hours of the radiologist's time at Pike Community Hospital, including increased involvement in quality assurance, inservice education, and safety aspects of the program; engaging a licensed nuclear medicine technician as an independent consultant; and conducting an extended 3-day session of the Radiation Safety Committee to review your program. Additionally, a number of specific corrective actions for the individual violations were discussed at the conference.

Although both the broad and specific corrective actions appear to be acceptable, we are concerned that many of these actions were not implemented earlier following our September 1992 inspection.

The NRC entrusts the responsibility for radiation safety to the management of the hospital. Incumbent upon each NRC licensee is the responsibility to protect the public health and safety, including the health and safety of licensee employees, by assuring that all NRC requirements are met and any potential violations are identified and promptly corrected.

To emphasize the need for effective management oversight of NRC licensed activities by your administration, the Radiation Safety Committee, and the Radiation Safety Officer, I have decided to issue the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice) in the amount of $3,750 for the Severity Level III problem.

The base value of a civil penalty for a Severity Level III problem is $2,500. The civil penalty adjustment factors in the Enforcement Policy were considered. The civil penalty was escalated 50 percent for the identification factor because the NRC identified the violations. Your corrective actions were not sufficiently prompt to warrant mitigation for the corrective action factor as discussed above. The other factors in the Enforcement Policy were considered and no further adjustment to the base civil penalty was considered appropriate. Therefore, based on the above, the base civil penalty has been increased by 50 percent.

Additionally, six concerns were identified during the inspection. Please address those concerns in your response.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your

response. In your response, you should document the specific actions taken and any additional actions you plan to prevent recurrence. After reviewing your response to this Notice, including your proposed corrective actions and the results of future inspections, the NRC will determine whether further NRC enforcement action is necessary to ensure compliance with NRC regulatory requirements.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter, its enclosure, and your responses will be placed in the NRC Public Document Room.

The responses directed by this letter and the enclosed Notice are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, Public Law No. 96-511.

Sincerely,

A. Bert Davis
Regional Administrator

Enclosure:
Notice of Violation and Proposed
Imposition of Civil Penalty

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

Pike Community Hospital
Waverly, Ohio

Docket No. 030-20620
License No. 34-21409-01
EA 92-247

During an NRC inspection conducted on September 29, 1992, violations of NRC requirements were identified. In accordance with the "Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C, the Nuclear Regulatory Commission proposes to impose a civil penalty pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (Act), 42 U.S.C. 2282, and 10 CFR 2.205. The particular violations and associated civil penalty are set forth below:

1. 10 CFR 20.201(b) requires that each licensee make such surveys as may be necessary to comply with the requirements of Part 20 and which are reasonable under the circumstances to evaluate the extent of radiation hazards that may be present. As defined in 10 CFR 20.201(a), "survey" means an evaluation of the radiation hazards incident to the production, use, release, disposal, or presence of radioactive materials or other sources of radiation under a specific set of conditions.

   Contrary to the above, as of September 29, 1992, the licensee did not make surveys to assure compliance with that part of 10 CFR 20.101 that limits the radiation exposure to the extremities and skin of the whole body. Specifically, the licensee did not evaluate the full extent of Tc-99m contamination which may have been present on a technologist who was involved in spills on September 3 and 4, 1992, to determine the radiation dose to the hands and forearms and skin of the whole body.

2. 10 CFR 35.21(a) requires that the licensee, through the Radiation Safety Officer, ensure that radiation safety activities are being performed in accordance with approved procedures. The licensee's procedures are described in the licensee's application dated June 22, 1988, and were approved by License Condition No. 13.

   The licensee's application dated June 22, 1988, states in Item 10.5 that the licensee will establish and implement the model spill procedures published in Appendix J of Regulatory Guide 10.8, Revision 2.

   Appendix J of Regulatory Guide 10.8, Revision 2, "Model Spill Procedures," requires the Radiation Safety Officer to follow up on the cleanup of a minor spill and complete the Radioactive Spill Report and the Radioactive Spill

Contamination Survey that are identified as Exhibit 10 and Exhibit 11 of Regulatory Guide 10.8, Revision 2.

Contrary to the above, as of September 29, 1992, the licensee, through its Radiation Safety Officer, failed to ensure that radiation safety activities were being performed in accordance with the above procedures. Specifically, the Radiation Safety Officer did not follow up on the cleanup of minor Tc-99m spills that occurred on September 3 and 4, 1992, and did not complete the Radioactive Spill Report (Exhibit 10) and the Radioactive Spill Contamination Survey (Exhibit 11).

3. 10 CFR 35.21(a) requires that the licensee, through the Radiation Safety Officer, ensure that radiation safety activities are being performed in accordance with approved procedures. The licensee's procedures for monitoring, calculating, and controlling air concentrations of byproduct material are described in the licensee's application dated June 22, 1988, and were approved by License Condition No. 13.

The licensee's application dated June 22, 1988, states in Item No. 10.13 that the licensee will establish and implement the model procedure for monitoring, calculating, and controlling air concentrations that was published in Appendix O of Regulatory Guide 10.8, Revision 2.

Appendix O of Regulatory Guide 10.8, Revision 2, "Model Procedure for Monitoring, Calculating, and Controlling Air Concentrations," requires the licensee to collect data and perform a calculation to estimate the occupational radiation dose from aerosols.

Contrary to the above, as of September 29, 1992, the licensee, through its Radiation Safety Officer, failed to ensure that radiation safety activities were being performed in accordance with the above procedures. Specifically, the Radiation Safety Officer did not collect the required data and perform the required calculations to estimate the occupational radiation dose from aerosols.

4. 10 CFR 35.20(c) requires the licensee's ALARA program to include, in part, a review of summaries of the types and amounts of byproduct material used, and occupational doses, and continuing education and training for all personnel who work with or in the vicinity of byproduct material.

Contrary to the above, as of September 29, 1992, the licensee's ALARA program did not include the program aspects listed above.

5. 10 CFR 35.21(a) requires that the licensee, through the Radiation Safety Officer, ensure that radiation safety activities are being performed in accordance with approved procedures. The licensee's procedures for evaluating implementation of the radiation safety program are described in the licensee's application dated June 22, 1988, and were approved by License Condition No. 13.

   The licensee's application dated June 22, 1988, states in Item 10.1 that the licensee will issue the model Radiation Safety Committee charter published in Appendix F of Regulatory Guide 10.8, Revision 2.

   Appendix F of Regulatory Guide 10.8, Revision 2, "Model Radiation Safety Committee Charter and Radiation Safety Officer Delegation of Authority," requires the Radiation Safety Committee to review at least annually the Radiation Safety Officer's summary report of the entire radiation safety program. The review must include an examination of records, reports from the Radiation Safety Officer, results of NRC inspections, written safety procedures, and the adequacy of the management control system.

   Contrary to the above, from September 1989 to September 1992, the Radiation Safety Committee did not review the Radiation Safety Officer's summary report of the entire radiation safety program annually. Further, the Committee review did not include an examination of records, reports from the Radiation Safety Officer, results of NRC inspections, written safety procedures, and the adequacy of the management control system.

6. 10 CFR 35.220 requires that a licensee authorized to use byproduct material for imaging and localization possess a portable radiation detection survey instrument capable of detecting dose rates over the range of 0.1 millirem per hour to 100 millirem per hour, and a portable radiation measurement survey instrument capable of measuring dose rates over the range 1 millirem per hour to 1000 millirem per hour.

   Contrary to the above, as of September 29, 1992, the licensee did not possess a portable radiation detection survey instrument and a portable radiation measurement survey instrument capable of measuring the above listed dose rates.

7. 10 CFR 35.50(b)(2), (3), and (4) require, in part, that a licensee perform tests for accuracy, linearity, and geometry dependence upon installation of the dose calibrator.

   Contrary to the above, the licensee did not perform tests

for accuracy, linearity, and geometry dependence upon installation of the dose calibrator that occurred on September 3, 1992.

8. 10 CFR 35.50(b)(3) requires, in part, that a licensee test each dose calibrator for linearity over the range of its use between the highest dosage that will be administered to a patient and 10 microcuries.

   Contrary to the above, the licensee's dose calibrator linearity tests performed on March 16, June 22, and September 15, 1992, covered only the range between 30 millicuries and 10 microcuries and the highest dosage that the licensee administers to a patient is 40 millicuries.

9. 10 CFR 35.50(b)(4) requires, in part, that a licensee test each dose calibrator for geometry dependence upon installation over the range of volumes and volume configurations for which it will be used.

   Contrary to the above, the licensee did not test its dose calibrator for geometry dependence at the time of installation. Specifically, the dose calibrator was not tested for geometry dependence when it was installed in Room 130, during the summer of 1991.

10. 10 CFR 35.50(e) requires, in part, that a licensee retain records of dose calibrator tests for three years unless directed otherwise, and that the records include the signature of the Radiation Safety Officer.

    Contrary to the above, as of September 29, 1992, the licensee retained records of dose calibrator tests which did not include the signature of the Radiation Safety Officer.

11. 10 CFR 35.70(a) requires that a licensee survey with a radiation detection survey instrument at the end of each day of use all areas where radiopharmaceuticals are routinely prepared for use or administered.

    Contrary to the above, as of September 29, 1992, the licensee failed on numerous occasions to survey with a radiation detection instrument at the end of the day those areas where radiopharmaceuticals were routinely administered.

12. 10 CFR 35.70(h) requires that a licensee retain a record of each contamination and ambient radiation exposure rate survey required by 10 CFR 35.70. The record must include, in part, a plan of each area surveyed and the removable contamination in each area expressed in disintegrations per minute per 100 square centimeters.

Contrary to the above, as of September 29, 1992, the licensee failed to retain records of surveys that included a plan of the area surveyed and the removable contamination in each area expressed in disintegrations per minute per 100 square centimeters.

13. 10 CFR 35.21(a) requires that the licensee, through the Radiation Safety Officer, ensure that radiation safety activities are being performed in accordance with approved procedures. The licensee's procedures are described in the licensee's application dated June 22, 1988, and were approved by License Condition No. 13.

The licensee's application dated June 22, 1988, states in Item No. 10.12 that the licensee will establish and implement the model procedure for area surveys that was published in Appendix N of Regulatory Guide 10.8, Revision 2.

Appendix N of Regulatory Guide 10.8, Revision 2, "Model Procedure for Area Surveys," requires the licensee's Radiation Safety Officer to review and sign the ambient dose rate and removable contamination survey records at least monthly and also promptly in those cases in which action levels were exceeded.

Contrary to the above, as of September 29, 1992, the licensee, through its Radiation Safety Officer, failed to ensure that radiation safety activities were being performed in accordance with the above procedures. Specifically, the Radiation Safety Officer did not sign records of ambient dose rate and removable contamination surveys as required.

14. 10 CFR 35.59(d) requires that a licensee retain records of leakage test results for five years; and that the records contain the model number, and serial number if assigned, of each source tested; the identity of each source radionuclide and its estimated activity; the measured activity of each test sample expressed in microcuries; a description of the method used to measure each test sample; the date of the test; and the signature of the Radiation Safety Officer.

Contrary to the above, as of September 29, 1992, the licensee's records of leakage test results did not contain the signature of the Radiation Safety Officer.

15. 10 CFR 35.59(g) requires, in part, that a licensee retain for five years records of quarterly physical inventories of sealed sources in its possession, and that the records contain the model number of each source, and serial number if one has been assigned, the identity of each source radionuclide and its nominal activity, the location of each

source, and the signature of the Radiation Safety Officer.

Contrary to the above, as of September 29, 1992, the licensee's records of physical inventories of its sealed source did not include the signature of the Radiation Safety Officer.

16. 10 CFR 19.11(a) and (b) require, in part, that the licensee post current copies of Part 19, Part 20, the license, license conditions, documents incorporated into the license, license amendments and operating procedures; or that the licensee post a notice describing these documents and where they may be examined. 10 CFR 19.11(c) requires that a licensee post Form NRC-3, "Notice to Employees."

Contrary to the above, on September 29, 1992, the licensee did not post copies of the following documents: 10 CFR Part 19; 10 CFR Part 20; License No. 34-21409-01 Amendment Nos. 1, 2, and 3; the licensee's application dated June 22, 1988; Regulatory Guide 10.8, Revision 2; and the licensee's letter dated June 21, 1989; or a notice describing these documents and where they may be examined.

This is a Severity Level III violation (Supplement VI).
Civil Penalty - $3,750.

Pursuant to the provisions of 10 CFR 2.201, Pike Community Hospital (Licensee) is hereby required to submit a written statement of explanation to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, within 30 days of the date of this Notice of Violation and Proposed Imposition of Civil Penalty (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each alleged violation: (1) admission or denial of the alleged violation, (2) the reasons for the violation if admitted, and if denied, the reasons why, (3) the corrective steps that have been taken and the results achieved, (4) the corrective steps that will be taken to avoid further violation, and (5) the date when full compliance will be achieved. If an adequate reply is not received within the time specified in this Notice, an order or a demand for information may be issued as to why the license should not be modified, suspended, or revoked or why such other actions as may be proper should not be taken. Consideration may be given to extending the response time for good cause shown. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, this response shall be submitted under oath or affirmation.

Within the same time as provided for the response required under 10 CFR 2.201, the Licensee may pay the civil penalty by letter addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, with a check, draft, money order, or electronic transfer payable to the Treasurer of the United States

in the cumulative amount of the civil penalty proposed above, or may protest imposition of the civil penalty in whole or in part, by a written answer addressed to the Director, Office of Enforcement, U. S. Nuclear Regulatory Commission. Should the Licensee fail to answer within the time specified, an order imposing the civil penalty will be issued. Should the Licensee elect to file an answer in accordance with 10 CFR 2.205 protesting the civil penalty, in whole or in part, such answer should be clearly marked as an "Answer to a Notice of Violation" and may: (1) deny the violation listed in this Notice in whole or in part, (2) demonstrate extenuating circumstances, (3) show error in this Notice, or (4) show other reasons why the penalty should not be imposed. In addition to protesting the civil penalty in whole or in part, such answer may request remission or mitigation of the penalty.

In requesting mitigation of the proposed penalty, the factors addressed in Section V.B of 10 CFR Part 2, Appendix C, should be addressed. Any written answer in accordance with 10 CFR 2.205 should be set forth separately from the statement or explanation in reply pursuant to 10 CFR 2.201, but may incorporate parts of the 10 CFR 2.201 reply by specific reference (e.g., citing page and paragraph numbers) to avoid repetition. The attention of the Licensee is directed to the other provisions of 10 CFR 2.205, regarding the procedure for imposing a civil penalty.

Upon failure to pay any civil penalty due which subsequently has been determined in accordance with the applicable provisions of 10 CFR 2.205, this matter may be referred to the Attorney General, and the penalty, unless compromised, remitted, or mitigated, may be collected by civil action pursuant to Section 234c of the Act, 42 U.S.C. 2282c.

The responses noted above (Reply to Notice of Violation, letter with payment of civil penalty, and Answer to a Notice of Violation) should be addressed to: Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555 with a copy to the Regional Administrator, U.S. Nuclear Regulatory Commission, Region III, 799 Roosevelt Road, Glen Ellyn, Illinois 60137.

FOR THE NUCLEAR REGULATORY COMMISSION

A. Bert Davis
Regional Administrator

Dated at Glen Ellyn, Illinois
this 22 day of January 1993

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

MAY 24 1993

Docket No. 030-20620
License No. 34-21409-01
EA 92-247

Pike Community Hospital
Attn: Richard Sobota
President and Chief
Executive Officer
100 Dawn Lane
Waverly, OH 45690

Dear Mr. Sobota:

SUBJECT: ORDER IMPOSING CIVIL MONETARY PENALTY - $3,750

This refers to the letters from you dated February 22, 1993, and February 24, 1993, in response to the Notice of Violation and Proposed Imposition of Civil Penalty (Notice) sent to you by our letter dated January 22, 1993. Our letter and Notice describe 16 violations identified during an NRC inspection conducted on September 29, 1992.

To emphasize the need for effective management oversight of NRC licensed activities by your administration, the Radiation Safety Committee, and the Radiation Safety Officer, a civil penalty of $3,750 was proposed.

In your responses, you partially deny Violation No. 2, and you request mitigation of the proposed civil penalty based upon your corrective action.

After consideration of your responses, we have concluded, for the reasons given in the Appendix attached to the enclosed Order Imposing Civil Monetary Penalty, that the violations occurred as stated and an adequate basis has not been provided for mitigation of the civil penalty. Accordingly, we hereby serve the enclosed Order on Pike Community Hospital imposing a civil monetary penalty in the amount of $3,750.

As a separate item, your corrective action, as noted in your February 22, 1993 response to Violation No. 1, is not complete. Apparently, at that time, you had not assessed the radiation dose to the skin and extremities of the nuclear medicine technologist involved in the spills. The radiation dose should be included in the official records of occupational radiation exposure for this individual. Please include a description of your corrective action to address this issue along with your response to this letter and accompanying Order.

We will review the effectiveness of your corrective actions during a subsequent inspection.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter and the enclosure will be placed in the NRC's Public Document Room.

Sincerely,

Hugh L. Thompson, Jr.
Deputy Executive Director for
Nuclear Materials Safety, Safeguards
and Operations Support

Enclosure: As stated

cc w/enclosure:
DCD/DCB (RIDS)

UNITED STATES
NUCLEAR REGULATORY COMMISSION

In the Matter of	)	
	)	
Pike Community Hospital	)	Docket No. 030-20620
Waverly, Ohio	)	License No. 34-21409-01
	)	EA 92-247

ORDER IMPOSING CIVIL MONETARY PENALTY

I

Pike Community Hospital (Licensee) is the holder of Byproduct Material License No. 34-21409-01 issued by the Nuclear Regulatory Commission (NRC or Commission) on September 21, 1983. The license was amended in its entirety on February 9, 1989, and is due to expire on April 30, 1994. The license was most recently amended on July 21, 1989. The license authorizes the Licensee to possess and use byproduct materials for medical use and in vitro studies in accordance with the conditions specified therein.

II

An inspection of the Licensee's activities was conducted on September 29, 1992. The results of this inspection indicated that the Licensee had not conducted its activities in full compliance with NRC requirements. A written Notice of Violation and Proposed Imposition of Civil Penalty (Notice) was served upon the Licensee by letter dated January 22, 1993. The Notice states the nature of the violations, the provisions of the NRC's requirements that the Licensee had violated, and the amount of the civil penalty proposed for the violations. The Licensee responded to the Notice by letters dated February 22, 1993, and

February 24, 1993. In its responses, the Licensee partially denies Violation No. 2 and requests mitigation of the proposed civil penalty based upon its corrective action.

III

After consideration of the Licensee's responses and the statements of fact, explanation, and argument for mitigation contained therein, the NRC staff has determined, as set forth in the Appendix to this Order, that the violations occurred as stated and that the penalty proposed for the violations designated in the Notice should be imposed.

IV

In view of the foregoing and pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (Act), 42 U.S.C. 2282, and 10 CFR 2.205, IT IS HEREBY ORDERED THAT:

The Licensee pay a civil penalty in the amount of $3,750 within 30 days of the date of this Order, by check, draft, money order, or electronic transfer, payable to the Treasurer of the United States and mailed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555.

V

The Licensee may request a hearing within 30 days of the date of this Order. A request for a hearing should be clearly marked as a "Request for an Enforcement Hearing" and shall be addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555. Copies also shall be sent to the Assistant General Counsel for Hearings and Enforcement at the same address and to the Regional Administrator, NRC Region III, 799 Roosevelt Road, Glen Ellyn, Illinois 60137.

If a hearing is requested, the Commission will issue an Order designating the time and place of the hearing. If the Licensee fails to request a hearing within 30 days of the date of this Order, the provisions of this Order shall be effective without further proceedings. If payment has not been made by that time, the matter may be referred to the Attorney General for collection.

In the event the Licensee requests a hearing as provided above, the issues to be considered at such hearing shall be:

(a) whether the Licensee was in violation of the Commission's requirements as set forth in Violation 2, and

b) whether, on the basis of such violation and the additional violations set forth in the Notice of Violation that the Licensee admitted, this Order should be sustained.

FOR THE NUCLEAR REGULATORY COMMISSION

Hugh L. Thompson, Jr.
Deputy Executive Director for
Nuclear Materials Safety, Safeguards
and Operations Support

Dated at Rockville, Maryland
this 24th day of May 1993

APPENDIX

EVALUATIONS AND CONCLUSIONS

On January 22, 1993, a Notice of Violation and Proposed Imposition of Civil Penalty (Notice) was issued for violations identified during an NRC inspection on September 29, 1992. Pike Community Hospital responded to the Notice in letters dated February 22, 1993, and February 24, 1993. In its responses, the Licensee partially denies Violation No. 2 and requests mitigation of the proposed civil penalty. The NRC's evaluation and conclusions regarding the licensee's requests are as follows:

Restatement of Violations

1. 10 CFR 20.201(b) requires that each licensee make such surveys as may be necessary to comply with the requirements of Part 20 and which are reasonable under the circumstances to evaluate the extent of radiation hazards that may be present. As defined in 10 CFR 20.201(a), "survey" means an evaluation of the radiation hazards incident to the production, use, release, disposal, or presence of radioactive materials or other sources of radiation under a specific set of conditions.

   Contrary to the above, as of September 29, 1992, the licensee did not make surveys to assure compliance with that part of 10 CFR 20.101 that limits the radiation exposure to the extremities and skin of the whole body. Specifically, the licensee did not evaluate the full extent of Tc-99m contamination which may have been present on a technologist who was involved in spills on September 3 and 4, 1992, to determine the radiation dose to the hands and forearms and skin of the whole body.

2. 10 CFR 35.21(a) requires that the licensee, through the Radiation Safety Officer, ensure that radiation safety activities are being performed in accordance with approved procedures. The licensee's procedures are described in the licensee's application dated June 22, 1988, and were approved by License Condition No. 13.

   The licensee's application dated June 22, 1988, states in Item 10.5 that the licensee will establish and implement the model spill procedures published in Appendix J of Regulatory Guide 10.8, Revision 2.

   Appendix J of Regulatory Guide 10.8, Revision 2, "Model Spill Procedures," requires the Radiation Safety Officer to follow up on the cleanup of a minor spill and complete the Radioactive Spill Report and the Radioactive Spill Contamination Survey that are identified as Exhibit 10 and Exhibit 11 of Regulatory Guide 10.8, Revision 2.

Contrary to the above, as of September 29, 1992, the licensee, through its Radiation Safety Officer, failed to ensure that radiation safety activities were being performed in accordance with the above procedures. Specifically, the Radiation Safety Officer did not follow up on the cleanup of minor Tc-99m spills that occurred on September 3 and 4, 1992, and did not complete the Radioactive Spill Report (Exhibit 10) and the Radioactive Spill Contamination Survey (Exhibit 11).

3. 10 CFR 35.21(a) requires that the licensee, through the Radiation Safety Officer, ensure that radiation safety activities are being performed in accordance with approved procedures. The licensee's procedures for monitoring, calculating, and controlling air concentrations of byproduct material are described in the licensee's application dated June 22, 1988, and were approved by License Condition No. 13.

   The licensee's application dated June 22, 1988, states in Item No. 10.13 that the licensee will establish and implement the model procedure for monitoring, calculating, and controlling air concentrations that was published in Appendix O of Regulatory Guide 10.8, Revision 2.

   Appendix O of Regulatory Guide 10.8, Revision 2, "Model Procedure for Monitoring, Calculating, and Controlling Air Concentrations," requires the licensee to collect data and perform a calculation to estimate the occupational radiation dose from aerosols.

   Contrary to the above, as of September 29, 1992, the licensee, through its Radiation Safety Officer, failed to ensure that radiation safety activities were being performed in accordance with the above procedures. Specifically, the Radiation Safety Officer did not collect the required data and perform the required calculations to estimate the occupational radiation dose from aerosols.

4. 10 CFR 35.20(c) requires the licensee's ALARA program to include, in part, a review of summaries of the types and amounts of byproduct material used, and occupational doses, and continuing education and training for all personnel who work with or in the vicinity of byproduct material.

   Contrary to the above, as of September 29, 1992, the licensee's ALARA program did not include the program aspects listed above.

5. 10 CFR 35.21(a) requires that the licensee, through the Radiation Safety Officer, ensure that radiation safety activities are being performed in accordance with approved

procedures. The licensee's procedures for evaluating implementation of the radiation safety program are described in the licensee's application dated June 22, 1988, and were approved by License Condition No. 13.

The licensee's application dated June 22, 1988, states in Item 10.1 that the licensee will issue the model Radiation Safety Committee charter published in Appendix F of Regulatory Guide 10.8, Revision 2.

Appendix F of Regulatory Guide 10.8, Revision 2, "Model Radiation Safety Committee Charter and Radiation Safety Officer Delegation of Authority," requires the Radiation Safety Committee to review at least annually the Radiation Safety Officer's summary report of the entire radiation safety program. The review must include an examination of records, reports from the Radiation Safety Officer, results of NRC inspections, written safety procedures, and the adequacy of the management control system.

Contrary to the above, from September 1989 to September 1992, the Radiation Safety Committee did not review the Radiation Safety Officer's summary report of the entire radiation safety program annually. Further, the Committee review did not include an examination of records, reports from the Radiation Safety Officer, results of NRC inspections, written safety procedures, and the adequacy of the management control system.

6. 10 CFR 35.220 requires that a licensee authorized to use byproduct material for imaging and localization possess a portable radiation detection survey instrument capable of detecting dose rates over the range of 0.1 millirem per hour to 100 millirem per hour, and a portable radiation measurement survey instrument capable of measuring dose rates over the range 1 millirem per hour to 1000 millirem per hour.

   Contrary to the above, as of September 29, 1992, the licensee did not possess a portable radiation detection survey instrument and a portable radiation measurement survey instrument capable of measuring the above listed dose rates.

7. 10 CFR 35.50(b)(2), (3), and (4) require, in part, that a licensee perform tests for accuracy, linearity, and geometry dependence upon installation of the dose calibrator.

   Contrary to the above, the licensee did not perform tests for accuracy, linearity, and geometry dependence upon installation of the dose calibrator that occurred on September 3, 1992.

8. 10 CFR 35.50(b)(3) requires, in part, that a licensee test each dose calibrator for linearity over the range of its use between the highest dosage that will be administered to a patient and 10 microcuries.

   Contrary to the above, the licensee's dose calibrator linearity tests performed on March 16, June 22, and September 15, 1992, covered only the range between 30 millicuries and 10 microcuries and the highest dosage that the licensee administers to a patient is 40 millicuries.

9. 10 CFR 35.50(b)(4) requires, in part, that a licensee test each dose calibrator for geometry dependence upon installation over the range of volumes and volume configurations for which it will be used.

   Contrary to the above, the licensee did not test its dose calibrator for geometry dependence at the time of installation. Specifically, the dose calibrator was not tested for geometry dependence when it was installed in Room 130, during the summer of 1991.

10. 10 CFR 35.50(e) requires, in part, that a licensee retain records of dose calibrator tests for three years unless directed otherwise, and that the records include the signature of the Radiation Safety Officer.

    Contrary to the above, as of September 29, 1992, the licensee retained records of dose calibrator tests which did not include the signature of the Radiation Safety Officer.

11. 10 CFR 35.70(a) requires that a licensee survey with a radiation detection survey instrument at the end of each day of use all areas where radiopharmaceuticals are routinely prepared for use or administered.

    Contrary to the above, as of September 29, 1992, the licensee failed on numerous occasions to survey with a radiation detection instrument at the end of the day those areas where radiopharmaceuticals were routinely administered.

12. 10 CFR 35.70(h) requires that a licensee retain a record of each contamination and ambient radiation exposure rate survey required by 10 CFR 35.70. The record must include, in part, a plan of each area surveyed and the removable contamination in each area expressed in disintegrations per minute per 100 square centimeters.

    Contrary to the above, as of September 29, 1992, the licensee failed to retain records of surveys that included a plan of the area surveyed and the removable contamination in

each area expressed in disintegrations per minute per 100 square centimeters.

13. 10 CFR 35.21(a) requires that the licensee, through the Radiation Safety Officer, ensure that radiation safety activities are being performed in accordance with approved procedures. The licensee's procedures are described in the licensee's application dated June 22, 1988, and were approved by License Condition No. 13.

    The licensee's application dated June 22, 1988, states in Item No. 10.12 that the licensee will establish and implement the model procedure for area surveys that was published in Appendix N of Regulatory Guide 10.8, Revision 2.

    Appendix N of Regulatory Guide 10.8, Revision 2, "Model Procedure for Area Surveys," requires the licensee's Radiation Safety Officer to review and sign the ambient dose rate and removable contamination survey records at least monthly and also promptly in those cases in which action levels were exceeded.

    Contrary to the above, as of September 29, 1992, the licensee, through its Radiation Safety Officer, failed to ensure that radiation safety activities were being performed in accordance with the above procedures. Specifically, the Radiation Safety Officer did not sign records of ambient dose rate and removable contamination surveys as required.

14. 10 CFR 35.59(d) requires that a licensee retain records of leakage test results for five years; and that the records contain the model number, and serial number if assigned, of each source tested; the identity of each source radionuclide and its estimated activity; the measured activity of each test sample expressed in microcuries; a description of the method used to measure each test sample; the date of the test; and the signature of the Radiation Safety Officer.

    Contrary to the above, as of September 29, 1992, the licensee's records of leakage test results did not contain the signature of the Radiation Safety Officer.

15. 10 CFR 35.59(g) requires, in part, that a licensee retain for five years records of quarterly physical inventories of sealed sources in its possession, and that the records contain the model number of each source, and serial number if one has been assigned, the identity of each source radionuclide and its nominal activity, the location of each source, and the signature of the Radiation Safety Officer.

Contrary to the above, as of September 29, 1992, the licensee's records of physical inventories of its sealed source did not include the signature of the Radiation Safety Officer.

16. 10 CFR 19.11(a) and (b) require, in part, that the licensee post current copies of Part 19, Part 20, the license, license conditions, documents incorporated into the license, license amendments and operating procedures; or that the licensee post a notice describing these documents and where they may be examined. 10 CFR 19.11(c) requires that a licensee post Form NRC-3, "Notice to Employees."

Contrary to the above, on September 29, 1992, the licensee did not post copies of the following documents: 10 CFR Part 19; 10 CFR Part 20; License No. 34-21409-01 Amendment Nos. 1, 2, and 3; the licensee's application dated June 22, 1988; Regulatory Guide 10.8, Revision 2; and the licensee's letter dated June 21, 1989; or a notice describing these documents and where they may be examined.

Summary of Licensee's Response to Violation No. 2

The Licensee admits that through its Radiation Safety Officer (RSO), it failed to follow up on the radioactive spills that occurred on September 3 and 4, 1992, by completing the Radioactive Spill Report and the Radioactive Spill Contamination Survey. However, the Licensee denies that the RSO "failed to investigate these spills and to implement necessary corrective actions to prevent recurrence."

The Licensee states that immediately following the spills, the RSO, acting in conjunction with the hospital's Chief Executive Officer (1) evaluated the mask used and identified an alternative mask that produced a more effective seal during aerosol procedures; and (2) initiated a policy discontinuing aerosol procedures of the type involved in the spill incidents (i.e., those performed on ventilator patients or others unable to assist in carrying out the procedure). According to the Licensee, subsequent to receipt of the NRC Inspection Report, the RSO continued and completed his investigation and the following corrective actions were taken: the RSO, Radiation Safety Committee, and technical staff thoroughly reviewed spill procedures; all aerosol procedures have been suspended until ventilation system changes and air flow studies are completed; and a new procedure was enacted requiring a trial use of the mouthpiece by the patient without the radiopharmaceutical aerosol, before the actual procedure is performed.

NRC Evaluation of Licensee's Response to Violation No. 2

The Licensee admits that the required radioactive spill reports and radioactive spill contamination survey were not prepared. The Licensee denies that the RSO "failed to investigate these spills and to implement necessary corrective actions to prevent recurrence." However, the citation was much more specific in that it addressed the failure of the RSO to follow up on the cleanup of Tc-99m spills that occurred on September 3 and 4, 1992.

With regard to followup on the cleanup of the spills, the RSO was not present at the Licensee's facilities when the spills occurred on September 3 and 4, 1992. The technologist telephoned the RSO on September 3, 1992, and explained difficulties with the lung imaging process. (During the TC-99m DTPA aerosol lung ventilation study, the technologist noticed leakage around the patient's inhalation mask and the resulting images indicated contamination on the patient and no activity in the lungs, i.e., a "radioactive spill.") The RSO instructed the technologist to contact the medical physics consultant, other area hospitals, and the imaging system applications specialist. These individuals gave assistance to the technologist. However, the RSO made no special efforts to follow up on the cleanup of the spill. On the contrary, the RSO did not even visit the Licensee's facilities until September 8, 1992, according to his routine schedule. Given the half-life of Tc-99m, by the time the RSO arrived on the site, it would have been impossible for him to determine what individuals and surfaces had been contaminated and whether the cleanup had been effective.

Therefore, based on the above, the Staff concludes that the Radiation Safety Officer did not follow up on the cleanup of spills that occurred on September 3 and 4, 1992, as required by Appendix J of Regulatory Guide 10.8, Revision 2.

Summary of Licensee's Request for Mitigation

The Licensee states that it believes the NRC is under the impression that the hospital was fully aware on September 29, 1992, the date of inspection visit by the inspector, of all of the violations cited in the inspection report. The Licensee further states that it received a verbal report from the inspector on September 29 which discussed the problem of having an incorrect survey meter; and that other issues and problems were discussed, but in a general fashion and without identifying those in an official sense as being either "violations" or "areas of concern."

The Licensee asserts that, at the inspector's exit interview, problems were discussed in a general fashion without identifying them in an official sense as being either violations or areas of

concern. The Licensee asserts that it became aware, as a result of the inspector's visit and report, that the hospital had a serious problem in terms of not following prescribed NRC policies and procedures. The Licensee asserts that its ability to initiate corrective action, however, was limited to the information that was made available. According to the Licensee, until the inspector's written report describing each individual violation and area of concern was received by the hospital by FAX on January 7, 1993, and by mail on January 11, 1993, the Licensee did not know what specific violations existed in order to begin a more extensive corrective action effort.

The Licensee asserts that, as indicated by the hospital's rapid response within four days of its receipt of the January 7 written Inspection Report, it likewise would have responded much earlier and with the same degree of diligence had the written Inspection Report been provided at an earlier date. The Licensee requests that the amount of civil penalty be reconsidered, and that it be allowed mitigation for its corrective action.

NRC Evaluation of Licensee's Request for Mitigation

The Notice of Violation and Proposed Imposition of Civil Penalty dated January 22, 1993, states that although both the broad and specific corrective actions appear to be acceptable, the NRC is concerned that many of these actions were not implemented following the September 1992 inspection.

The NRC Enforcement Policy provides that, notwithstanding good comprehensive corrective action, if immediate corrective action was not taken to restore safety and compliance once the violation was identified, mitigation of the civil penalty will not normally be considered and escalation may be considered to address the licensee's failure. The inspector's exit meeting was conducted with the hospital's President and Chief Executive Officer, and two medical technologists. The meeting lasted approximately 45 minutes. The inspector discussed all of the violations included in the Notice and, in accordance with established NRC procedure, characterized them as apparent violations of NRC requirements. The President and Chief Executive Officer took notes during the meeting and asked pertinent questions. Even granting the Licensee's apparent confusion about what constituted a violation and what constituted an area of concern, the exit meeting provided sufficient notice for Licensee management, after consultation with its Radiation Safety Officer, to further investigate the problems that were discussed and to initiate corrective action to restore safety and compliance.

Although in its response to Violation 2, the Licensee claims that the RSO took certain actions "immediately following the spills," these actions cannot be characterized as "immediate." When the RSO arrived on September 8, he instructed the technologist to

prepare an incident report. On September 14, 1992, the technologist prepared an incident report that was reviewed at the Radiation Safety Committee on September 28, 1992. The NRC inspection was conducted on September 29, 1992. Although the spills occurred on September 3 and 4, no corrective actions were taken prior to the NRC inspection.

Based on the above, the Staff concludes that mitigation is not warranted based upon the Licensee's corrective action.

NRC Conclusion

Based on its evaluation of the licensee's response, the NRC staff concludes that the violations did occur as stated, and that an adequate basis for mitigation of the civil penalty has not been provided by the Licensee. Accordingly, NRC concludes that the proposed civil penalty in the amount of $3,750 should be imposed.

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION II
101 MARIETTA STREET, N.W.
ATLANTA, GEORGIA 30323

JUN 23 1993

Docket No. 030-29953
License No. 52-24908-01
EA 92-240

Ponce I&M Engineering Lab., Inc.
ATTN: Mr. José L. Irizarry
President
San Cristóbal Avenue Number 3
Post Office Box 515
Coto Laurel, Puerto Rico 00644-0515

Gentlemen:

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY - $2,000 (NRC INSPECTION REPORT NO. 52-24908-01/92-01 AND NRC OFFICE OF INVESTIGATIONS CASE NO. 2-92-039R)

This refers to the Nuclear Regulatory Commission (NRC) inspection conducted by Mr. H. Bermudez on October 21 and 23, 1992, at Ponce I&M Engineering facility, Coto Laurel, Puerto Rico, and to an investigation conducted by the NRC's Office of Investigations (OI) which was completed on March 23, 1993. The inspection included a review of activities conducted under NRC License Nos. 52-24908-01 and 52-24908-02 with respect to radiation safety and compliance with NRC regulations and the conditions of your license. The inspection report was sent to you by letter dated December 10, 1992. The investigation was initiated to determine if a willful violation occurred when licensed material, cesium-137 and americium-241 sealed sources contained in moisture density gauges, was used after the expiration of NRC License No. 52-24908-01 on August 31, 1992. A copy of the investigation synopsis was sent to you by letter dated May 6, 1993. As a result of the inspection and investigation, violations of NRC requirements were identified. An enforcement conference was held on May 14, 1993, in the NRC Region II office to discuss the violations, their cause, and your corrective actions to preclude recurrence. A summary of the conference was sent to you by letter dated May 20, 1993.

The violations are described in the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice). The first violation, which is set forth in Part I of the enclosed Notice, involved the willful use of NRC licensed material during the period September 1, 1992 to October 21, 1992, without a valid NRC license. NRC License No. 52-24908-01 expired on August 31, 1992, and a new license was not received until October 22, 1992. This new NRC license (No. 52-24908-02) supersedes the expired license. The NRC is concerned that licensed material was used without a valid license and that this was done knowingly despite the fact you had received notice in May 1992 that your license was due to expire and that you needed to take action to renew the license. Further, by letter dated September 11, 1992, you were formally advised that your NRC license had expired and you were issued a

Notice of Violation for operating with an expired license. The letter of September 11th also directed you to "place any radioactive material on hand in secure storage until such time as you acquire a valid license."

Based on the results of the NRC investigation and all other available information in this case, the NRC concludes that you willfully violated NRC requirements when you permitted the use of licensed material without a valid NRC license. During discussions with the NRC inspector on October 21, 1992, you stated that you were aware you violated NRC requirements relative to using licensed material without a valid license. The cause of the violation appears to have been the concern of financial loss pending receipt of the new license. The NRC expects no less than full compliance with all applicable regulatory requirements and willful disregard for those requirements by you and your staff cannot be tolerated. Therefore, in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy) 10 CFR Part 2, Appendix C, this violation has been categorized at Severity Level III. Although this violation would normally be categorized at Severity Level IV based on your staff's qualifications and use of previously approved procedures, this violation has been categorized at Severity Level III because of the wilfullness.

In order to emphasize the significance of willfully violating regulatory requirements and the need for licensees to ensure full compliance with applicable NRC requirements and license conditions, I have been authorized, after consultation with the Director, Office of Enforcement, and the Deputy Executive Director for Nuclear Materials Safety, Safeguards, and Operations Support, to issue the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice) in the amount of $2,000 for the Severity Level III violation. The base civil penalty for a Severity Level III violation is $500. The escalation and mitigation factors in the Enforcement Policy were considered as discussed below.

The base civil penalty was escalated by 50 percent because the violation was identified by the NRC. Neither escalation nor mitigation was warranted for corrective action. Escalation of 50 percent was warranted for licensee performance based on previous enforcement history that included the initial inspection conducted on October 5, 1988. During that inspection, four violations (Severity Levels IV and V) were identified. During the inspection conducted on October 21, 1992, three violations similar to those identified in 1988 were again cited.

To emphasize the point that a licensee should not benefit economically by willfully violating regulatory requirements, the NRC has decided to further escalate the civil penalty in accordance with Section VII.A.(1) of the Enforcement Policy. The base civil penalty has been increased an additional 200 percent to reflect the significance NRC attaches to willful violations of regulatory requirements, particularly when a principal officer of the licensee is directly responsible for the violation.

The violations in Part II of the Notice are not being assessed a civil penalty. These violations involve the failure to 1) conduct tests for leakage and/or contamination at intervals not to exceed six months, 2) conduct physical inventories every six months to account for all licensed material, 3) control radiation levels outside the licensed material storage area, 4) properly mark an overpack used in transporting licensed material, 5) have shipping papers readily available during the transportation of licensed material, and 6) properly post Form NRC-3, "Notice to Employees." The first five violations were categorized at Severity Level IV, while the last one was categorized at Severity Level V. These violations, some of which are repeat violations from a previous inspection, are of concern to the NRC because they indicate management inattention to compliance with regulatory requirements. If these violations recur in the future, they may be considered for escalated enforcement action, including civil penalties.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. In your response, you should document the specific actions taken and any additional actions you plan to prevent recurrence. After reviewing your response to this Notice, including your proposed corrective actions and the results of future inspections, the NRC will determine whether further NRC enforcement action is necessary to ensure compliance with NRC regulatory requirements.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter and its enclosure will be placed in the NRC Public Document Room.

The responses directed by this letter and the enclosed Notice are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, Pub. L. No. 96-511.

Should you have any questions concerning this letter, please contact us.

Sincerely,

Stewart D. Ebneter
Regional Administrator

Enclosure:
Notice of Violation and Proposed
Imposition of Civil Penalty

cc w/encl:
Commonwealth of Puerto Rico

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

Ponce I&M Engineering Lab., Inc.
Coto Laurel, Puerto Rico

Docket No. 030-29953
License No. 52-24908-01
EA 92-240

During an NRC inspection conducted on October 21 and 23, 1992, and an NRC investigation completed on March 23, 1993, violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C, the Nuclear Regulatory Commission proposes to impose a civil penalty pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (Act), 42 U.S.C. 2282, and 10 CFR 2.205. The particular violation and associated civil penalty are set forth below:

I. Violation Assessed a Civil Penalty

10 CFR 30.3 requires that except for persons exempt as provided in this part and part 150 of this chapter, no person shall manufacture, produce, transfer, receive, acquire, own, possess, or use byproduct material except as authorized in a specific or general license issued pursuant to the regulations in this chapter.

10 CFR 30.36(a) states, in part, that each specific license expires at the end of the day, in the month and year stated in the license.

Condition No. 4 of NRC License No. 52-24908-01 specifies the expiration date of the license to be August 31, 1992.

Contrary to the above, from September 1 to October 21, 1992, the licensee knowingly possessed and used licensed materials without a valid license, as NRC License No. 52-24908-01 had expired on August 31, 1992 and a new license was not issued until October 22, 1992.

This is a Severity Level III violation (Supplement VI).
Civil Penalty - $2,000

II. Violations Not Assessed a Civil Penalty

A. Condition No. 12 of NRC License No. 52-24908-01 requires that the sources specified in items 7.A, 7.B, and 7.C be tested for leakage and/or contamination at intervals not to exceed six months.

Contrary to the above, between May 9, 1989 and August 6, 1991, tests of the specified sources for leakage and/or contamination were performed at intervals ranging from seven to ten months on five occasions.

This is a Repeat Severity Level IV violation (Supplement VI).

B. Condition No. 14 of NRC License No. 52-24908-01 requires the licensee to conduct a physical inventory every six months to account for all sources and/or devices received and possessed under the license.

Contrary to the above, between May 9, 1989 and August 6, 1991, inventories of sealed sources possessed under the license were performed at intervals ranging from seven to ten months on five occasions.

This is a Repeat Severity Level IV violation (Supplement VI).

C. 10 CFR 20.105(b) requires that, except as authorized by the Commission in 10 CFR 20.105(a), no licensee allow the creation of radiation levels in unrestricted areas such that an individual who was continuously present in the area could receive a dose in excess of 2 millirems in any one hour or 100 millirems in any seven consecutive days.

Contrary to the above, on October 21, 1992, the licensee allowed the creation of radiation levels outside the licensed material storage area, an unrestricted area, such that an individual who was continuously present in the area could have received a dose in excess of 100 millirems in any seven consecutive days. Specifically, the radiation levels were 1.2 milliroentgen per hour and an individual could have received over 100 millirems in any seven consecutive days.

This is a Severity Level IV violation (Supplement IV).

D. 10 CFR 71.5(a) requires that a licensee who transports licensed material outside the confines of its plant or other place of use, or who delivers licensed material to a carrier for transport, comply with the applicable requirements of the regulations appropriate to the mode of transport of the Department of Transportation (DOT) in 49 CFR Parts 170 through 189.

1. 49 CFR 173.25 requires, in part, for packages containing hazardous materials and offered for transportation in an overpack, that: a) the overpack be marked with the proper shipping name and identification number, and labeled as required by 49 CFR Parts 171-177 for each hazardous material contained therein unless markings and labels representative of each hazardous material in the overpack are visible; and b) the overpack be marked with a statement indicating that the inside (inner) packages comply with prescribed specifications when specification packagings are required, unless specification markings on the inside packages are visible. Pursuant to 49 CFR 172.101, radioactive material is classified as hazardous material.

Contrary to the above, as of October 21, 1992, the licensee offered for transportation licensed material in an overpack that was not marked with the proper shipping name (radioactive contents) and identification number, nor with any statement indicating that the inner package complied with the prescribed specifications; and the markings on the inside package were not visible.

This is a Severity Level IV violation (Supplement V).

2. 49 CFR 177.817(e) requires, in part, that the driver of a motor vehicle containing hazardous material ensure that the shipping paper is readily available to, and recognizable by, authorities in the event of accident or inspection. Specifically, (i) when the driver is at the vehicle's controls, the shipping paper shall be: (A) within his immediate reach while he is restrained by the lap belt; and (B) either readily visible to a person entering the driver's compartment or in a holder which is mounted to the inside of the door on the driver's side of the vehicle; (ii) when the driver is not at the vehicle's controls, the shipping paper shall be: (A) in a holder which is mounted to the side of the door on the driver's side of the vehicle; or (B) on the driver's seat in the vehicle.

Pursuant to 49 CFR 172.101, radioactive material is classified as a hazardous material.

Contrary to the above, on October 21, 1992, the licensee transported licensed material outside the confines of its plant and the driver of the vehicle did not ensure that the shipping paper was visible to a person entering the driver's compartment or in a holder mounted to the inside of the door on the driver's side of the vehicle. Specifically, the shipping paper was kept under the vehicle sun visor and was not visible to a person entering the driver's compartment.

This is a Severity Level IV violation (Supplement V).

E. 10 CFR 19.11(c) provides in part, that a licensee post Form NRC-3, "Notice to Employees" as required by 10 CFR Part 30.

10 CFR 30.7(e) provides in part, that a licensee shall post Form-3, "Notice to Employees" on its premises.

Contrary to the above, on October 21,1992, the licensee did not post Form NRC-3, "Notice to Employees" on its premises.

This is a Repeat Severity Level V violation (Supplement IV).

Pursuant to the provisions of 10 CFR 2.201, Ponce I&M Engineering Lab., Inc., (Licensee) is hereby required to submit a written statement or explanation to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, within 30 days of the date of this Notice of Violation and Proposed Imposition of Civil Penalty (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each alleged violation: (1) admission or denial of the alleged violation, (2) the reasons for the violation if admitted, and if denied, the reasons why, (3) the corrective steps that have been taken and the results achieved, (4) the corrective steps that will be taken to avoid further violations, and (5) the date when full compliance will be achieved. If an adequate reply is not received within the time specified in this Notice, an order or a Demand for Information may be issued as to why the license should not be modified, suspended, or revoked or why such other action as may be proper should not be taken. Consideration may be given to extending the response time for good cause shown. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, this response shall be submitted under oath or affirmation.

Within the same time as provided for the response required above under 10 CFR 2.201, the Licensee may pay the civil penalty by letter addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, with a check, draft, money order, or electronic transfer payable to the Treasurer of the United States in the amount of the civil penalty proposed above, or the cumulative amount of the civil penalties if more than one civil penalty is proposed, or may protest imposition of the civil penalty in whole or in part, by a written answer addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission. Should the Licensee fail to answer within the time specified, an order imposing the civil penalty will be issued. Should the Licensee elect to file an answer in accordance with 10 CFR 2.205 protesting the civil penalty, in whole or in part, such answer should be clearly marked as an "Answer to a Notice of Violation" and may: (1) deny the violation listed in this Notice in whole or in part, (2) demonstrate extenuating circumstances, (3) show error in this Notice, or (4) show other reasons why the penalty should not be imposed. In addition to protesting the civil penalty in whole or in part, such answer may request remission or mitigation of the penalty.

In requesting mitigation of the proposed penalty, the factors addressed in Section VI.B.2 of 10 CFR Part 2, Appendix C, should be addressed. Any written answer in accordance with 10 CFR 2.205 should be set forth separately from the statement or explanation in reply pursuant to 10 CFR 2.201, but may incorporate parts of the 10 CFR 2.201 reply by specific reference (e.g., citing page and paragraph numbers) to avoid repetition. The attention of the Licensee is directed to the other provisions of 10 CFR 2.205 regarding the procedure for imposing a civil penalty.

Upon failure to pay any civil penalty due which subsequently has been determined in accordance with the applicable provisions of 10 CFR 2.205, this matter may be referred to the Attorney General, and the penalty, unless compromised, remitted, or mitigated, may be collected by civil action pursuant to Section 234c of the Act, 42 U.S.C. 2282c.

The response noted above (Reply to Notice of Violation, letter with payment of civil penalty, and Answer to a Notice of Violation) should be addressed to: Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555 with a copy to the Regional Administrator, U.S. Nuclear Regulatory Commission, Region II, Atlanta, Georgia.

Dated at Atlanta, Georgia
this 23rd day of June 1993

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION II
101 MARIETTA STREET, N.W., SUITE 2900
ATLANTA, GEORGIA 30323-0199

SEP 16 1993

Docket No. 030-10772
License No. 47-16307-01
EA 93-212

Princeton Community Hospital
ATTN: Mr. William Sheppard
Chief Executive Officer
Post Office Box 1369
Princeton, West Virginia 24740

Gentlemen:

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTIES - $5,000 (NRC INSPECTION REPORT NO. 47-16307-01/93-01)

This refers to the Nuclear Regulatory Commission (NRC) inspection conducted by Mr. Wade T. Loo on July 26-27, 1993, at your facility in Princeton, West Virginia. The inspection included a review of activities conducted under your NRC license with respect to radiation safety and compliance with NRC regulations and the conditions of your license. The report documenting the inspection was sent to you by letter dated August 30, 1993. During the inspection, violations of NRC requirements were identified. An enforcement conference was conducted in the NRC Region II office on September 9, 1993, to discuss the violations, their cause, and your corrective actions to preclude recurrence. This enforcement conference was open for public observation in accordance with the Commission's trial program for conducting open enforcement conferences as discussed in the Federal Register, 57 FR 30762, July 10, 1992. A summary of this conference was sent to you by letter dated September 10, 1993.

Violation A described in Part I of the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice) was identified by the NRC and involved the failure to secure licensed material from unauthorized removal or to maintain the licensed material under constant surveillance. The NRC is concerned with this violation as it presented the potential for theft of significant amounts of licensed material which was available in the Nuclear Medicine Hot Laboratory or the handling of licensed material by persons not authorized to do so and possibly could have resulted in unnecessary radiation exposure. Therefore, in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," this violation has been categorized at Severity Level III to reflect the significant regulatory concern associated with the violation.

Violation B described in Part I of the Notice was also identified by the NRC and involved the failure to prepare a written directive dated and signed by an authorized user indicating the dosage to be administered to the patient.

Specifically, for seven I-131 dose administrations performed between February 1 and June 1, 1992, and November 1, 1992 and April 1, 1993, there were no written directives prepared, dated and signed by the authorized user indicating the dosage to be administered. The written Quality Management Program for your facility specifically requires written directives. These directives are important because they are intended to provide appropriate safeguards against the misadministration of licensed material. Therefore, in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," this violation has been categorized at Severity Level III to reflect the importance of ensuring that adequate safeguards are utilized to prevent misadministrations.

These violations were the result of a lack of effective management oversight of the nuclear medicine program at your facility. It appears that there was over-reliance on the staff with minimal management oversight. During the enforcement conference, your staff recognized this and clearly defined the problems that contributed to the violations and provided a detail explanation of the corrective actions to preclude recurrence. Most notable in your staff's presentation was the forthrightness of their discussions relative to the root causes of, and responsibility for, the violations.

To emphasize the importance of maintaining effective control over the radiation safety program and complying with regulatory requirements and license conditions, I have been authorized to issue the enclosed Notice of Violation and Proposed Imposition of Civil Penalties in the amount of $5,000 for the two Severity Level III violations set forth in Part I of the enclosed Notice. The base civil penalty for a Severity Level III violation is $2,500. The escalation and mitigation factors in the Policy were considered as discussed below.

For Violation A in the enclosed Notice, escalation of 50 percent was applied for the factor of identification because the violation was identified by the NRC. Mitigation of 50 percent was warranted for good corrective action. Neither escalation nor mitigation was warranted for the factor of licensee performance because of two previous inspections conducted by the NRC during which violations were identified. In considering this factor, the repetitive aspect of several violations identified in Part II of the Notice were considered. The other adjustment factors in the Policy were considered and no further adjustment to the base civil penalty is considered appropriate. Therefore, on balance, no adjustment to the base civil penalty of $2500 has been deemed appropriate.

For Violation B in the enclosed Notice, escalation of 50 percent was applied for the factor of identification because the violation was identified by the NRC. Mitigation of 50 percent was warranted for good corrective action. Neither escalation nor mitigation was warranted for the factor of licensee performance for the reasons cited above relative to Violation A. The other

adjustment factors in the Policy were considered and no further adjustment to the base civil penalty is considered appropriate. Therefore, on balance, no adjustment to the base civil penalty of $2,500 has been deemed appropriate.

The violations in Part II of the Notice are not assessed a civil penalty because they were categorized at either Severity Level IV or V. Nevertheless, these violations are of concern to the NRC because several were repeat violations from previous inspections and they were additional indicators that the nuclear medicine program lacked the requisite management oversight to ensure compliance with regulatory requirements.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. In your response, you should document the specific actions taken and any additional actions you plan to prevent recurrence. After reviewing your response to this Notice, including your proposed corrective actions and the results of future inspections, the NRC will determine whether further NRC enforcement action is necessary to ensure compliance with NRC regulatory requirements.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter and its enclosures will be placed in the NRC Public Document Room.

The responses directed by this letter and the enclosed Notice are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, Pub. L. No. 96-511.

Should you have any questions concerning this letter, please contact us.

Sincerely,

Stewart D. Ebneter

Stewart D. Ebneter
Regional Administrator

Enclosure:
Notice of Violation and Proposed
Imposition of Civil Penalties

cc w/encl:
State of West Virginia

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

Princeton Community Hospital
Princeton, West Virginia

Docket No. 030-10772
License No. 47-16307-01
EA 93-212

During an NRC inspection conducted on July 26-27, 1993, violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C, the Nuclear Regulatory Commission proposes to impose a civil penalty pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (Act), 42 U.S.C. 2282, and 10 CFR 2.205. The particular violations and associated civil penalties are set forth below:

I. Violations Assessed a Civil Penalty

A. 10 CFR 20.207(a) requires that licensed materials stored in an unrestricted area be secured against unauthorized removal from the place of storage. 10 CFR 20.207(b)) requires that materials not in storage be under constant surveillance and immediate control of the licensee. As defined in 10 CFR 20.3(a)(17), an unrestricted area is any area access which is not controlled by the licensee for purposes of protection of individuals from exposure to radiation and radioactive materials.

Contrary to the above, on July 27, 1993, licensed material consisting of approximately 704 millicuries (mCi) of cesium-137 brachytherapy sealed sources and 156.16 microcuries (uCi) of cesium-137 contained in a dose calibrator check source, 0.85 curies of molybdenum-99 contained in two radiopharmaceutical generators, 273 uCi of barium-133, approximately 70 uCi of iodine-131 and millicurie quantities of technetium-99m radiopharmaceutical waste located in the nuclear medicine hot laboratory, an unrestricted area, was not secured against unauthorized removal, and was not under the constant surveillance and immediate control of the licensee.

This is a Severity Level III violation (Supplement IV).
Civil Penalty - $2,500

B. 10 CFR 35.32(a)(1)(iv) requires, in part, that each licensee establish and maintain a written quality management program to provide high confidence that byproduct material will be administered as directed by the authorized user. The quality management program must include written policies and procedures to meet the objective that, prior to administration, a written directive is prepared for any administration of quantities greater than 30 microcuries (uCi) of either sodium iodide I-125 or I-131.

10 CFR 35.2 defines a written directive for an administration of quantities greater than 30 uCi of either sodium iodide I-125 or I-131 as an order in writing for a specific

patient, dated and signed by an authorized user prior to the administration of the radiopharmaceutical and which contains the dosage.

Contrary to the above, on May 29 and November 17, 1992, and January 29, February 19, March 2, March 11, and April 17, 1993, the licensee administered radiopharmaceutical dosages consisting of sodium iodide I-131 in quantities greater than 30 uCi, and prior to administration, the licensee's authorized user failed to prepare a written directive containing the date, signature of the authorized user and dosage for the respective patients.

This is a Severity Level III violation (Supplement VI).
Civil Penalty - $2,500

II. Violations Not Assessed a Civil Penalty

A. 10 CFR 35.70(a) requires that a licensee survey with a radiation detection survey instrument at the end of each day of use all areas where radiopharmaceuticals are routinely prepared for use or administered.

Contrary to the above, on 44 occasions between August 1, 1991 and June 30, 1993, the licensee did not survey with a radiation detection instrument at the end of the day areas where radiopharmaceuticals were routinely prepared for use and administered.

This is a repeat Severity Level IV violation (Supplement VI).

B. 10 CFR 35.70(e) requires that a licensee survey for removable contamination once each week all areas where radiopharmaceuticals are routinely prepared for use, administered, or stored.

Contrary to the above, for 16 weeks between August 1, 1991 and April 30, 1993, the licensee did not survey for removable contamination in the nuclear medicine department, an area where radiopharmaceuticals were routinely prepared for use, administered, and stored.

This is a repeat Severity Level IV violation (Supplement VI).

C. 10 CFR 35.50(b)(3) requires, in part, that a licensee test each dose calibrator for linearity over the range of its use between the highest dosage that will be administered to a patient and 10 microcuries (uCi).

Contrary to the above:

1. The licensee's dose calibrator linearity tests performed on ten occasions between July 1, 1991 and July 26, 1993, covered only the range between 23.7 millicuries (mCi) and 0.004 microcuries (uCi) and the highest dosage that the licensee administered to a patient included activities up to 55 mCi of technetium-99m DTPA for lung ventilation procedures and 150 mCi of iodine-131 for thyroid therapy procedures.

2. The licensee's dose calibrator linearity test performed October 12, 1992, covered only the range between 23.7 mCi and 37.4 uCi.

This is a Severity Level IV violation (Supplement VI).

D. 10 CFR 35.59(b)(2) requires, in part, that a licensee in possession of a sealed source test the source for leakage at intervals not to exceed six months or at other intervals approved by the Commission or an Agreement State.

Contrary to the above, the licensee did not test twelve brachytherapy sealed sources containing activities between 13.6 and 55.5 millicuries of cesium-137 each for leakage between August 24, 1992 and July 26, 1993, an interval in excess of six months, and no other interval was approved by the Commission or an Agreement State.

This is a Severity Level IV violation (Supplement VI).

E. Condition 15 of NRC License No. 47-16307-01 requires that licensed material be possessed and used in accordance with the statements, representations and procedures described in the license application dated June 8, 1992, and in the documents submitted in support of that application.

Item No. 9.3 of the license application states that the licensee will establish and implement the model procedure for calibrating the dose calibrator in Appendix C to Regulatory Guide 10.8, Revision 2. Item 7 of Appendix C states, in part, that the licensee will perform an accuracy test by assaying a calibrated reference source three times, average the three determinations, and compare that averaged value to the certified activity of the reference source.

Contrary to the above, on nine occasions between April 30, 1991 and May 31, 1993, the licensee did not perform accuracy tests by assaying a calibrated reference source three times, averaging the three determinations, and comparing the averaged value to the

certified activity of the reference source. Specifically, the licensee assayed a calibrated reference source one time and compared that value to the certified activity of the reference source.

This is a Severity Level IV violation (Supplement VI).

F. 10 CFR 20.203(e) requires that rooms in which specified amounts of licensed material are used or stored be conspicuously posted "Caution Radioactive Material."

Contrary to the above, between July 22-26, 1993, a physician's office located adjacent to the nuclear medicine hot laboratory which contained approximately 328 millicuries of cesium-137 brachytherapy sealed sources, was not posted as required.

This is a repeat Severity Level V violation (Supplement IV).

G. 10 CFR 21.6 requires, in part, that the licensee post current copies of Part 21 and Section 206 of the Energy Reorganization Act of 1974, and procedures adopted pursuant to the regulations in this part: or, if posting the regulations and procedures adopted pursuant to the regulations in this part is not practicable, the licensee, in addition to posting Section 206, post a notice describing these documents and where they may be examined.

Contrary to the above, on July 30, 1993, the licensee did not post Section 206 or any of the regulations and procedures adopted pursuant to Part 21.

This is a Severity Level V violation (Supplement IV).

H. 10 CFR 35.406(b) requires that a licensee make a record of brachytherapy source use, including: (1) The names of the individuals permitted to handle the sources, (2) The number and activity of sources removed from storage, the patient's name and room number, the time and date they were removed from storage, the number and activity of the sources in storage after the removal, and the initials of the individual who removed the sources from storage; (3) The number and activity of sources returned to storage, the patient's name and room number, the time and date they were returned to storage, the number and activity of sources in storage after the return, and the initials of the individual who returned the sources to storage.

Contrary to the above, as of July 26, 1993, the licensee did not make a record of brachytherapy source usage for a brachytherapy dose administration performed on July 20, 1993.

This is a Severity Level V violation (Supplement VI).

Pursuant to the provisions of 10 CFR 2.201, Princeton Community Hospital, (Licensee) is hereby required to submit a written statement or explanation to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, within 30 days of the date of this Notice of Violation and Proposed Imposition of Civil Penalty (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each alleged violation: (1) admission or denial of the alleged violation, (2) the reasons for the violation if admitted, and if denied, the reasons why, (3) the corrective steps that have been taken and the results achieved, (4) the corrective steps that will be taken to avoid further violations, and (5) the date when full compliance will be achieved. If an adequate reply is not received within the time specified in this Notice, an order or a Demand for Information may be issued as to why the license should not be modified, suspended, or revoked or why such other action as may be proper should not be taken. Consideration may be given to extending the response time for good cause shown. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, this response shall be submitted under oath or affirmation.

Within the same time as provided for the response required above under 10 CFR 2.201, the Licensee may pay the civil penalty by letter addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, with a check, draft, money order, or electronic transfer payable to the Treasurer of the United States in the amount of the civil penalty proposed above, or the cumulative amount of the civil penalties if more than one civil penalty is proposed, or may protest imposition of the civil penalty in whole or in part, by a written answer addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission. Should the Licensee fail to answer within the time specified, an order imposing the civil penalty will be issued. Should the Licensee elect to file an answer in accordance with 10 CFR 2.205 protesting the civil penalty, in whole or in part, such answer should be clearly marked as an "Answer to a Notice of Violation" and may: (1) deny the violation listed in this Notice in whole or in part, (2) demonstrate extenuating circumstances, (3) show error in this Notice, or (4) show other reasons why the penalty should not be imposed. In addition to protesting the civil penalty in whole or in part, such answer may request remission or mitigation of the penalty.

In requesting mitigation of the proposed penalty, the factors addressed in Section VI.B.2 of 10 CFR Part 2, Appendix C, should be addressed. Any written answer in accordance with 10 CFR 2.205 should be set forth separately from the statement or explanation in reply pursuant to 10 CFR 2.201, but may incorporate parts of the 10 CFR 2.201 reply by specific reference (e.g., citing page and paragraph numbers) to avoid repetition. The attention of the Licensee is directed to the other provisions of 10 CFR 2.205, regarding the procedure for imposing a civil penalty.

Upon failure to pay any civil penalty due which subsequently has been determined in accordance with the applicable provisions of 10 CFR 2.205, this matter may be referred to the Attorney General, and the penalty, unless compromised, remitted, or mitigated, may be collected by civil action pursuant to Section 234c of the Act, 42 U.S.C. 2282c.

The response noted above (Reply to Notice of Violation, letter with payment of civil penalty, and Answer to a Notice of Violation) should be addressed to: Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555 with a copy to the Regional Administrator, U.S. Nuclear Regulatory Commission, Region II, Atlanta, Georgia.

Dated at Atlanta, Georgia
this 16th day of September 1993

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION II
101 MARIETTA STREET, N.W., SUITE 2900
ATLANTA, GEORGIA 30323-0199

JUL 22 1993

Docket No. 030-30910
License No. 41-25027-01
EA 93-116

Scientific Inspection Technology, Inc.
ATTN: Mr. Danny L. Cox
President
Post Office Box 385
Hixson, Tennessee 37343

Gentlemen:

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY - $4,000 (NRC INSPECTION REPORT NO. 41-25027-01/93-02)

This refers to the Nuclear Regulatory Commission (NRC) inspection conducted by Mr. D. Collins and Mr. M. Fuller on April 19 and 21, 1993 and May 20, 1993. The inspection included a review of the facts and circumstances associated with a radiography event on April 16, 1993, in Salem County, New Jersey, which resulted in a radiographer receiving a radiation dose to his right hand in excess of NRC limits. The inspection also included an examination of activities conducted under your license with respect to radiation safety and compliance with NRC regulations and the conditions of your license. The report documenting this inspection was sent to you by letter dated May 28, 1993. During the inspection, violations of NRC requirements were identified. An enforcement conference was held on June 7, 1993, in the Region II office to discuss the violations, their cause, and your corrective actions to preclude recurrence. A summary of the enforcement conference was sent to you by letter dated June 10, 1993.

The violations are described in the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice). Violation A in Part I of the Notice involved a radiographer who received a radiation dose of approximately 275 rems to the right hand on April 16, 1993. This event occurred as preparations were being made to begin radiography at a work site in Salem County, NJ. The radiographer's assistant had set up the exposure device which contained a 98-curie iridium-192 source and then left the area to begin setting up the restricted area boundaries. Shortly thereafter, the radiographer approached the exposure device from the rear without a radiation survey meter as the survey meter had already been positioned on the floor in front of the device. In checking the device, he experienced difficulty in rotating the selector ring and returning it to the locked position. He left the device and attempted to move the source with the drive cables and thought he had successfully secured the source in the locked position.

He returned to the device and again attempted to rotate the selector ring to the locked position. He then noticed the survey meter was off scale and when he leaned forward to pick up the meter, his alarm ratemeter alarmed. He then

leaned forward with the survey meter extended whereupon it again went off scale and his alarm ratemeter alarmed. At this point he turned off his alarm ratemeter and directed the assistant to extend the restricted area boundaries.

The radiographer again attempted to manipulate the source with the drive cables after which he returned to the device and tried to turn the selector ring to the locked position. He knelt along the right side of the device and attempted to manually loosen the source guide tube connector nut without success. He tried again and was able to loosen the nut and with a third attempt was able to disconnect the guide tube completely. With his alarm ratemeter still turned off and the survey meter off scale, he stood up at the rear of the device and leaned forward and observed the source just inside the front plane of the guide tube connector nut. He returned to the drive cables and retracted the source with the crank, went back to the device and rotated the selector ring to the locked position.

Violation B in Part I of the Notice involved the failure of the radiographer to follow established emergency procedures during the event described above in that he did not immediately contact the Radiation Safety Officer (RSO) for directions after he assessed that an emergency situation existed. In this particular case, when the radiographer first observed that a problem existed as indicated by the off scale reading on the survey meter, his evaluation should have caused him to immediately terminate any further activity and contact the RSO. Instead, he continued to attempt to correct the situation and his attempts caused the unnecessary exposure.

Violation C in Part I of the Notice involved the failure of the radiographer to wear an operable alarm ratemeter at all times during radiographic operations. As the event was developing, the radiographer turned off the alarm ratemeter when it alarmed. It is significant to note that the alarm ratemeter alarmed twice and effectively alerted the radiographer to the fact that he was being exposed to a radiation field of at least 500 milliroentgens per hour (mR/hr), the preset dose rate of the ratemeter. Turning off the alarm clearly defeated the purpose of the alarm ratemeter which was to provide an audible warning of significant radiation. Again the radiographer did not respond properly to the situation.

The performance of the radiographer was simply unacceptable. The NRC is further concerned that an experienced radiographer, as a result of his failure to take appropriate emergency actions, caused significant exposure to his hand. His failure to initiate prescribed emergency actions at various times represented missed opportunities that could have precluded the overexposure. The signals from the alarm ratemeter were clear warnings that a potentially serious problem existed. Had emergency procedures been followed, the problem could have been corrected without the significant exposure.

In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy) 10 CFR Part 2, Appendix C, the violations associated with this event are classified in the aggregate as a Severity Level II problem because the overexposure was in excess of 75 rem to the hand of the radiographer.

The NRC recognizes that corrective actions, as described at the enforcement conference, have been taken to ensure that appropriate management attention is focused on radiographic operations to preclude recurrence of such violations. These actions included: (1) arranging prompt initial follow up to determine the probable causes and consequences of the event, (2) verbally informing every radiographer of the event with a followup in writing; (3) placing increased emphasis on emergency procedures during audits of radiographers; (4) scheduling all radiographers for classroom training on emergency procedures and use of alarming ratemeters; (5) requiring radiographers to verify status of other employees assigned to work with them; (6) reiterating management expectations relative to emergency procedures and the review and assessment of incidents to stress safety; (7) issuing a written reprimand to the radiographer involved in the incident; and (8) placing increased management emphasis on examination of equipment prior to placing it in operational use.

In order to emphasize the importance of ensuring that appropriate emergency procedures are followed and to ensure that operational activities are conducted safely and in accordance with requirements, I have been authorized, after consultation with the Director, Office of Enforcement, and the Deputy Executive Director for Nuclear Materials Safety, Safeguards, and Operations Support, to issue the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice) in the amount of $4,000 for the Severity Level II problem. The base civil penalty for a Severity Level II violation or problem is $8,000. Application of the escalation and mitigation factors as described in the Enforcement Policy would normally result in complete mitigation of the civil penalty because of your prompt investigation and reporting of the event, which was considered to be self-disclosing; your prompt and comprehensive corrective actions; and your prior good performance. However, Section VI.B.2 of the Enforcement Policy provides that notwithstanding the application of mitigating factors, a civil penalty of at least 50 percent of the base amount is warranted for Severity Level II violations or problems involving overexposures. Consistent with that guidance, and given the significance of the overexposure and associated violations, the $4,000 civil penalty is proposed.

The violation in Part II of the enclosed Notice involved the failure of the radiographer to adequately supervise an assistant radiographer while the exposure device was being set up. Although this violation was categorized at Severity Level IV, it also reflects the lack of attention to operational activities and the need to ensure proper performance of radiographic operations at all times.

An additional apparent violation discussed in the inspection report involved a question of whether the individual named in the NRC license as RSO was actually performing those duties. You explained at the enforcement conference that the NRC and Agreement State licenses name different RSO's, that there are separate procedure manuals for each license, and that each RSO functions in the appropriate capacity for the activities conducted under that respective license. Therefore, a violation is not being cited.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. In your response, you should document the specific actions taken and any additional actions you plan to prevent recurrence. After reviewing your response to this Notice, including your proposed corrective actions and the results of future inspections, the NRC will determine whether further NRC enforcement action is necessary to ensure compliance with NRC regulatory requirements.

The radiographer involved in the event described above acknowledged that he was trained in the emergency procedure and knew what it required, yet when the emergency arose, he did not follow the procedure. Therefore, in your response you should also include your basis for having confidence that, in the future, this individual will conduct activities in the manner in which he has been trained and in accordance with NRC regulatory requirements. A separate letter has been sent to the radiographer requesting that he provide his explanation of the events and provide reasonable assurance that he will conduct licensed activities in the manner in which he has been trained and in accordance with NRC regulatory requirements (Enclosure 2).

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter and its enclosures will be placed in the NRC Public Document Room.

The responses directed by this letter and the enclosed Notice are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, Pub. L. No. 96-511.

Should you have any questions concerning this letter, please contact us.

Sincerely,

for

Stewart D. Ebneter
Regional Administrator

Enclosures:
1. Notice of Violation and Proposed Imposition of Civil Penalty
2. Demand for Information

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

Scientific Inspection Technology, Inc.
Hixson, Tennessee

Docket No. 030-30910
License No. 41-25027-01
EA 93-116

During an NRC inspection conducted April 19 and 21, 1993, and May 20, 1993, violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C, the Nuclear Regulatory Commission proposes to impose a civil penalty pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (Act), 42 U.S.C. 2282, and 10 CFR 2.205. The particular violations and associated civil penalty are set forth below:

I. Violations Assessed a Civil Penalty

A. 10 CFR 20.101 (a) requires, in part, that the licensee limit the radiation dose to the hands and forearms of an individual working in a restricted area to eighteen and three-quarters rems per calendar quarter.

Contrary to the above, the licensee did not limit the radiation dose to the hands of an individual working in a restricted area to eighteen and three-quarters rems per calendar quarter. Specifically, an individual received a radiation dose to the right hand estimated by the Licensee to be 275 rems during the second calendar quarter of 1993 while performing radiographic operations in Salem County, New Jersey, on April 16, 1993.

B. Condition 17 of License Number 41-25027-01 requires that the licensee conduct its program in accordance with the statements, representations, and procedures contained in the application dated November 22, 1988. Attachment five to the application includes Emergency Procedure RSP-1.

Emergency Procedure RSP-1, Section 4.1 requires, in part, that in an emergency situation the radiographer calmly review and assess the situation with respect to any possible overexposure or damage to radiographic equipment and after the assessment to "IMMEDIATELY" notify the respective corporate radiation safety officer for direction and resolution of the situation. Section 5.1 of RSP-1 states that the corporate radiation safety officer is responsible for determining what steps must be taken during an emergency situation.

Contrary to the above, on April 16, 1993, the licensee's radiographer failed to immediately notify the corporate radiation safety officer for direction and resolution after he had assessed that an emergency situation existed. Specifically, the

radiographer, after determining that he could not retract a radioactive source to its locked position and after observing off scale readings on his survey meter and receiving audible alarms from his alarm ratemeter, resolved the situation himself instead of immediately notifying the radiation safety officer.

C. 10 CFR 34.33 requires, in part, that a licensee may not permit any individual to act as a radiographer or radiographer's assistant unless at all times during radiographic operations, each such individual wears an alarm ratemeter, except under certain circumstances not relevant here, and that the alarm ratemeter be set to give an alarm signal at a preset dose rate of 500 milliroentgens per hour (mR/hr).

Contrary to the above, on April 16, 1993, the licensee's radiographer failed to wear an alarm ratemeter at all times during radiographic operations that was set to give an alarm at a preset dose rate of 500 mR/hr. Specifically, while performing radiographic operations, the radiographer turned the alarm ratemeter off when it alarmed, at which time it ceased to be set to give an alarm at a preset dose rate of 500 mR/hr.

These violations represent a Severity Level II problem Supplements IV and VI).

Civil Penalty - $4,000

II. Violation Not Assessed a Civil Penalty

10 CFR 34.44 requires that whenever a radiographer's assistant uses radiographic exposure devices, uses sealed sources or related source handling tools, or conducts radiation surveys required by 10 CFR 34.43(b) to determine that the sealed source has returned to its shielded position after an exposure, he shall be under the personal supervision of a radiographer. The personal supervision shall include: (a) the radiographer's personal presence at the site where the sealed sources are being used; (b) the ability of the radiographer to give immediate assistance if required; and (c) the radiographer watching the assistant's performance of the operations referred to in this section.

Contrary to the above, on April 16, 1993, a licensee radiographer's assistant utilized a radiographic exposure device at a work site in Salem County, New Jersey, without adequate personal supervision by a radiographer. Specifically, the radiographer did not watch the assistant radiographer set up radiographic equipment and unlock the exposure device and was not able to give immediate assistance while he was performing those activities.

This is a Severity Level IV violation (Supplement IV).

Pursuant to the provisions of 10 CFR 2.201, Scientific Inspection Technology, Inc., (Licensee) is hereby required to submit a written statement or explanation to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, within 30 days of the date of this Notice of Violation and Proposed Imposition of Civil Penalty (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each alleged violation: (1) admission or denial of the alleged violation, (2) the reasons for the violation if admitted, and if denied, the reasons why, (3) the corrective steps that have been taken and the results achieved, (4) the corrective steps that will be taken to avoid further violations, and (5) the date when full compliance will be achieved. If an adequate reply is not received within the time specified in this Notice, an Order or a Demand for Information may be issued as to why the license should not be modified, suspended, or revoked or why such other action as may be proper should not be taken. Consideration may be given to extending the response time for good cause shown. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, this response shall be submitted under oath or affirmation.

Within the same time as provided for the response required above under 10 CFR 2.201, the Licensee may pay the civil penalty by letter addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, with a check, draft, money order, or electronic transfer payable to the Treasurer of the United States in the amount of the civil penalty proposed above, or the cumulative amount of the civil penalties if more than one civil penalty is proposed, or may protest imposition of the civil penalty, in whole or in part, by a written answer addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission. Should the Licensee fail to answer within the time specified, an order imposing the civil penalty will be issued. Should the Licensee elect to file an answer in accordance with 10 CFR 2.205 protesting the civil penalty, in whole or in part, such answer should be clearly marked as an "Answer to a Notice of Violation" and may: (1) deny the violations listed in this Notice in whole or in part, (2) demonstrate extenuating circumstances, (3) show error in this Notice, or (4) show other reasons why the penalty should not be imposed. In addition to protesting the civil penalty in whole or in part, such answer may request remission or mitigation of the penalty.

In requesting mitigation of the proposed penalty, the factors addressed in Section VI.B.2 of 10 CFR Part 2, Appendix C, should be addressed. Any written answer in accordance with 10 CFR 2.205 should be set forth separately from the statement or explanation in reply pursuant to 10 CFR 2.201, but may incorporate parts of the 10 CFR 2.201 reply by specific reference (e.g., citing page and paragraph numbers) to avoid repetition. The attention of the Licensee is directed to the other provisions of 10 CFR 2.205, regarding the procedure for imposing a civil penalty.

Upon failure to pay any civil penalty due which subsequently has been determined in accordance with the applicable provisions of 10 CFR 2.205, this matter may be referred to the Attorney General, and the penalty, unless compromised, remitted, or mitigated, may be collected by civil action pursuant to Section 234c of the Act, 42 U.S.C. 2282c.

The response noted above (Reply to Notice of Violation, letter with payment of civil penalty, and Answer to a Notice of Violation) should be addressed to: Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555 with a copy to the Regional Administrator, U.S. Nuclear Regulatory Commission, Region II, 101 Marietta Street, NW, Suite 2900, Atlanta, Georgia 30323.

Dated at Atlanta, Georgia
this 22nd day of July 1993

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION V

1450 MARIA LANE
WALNUT CREEK, CALIFORNIA 94596-5368

July 2, 1993

Docket No. 70-1257
License No. SNM-1227
EA 93-085

Siemens Power Corporation
ATTN: Mr. R. G. Frain, Vice President
Manufacturing
2101 Horn Rapids Road
Post Office Box 130
Richland, Washington 99352-0130

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY OF $12,500
(NRC INSPECTION REPORT NOS. 70-1257/93-02 AND 70-1257/93-05)

This refers to the special NRC inspection conducted on April 19-22, 1993 at your Siemens Power Corporation facility in Richland, Washington. The inspection included a review of the findings identified during the onsite Augmented Inspection Team (AIT) inspection (Report No. 70-1257/93-02) conducted on February 9-12, 1993. The purpose of the AIT inspection was to review the circumstances of an event that occurred on February 7, 1993, involving the inadvertent discharge of approximately 124 kilograms of low enriched uranium powder from a process system into a lexan enclosure. The discharge was a result of taping a safety related interlock that prevented it from performing its intended function.

NRC Inspection Report No. 70-1257/93-05 identified four examples of failure to follow NRC requirements which have been grouped into two violations. These violations are described in the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice). The details of the AIT findings and the apparent violations were mailed to you by letters dated March 10 and April 30, 1993, respectively. Although you identified and reported the February 7, 1993, event, and you documented it in an investigation report provided to the NRC, we identified the two examples of the second violation. On May 17, 1993, an enforcement conference was conducted with you and members of your staff in the Region V office to discuss the circumstances surrounding the violations, their causes, your corrective actions, and your actions to prevent recurrence. The details of the enforcement conference (Report No. 70-1257/93-06) were sent to you by letter dated June 2, 1993.

Violation I, described in the enclosed Notice, describes two examples of failure to comply with established operating procedures. The first example involved the failure to comply with procedures for modification of systems that involve fissile material. Modifications were made to the powder preparation system (PPS) by the addition of interlocks through the use of a "Work Order," contrary to your procedures specifically requiring the use of an "Engineering Change Notice" for modifications that involve fissile material. The second example involved the failure to comply with operating procedures prohibiting the bypassing of interlocks. Immediately after the February event it was self-evident that the interlocks on the discharge tube of the feed hopper from the blenders on the Line 2 and Line 3 PPS had been taped (bypassed). As a result, the powder transfer process was not automatically shutdown after the transfer tube dislodged from the feed hopper.

The examples in Violation I are of particular concern because they indicate that you did not maintain rigorous control over modifications to your fissile material process systems. One of the most troubling aspects of this event was the bypassing of the interlock switches, as it is indicative of an environment where operators fix production problems without fully understanding the impact of their actions and without informing management of the problems, indicating a lack of effective communication of management expectations to operators. Effective communication of management expectations, including management confirmation that those expectations are being met, is vital for safe operation.

Violation II describes two examples of weaknesses in your Criticality Safety Analyses (CSAs). The first example involves the failure to evaluate in CSAs your modifications to safety controls (i.e., installation of interlocks on the discharge tubes of the feed hoppers), and the second example involves the failure to maintain an evaluation to demonstrate that liquid moderating systems do not pose a criticality safety concern with your unfavorable geometry powder preparations systems. Both examples are safety significant. The first example is safety significant because addition of the interlocks to the CSAs, Criticality Safety Specifications (CSSs), and operating procedures would have alerted operations personnel to the switches' importance (to ensure that uranium powder is retained within the process system and not subject to moderating spray or flooding). The second example is safety significant because the evaluation you performed in response to our February 12, 1993, Confirmatory Action Letter (CAL) clearly found that a single accident involving flooding or spray from a water line break in the vicinity of your powder preparation system could pose a criticality concern within a short time, independent of the new interlock switch. This is a concern to the NRC because the

applicable CSAs, CSSs, and operating procedure for the powder preparation system did not specify physical or administrative controls for mitigating such an accident.

We have grouped the violations as a Level III problem. Collectively, these violations represent a potentially significant lack of attention toward licensed responsibilities and are cause for significant regulatory concern. Based on our review of your program involving the engineering process for the installation of the interlocks, and on our review of the failure to notify operations personnel that the interlocks had been installed, we have concluded that the violations were caused by management's failure to assure rigorous attention to regulatory requirements and to insist on discipline in modifying systems important to criticality safety. Management must assure that all personnel understand that formality is required for all modifications to equipment installed to mitigate accidents, and that the criticality safety program can and does assure such formality in dealing with this equipment.

The NRC notes that as a result of the powder spill, you shut down all three powder preparation and affected vacuum transfer lines, created an Incident Investigation Board, established a "Generic Implications" Task Team, revised your Work Order and Engineering Change Notice procedures, reviewed the use of interlocks plant wide, provided additional training to the operations staff and initiated other improvements that were discussed during the enforcement conference.

During the enforcement conference you stated that you disagreed with both examples of the second violation. Specifically, you argued that you rigorously evaluated the installation of the interlocks and reasonably concluded at the time that they should not be included as criticality safety controls in the CSA. In particular, you stated that failure to update the CSA associated with the addition of the interlock switch should not be a violation since, prior to the modification, a criticality specialist had determined that addition of the switch was within the bounds of the existing CSA. You also stated that failure to evaluate moderation exclusion controls in applicable CSAs should not be a violation since the existing CSAs included appropriate controls, assuming that plant operators would take manual action to shut down the process path in the event of any unforeseen moderator intrusion. You concluded by noting that although CSA license condition requirements were not violated, the existing CSAs did not meet current management expectations and were being revised to address the concerns noted by the NRC. In this regard, your staff stated that a citation for these problems was inappropriate under the NRC Enforcement Policy because the problems represented conditions for which corrective actions related to prior enforcement action were already underway.

We responded to these statements during the enforcement conference. In particular, we noted that regardless of whether the CSAs had previously been considered adequate, they had not established appropriate criticality controls for potential moderator intrusion (a conclusion supported by your analysis performed in response to our February 12, 1993, CAL). Furthermore, we noted that while the Enforcement Policy provides discretion to refrain from citing violations that were licensee identified as part of the corrective action for a previous escalated enforcement action, the current problems in the CSAs were not licensee identified as part of the corrective actions for the October 1992 enforcement action (i.e., commitment to review and upgrade existing CSAs); instead, the NRC identified the problems in response to a self-revealing event.

The NRC staff recognizes that your investigation surfaced the problems that led to the February 7th event, and that you promptly initiated corrective actions to preclude recurrence of similar events. The staff also recognizes that you have implemented extensive program improvements, as discussed above, to convey management expectations regarding safe operations. You are commended for your efforts in these areas. However, to emphasize the importance of ensuring that activities are conducted with discipline by all personnel and that equipment important to criticality safety is correctly maintained, I have been authorized, after consultation with the Director, Office of Enforcement, and the Deputy Executive Director for Nuclear Materials Safety, Safeguards and Operations Support, to issue the enclosed Notice of Violation and Proposed Imposition of Civil Penalty in the amount of $12,500 for the Severity Level III problem.

The base value of a civil penalty for a Severity Level III problem is $12,500. The escalation and mitigation factors in the Enforcement Policy were considered. The base civil penalty was neither escalated nor mitigated for the identification factor. Although you identified the violations in Section I of the Notice during your investigation of the powder spill, the specific examples of inadequate CSAs were identified during the NRC inspection. The civil penalty was mitigated by 50 percent for your prompt and planned corrective actions. The NRC notes that in addition to the corrective actions discussed above, you had already initiated a comprehensive, long-term program to review and upgrade your CSAs as a result of a previous escalated enforcement action (EA 92-163). We considered 100 percent escalation of the civil penalty based on previous performance problems (i.e. 26 cited and 4 non-cited violations during the last two years, including those cited in EA 92-163). However, since the violations cited in Section II of the Notice stem from a basic problem of insufficiently detailed or prescriptive criticality controls, a problem which you have already recognized

and initiated comprehensive actions to correct, the civil penalty is only escalated 50 percent for past performance. The other adjustment factors in the Policy were considered, but no further adjustments were deemed appropriate.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. In your response, you should document the specific actions taken and any additional actions you plan to prevent recurrence. You should also discuss whether the schedule outlined in your Criticality Safety Analysis Program (forwarded to the NRC in a letter dated December 30, 1992) needs revision in light of this event. After reviewing your response to this Notice, including your proposed corrective actions and the results of future inspections, the NRC will determine whether further NRC enforcement action is necessary to ensure compliance with NRC regulatory requirements.

In accordance with 10 CFR 2.790 of the Commission's regulations, a copy of this letter and the enclosures will be placed in the NRC's Public Document Room.

The responses directed by this letter and the enclosed Notice are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, Pub. L. No. 96-511.

Sincerely,

Bobby H. Faulkenberry
Regional Administrator

Enclosure:
Notice of Violation and Proposed Imposition
of Civil Penalty

cc:
State of Washington
L. J. Maas, Manager, Regulatory Compliance

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

Siemens Power Corporation
Richland, Washington

Docket No. 70-1257
License No. SNM-1227
EA 93-085

During an NRC inspection conducted on April 19-22, 1993, two violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C, the Nuclear Regulatory Commission proposes to impose a civil penalty pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (Act), 42 U.S.C. 2282, and 10 CFR 2.205. The particular violations and associated civil penalty are set forth below:

I. License Condition No. 9 of License No. SNM-1227 authorizes the use of licensed materials in accordance with the statements, representations, and conditions contained in Part I of the licensee's application dated July 1987, and supplements dated November 12, 1987, through January 20, 1993.

Section 2.5, "Operating Procedures, Standards and Guides," Part I of the license application, states in part that the licensee conducts its business in accordance with a system of Standard Operating Procedures, Company Standards, and Policy Guides.

A. Section 2.1, "Scope," of procedure EMF-858, No. 1.13, "Engineering Change Notice (ECN)," requires that ECNs be used for additions or deletions of, or modification to, facilities, services and equipment when work meets one or more of the following criteria:

> Affects the basic principles of operation of the manufacturing process.
>
> Directly involves fissile material.
>
> Affects criticality or radiological safety."

Contrary to the above, between September 11-14, 1992, an ECN was not used for modification of the discharge tube of the feed hoppers on all four blenders by installing interlocks for the direct control of unanticipated discharges of fissile material.

B. Section 3.0, "Radiological, Industrial and Fire Safety," item 3.6, of procedure EMF-22, No. P66,813, "Preparation of UO_2 Powder as Press Feed," Revision No. 5, dated September 24, 1992, stated:

> "Interlocks are not to be bypassed during operation of the powder preparation process."

Contrary to the above, as of February 7, 1993, interlocks on the discharge tube on the feed hoppers of the Line 2 and Line 3 blenders had been bypassed (taped to prevent operation) during the

operation of the UO_2 powder preparation process.

II. License Condition No. 9 of License No. SNM-1227 authorizes the use of licensed materials in accordance with the statements, representations, and conditions contained in Part I of the licensee's application dated July 1987, and supplements dated November 12, 1987, through January 20, 1993.

Section 2.5 "Operating Procedures, Standards and Guide ," Part I of the license application, states in part that the licensee conducts its business in accordance with a system of Standard Operating Procedures, Company Standards, and Policy Guides.

A. Section 4.5, " CSA [Criticality Safety Analysis] Documentation," Chapter 3, "Nuclear Criticality Safety Standards," of the licensee's Safety Manual (EMF-30), states in part:

> "All limits and controls to assure criticality safety shall be clearly specified."

Appendix 2, "Guidelines for Requesting CSA for Plant Design Changes and the Addition of New Equipment," Chapter 3, "Nuclear Criticality Safety Standards," of the licensee's Safety Manual (EMF-30), states in part:

> "...As the manufacturing process is improved and refined, equipment in the plant is changed and/or new equipment is added. Each change or addition of equipment requires a new CSA...."

Contrary to the above, between September 11-14, 1992, equipment was added to a manufacturing process but a new CSA was not performed to evaluate the addition. Specifically, interlocks used as controls to prevent discharges of low enriched UO_2 from the confines of the process system were added to the discharge tube of the feed hoppers on four blenders in September 1992, and the new controls were not described in a CSA.

B. Section 4.1, "Purpose and Scope," Chapter 3, "Nuclear Criticality Safety Standards," of the licensee's Safety Manual (EMF-30), states:

> "The CSA is a study of equipment/operations involving fissile material at normal conditions and at credible accident conditions to determine if the criticality safety criteria are satisfied."

Section 4.1.1, "Process Analysis (Criticality Safety Determinations)," Part I of the license application, states

in part:

> "Before any operation with special nuclear material [SNM] is begun or changed, it is determined that the entire process will be subcritical under both normal and credible abnormal conditions, and within the technical requirements specified in Section 4.2. Criticality Safety Analyses are performed on all applicable processes ...."

Section 4.2.1, "Double Contingency Policy," Part I of the license application, states:

> "Process and equipment designs and operating procedures incorporate sufficient factors of safety to require at least two unlikely, independent, and concurrent errors, accidents, equipment malfunctions, or changes in process conditions before a criticality accident is possible."

Section 2.0, "Philosophy and Criteria," Chapter 3, "Nuclear Criticality Safety Standards," of the licensee's Safety Manual (EMF-30), states that "No single accident, error of equipment, or process malfunction shall allow criticality to occur."

Section 4.4, "Safety Evaluation," Chapter 3, "Nuclear Criticality Safety Standards," of the licensee's Safety Manual (EMF-30), paragraph 4.4.5.3, "Moderation Limits," states:

> "The potential of accidental moderation due to water/oil leaks, sprays, overflows, condensation, siphoning, etc., must be carefully evaluated and controls implemented as appropriate."

Section 4.5, "CSA Documentation," Chapter 3, "Nuclear Criticality Safety Standards," of the licensee's Safety Manual (EMF-30), states in part:

> "All limits and controls to assure criticality safety shall be clearly specified."

Contrary to the above, as of February 12, 1993, the licensee had not determined that the conversion Line 2 unfavorable geometry UO_2 powder preparation systems (PPSs) would be subcritical under both normal and credible abnormal conditions and had not carefully evaluated the potential of accidental moderation due to water leaks, sprays, overflows and siphoning. Specifically, the licensee did not maintain an evaluation with the technical basis to demonstrate that

liquid moderating systems within the same room and near conversion Line 2 PPSs did not pose a criticality concern. As a consequence, the controls necessary to preclude the intrusion of moderating liquids into the PPSs from breaks in nearby moderating liquid lines were not clearly specified.

These violations represent a Severity Level III problem (Supplement VI).

Civil Penalty - $12,500

Pursuant to the provisions of 10 CFR 2.201, Siemens Power Corporation (Licensee) is hereby required to submit a written statement or explanation to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, within 30 days of the date of this Notice of Violation and Proposed Imposition of Civil Penalty (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each alleged violation: (1) admission or denial of the alleged violation, (2) the reasons for the violation if admitted, and if denied, the reasons why, (3) the corrective steps that have been taken and the results achieved, (4) the corrective steps that will be taken to avoid further violations, and (5) the date when full compliance will be achieved. If an adequate reply is not received within the time specified in this Notice, an order or a Demand for Information may be issued as to why the license should not be modified, suspended, or revoked or why such other action as may be proper should not be taken. Consideration may be given to extending the response time for good cause shown. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, this response shall be submitted under oath or affirmation.

Within the same time as provided for the response required above under 10 CFR 2.201, the Licensee may pay the civil penalty by letter addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, with a check, draft, money order, or electronic transfer payable to the Treasurer of the United States in the amount of the civil penalty proposed above, or may protest imposition of the civil penalty in whole or in part, by a written answer addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission. Should the Licensee fail to answer within the time specified, an order imposing the civil penalty will be issued. Should the Licensee elect to file an answer in accordance with 10 CFR 2.205 protesting the civil penalty, in whole or in part, such answer should be clearly marked as an "Answer to a Notice of Violation" and may: (1) deny the violations listed in this Notice, in whole or in part, (2) demonstrate extenuating circumstances, (3) show error in this Notice, or (4) show other reasons why the penalty should not be imposed. In addition to protesting the civil penalty in whole or in part, such answer may request remission or mitigation of the penalty.

In requesting mitigation of the proposed penalty, the factors addressed in Section VI.B.2 of 10 CFR Part 2, Appendix C, should be addressed. Any written answer in accordance with 10 CFR 2.205 should be set forth separately from the statement or explanation in reply pursuant to 10 CFR 2.201, but may incorporate parts of the 10 CFR 2.201 reply by specific reference (e.g.,

citing page and paragraph numbers) to avoid repetition. The attention of the Licensee is directed to the other provisions of 10 CFR 2.205, regarding the procedure for imposing a civil penalty.

Upon failure to pay any civil penalty due which subsequently has been determined in accordance with the applicable provisions of 10 CFR 2.205, this matter may be referred to the Attorney General, and the penalty, unless compromised, remitted, or mitigated, may be collected by civil action pursuant to Section 234c of the Act, 42 U.S.C. 2282(c).

The response noted above (Reply to Notice of Violation, letter with payment of civil penalty, and Answer to a Notice of Violation) should be addressed to: Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555 with a copy to the Regional Administrator, U.S. Nuclear Regulatory Commission, Region V.

Dated at Walnut Creek, California
this 2nd day of July 1993

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
799 ROOSEVELT ROAD
GLEN ELLYN, ILLINOIS 60137-5927

July 13, 1993

Docket No. 030-02700
License No. 34-02176-01
EA 93-165

St. Elizabeth Medical Center
ATTN: Aurelia Schuster
Vice President for Operations
601 Edwin C. Moses Blvd.
Dayton, Ohio 45408

Dear Ms. Schuster:

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY - $1,250
(NRC INSPECTION REPORT NO. 030-02700/93001)

This refers to the safety inspection conducted from May 26 to June 9, 1993 at St. Elizabeth Medical Center, Dayton, Ohio, to review the circumstances surrounding improper transfers of NRC licensed materials to a sanitary landfill. One such event occurred on December 3-4, 1992, when 12 packages, containing a total activity of approximately 600 microcuries of iodine-125 in the form of in-vitro kits, were removed from your radiation waste storage facility by the custodial staff without the authorization of the facility Radiation Safety Officer (RSO) and transferred to a sanitary landfill where the material was incinerated on December 4, 1992. The inspection also determined that additional instances of improper transfers of licensed materials had occurred. The report documenting this inspection was mailed to you by letter, dated June 23, 1993. Significant violations of NRC requirements were identified during the inspection, and on July 2, 1993, an enforcement conference was held in the Region III office.

The root causes of the violations and the subsequent corrective actions were discussed during the enforcement conference. The major factors contributing to the violations appeared to be: (1) poor communications between your RSO and your Housekeeping Department; (2) poor security of your radwaste storage area by allowing the Housekeeping Department to have a master key to that area; and (3) inadequate radiation safety training of your custodial staff. The NRC recognizes that immediate corrective actions were taken, including, but were not limited to: (1) requiring a written requisition by the RSO for trash removal; (2) retrieving the master key to the radiation restricted area from the custodial staff; and (3) providing refresher radiation safety

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training to the custodial staff.

The violations are fully described in the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice) and concern the improper disposal or transfer of radioactive materials. The violations collectively represent a failure to control access to licensed materials for radiation purposes as specified by NRC requirements. Therefore, in accordance with the "Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy) 10 CFR Part 2, Appendix C, the violations are classified in the aggregate as a Severity Level III problem.

As a holder of a Byproduct Material License, the NRC entrusts St. Elizabeth Medical Center with the responsibility to protect the public health and safety, including that of its employees, from any unnecessary exposure to radiation. To emphasize the need for strict adherence to NRC requirements for the proper disposal of radioactive materials, I have decided to issue the enclosed Notice in the amount of $1,250 for the Severity Level III problem.

The base value of a civil penalty for a Severity Level III problem is $2,500. The civil penalty adjustment factors in the Enforcement Policy were considered and the civil penalty was mitigated 50 percent for your prompt and extensive corrective actions. While you identified that licensed materials were improperly transferred to the landfill on December 4, 1992, you did not identify the other instances of improper transfer of licensed materials; therefore, no adjustment was made for identifying the problem. The remaining factors in the enforcement policy were also considered and no further adjustment to the base civil penalty was considered appropriate.

The inspection also found that the dose calibrator at your facility was not checked for constancy on the most frequently used settings at the beginning of each day of use. While this is a violation of 10 CFR 35.50(b)(1), it is not cited here because the criteria of Section VII.B. of the NRC Enforcement Policy were met prior to the conclusion of the NRC inspection.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. In your response, you should document the specific actions taken and any additional actions you plan to prevent recurrence. After reviewing your response to this Notice, including your proposed corrective actions and the results of future inspections, the NRC will determine whether further NRC enforcement action is necessary to ensure compliance with NRC regulatory requirements.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter, its enclosure, and your response will be placed in the NRC Public Document Room.

The response directed by this letter and the enclosed Notice are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, Public Law No. 96-511.

Sincerely,

John B. Martin
Regional Administrator

Enclosure:
Notice of Violation and Proposed
Imposition of Civil Penalty

cc/enclosure
DCD/DCB (RIDS)

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

St. Elizabeth Medical Center
Dayton, Ohio

Docket No. 030-02700
License No. 34-021176-01
EA 93-165

During an NRC inspection conducted from May 26 to June 9, 1993, violations of NRC requirements were identified. In accordance with the "Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C, the Nuclear Regulatory Commission proposes to impose a civil penalty pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (Act), 42 U.S.C. 2282, and 10 CFR 2.205. The particular violations and associated civil penalty are set forth below:

A. 10 CFR 20.207(a) requires that licensed materials stored in an unrestricted area be secured against unauthorized removal from the place of storage. 10 CFR 20.207(b) requires that licensed materials in an unrestricted area and not in storage be tended under constant surveillance and immediate control of the licensee. As defined in 10 CFR 20.3(a)(17), an unrestricted area is any area access to which is not controlled by the licensee for purposes of protection of individuals from exposure to radiation and radioactive materials.

Contrary to the above, on December 3, 1992, license material consisting of approximately 600 microcuries of iodine-125 located in the West Pavilion, an unrestricted area, was not secured against unauthorized removal, and was not under constant surveillance and immediate control of the licensee.

B. 10 CFR 30.41(a) and (b)(5) require, in part, that no licensee transfer byproduct material except to a person authorized to receive such byproduct material under the terms of a specific or general license issued by the Commission or an Agreement State.

Contrary to the above, on December 3, 1992, the licensee transferred approximately 12 boxes, containing approximately 600 microcuries of iodine-125 to an area landfill, a person who was not authorized to receive such byproduct material under the terms of a specific or general license issued by the Commission or an Agreement State.

C. 10 CFR 35.92(a) permits a licensee to dispose of byproduct material with a physical half-life of less than 65 days in ordinary trash provided, in part, that the licensee first monitors such byproduct material at the container surface and determines that its radioactivity cannot be distinguished from the background radiation level with a radiation detection survey meter set on its most sensitive

scale and with no interposed shielding.

Contrary to the above, on or about July 20, 1992, February 3 and March 10, 1993, the licensee disposed of unknown quantities of xenon-133 and technetium-99(m) in ordinary trash without first monitoring the material to determine that its radioactivity could not be distinguished from the background radiation level.

This is a Severity Level III problem (Supplements IV and VI). Cumulative Civil Penalty - $1,250.

Pursuant to the provisions of 10 CFR 2.201, St. Elizabeth Medical Center (Licensee) is hereby required to submit a written statement or explanation to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, within 30 days of the date of this Notice of Violation and Proposed Imposition of Civil Penalty (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each alleged violation: (1) admission or denial of the alleged violation, (2) the reasons for the violation if admitted, and if denied, the reasons why, (3) the corrective steps that have been taken and the results achieved, (4) the corrective steps that will be taken to avoid further violations, and (5) the date when full compliance will be achieved. If an adequate reply is not received within the time specified in this Notice, an order or a demand for information may be issued as to why the license should not be modified, suspended, or revoked or why such other action as may be proper should not be taken. Consideration may be given to extending the response time for good cause shown. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, this response shall be submitted under oath or affirmation.

Within the same time as provided for the response required under 10 CFR 2.201, the Licensee may pay the civil penalty by letter addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, with a check, draft, money order, or electronic transfer payable to the Treasurer of the United States in the amount of the civil penalty proposed above, or may protest imposition of the civil penalty in whole or in part, by a written answer addressed to the Director, Office of Enforcement, U. S. Nuclear Regulatory Commission. Should the Licensee fail to answer within the time specified, an order imposing the civil penalty will be issued. Should the Licensee elect to file an answer in accordance with 10 CFR 2.205 protesting the civil penalty, in whole or in part, such answer should be clearly marked as an "Answer to a Notice of Violation" and may: (1) deny the violations listed in this Notice in whole or in part, (2) demonstrate extenuating circumstances, (3) show error in this Notice, or (4) show other reasons why the penalty should not be imposed. In addition to protesting the civil penalty in whole or in part, such answer may request remission or mitigation of the penalty.

In requesting mitigation of the proposed penalty, the factors addressed in Section V.B of 10 CFR Part 2, Appendix C, should be addressed. Any written answer in accordance with 10 CFR 2.205 should be set forth separately from the statement or explanation in reply pursuant to 10 CFR 2.201, but may incorporate parts of the 10 CFR 2.201 reply by specific reference (e.g., citing page and paragraph numbers) to avoid repetition. The attention of the Licensee is directed to the other provisions of 10 CFR 2.205, regarding the procedure for imposing a civil penalty.

Upon failure to pay any civil penalty due which subsequently has been determined in accordance with the applicable provisions of 10 CFR 2.205, this matter may be referred to the Attorney General, and the penalty, unless compromised, remitted, or mitigated, may be collected by civil action pursuant to Section 234c of the Act, 42 U.S.C. 2282c.

The responses noted above (Reply to Notice of Violation, letter with payment of civil penalty, and Answer to a Notice of Violation) should be addressed to: Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555 with a copy to the Regional Administrator, U.S. Nuclear Regulatory Commission, Region III, 799 Roosevelt Road, Glen Ellyn, Illinois 60137.

FOR THE NUCLEAR REGULATORY COMMISSION

John B. Martin
Regional Administrator

Dated at Glen Ellyn, Illinois
this 13th day of July 1993

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
799 ROOSEVELT ROAD
GLEN ELLYN, ILLINOIS 60137-5927

June 8, 1993

Docket No. 99990003
General Licensee
EA 93-115

Steel Warehouse Company, Inc.
ATTN: David M. Dopp
Manager
Engineering and Maintenance
2722 West Tucker Drive
South Bend, IN 46624

Dear Mr. Dopp:

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY - $250
NRC INSPECTION REPORT 99990003/93005

This refers to the inspection conducted from April 22-30, 1993, at the Steel Warehouse Company facility in South Bend, Indiana, to review the circumstances surrounding the unauthorized removal and transport of a nuclear gauge containing one curie of Am-241 without regard to proper shipping requirements. The report documenting this inspection was sent to you by letter dated May 21, 1993. Significant violations of NRC requirements were identified during the inspection, and on May 28, 1993, an enforcement conference was held in the Region III office. Attending the conference were you, Mr. Charles E. Norelius, Director, Division of Radiation Safety and Safeguards, and other members of our respective staffs.

On November 29, 1992, a foreman noticed damage to a fixed gauging device which contained one curie of Am-241. The foreman notified the electrical supervisor who, with help from an electrician, removed the gauge from the mill. The supervisor was not authorized to remove the gauge, but he was qualified because he had received training from the vendor (Data Measurement Corporation, DMC). In preparation for shipment of the gauge to DMC, the supervisor instructed the electrician to contact the vendor and obtain a return materials authorization. In doing so, the electrician stated that he was returning an x-ray source and did not mention that he was returning a radioactive source. The electrician wrapped the device in a cardboard box for shipping. It contained no labelling or marking to indicate it contained radioactive material. It also was not checked for contamination prior to shipment. The box was then shipped via United Parcel Service and

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received undamaged by DMC the next day. DMC discovered that it contained radioactive material and notified you; you then notified the NRC.

The electrical supervisor did not contact DMC prior to removal of the gauge because he thought he recalled that Steel Warehouse had installed the device, and therefore he believed he should be able to remove it. The fact that Steel Warehouse installed the device was confirmed by DMC on April 27, 1993. The device had been shipped on December 29, 1989, but it had already been installed by you when DMC's representative arrived on site to install it. The device was required to be labelled by the manufacturer warning licensees not to remove or install it, but neither you nor the manufacturer could recall if this particular device was labelled at the time of the incident. The device's radiation safety manual, provided to licensees by the manufacturer, states that installation by licensees is permitted. The NRC acknowledges that this information is contradictory to our regulations which require that such devices be installed and removed only by authorized individuals. We are pursuing that issue separately with the vendor.

Four violations related to the transportation of the gauge were identified and are described in Section I of the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice). The violations are significant because they collectively reflect a potentially significant lack of attention toward licensed responsibilities. The violations reflect your failure to (1) provide proper shipping papers with the package; (2) ship the gauge in an approved shipping container; (3) mark the container with the words "Type A"; and (4) to provide any labelling as required. Proper shipping papers, containers, and labelling allow civil authorities, in case of an accident during transport, to properly identify the type, quantity, and form of material; allow the carrier and recipient to exercise adequate controls; and minimize the potential for overexposure, contamination, and improper transfer of material. Therefore, in accordance with the "Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy) 10 CFR Part 2, Appendix C, the violations are classified as a Severity Level III problem.

The root cause of the violations appeared to be a lack of training, understanding and knowledge by your staff. At the enforcement conference, the electrical supervisor and the electrician both stated that employees had a bad habit of calling all gauges "x-ray gauges" because the company has many of those but only 3 radioisotope gauges. The electrician stated that he did not know the difference between the two. He had shipped many x-ray gauges in the past and was aware that they weighed several hundred pounds. The Am-241 gauge weighed only about 40-50 pounds and he thought it was just a smaller x-ray gauge. Your representatives at the enforcement conference acknowledged this was not an uncommon belief

by employees.

We acknowledge your immediate and substantial corrective actions including (1) conducting a safety meeting with every employee and instructing them not to handle any radioactive material; (2) contracting with DMC to conduct a training session, videotaping that session, and making the tape required training for all new employees; (3) color coding all radioactive devices; (4) making a policy decision to not ship any more radioactive gauges but rather to contract with DMC to do so; (5) contrary to instructions from the vendor, you will not install any new devices but will require the vendor to do so; and (6) purchasing a survey instrument and training 6 electricians to use it. These actions should prevent future similar violations.

To emphasize the need for strict adherence to all NRC regulations and especially to those for the transportation of radioactive material, I have been authorized to issue the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice) in the amount of $250. The base value of a civil penalty for a Severity Level III problem is $500. The civil penalty adjustment factors in the Enforcement Policy were considered and the base civil penalty was mitigated 50% for your good corrective actions. The other factors were considered and no further adjustment to the base civil penalty was deemed appropriate.

Section II of the enclosed Notice describes two violations not assessed a civil penalty. The first violation pertains to your unauthorized removal of the gauge. While we recognize that the electrical supervisor was qualified to remove it, he was not authorized to do so. We also acknowledge that there appeared to be conflicting information from the vendor in that the instructions state that purchasers can install it, whereas the labelling requires a statement that only the vendor can install it. Nevertheless, NRC regulations are silent on vendor instructions but instead refer to the label of the device. In this case, the label clearly states that the device should only be installed and removed by an authorized person. The second violation pertains to your failure to report a damaged gauge. These violations are categorized at Severity Level IV in accordance with the NRC Enforcement Policy.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. In your response, you should document the specific actions taken and any additional actions you plan to prevent recurrence. After reviewing your response to this Notice, including your proposed corrective actions and the results of future inspections, the NRC will determine whether further NRC enforcement is necessary to ensure compliance with NRC regulatory requirements.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter and its enclosure will be placed in the NRC Public Document Room.

The responses directed by this letter and the enclosed Notice are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, Pub. L. No. 96-511.

Sincerely,

J. B. Martin
Regional Administrator

Enclosure:
Notice of Violation and Proposed Imposition
of Civil Penalty

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

Steel Warehouse Company, Inc.
South Bend, Indiana

Docket No. 99990003
General Licensee
EA 93-115

During an NRC inspection conducted on April 22-30, 1993, violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C, the Nuclear Regulatory Commission proposes to impose a civil penalty pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (Act), 42 U.S.C. 2282, and 10 CFR 2.205. The particular violations and associated civil penalty are set forth below:

I. Violations Assessed a Civil Penalty

10 CFR 71.5(a) requires that licensees who transport licensed material outside the confines of their plant or deliver licensed material to a carrier for transport comply with the applicable requirements of the regulations appropriate to the mode of transport of the Department of Transportation (DOT) in 49 CFR Parts 170-189.

Pursuant to 49 CFR 172.101, radioactive material is classified as hazardous material.

1. 49 CFR 177.817(a) requires that a carrier not transport a hazardous material unless it is accompanied by a shipping paper prepared in accordance with 49 CFR 172.200 through 172.203.

   Contrary to the above, on November 30, 1992, the licensee transported a hazardous material outside the confines of its plant and it was not accompanied by a shipping paper prepared in accordance with 49 CFR 172.200 through 172.203. Specifically, a Data Measurement Corporation gauging device, Model No. AM-5A and Serial No. BS954804, containing 1 curie of Am-241, was transported without shipping papers.

2. 49 CFR 173.465(a) requires, in part, that Type A packaging be capable of withstanding the tests described in Section 173.465.

   49 CFR 173.461 requires, in part, that compliance with the test requirements in Section 173.465 shall be shown by methods prescribed in Section 173.461(a).

   Contrary to the above, on November 30, 1992, the licensee delivered to a carrier for transport one Data Measurement Corporation fixed gauging device, Model No. AM-5A and

Serial No. BS954804, containing 1 curie of Am-241 sealed source, a quantity that requires DOT Specification 7A Type A packaging. The packaging, a cardboard box with bubble wrap and foam pellets, had not been tested or evaluated using the methods of Section 173.461 to demonstrate compliance with the test requirement in Section 173.465, for the material offered for shipment.

3. 49 CFR 172.300(a) requires, in part, that each person who offers a hazardous material for transport shall mark each package containing the hazardous material in the manner required.

49 CFR 172.310 requires, in part, that each package of radioactive material which conforms to the requirements for Type A or Type B packaging, be plainly and durably marked on the outside of the package in letters at least 1/2 inch (13 mm) high, with the words "TYPE A" or "TYPE B" as appropriate.

Contrary to the above, on November 30, 1992, the licensee offered a hazardous material for transport and did not mark the package containing the hazardous material in the manner required. Specifically, a Data Measurement Corporation fixed gauging device, Model No. AM-5A and Serial No. BS954804, containing 1 curie of Am-241, was transported without any of the required markings.

4. 49 CFR 172.400(a) requires, in part, that each person who offers a package containing a hazardous material for transport shall label it, when required, with labels prescribed for the material as specified in 172.101 and in accordance with 49 CFR Part 172, Subpart E.

Contrary to the above, on November 30, 1992, the licensee transported hazardous material without labels as prescribed for the material as specified in 172.101 and in accordance with 49 CFR Part 172, Subpart E. Specifically, a Data Measurement Corporation fixed gauging device, Model Number AM-5A and Serial Number BS954804, containing 1 curie of Am-241, was transported without any of the required labelling.

This is a Severity Level III problem (Supplement V).
Cumulative Civil Penalty - $250 (assessed equally among the four violations).

II. VIOLATIONS NOT ASSESSED A CIVIL PENALTY

1. 10 CFR 31.5(c)(3) requires that any person who acquires, receives, possesses, uses or transfers byproduct material in a device pursuant to a general license shall assure

that tests for leakage of radioactive material and proper operation of the on-off mechanism and indicator, if any, and other testing, installation, servicing, and removal from installation involving the radioactive material, its shielding or containment, are performed: (1) in accordance with the instructions provided by the labels; or (2) by a person holding a specific license pursuant to 10 CFR Parts 30 and 32 or from an Agreement State to perform such activities.

Contrary to the above, in January 1990, the licensee installed a Data Measurement Corporation fixed gauging device, Model Number AM-5A and Serial Number BS954804, containing a 1 curie Am-241 sealed source and removed the same device from installation on November 29, 1992. The installation and removal were not performed in accordance with the instructions provided by the labels or by a person holding a specific license pursuant to 10 CFR Parts 30 and 32 or from an Agreement State to perform such activities.

This is a Severity Level IV violation (Supplement VI).

2. 10 CFR 31.5(c)(5) requires, in part, that upon any indication of a possible failure of, or damage to, the on-off mechanism or indicator, the licensee shall, within 30 days, furnish to the Regional Administrator of the appropriate Nuclear Regulatory Commission Region, a report containing a brief description of the event and the remedial action taken.

Contrary to the above, on November 30, 1992, the licensee observed the indicator window to be damaged on a fixed gauging device, Model Number AM-5A and Serial Number BS954804, containing a 1 curie Am-241 sealed source. The licensee did not furnish the appropriate Regional Administrator, within 30 days, a report containing a brief description of the event and the remedial actions taken. Specifically, a report was not sent to Region III until February 4, 1993, a date exceeding the 30 days.

This is a Severity Level IV violation (Supplement VI).

Pursuant to the provisions of 10 CFR 2.201, Steel Warehouse Company, Inc., (Licensee) is hereby required to submit a written statement or explanation to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, within 30 days of the date of this Notice of Violation and Proposed Imposition of Civil Penalty (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each alleged violation: (1) admission or denial of the alleged violation, (2) the reasons for the violation if admitted, and if denied, the reasons why, (3)

the corrective steps that have been taken and the results achieved, (4) the corrective steps that will be taken to avoid further violations, and (5) the date when full compliance will be achieved.

If an adequate reply is not received within the time specified in this Notice, an order or a Demand for Information may be issued to show cause why the license should not be modified, suspended, or revoked or why such other action as may be proper should not be taken. Consideration may be given to extending the response time for good cause shown. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, this response shall be submitted under oath or affirmation.

Within the same time as provided for the response required above under 10 CFR 2.201, the licensee may pay the civil penalty by letter addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, with a check, draft, money order, or electronic transfer payable to the Treasurer of the United States in the amount of the civil penalty proposed above, or the cumulative amount of the civil penalties if more than one civil penalty is proposed, or may protest imposition of the civil penalty in whole or in part, by a written answer addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission. Should the Licensee fail to answer within the time specified, an order imposing the civil penalty will be issued. Should the Licensee elect to file an answer in accordance with 10 CFR 2.205 protesting the civil penalty, in whole or in part, such answer should be clearly marked as an "Answer to a Notice of Violation" and may: (1) deny the violations listed in this Notice, in whole or in part, (2) demonstrate extenuating circumstances, (3) show error in this Notice, or (4) show other reasons why the penalty should not be imposed. In addition to protesting the civil penalty in whole or in part, such answer may request remission or mitigation of the penalty.

In requesting mitigation of the proposed penalty, the factors addressed in Section VI.B.2 of 10 CFR Part 2, Appendix C, should be addressed. Any written answer in accordance with 10 CFR 2.205 should be set forth separately from the statement or explanation in reply pursuant to 10 CFR 2.201, but may incorporate parts of the 10 CFR 2.201 reply by specific reference (e.g., citing page and paragraph numbers) to avoid repetition. The attention of the Licensee is directed to the other provisions of 10 CFR 2.205, regarding the procedure for imposing a civil penalty.

Upon failure to pay any civil penalty due which subsequently has been determined in accordance with the applicable provisions of 10 CFR 2.205, this matter may be referred to the Attorney General, and the penalty, unless compromised, remitted, or mitigated, may be collected by civil action pursuant to Section 234c of the Act, 42 U.S.C. 2282c.

The response noted above (Reply to Notice of Violation, letter with payment of civil penalty, and Answer to a Notice of Violation) should be addressed to: Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555 with a copy to the Regional Administrator, U.S. Nuclear Regulatory Commission, Region III, 799 Roosevelt Road, Glen Ellyn, IL, 60137.

For the Nuclear Regulatory Commission

J. B. Martin
Regional Administrator

Dated at Glen Ellyn, IL
this 3rd day of June 1993

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

March 26, 1993

Docket Nos. 030-04530 and 030-06923
License Nos. 19-00915-03 and 19-00915-06
EAs 92-232 and 93-028

Mr. R. D. Plowman, Administrator
Agricultural Research Service
U.S. Department of Agriculture (USDA)
Administration Building
14th and Independence, S.W.
Washington, D.C. 20250

Dear Mr. Plowman:

Subject: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY - $10,000 AND CONFIRMATORY ORDER MODIFYING LICENSE (EFFECTIVE IMMEDIATELY)
(NRC Combined Inspection Report Nos. 030-04530/92-001 through 92-010 and 030-06923/92-001)

This letter refers to the ten NRC inspections conducted during the period of March through October 1992, at several of your facilities throughout the country, including your office in Greenbelt, Maryland where your radiation safety staff is located. The inspections consisted of reviews, evaluations and observations of activities authorized by NRC License Nos. 19-00915-03 and 19-00915-06. The report of these inspections was sent to you on January 5, 1993. During the inspection, twelve violations of NRC requirements were identified, five of which were similar to violations identified during previous inspections, and some of which involved multiple examples. Some of the violations were identified at more than one of the facilities inspected. On January 19, 1993, an enforcement conference was conducted with Dr. Essex Finney and other members of your staff, to discuss the violations, their causes and your corrective actions.

The violations are described in the enclosed Notice of Violation and Proposed Imposition of Civil Penalty. The five repetitive violations involved: (1) failure by management to ensure that all facilities were inspected by your radiation safety staff at the required frequencies; (2) failure to perform leak tests of sealed sources at the required frequency and maintain required records of the results; (3) failure to evaluate incinerator ash and failure to maintain records of licensed material disposed of by incineration; (4) failure to secure licensed material at certain locations; and (5) failure to post required documents at certain facilities. The other seven violations involved

(1) failure to provide training to ancillary personnel; (2) failure to maintain shipping papers within the driver's reach at one facility; (3) transfer of licensed material to persons who were not authorized to possess the material; (4) failure to collect and review quarterly survey results; (5) possession or use of licensed material in quantities or applications other than those authorized by USDA permits; (6) failure to report inventories of unsealed material; and (7) failure to perform six-month inventories of sealed sources.

The violations demonstrate a lack of adequate control by management of activities involving licensed material. This finding is particularly disturbing given the fact that a $5,000 civil penalty was issued to you on August 16, 1990 (EA 90-120), for violations that were indicative of the lack of management control of your radiation safety program. Notwithstanding the issuance of that penalty and the discussions during a previous enforcement conference on July 11, 1990 (and related commitments made at that time), you have not been successful in substantially upgrading the control and implementation of USDA's radiation safety program, as evidenced by the violations identified during the inspections in 1992.

The NRC license issued to the USDA entrusts substantial responsibility for radiation safety and control of licensed activities to your management; therefore, the NRC expects effective oversight of all activities authorized by the license. Incumbent upon each NRC licensee is the responsibility of management, in general, and the Radiation Safety Committee (RSC) and Radiation Safety Officer (RSO), in particular, to protect the public health and safety by ensuring that all requirements of the NRC license are met and that any potential violations of NRC requirements are identified and corrected expeditiously.

At the recent enforcement conference on January 19, 1993, your staff acknowledged the continued need for improved oversight of, and attention to, your radiation safety program, not only by the radiation safety staff and RSC, but also by management at the individual facilities. Improvements in local control are particularly important because you possess a multi-site broad scope license and have authorized use of licensed materials by more than 3,500 users at over 300 facilities throughout the country.

At the enforcement conference, you described additional actions that have been taken or planned to correct the violations and prevent recurrence. These actions include: (1) scheduling of all USDA facilities overdue for inspection, with the inspections scheduled and completed by February 28, 1993; (2) planned increase in the radiation safety staff through the hiring of two

additional health physicists; (3) completion of an upgraded management information system to provide for better oversight by the radiation safety staff and the RSC of the program implementation at the individual facilities; (4) planned completion of an audit of the USDA program, which was first proposed in response to an enforcement conference held in 1990; (5) consideration of appointing a local Radiation Protection Officer at each of the facilities, and (6) development of written procedures for executing the radiation safety responsibilities. These corrective actions are considered to be neither prompt nor comprehensive because they are largely the continuation of actions begun following the 1990 inspections, and these corrective actions should have been virtually complete at the time of the 1992 inspections.

The number of violations of license requirements identified during the inspection, as well as the repetitive nature of some of the violations, are indicative of a continued lack of management control and oversight of your radiation safety program. In particular, the lack of adequate management oversight was evidenced in your repeated failure to conduct required safety inspections at certain USDA facilities during 1988, 1989, 1990, and 1992. Therefore, the violations are classified in the aggregate as a Severity Level III problem in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C (Enforcement Policy) (57 Fed. Reg. 5791; February 18, 1992).

To emphasize the importance of management, the Radiation Safety Committee, and the Radiation Safety Officer (RSO) (1) aggressively monitoring and evaluating licensed activities to assure that these activities are conducted safely and in accordance with the terms of your license, and (2) assuring that your corrective actions are long-lasting, I am issuing the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice) in the amount of $10,000 for the violations described in the enclosed Notice.

The base civil penalty for a Severity Level III violation or problem is $2,500. The escalation and mitigation factors set forth in the Enforcement Policy were considered, and on balance, the base civil penalty has been escalated 50% because the violations were identified by the NRC rather than through your own audit processes; 50% because your corrective actions, as described above, were neither prompt nor comprehensive; 100% for your prior enforcement history which includes violations that resulted in the $5,000 civil penalty in 1990; and 100% because some of the violations existed for an extended duration.

Normally, only a civil penalty is proposed for violations categorized as a Severity Level III problem and the amount of the penalty is determined by using the routine mitigation and escalation factors as described above. However, in this case, given the reliance by NRC on the USDA to fulfill its responsibility for oversight and control of its NRC-licensed programs, including requirements to conduct inspections of its numerous field locations, and the repeated failure of USDA to fulfill this responsibility, we are issuing the enclosed Confirmatory Order Modifying License (Order) which requires, in part, that you (1) retain an independent consultant knowledgeable of large broad scope licenses to perform an assessment of the USDA program, and (2) develop and implement in a timely manner an improvement plan in response to the consultant's findings. The Order includes the elements of a comprehensive assessment of your licensed programs that you committed to undertake during a telephone conversation on March 2, 1993, between Ms. Jean Giles, of your staff, and Mr. Richard Cooper and Ms. Betsy Ullrich, of the NRC Region II staff.

You are required to respond to this letter, the enclosed Notice and Order and should follow the instructions specified in the enclosed Notice and Order when preparing your response. In your response, you should document the specific actions taken and any additional actions you plan to prevent recurrence. After reviewing your response to this Notice and Order, including your proposed corrective actions, and the results of future inspections, the NRC will determine whether further enforcement action is necessary to ensure compliance with NRC regulatory requirements.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter and the enclosures will be placed in the NRC Public Document Room.

The responses directed by this letter, the enclosed Notice, and the Order are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, Pub. L. 96-511.

Sincerely,

Hugh L. Thompson, Jr.
Deputy Executive Director for
Nuclear Materials Safety, Safeguards
and Operations Support

See next page for encls. and cc's.

Enclosures:
1. Notice of Violation and Proposed Imposition of Civil Penalty
2. Confirmatory Order Modifying License (Effective Immediately)

cc w/encls:
Public Document Room (PDR)
Nuclear Safety Information Center (NSIC)
Roland Fletcher, State of Maryland

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

U.S. Department of Agriculture
Washington, D.C.

Docket Nos. 030-04530
030-06923
License Nos. 19-00915-03
19-00915-06
EA 92-232

During NRC inspections conducted between March 5 and October 19, 1992, violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C, 57 Fed. Reg. 5791 (February 18,1992), the Nuclear Regulatory Commission proposes to impose a civil penalty pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (Act), 42 U.S.C. 2282, and 10 CFR 2.205. The particular violations and associated civil penalty are set forth below:

A. Condition 25 of License No. 19-00915-03 requires that licensed material be possessed and used in accordance with statements, representations, and procedures contained in an application dated July 11, 1989, and the letter dated March 9, 1990.

Item 3 of the application dated July 11, 1989, requires, in part, that Category I locations (major isotope users; facilities that use millicurie quantities of radioiodine and/or perform iodinations; and facilities that perform studies involving human subjects) be inspected at intervals not to exceed three years, and Category II locations (all non-Category I facilities that use licensed material in an unsealed form) be inspected by the Radiation Safety Staff at intervals not to exceed five years.

Condition 17 of License No. 19-00915-06 requires that licensed material be possessed and used in accordance with statements, representations, and procedures contained, in part, in an application dated August 27, 1985, and letters dated April 7, 1986, June 27, 1986, and April 14, 1987. Item K.11. of the application dated August 27, 1985, requires that irradiator facilities be inspected by the Radiation Safety Staff at least every three years.

Contrary to the above, as of September 9, 1992, certain USDA facilities were not inspected at the required intervals as specified above. Specifically, two Category I facilities, (namely, Miles City, Montana, and Greenport, New York) had not been inspected in the previous three years; and 12 Category II facilities (Hamden, Connecticut; West Lafayette, Indiana; Morris, Montana; Raleigh, North Carolina; University Park, Pennsylvania; Brookings, South Dakota; Lubbock, Texas; Kearneysville, West Virginia; Columbia,

Missouri; Wooster, Ohio; Fresno, California; and Salinas, California) had not been inspected in the previous five years; and one irradiator facility (namely, Otis Air Force Base, Massachusetts) had not been inspected in the previous three years.

This is a repetitive violation.

B. Condition 12 of License No. 19-00915-03 and Condition 13 of License No. 19-00915-06 require, in part, that sealed sources be tested for leakage and/or contamination at intervals not to exceed 6 months or at other intervals as specified by the certificate of registration, not to exceed 3 years; and that records of leak test results be maintained for inspection by the Commission.

Contrary to the above, as of September 9, 1992, 65 sealed sources had not been tested for leakage at six-month intervals, as required, and no other interval was specified by the certificates of registration. In addition, leak test results were not maintained for inspection by the Commission in that leak test records for sealed sources possessed by 13 different users were missing from 29 user files which were reviewed.

This is a repetitive violation.

C. Condition 19 of License No. 19-00915-03 requires, in part, that ash residues may be disposed of as ordinary waste provided appropriate surveys pursuant to Section 20.201 of 10 CFR Part 20 are made to determine that concentrations of licensed material appearing in the ash residues do not exceed the concentrations (in terms of microcuries per gram) specified for water in 10 CFR Part 20, Appendix B, Table II.

Condition 25 of License No. 19-00915-03 requires that licensed material be possessed and used in accordance with statements, representations, and procedures contained in an application dated July 11, 1989 and a letter dated March 9, 1990.

Item 11.2 of the application dated July 11, 1989 requires that quarterly summaries of the records of incinerations be furnished to the radiation safety staff.

Contrary to the above, as of September 9, 1992, quarterly summaries were not furnished to the radiation safety staff during the period of July 1991 through June 1992 for seven incinerators at four sites (namely, Athens, Georgia; Clay Center, Nebraska; Fargo, North Dakota; and Ames, Iowa), and surveys of ash residues were not performed for three

incinerators at three sites (namely, Clay Center, Nebraska; Grand Forks, North Dakota; and Plum Island, New York) during the period of July 1991 through June 1992 to assure that ash residue disposed of as ordinary waste did not exceed the concentrations specified for water in 10 CFR Part 20, Appendix B, Table II.

This is a repetitive violation.

D. 10 CFR 20.207(a) requires that licensed material stored in an unrestricted area be secured against unauthorized removal from the place of storage. 10 CFR 20.207(b) requires that licensed materials in an unrestricted area and not in storage be tended under constant surveillance and immediate control of the licensee. As defined in 10 CFR 20.3(a)(17), an unrestricted area is any area access to which is not controlled by the licensee for purposes of protection of individuals from exposure to radiation and radioactive materials.

Contrary to the above, on September 22, 1992, licensed material consisting of a nickel-63 electron capture device in a gas chromatograph located in an unlocked storage building, an unrestricted area at the Boll Weevil Research Laboratory in Mississippi State Mississippi, was not secured against unauthorized removal and was not under constant surveillance and immediate control of the licensee.

This is a repetitive violation.

E. 10 CFR 20.301 requires that no licensee dispose of licensed material except by certain specified procedures. 10 CFR 20.301(a) requires that no licensee dispose of licensed material except by transfer to an authorized recipient as provided in the regulations in Parts 30, 40, 60, 61, 70, or 72, whichever may be applicable.

Contrary to the above, on October 31, 1991, a USDA facility in Albany, California sent a drum containing 0.51 millicuries of sulfur-35, 0.003 millicuries of carbon-14, and 0.002 millicuries of cadmium-109 to a normal landfill for disposal in the normal trash, a method not authorized by 10 CFR 20.301. In addition, as of September 2, 1992, byproduct material was routinely disposed of by transfer to other licensees (namely, Pennsylvania State University and Cornell University) who were not authorized to receive radioactive waste for disposal in University Park, Pennsylvania and Ithaca, New York.

F. Condition 25 of License No. 19-00915-03 requires that licensed material be possessed and used in accordance with

statements, representations, and procedures contained in an application dated July 11, 1989, and the letter dated March 9, 1990.

1. Item 9.18 of the application dated July 11, 1989, requires, in part, that a contamination level survey be performed by permit holders at least every three months and the results be reported to the Radiation Safety Officer.

   Contrary to the above, as of September 9, 1992, results of contamination level surveys performed by various permit holders every three months were not reported to the Radiation Safety Officer. Specifically, 14 permit holders failed to report the results of one or more quarterly contamination level surveys during the period of January 1991 through June 1992.

2. Item 10.4.2 of the application dated July 11, 1989, requires that licensed material be used by Radiation Safety Committee-approved users in accordance with generally accepted safe practices, the rules and procedures specified in the USDA Radiological Safety Handbook, and as specifically prescribed by the Committee and/or the Radiation Safety Officer.

   Contrary to the above, as of September 9, 1992, licensed material was used in a manner different than prescribed by the Radiation Safety Committee (RSC) and/or the Radiation Safety Officer (RSO). Specifically, (1) a permit holder in Pullman, Washington authorized to possess one 50-millicurie americium-241 sealed source possessed five 50-millicurie and one 1000-millicurie americium-241 sealed sources, quantities in excess of those prescribed by the RSC or RSO; (2) a permit holder in Fargo, North Dakota authorized to use one millicurie of nickel-63, possessed an 8-millicurie sealed source of nickel-63, a quantity in excess of that prescribed by the RSC or RSO; (3) in Ithaca, New York, a permit holder possessed a source of cobalt-60 which no person performing activities under this license is authorized by the RSC or RSO to possess; and (4) in Mississippi State, Mississippi the permit holder used its irradiator for purposes other than the boll weevil studies authorized by the RSO, such as irradiation of blood, spiders, and grasshoppers.

3. Item 11.1.7 of the application dated July 11, 1989, requires that users maintain accurate inventories of radioactive materials under their control so that

reports can be prepared and submitted when requested by the Radiation Safety Officer.

Contrary to the above, as of September 9, 1992, users' reports of inventories were not submitted when requested. Specifically, 7 of 18 users reviewed did not submit results of inventories requested by the Radiation Safety Officer in 1991.

G. Condition 15 of License No. 19-00915-03 requires that a physical inventory be performed every six months to account for all sources and/or devices received and possessed by the licensee, and that records of inventories be maintained for two years from the date of each inventory.

Contrary to the above, between June 15, 1990, and September 9, 1992, a period in excess of six months, physical inventories of at least 65 sealed sources were not performed and inventory records were not maintained as required.

H. 10 CFR 71.5(a) requires that licensees who transport licensed material outside the confines of their facilities or deliver licensed material to a carrier for transport comply with the applicable requirements of the regulations appropriate to the mode of transport of the Department of Transportation in 49 CFR Parts 170 through 189.

49 CFR 177.817(e)(2)(i) requires, in part, that when a driver of a motor vehicle transporting licensed material is at the vehicle's controls, the shipping paper shall be within his reach and either readily visible to a person entering the driver's compartment or in a holder which is mounted on the inside of the door on the driver's side of the vehicle.

Contrary to the above, as of September 1, 1992, a USDA employee at the University Park, Pennsylvania, facility routinely stored shipping papers in the portable gauge case during transportation to and from temporary job sites, and therefore, the shipping papers were not within the driver's reach, readily visible to a person entering the driver's compartment, or in a holder mounted on the inside of the door on the driver's side of the vehicle during transportation of a portable gauge.

I. 10 CFR 19.12 requires, in part, that all individuals working in a restricted area are instructed in the precautions and procedures to minimize exposure to radioactive materials, in the purpose and functions of protective devices employed,

and in the applicable provisions of the Commission's regulations and licenses.

Contrary to the above, as of March 5, 1992, an ancillary staff member working in a restricted area at the Pacific Southwest Research Station in Berkeley, California had not been instructed in the precautions and procedures to be followed when he performed duties in the laboratory where licensed material was used and had not been instructed in the applicable provisions of the regulations and the conditions of the license.

J. 10 CFR 19.11(a) and (b) require, in part, that the licensee post current copies of 10 CFR Part 19, 10 CFR Part 20, the license, the license conditions, documents incorporated into the license, license amendments, and operating procedures; or, if posting of a document is not practicable, that the licensee post a notice describing these documents and where they may be examined. 10 CFR 19.11(c) requires that a licensee post Form NRC-3, "Notice to Employees". 10 CFR 21.6 requires, in part, that the licensee post current copies of 10 CFR Part 21.

Contrary to the above, on March 6, 1992, at the licensee's facility in Placerville, California, current copies of 10 CFR Parts 19 and 20 were not posted; on September 1, 1992, at the licensee's facility in University Park, Pennsylvania, a current copy of Form NRC-3 was not posted; and as of September 23, 1992, at the licensee's facilities in Mississippi State, Mississippi and Tuscaloosa, Alabama, copies of 10 CFR Part 21 were not posted.

This is a repetitive violation.

These violations are categorized in the aggregate as a Severity Level III problem. (Supplements IV and VI)
Civil Penalty - $10,000

Pursuant to the provisions of 10 CFR 2.201, USDA (Licensee) is hereby required to submit a written statement or explanation to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, within 30 days of the date of this Notice of Violation and Proposed Imposition of Civil Penalty (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each alleged violation: (1) admission or denial of the alleged violation, (2) the reasons for the violation if admitted, and if denied, the reasons why, (3) the corrective steps that have been taken and the results achieved, (4) the corrective steps that will be taken to avoid further violations, and (5) the date when full compliance will be achieved. If an adequate reply is not received within the time specified in this Notice, an order or a demand for information may be issued as to why the license should not be modified, suspended, or revoked or why such other action as may be proper

should not be taken. Consideration may be given to extending the response time for good cause shown. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, this response shall be submitted under oath or affirmation.

Within the same time as provided for the response required above under 10 CFR 2.201, the Licensee may pay the civil penalty by letter addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, with a check, draft, money order, or electronic transfer payable to the Treasurer of the United States in the amount of the civil penalty proposed above, or may protest imposition of the civil penalty in whole or in part, by a written answer addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission. Should the Licensee fail to answer within the time specified, an order imposing the civil penalty will be issued. Should the Licensee elect to file an answer in accordance with 10 CFR 2.205 protesting the civil penalty, in whole or in part, such answer should be clearly marked as an "Answer to a Notice of Violation" and may: (1) deny the violation(s) listed in this Notice, in whole or in part, (2) demonstrate extenuating circumstances, (3) show error in this Notice, or (4) show other reasons why the penalty should not be imposed. In addition to protesting the civil penalty in whole or in part, such answer may request remission or mitigation of the penalty.

In requesting mitigation of the proposed penalty, the factors addressed in Section VI.B.2 of 10 CFR Part 2, Appendix C (1992), should be addressed. Any written answer in accordance with 10 CFR 2.205 should be set forth separately from the statement or explanation in reply pursuant to 10 CFR 2.201, but may incorporate parts of the 10 CFR 2.201 reply by specific reference (e.g., citing page and paragraph numbers) to avoid repetition. The attention of the Licensee is directed to the other provisions of 10 CFR 2.205, regarding the procedure for imposing a civil penalty.

Upon failure to pay any civil penalty due which subsequently has been determined in accordance with the applicable provisions of 10 CFR 2.205, this matter may be referred to the Attorney General, and the penalty, unless compromised, remitted, or mitigated, may be collected by civil action pursuant to Section 234c of the Act, 42 U.S.C. 2282(c).

The response noted above (Reply to Notice of Violation, letter with payment of civil penalty, and Answer to a Notice of Violation) should be addressed to: Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555 with a copy to the Regional Administrator, U.S. Nuclear Regulatory Commission, Region I, 475 Allendale Road, King of Prussia, Pennsylvania 19406.

Dated at Rockville, Maryland
this 26th day of March 1993

UNITED STATES
NUCLEAR REGULATORY COMMISSION

In the Matter of	)	Docket Nos. 030-04530
U.S. Department of Agriculture	)	030-06923
Washington, D.C. 20250	)	License Nos. 19-00915-03
	)	19-00915-06
	)	EA 93-028

CONFIRMATORY ORDER MODIFYING LICENSE
(EFFECTIVE IMMEDIATELY)

I

The U.S. Department of Agriculture (Licensee), Washington, D.C. is the holder of Byproduct/Source Material Licenses Nos. 19-00915-03 and 19-00915-06 (Licenses), issued by the U. S. Nuclear Regulatory Commission (NRC or Commission) pursuant to 10 CFR Parts 30 and 33. License No. 19-00915-03 authorizes the Licensee to use byproduct material for research and development; in gauging and measuring devices; in field applications as approved by the Radiation Safety Committee (RSC); and for research studies in humans as approved by a Radioactive Drug Research Committee that has been approved by the Food and Drug Administration, and by the Licensee's Radiation Safety Committee (RSC). This is a large, multi-site, broad scope license with no stated possession limit. License No. 19-00915-06 authorizes the Licensee to use cobalt-60 and cesium-137 sealed sources in irradiators at sites and by users approved by the Licensee's RSC.

Licensed activities are conducted by a number of organizations within the Licensee's organization, including (1) the Agriculture Marketing Service (AMS); (2) the Animal, Plant, and Health Inspection Service (APHIS); (3) the Agricultural Research Service

(ARS); (4) the Federal Grain Inspection Service (FGIS); (5) the Food Safety and Inspection Service (FSIS); (6) the National Forest Service (NFS); and (7) the Soil Conservation Service (SCS). Over 3500 permits have been currently issued to individuals in these services to use licensed material at numerous locations around the country.

The Licenses were most recently renewed on February 10, 1990 and May 22, 1986, respectively, and would have expired on February 28, 1991 and May 31, 1991, respectively. Both Licenses continue in force, pursuant to 10 CFR 30.37(b), because of the timely filing of applications by the Licensee to renew the Licenses.

II

Between March 5 and September 23, 1992, the NRC performed inspections of licensed activities at ten of the Licensee's facilities throughout the country. The inspections were continued until October 19, 1992, so that the NRC could review additional information submitted by the licensee. During the inspections, twelve violations of NRC requirements were identified, five of which were repetitive of violations identified during previous NRC inspections. Those repetitive violations involved: (1) failure by the Licensee's radiation safety staff to inspect USDA facilities at the required

frequency; (2) the failure to perform leak tests of sealed sources at certain locations at the required frequency, as well as the failure, at times, to maintain records of results of leak tests when they were performed; (3) the failure to evaluate incinerator ash and to maintain records of licensed material disposed of by incineration; (4) the failure to secure licensed material at certain locations; and (5) the failure to post required documents at certain facilities. In addition to the repetitive violations, seven other violations were identified, as described in the Notice of Violation and Proposed Imposition of Civil Penalty issued concurrently.

These repetitive violations, and, in particular, the violation involving the failure by the Licensee to inspect certain locations at the required frequency, are particularly disturbing to the NRC since the Licensee possesses a multi-site, broad scope license which places a significant responsibility on the RSC, as well as the Radiation Safety Officer (RSO), to ensure that licensed activities are conducted safely and in accordance with NRC requirements. Although the NRC issued a proposed civil penalty to the Licensee on August 16, 1990, for other violations of NRC requirements to emphasize the importance of Licensee management (including the RSC and the RSO) aggressively monitoring and evaluating licensed activities, sufficient management attention has not been provided to the program, as evidenced by the recent findings.

In the letter to the Licensee dated August 16, 1990, transmitting the Notice of Violation and Proposed Civil Penalty, the NRC noted that the Licenses issued to the Licensee allow great latitude in the management of the radiation safety program, and that in return for that latitude, the NRC expects an unusually high degree of responsibility by the Licensee to assure that all requirements of the NRC Licenses are met, and to identify and promptly correct potential violations of NRC requirements. The Licensee's repeated failure to maintain sufficient control of radioactive materials raises significant questions regarding the adequacy of its oversight of activities at its facilities, as well as the ability of the Licensee to assure that activities at those facilities are conducted safely and in accordance with Commission requirements.

Furthermore, although the Licensee made commitments, in a letter dated September 10, 1990, to have an audit of the program performed within six months, and to augment its inspection program by having Area Health and Safety Managers perform site reviews, these commitments were not implemented. The continued failure to perform inspections at the required frequencies, as identified during NRC's 1988, 1989, 1990, and 1992 inspections, demonstrates that the Licensee has not adequately discharged its responsibilities to assure that all requirements of the NRC Licenses are met. The failure of the Licensee to perform inspections of the various locations authorized under the

Licenses at appropriate intervals has resulted in a lack of oversight of licensed activities and repeated failures to identify and correct other violations of regulatory requirements.

Accordingly, without additional requirements, there is inadequate assurance that licensed activities will be adequately controlled at the Licensee's facilities.

III

During an enforcement conference on January 19, 1993, and in a telephone conversation on March 2, 1993, between Ms. Jean Giles of the Licensee's staff and Mr. Richard Cooper and Ms. Betsy Ullrich of the NRC Region I staff, the Licensee committed to retaining an independent expert to perform an assessment of its radiation safety program. In addition, the Licensee committed to developing and implementing an improvement program based on the findings of the assessment. In view of the concerns set forth in Section II of this Order, I have concluded that these additional actions are needed to increase and improve management attention to licensed activities and that the Licensee's commitments, as described in Section IV, are necessary to assure that these activities are conducted safely and in accordance with NRC requirements. Specifically, I have determined that the public health and safety require that License Nos. 19-00915-03 and 19-00915-06 be modified to confirm the Licensee's commitment to: (1) obtain an independent assessment of

the Licensee's radiation safety program with particular attention to the management of that program, including an evaluation of which, if any, activities should be suspended until compliance with NRC requirements can be assured and (2) develop and implement in a timely manner an improvement program to correct the deficiencies identified by the assessment. The Licensee consented to the issuance of this Confirmatory Order during the March 2, 1993 telephone call referenced above. Pursuant to 10 CFR 2.202, based on the significance of the violations described above and on the licensee's consent to the Order, I have also determined that the public health and safety require that this Order be immediately effective.

IV

Accordingly, pursuant to sections 81, 161b, 161i, 161o, 182 and 186 of the Atomic Energy Act of 1954, as amended, and the Commission's regulations in 10 CFR 2.202 and 10 CFR Parts 30 and 33, IT IS HEREBY ORDERED, EFFECTIVE IMMEDIATELY, THAT LICENSE NOS. 19-00915-03 and 19-00915-06 ARE MODIFIED AS FOLLOWS:

A. The Licensee shall retain an expert, independent of the Licensee's staff, to perform an assessment of the Licensee's radiation safety program and provide recommendations for a performance improvement program based on the assessment findings and the specific concerns and violations described

in the letter transmitting this Order and the attached Notice of Violation. Within 60 days from the date of this Order, the Licensee shall submit to the Regional Administrator, NRC Region I, for approval, the credentials of one or more experts (Consultant) with experience in the management and implementation of a broad scope radiation program, including activities similar to those authorized under the Licensee's program, to perform an assessment of the Licensee's radiation safety program. The Consultant shall have extensive experience in: (1) assessing the adequacy of organizational and management structures; (2) planning and implementation of broad scope radiation protection and health physics programs; (3) assessing the adequacy of implementation of these programs; (4) developing recommendations for changes in resources, management, training, assignment of responsibilities and program requirements to ensure resolution of identified deficiencies; and (5) NRC licensing and regulatory requirements.

B. Within 30 days of NRC approval of the consultant selection as described above, the Licensee shall submit to the Regional Administrator, NRC Region I, for approval, an assessment plan. In developing the assessment plan, the Licensee or Consultant shall review the documents submitted to NRC in support of the license renewal applications and

consider incorporation within the scope of the assessment any proposed changes in the Licensee's program. The consultant must commit to notify the licensee at any time during the program review if a specific location using radioactive materials does not have sufficient personnel or financial resources to comply with the USDA license. The assessment of the Licensee's radiation safety program shall include, but not be limited to, a review of the following:

1. The adequacy of organizational and management structures. For example, review the assigned responsibilities and authorities within the USDA organization including the relationship of the RSO with management and the respective users in each organizational unit, the relationship between the RSC and the organizational units, and the authority granted to the RSC and RSO. Additionally, review the USDA management methods for assuring that the radiation safety program complies with NRC requirements and that the program is provided the resources needed to implement potential corrective actions.

2. The adequacy of the radiation safety programs at specific locations:
   (a) the Licensee's program for training and periodic retraining of individuals working with NRC-

licensed materials in NRC regulations, the conditions of the Licenses, the Licensee's procedures, and in safe practices for using licensed material;

(b) the Licensee's program for approving individuals for the use of licensed materials, the adequacy of the RSC's review of specific projects authorized under the Licenses, and the adequacy of the RSC's periodic reviews of approved users; and

(c) the Licensee's program for developing and implementing procedures for the safe use of licensed materials.

3. The adequacy of the Licensee's management, oversight, and inspection functions including:

(a) the Licensee's program for training and qualifying management, users, RSC members, the RSO, and radiation safety staff involved in managing, supervising, inspecting and auditing licensed activities;

(b) the scope, methods, and frequency of the Licensee's program for surveillance and audits performed by the corporate and local radiation safety staff at individual locations to determine compliance by individual users of licensed materials with NRC regulations, the conditions of

the Licenses, and the Licensee's own procedures for the safe use of radioactive material. This review should also include the licensee's effectiveness in ensuring broad and lasting corrective action for problems identified;

(c) the radiation safety staffing, both within the radiation safety department and at individual locations throughout the country; and

(d) the adequacy of the record keeping and documentation systems.

The assessment shall include: (1) reviews performed at the licensee's corporate radiation safety office; (2) on-site reviews of activities and records maintained at sufficient numbers and types of users and geographical areas to represent an adequate sample of the Licensee's program; and (3) interviews and observations of selected authorized users working at the various locations.

C. Within 120 days of NRC approval of the assessment plan, the Consultant shall submit to the Licensee and the Regional Administrator, NRC Region I, the written assessment report; recommendations for a performance improvement program; and recommendation of groups and categories of activities that might be suspended from licensed activities until such time that the Licensee

has sufficient financial and personnel resources and expertise to properly manage these activities.

D. Within 60 days of receipt of the Consultant's report, the Licensee shall submit a performance improvement plan to the Regional Administrator, NRC Region I, either describing the methods of implementing each of the recommendations of the assessment report, or providing justification for not adopting any of the specific recommendations. This plan shall include:

1. action items completed or to be completed with appropriate priorities assigned;

2. completion date or date scheduled for completion of each specific action item; and

3. the system for monitoring and tracking the status and completion of the action items.

E. During implementation of the Consultant's assessment, as well as the subsequent performance improvement plan, the Licensee shall provide written quarterly status reports to the NRC Region I office concerning the findings of the assessment, the development of the improvement plan, and the implementation of the plan. Upon completion of all action

items, a final report shall be submitted to the Regional Administrator, NRC Region I.

The Regional Administrator, NRC Region I, may, in writing, relax or rescind any of the above conditions upon demonstration by the Licensee of good cause.

V

Any person, other than the Licensee, adversely affected by this Confirmatory Order, may request a hearing within 20 days of its issuance. Any request for a hearing shall be submitted to the Secretary, U.S. Nuclear Regulatory Commission, ATTN: Chief, Docketing and Service Section, Washington, D.C. 20555. Copies also shall be sent to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, to the Assistant General Counsel for Hearings and Enforcement at the same address, to the Regional Administrator, NRC Region I, 475 Allendale Road, King of Prussia, Pennsylvania 19406, and to the Licensee. If such a person requests a hearing, that person shall set forth with particularity the manner in which his interest is adversely affected by this Order and shall address the criteria set forth in 10 CFR 2.714(d).

If a hearing is requested by a person whose interest is adversely affected, the Commission will issue an Order designating the time

and place of any hearing. If a hearing is held, the issue to be considered at such hearing shall be whether this Confirmatory Order should be sustained.

Pursuant to 10 CFR 2.202(c)(2)(i), 57 FR 20194 (May 12, 1992), any person other than the licensee adversely affected by this Order, may, in addition to demanding a hearing, at the time the answer is filed or sooner, move the presiding officer to set aside the immediate effectiveness of the Order on the ground that the Order, including the need for immediate effectiveness, is not based on adequate evidence but on mere suspicion, unfounded allegations, or error.

In the absence of any request for hearing, the provisions specified in Section IV above shall be final 20 days from the date of this Order without further order or proceedings. AN ANSWER OR A REQUEST FOR HEARING SHALL NOT STAY THE IMMEDIATE EFFECTIVENESS OF THIS ORDER.

FOR THE NUCLEAR REGULATORY COMMISSION

Hugh L. Thompson, Jr.
Deputy Executive Director for
Nuclear Materials Safety, Safeguards,
and Operations Support

Dated at Rockville, Maryland
this 26th day of March 1993

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

JUN 23 1993

Docket Nos. 030-04530 and 030-06923
License Nos. 19-00915-03 and 19-00915-06
EAs 92-232 and 93-028

U.S. Department of Agriculture (USDA)
ATTN: Mr. R. Plowman, Administrator
Agricultural Research Service
Administration Building
14th Street and Independence Avenue, S.W.
Washington, D.C. 20250

Dear Mr. Plowman:

SUBJECT: ORDER IMPOSING A CIVIL MONETARY PENALTY - $10,000
(NRC Combined Inspection Report Nos. 030-04530/92-001 through 92-010 and 030-06923/92-001)

This letter refers to your two letters dated April 22, 1993, in response to the Notice of Violation and Proposed Imposition of Civil Penalty (Notice) sent to you by our letter dated March 26, 1993. Our letter and Notice described twelve violations of NRC requirements, five of which were repetitive violations identified during previous NRC inspections (the previous violations were the subject of an enforcement conference on July 11, 1990, and resulted in a $5,000 civil penalty to USDA on August 16, 1990; EA 90-120). To emphasize the importance of involvement by licensee management representatives, the Radiation Safety Committee, and the Radiation Safety Officer (RSO) in (1) aggressively monitoring and evaluating licensed activities to assure that these activities are conducted safely and in accordance with the terms of your license, and (2) assuring that your corrective actions are long-lasting, a Notice of Violation and Proposed Imposition of Civil Penalty in the amount of $10,000 was proposed for the 12 violations identified in the 1992 NRC inspection.

In your response, you admitted all of the violations. However, you requested mitigation of the civil penalty, for the reasons set forth in your response, as summarized in the Appendix attached to the enclosed Order. After consideration of your response, we have concluded, for the reasons given in the Appendix to the enclosed Order Imposing a Civil Monetary Penalty, that an adequate basis was not provided for mitigation of the penalty. While we acknowledge that USDA is committed to following through with the necessary program improvements, this does not provide a basis for mitigation

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

of the civil penalty. Accordingly, we hereby serve the enclosed Order on you imposing a civil monetary penalty in the amount of $10,000. We will review the effectiveness of your corrective actions during a subsequent inspection.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter and the enclosures will be placed in the NRC's Public Document Room.

Sincerely,

Hugh L. Thompson, Jr.
Deputy Executive Director for
Nuclear Materials Safety, Safeguards
and Operations Support

Enclosures: As Stated

cc w/encls:
Public Document Room (PDR)
Roland Fletcher,
State of Maryland

UNITED STATES
NUCLEAR REGULATORY COMMISSION

In the Matter of	)	Docket Nos. 030-04530 and
	)	030-06923
U.S. DEPARTMENT OF AGRICULTURE	)	License Nos. 19-00915-03
Washington, D.C. 20250	)	and 19-00915-06
	)	EAs 92-232 and 93-028

ORDER IMPOSING CIVIL MONETARY PENALTY

I

The U.S. Department of Agriculture (Licensee), Washington, D.C. is the holder of Byproduct/Source Material Licenses Nos. 19-00915-03 and 19-00915-06 (Licenses), issued by the U. S. Nuclear Regulatory Commission (NRC or Commission) pursuant to 10 CFR Parts 30 and 33. License No. 19-00915-03 authorizes the Licensee to use byproduct material for research and development; in gauging and measuring devices; in field applications as approved by the Radiation Safety Committee (RSC); and for research studies in humans as approved by a Radioactive Drug Research Committee that has been approved by the Food and Drug Administration, and by the Licensee's Radiation Safety Committee (RSC). This is a large, multi-site, broad scope license with no stated possession limit. License No. 19-00915-06 authorizes the Licensee to use cobalt-60 and cesium-137 sealed sources in irradiators at sites and by users approved by the Licensee's RSC.

Licensed activities are conducted by a number of organizations within the Licensee's organization, including (1) the Agriculture Marketing Service (AMS); (2) the Animal, Plant, and Health

Inspection Service (APHIS); (3) the Agricultural Research Service (ARS); (4) the Federal Grain Inspection Service (FGIS); (5) the Food Safety and Inspection Service (FSIS); (6) the National Forest Service (NFS); and (7) the Soil Conservation Service (SCS). Over 3500 permits currently have been issued to individuals in these services to use licensed material at numerous locations around the country.

The Licenses most recently were renewed on February 10, 1990 and May 22, 1986, respectively, and would have expired on February 28, 1991 and May 31, 1991, respectively. Both Licenses continue in force, pursuant to 10 CFR 30.37(b), because of the timely filing of applications by the Licensee to renew the Licenses.

II

Ten inspections of the Licensee's activities were conducted by the NRC between March and October 1992 at several Licensee facilities throughout the country. During the inspections, twelve violations of NRC requirements were identified, five of which were repetitive violations identified during previous NRC inspections. A written Notice of Violation and Proposed Imposition of Civil Penalty (Notice) was served upon the Licensee by letter dated March 26, 1993. The Notice states the nature of the violations, the

provisions of the NRC's requirements that the Licensee had violated, and the amount of the civil penalty proposed for the violations.

The Licensee responded to the Notice by letters dated April 22, 1993. In its response, the Licensee admits all of the violations, but requests mitigation of the civil penalty.

III

After consideration of the Licensee's response and the statements of fact, explanation, and argument for mitigation contained therein, the NRC staff has determined, as set forth in the Appendix to this Order, that the violations occurred as stated and that the penalty proposed for the violations designated in the Notice should be imposed.

IV

In view of the foregoing and pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (Act), 42 U.S.C. 2282, and 10 CFR 2.205, IT IS HEREBY ORDERED THAT:

The Licensee pay a civil penalty in the amount of $10,000 within 30 days of the date of this Order, by check, draft, money order, or electronic transfer, payable to the Treasurer

of the United States and mailed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555.

V

The Licensee may request a hearing within 30 days of the date of this Order. A request for a hearing should be clearly marked as a "Request for an Enforcement Hearing" and shall be addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission Washington, D.C. 20555, with a copy to the Commission's Document Control Desk, Washington, D.C. 20555. Copies also shall be sent to the Assistant General Counsel for Hearings and Enforcement at the same address and to the Regional Administrator, NRC Region I, 475 Allendale Road, King of Prussia, Pennsylvania 19406.

If a hearing is requested, the Commission will issue an Order designating the time and place of the hearing. If the Licensee fails to request a hearing within 30 days of the date of this Order, the provisions of this Order shall be effective without further proceedings. If payment has not been made by that time, the matter may be referred to the Attorney General for collection.

In the event the Licensee requests a hearing as provided above, the issues to be considered at such hearing shall be whether, on the basis of the violations admitted by the Licensee, this Order should be sustained.

FOR THE NUCLEAR REGULATORY COMMISSION

Hugh L. Thompson, Jr.
Deputy Executive Director for
Nuclear Materials Safety, Safeguards
and Operations Support

Dated at Rockville, Maryland
this 3rd day of June 1993

APPENDIX

EVALUATIONS AND CONCLUSION

On March 26, 1993, a Notice of Violation and Proposed Imposition of Civil Penalty (Notice) was issued for twelve violations identified during ten NRC inspections conducted between March and October 1992. The licensee responded to the Notice in letters dated April 22, 1993, and admits all of the violations, but requests mitigation of the civil penalty. The NRC's evaluations and conclusions regarding the licensee's requests are as follows:

1. **Restatement of Violations**

   A. Condition 25 of License No. 19-00915-03 requires that licensed material be possessed and used in accordance with statements, representations, and procedures contained in an application dated July 11, 1989, and the letter dated March 9, 1990.

   Item 3 of the application dated July 11, 1989, requires, in part, that Category I locations (major isotope users; facilities that use millicurie quantities of radioiodine and/or perform iodinations; and facilities that perform studies involving human subjects) be inspected at intervals not to exceed three years, and Category II locations (all non-Category I facilities that use licensed material in an unsealed form) be inspected by the Radiation Safety Staff at intervals not to exceed five years.

   Condition 17 of License No. 19-00915-06 requires that licensed material be possessed and used in accordance with statements, representations, and procedures contained, in part, in an application dated August 27, 1985, and letters dated April 7, 1986, June 27, 1986, and April 14, 1987. Item K.11. of the application dated August 27, 1985, requires that irradiator facilities be inspected by the Radiation Safety Staff at least every three years.

   Contrary to the above, as of September 9, 1992, certain USDA facilities were not inspected at the required intervals as specified above. Specifically, two Category I facilities, (namely, Miles City, Montana, and Greenport, New York) had not been inspected in the previous three years; and 12 Category II facilities (Hamden, Connecticut; West Lafayette, Indiana; Morris, Montana; Raleigh, North Carolina; University Park, Pennsylvania; Brooking, South Dakota; Lubbock, Texas; Kearneysville, West Virginia; Columbia, Missouri; Wooster, Ohio; Fresno, California; and Salinas, California) had not been inspected in the previous five years; and one irradiator facility (namely, Otis Air

Force Base, Massachusetts) had not been inspected in the previous three years.

This is a repetitive violation.

B. Condition 12 of License No. 19-00915-03 and Condition 13 of License No. 19-00915-06 require, in part, that sealed sources be tested for leakage and/or contamination at intervals not to exceed 6 months or at other intervals as specified by the certificate of registration, not to exceed 3 years; and that records of leak test results be maintained for inspection by the Commission.

Contrary to the above, as of September 9, 1992, 65 sealed sources had not been tested for leakage at six-month intervals, as required, and no other interval was specified by the certificates of registration. In addition, leak test results were not maintained for inspection by the Commission in that leak test records for sealed sources possessed by 13 different users were missing from 29 user files which were reviewed.

This is a repetitive violation.

C. Condition 19 of License No. 19-00915-03 requires, in part, that ash residues may be disposed of as ordinary waste provided appropriate surveys pursuant to Section 20.201 of 10 CFR Part 20 are made to determine that concentrations of licensed material appearing in the ash residues do not exceed the concentrations (in terms of microcuries per gram) specified for water in 10 CFR Part 20, Appendix B, Table II.

Condition 25 of License No. 19-00915-03 requires that licensed material be possessed and used in accordance with statements, representations, and procedures contained in an application dated July 11, 1989 and a letter dated March 9, 1990.

Item 11.2 of the application dated July 11, 1989 requires that quarterly summaries of the records of incinerations be furnished to the radiation safety staff.

Contrary to the above, as of September 9, 1992, quarterly summaries were not furnished to the radiation safety staff during the period of July 1991 through June 1992 for seven incinerators at four sites (namely, Athens, Georgia; Clay Center, Nebraska; Fargo, North Dakota; and Ames, Iowa), and surveys of ash residues were not performed for three incinerators at three sites (namely, Clay Center, Nebraska; Grand Forks, North Dakota; and

Plum Island, New York) during the period of July 1991 through June 1992 to assure that ash residue disposed of as ordinary waste did not exceed the concentrations specified for water in 10 CFR Part 20, Appendix B, Table II.

This is a repetitive violation.

D. 10 CFR 20.207(a) requires that licensed material stored in an unrestricted area be secured against unauthorized removal from the place of storage. 10 CFR 20.207(b) requires that licensed materials in an unrestricted area and not in storage be tended under constant surveillance and immediate control of the licensee. As defined in 10 CFR 20.3(a)(17), an unrestricted area is any area access to which is not controlled by the licensee for purposes of protection of individuals from exposure to radiation and radioactive materials.

Contrary to the above, on September 22, 1992, licensed material consisting of a nickel-63 electron capture device in a gas chromatograph located in an unlocked storage building, an unrestricted area, at the Boll Weevil Research Laboratory in Mississippi State, Mississippi, was not secured against unauthorized removal and was not under constant surveillance and immediate control of the licensee.

This is a repetitive violation.

E. 10 CFR 20.301 requires that no licensee dispose of licensed material except by certain specified procedures. 10 CFR 20.301(a) requires that no licensee dispose of licensed material except by transfer to an authorized recipient as provided in the regulations in Parts 30, 40, 60, 61, 70, or 72, whichever may be applicable.

Contrary to the above, on October 31, 1991, a USDA facility in Albany, California sent a drum containing 0.51 millicuries of sulfur-35, 0.003 millicuries of carbon-14, and 0.002 millicuries of cadmium-109 to a normal landfill for disposal in the normal trash, a method not authorized by 10 CFR 20.301. In addition, as of September 2, 1992, byproduct material was routinely disposed of by transfer to other licensees (namely, Pennsylvania State University and Cornell University) who were not authorized to receive radioactive waste for disposal in University Park, Pennsylvania and Ithaca, New York.

F. Condition 25 of License No. 19-00915-03 requires that licensed material be possessed and used in accordance with statements, representations, and procedures contained in an application dated July 11, 1989, and the letter dated March 9, 1990.

1. Item 9.18 of the application dated July 11, 1989, requires, in part, that a contamination level survey be performed by permit holders at least every three months and the results be reported to the Radiation Safety Officer.

   Contrary to the above, as of September 9, 1992, results of contamination level surveys performed by various permit holders every three months were not reported to the Radiation Safety Officer. Specifically, 14 permit holders failed to report the results of one or more quarterly contamination level surveys during the period of January 1991 through June 1992.

2. Item 10.4.2 of the application dated July 11, 1989, requires that licensed material be used by Radiation Safety Committee-approved users in accordance with generally accepted safe practices, the rules and procedures specified in the USDA Radiological Safety Handbook, and as specifically prescribed by the Committee and/or the Radiation Safety Officer.

   Contrary to the above, as of September 9, 1992, licensed material was used in a manner different than prescribed by the Radiation Safety Committee (RSC) and/or the Radiation Safety Officer (RSO). Specifically, (1) a permit holder in Pullman, Washington authorized to possess one 50-millicurie americium-241 sealed source possessed five 50-millicurie and one 1000-millicurie americium-241 sealed sources, quantities in excess of those prescribed by the RSC or RSO; (2) a permit holder in Fargo, North Dakota authorized to use one millicurie of nickel-63, possessed an 8-millicurie sealed source of nickel-63, a quantity in excess of that prescribed by the RSC or RSO; (3) in Ithaca, New York, a permit holder possessed a source of cobalt-60 which no person performing activities under this license is authorized by the RSC or RSO to possess; and (4) in Mississippi State, Mississippi the permit holder used its irradiator for purposes other than the boll weevil studies

authorized by the RSO, such as irradiation of blood, spiders, and grasshoppers.

3. Item 11.1.7 of the application dated July 11, 1989, requires that users maintain accurate inventories of radioactive materials under their control so that reports can be prepared and submitted when requested by the Radiation Safety Officer.

   Contrary to the above, as of September 9, 1992, users' reports of inventories were not submitted when requested. Specifically, 7 of 18 users reviewed did not submit results of inventories requested by the Radiation Safety Officer in 1991.

G. Condition 15 of License No. 19-00915-03 requires that a physical inventory be performed every six months to account for all sources and/or devices received and possessed by the licensee, and that records of inventories be maintained for two years from the date of each inventory.

   Contrary to the above, between June 15, 1990, and September 9, 1992, a period in excess of six months, physical inventories of at least 65 sealed sources were not performed and inventory records were not maintained as required.

H. 10 CFR 71.5(a) requires that licensees who transport licensed material outside the confines of their facilities or deliver licensed material to a carrier for transport comply with the applicable requirements of the regulations appropriate to the mode of transport of the Department of Transportation in 49 CFR Parts 170 through 189.

   49 CFR 177.817(e)(2)(i) requires, in part, that when a driver of a motor vehicle transporting licensed material is at the vehicle's controls, the shipping paper shall be within his reach and either readily visible to a person entering the driver's compartment or in a holder which is mounted on the inside of the door on the driver's side of the vehicle.

   Contrary to the above, as of September 1, 1992, a USDA employee at the University Park, Pennsylvania, facility routinely stored shipping papers in the portable gauge case during transportation to and from temporary job sites, and therefore, the shipping papers were not within the driver's reach, readily visible to a person entering the driver's compartment, or in a holder mounted on the

inside of the door on the driver's side of the vehicle during transportation of a portable gauge.

I. 10 CFR 19.12 requires, in part, that all individuals working in a restricted area are instructed in the precautions and procedures to minimize exposure to radioactive materials, in the purpose and functions of protective devices employed, and in the applicable provisions of the Commission's regulations and licenses.

Contrary to the above, as of March 5, 1992, an ancillary staff member working in a restricted area at the Pacific Southwest Research Station in Berkeley, California had not been instructed in the precautions and procedures to be followed when he performed duties in the laboratory where licensed material was used and had not been instructed in the applicable provisions of the regulations and the conditions of the license.

J. 10 CFR 19.11(a) and (b) require, in part, that the licensee post current copies of 10 CFR Part 19, 10 CFR Part 20, the license, the license conditions, documents incorporated into the license, license amendments, and operating procedures; or, if posting of a document is not practicable, that the licensee post a notice describing these documents and where they may be examined. 10 CFR 19.11(c) requires that a licensee post Form NRC-3, "Notice to Employees". 10 CFR 21.6 requires, in part, that the licensee post current copies of 10 CFR Part 21.

Contrary to the above, on March 6, 1992, at the licensee's facility in Placerville, California, current copies of 10 CFR Parts 19 and 20 were not posted; on September 1, 1992, at the licensee's facility in University Park, Pennsylvania, a current copy of Form NRC-3 was not posted; and as of September 23, 1992, at the licensee's facilities in Mississippi State, Mississippi and Tuscaloosa, Alabama, copies of 10 CFR Part 21 were not posted.

This is a repetitive violation.

These violations are categorized in the aggregate as a Severity Level III problem. (Supplements IV and VI)

Civil Penalty - $10,000

2. **Summary of Licensee Response**

In its written responses, the licensee admits all of the violations. However, the licensee requests that the penalty

be mitigated in its entirety. In support of its request for full mitigation, the licensee notes its commitment to an independent assessment of the Radiation Safety Program to achieve and maintain compliance with NRC requirements, as well as recent improvements in its program operations. The licensee also states that the violations do not represent a significant health and safety risk to the public, and it has taken or planned effective corrective actions.

The licensee further notes that the Enforcement Conference in January 1993 resulted in a significant elevation of the importance of the program within the licensee's organization, and its management has become involved in the program improvement plan and has committed its support to it. The licensee also indicates that it has been granted exemptions to the USDA hiring freeze for two additional health physicist positions on the radiation safety staff. In view of the above, the licensee contends that payment of the civil penalty is not necessary to assure management attention to this program or to the licensee's commitment to the improvement process.

3. **NRC Evaluation of Licensee Response**

The NRC has evaluated the licensee response and has determined that the licensee has not provided an adequate basis for mitigation of the civil penalty. The severity level of the violations and the civil penalty amount were determined in accordance with the NRC's Enforcement Policy and the enforcement action was consistent with action taken for similar violations by other licensees. Supplement VI.C.7 of the NRC Enforcement Policy gives as an example of a Severity Level III violation, a breakdown in the control of licensed activities involving a number of violations that are related (or, if isolated, that are recurring violations) that collectively represent a potentially significant lack of attention or carelessness toward licensed responsibilities. The NRC places great importance on management control of activities involving licensed materials to ensure that all NRC requirements are met and that any potential violation of an NRC requirement is identified and corrected expeditiously. Thus, the violations are of significant regulatory concern and were properly categorized in the aggregate as a Severity Level III problem.

Further, in determining the amount of the civil penalty for the Severity Level III problem, the NRC considered the escalation and mitigation factors set forth in the NRC Enforcement Policy. As part of that evaluation, the NRC concluded that the base civil penalty amount for this Severity Level III problem should be increased by 300% because the

violations were identified by the NRC, the corrective actions were neither prompt nor comprehensive, the licensee's prior enforcement history included violations that resulted in the issuance of a $5,000 civil penalty in August 1990, and some of the violations existed for an extended duration.

With respect to the issues provided in the licensee's response as a basis for mitigation of the penalty, the NRC acknowledges that the licensee did commit to an independent assessment to improve implementation of the radiation safety program. However, this commitment was made only after these violations were identified by the NRC in 1992 and an Enforcement Conference was scheduled, notwithstanding the fact that many of these violations were repetitive, existed for an extended duration, and should reasonably have been prevented if appropriate management attention had been provided to the program after the NRC had previously conducted an enforcement conference with the licensee on July 11, 1990, and issued the $5,000 proposed civil penalty to the licensee on August 16, 1990.

The NRC acknowledges that there was a significant elevation of the importance of the program within the licensee's organization, subsequent to the more recent enforcement conference with the licensee on January 19, 1993. Further, management has apparently become involved in the program improvement plan and has committed its support to it. Nonetheless, these actions were not timely, given the licensee's existing enforcement history. If these plans for improvement had not been taken by the licensee, the NRC would have considered more significant enforcement action. The Licensee's answer and reply to a Notice of Violation provide no new information which changes the conclusion reached in the Notice.

4. NRC Conclusion

The NRC concludes that the licensee has not provided an adequate basis for mitigating any portion of the civil penalty. Accordingly, the NRC has determined that the proposed civil penalty in the amount of $10,000 should be imposed.

II.B. MATERIALS LICENSEES, SEVERITY LEVEL I, II, III VIOLATIONS, NO CIVIL PENALTY

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
799 ROOSEVELT ROAD
GLEN ELLYN, ILLINOIS 60137-5927

July 30, 1993

Docket No. 030-02713
License No. 34-03111-02
EA 93-183

Children's Hospital
ATTN: Keith Goodwin
Assistant Executive Director
700 Children's Drive
Columbus, Ohio 43205

Dear Mr. Goodwin:

SUBJECT: NOTICE OF VIOLATION
(NRC INSPECTION REPORT NO. 030-02713/93001)

This refers to the routine safety inspection conducted on March 15 and 16, 1993 at Children's Hospital, Columbus, Ohio, during which a significant violation of NRC requirements was identified. The report documenting the inspection was mailed to you on July 14, 1993, and on July 21, 1993, an enforcement conference was held in the Region III office.

The inspection found that your Quality Management Plan (QMP), submitted to the NRC on January 17, 1992, was limited to the therapeutic uses of NRC licensed materials and did not contain provisions for using licensed materials in certain diagnostic studies. You attributed this failure to a misunderstanding that the QMP was limited to the therapeutic uses of licensed materials. As a result, the QMP did not contain policies and procedures for the preparation of a written directive by an authorized user prior to the administration of iodine-125 or iodine-131 in excess of 30 microcuries for diagnostic procedures. Consequently, two patients each received 2 millicuries of iodine-131 (on February 11, 1992, and January 23, 1993) for diagnostic studies and a written directive was not prepared by an authorized user prior to administration. The NRC recognizes that written directives were properly prepared for seven therapeutic administrations of radioiodine.

10 CFR 35.32 is specific about the objectives to be included in a QMP and does not differentiate between diagnostic or therapeutic uses of radioiodine. In fact, the specific objective is the development of policies and procedures for <u>any</u> administration of iodine-125 or iodine-131 in excess of 30 microcuries. The failure to include provisions in your QMP for the administration of any quantity of iodine-125 or iodine-131 in excess of 30 microcuries is considered a substantial failure to implement the QMP as required by 10 CFR 35.32.

<u>CERTIFIED MAIL</u>
<u>RETURN RECEIPT REQUESTED</u>

The violation is fully described in the enclosed Notice of Violation (Notice). In accordance with the "Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy)10 CFR Part 2, Appendix C, this violation has been categorized at Severity Level III. The NRC recognizes that you immediately corrected the violation by: modifying your QMP; developing a form to be used by your authorized users as the written directive; developing a second form to verify that the written directive was followed; and training your staff in these changes.

To emphasize the need to include in your QMP all of the specific objectives listed in 10 CFR 35.32, I have decided to issue the enclosed Notice of Violation for the Severity Level III violation. The civil penalty adjustment factors in the Enforcement Policy were considered and the civil penalty was fully mitigated. While the NRC identified the violation, that adjustment factor was offset by your corrective actions, described above, and your good past performance.

Two other violations were identified during the inspection. One violation pertained to the calibration of a survey instrument and is described in the enclosed Notice. That violation is categorized at Severity Level IV. The second violation concerned the retention of records for dose calibrator linearity tests and is not cited because it met the criteria of Section VII.B.1 of the NRC Enforcement Policy.

The NRC is concerned with the adequacy of your radiation safety staffing considering that you possess a broad scope license permitting the use of NRC licensed materials for humans and in research programs. Although you have somewhat increased the time that your consultant Radiation Safety Officer spends at your facility, as discussed at the enforcement conference, please provide us with the conclusions reached following your internal review of this staffing issue.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. In your response, you should document the specific actions taken and any additional actions you plan to prevent recurrence. After reviewing your response to this Notice, including your proposed corrective actions and the results of future inspections, the NRC will determine whether further NRC enforcement action is necessary to ensure compliance with NRC regulatory requirements.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter, its enclosure, and your responses will be placed in the NRC Public Document Room.

The responses directed by this letter and the enclosed Notice are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, Public Law No. 96-511.

Sincerely,

John B. Martin
Regional Administrator

Enclosure:
Notice of Violation

NOTICE OF VIOLATION

Children's Hospital
Columbus, Ohio

Docket No. 030-02713
License No.34-0311-02
EA No. 93-183

During an NRC inspection conducted on March 15 and 16, 1993, violations of NRC requirements were identified. In accordance with the "Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C), the violations are listed below:

A. 10 CFR 35.32(a) requires, in part, that each licensee establish and maintain a written quality management program to provide high confidence that byproduct material or radiation from byproduct material will be administered as directed by the authorized user. The quality management program must include written policies and procedures to meet specific objectives including the preparation of a written directive prior to any administration of quantities greater than 30 microcuries of either sodium iodide-125 or iodide-131.

Contrary to the above, as of March 16, 1993, the licensee's Quality Management Assessment Program, dated January 17, 1992, did not include written policies and procedures for the preparation of a written directive prior to the administration of quantities greater than 30 microcuries of sodium iodide-125 or iodide-131 for diagnostic studies.

This is a Severity Level III violation (Supplement VI).

B. 10 CFR 35.51(a) requires that a licensee calibrate the survey instruments used to show compliance with 10 CFR Part 35 before first use, annually, and following repair.

Contrary to the above, as of March 16, 1993, the licensee was using a Bicron-2000 survey instrument in the nuclear medicine department to show compliance with 10 CFR Part 35, and this survey instrument had not been calibrated following repair and return to service during the week of March 1, 1993.

This is a Severity Level IV violation (Supplement VI).

Pursuant to the provisions of 10 CFR 2.201, Children's Hospital (Licensee) is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555 with a copy to the Regional Administrator, Region III, 799 Roosevelt Road, Glen Ellyn, Illinois 60137, within 30 days of the date of the letter transmitting this Notice of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each violation: (1) the reason for the violation, or, if contested, the basis for disputing the violation, (2) the corrective steps that have been taken and the results achieved, (3)

the corrective steps that will be taken to avoid further violations, and (4) the date when full compliance will be achieved. If an adequate reply is not received within the time specified in this Notice, an order or a demand for information may be issued as to why the license should not be modified, suspended, or revoked, or why such other action as may be proper should not be taken. Where good cause is shown, consideration will be given to extending the response time. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, this response shall be submitted under oath or affirmation.

Dated at Glen Ellyn, Illinois
the 30 day of July 1993

SEP 13 1993

Docket No. 999-90002
License No. General License (10 CFR 31.5)
EA 93-213

Childress Service Corporation
ATTN: Mr. Joey Childress
Executive Vice President
Post Office Box 189
Beaver, West Virginia 25813

Gentlemen:

SUBJECT: NOTICE OF VIOLATION
(NRC INSPECTION REPORT NO. 999-90002/93-01)

This refers to the Nuclear Regulatory Commission (NRC) inspection conducted by Mr. Wade T. Loo on July 27-28, 1993, at your Coal Mountain, West Virginia facility. The inspection included a review of activities conducted under your NRC general license with respect to compliance with NRC regulations and the facts and circumstances related to the removal of a fixed nuclear density gauge from its installed location by an individual not licensed to perform such activities and its subsequent apparent theft. The report documenting the inspection was sent to you by letter dated August 27, 1993. During the inspection, a violation of NRC requirements was identified. An enforcement conference was conducted in the NRC Region II office on September 8, 1993, to discuss the violation, its cause, and your corrective actions to preclude recurrence. This enforcement conference was open for public observation in accordance with the Commission's trial program for conducting open enforcement conferences as discussed in the Federal Register, 57 FR 30762, July 10, 1992. A summary of this conference was sent to you by letter dated September 9, 1993.

The violation in the enclosed Notice of Violation (Notice) involved the relocation of a fixed nuclear density gauge containing approximately 100 millicuries of cesium-137. This relocation, performed because the facility was being dismantled, was done by an employee who was not authorized by NRC or an Agreement State to do so. The significance of this individual relocating the gauge relates to his not being authorized to perform such licensed activity, the possibility of damaging the device during relocation, and the possibility of unnecessary radiation exposure. Furthermore, as a result of the relocation, control of the gauge was lost and it was apparently stolen. As of yet, the gauge has not been recovered. Therefore, this violation has been categorized at Severity Level III to reflect the significant regulatory concern associated with the violation.

The staff recognizes that before the device was relocated, the licensee employee involved in the relocation contacted the gauge manufacturer's representative regarding the relocation and was advised that the pipe to which

the gauge was attached could be cut on each side of the gauge and both the section of pipe and gauge could then be moved to a secure storage location. Even though the licensee's employee acted upon the advice of the manufacturer's representative, his actions were nevertheless in conflict with the NRC regulations for general licensees.

In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions" (Enforcement Policy), 10 CFR Part 2, Appendix C, Severity Level III violations generally are considered for escalated enforcement action and associated civil penalty. The base civil penalty for this Severity Level III violation is $500. However, I have decided that a civil penalty will not be proposed for this case based on consideration of the escalation and mitigation factors in the Enforcement Policy. Mitigation of 50 percent was warranted because you identified the loss of the gauge, notified the NRC and took prompt corrective action. Mitigation of 50 percent was warranted for your good corrective actions that included retraining all company personnel in the safety and regulatory requirements associated with fixed nuclear density gauges and informing company personnel of the circumstances associated with the unauthorized relocation of the gauge. Furthermore, your actions relating to the recovery attempts were far reaching and exhaustive. The other adjustment factors in the Enforcement Policy were considered and no further adjustment to the base civil penalty is considered appropriate. Therefore, based on the above, the base civil penalty has been fully mitigated.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. In your response, you should document the specific actions taken and any additional actions you plan to prevent recurrence. After reviewing your response to this Notice, including your proposed corrective actions and the results of future inspections, the NRC will determine whether further NRC enforcement action is necessary to ensure compliance with NRC regulatory requirements.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter and its enclosure will be placed in the NRC Public Document Room.

The responses directed by this letter and the enclosed Notice are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, Pub. L. No. 96-511.

Should you have any questions concerning this letter, please contact us.

Sincerely,
ORIGINAL SIGNED BY L. A. REYES

Stewart D. Ebneter
Regional Administrator

Enclosure:
Notice of Violation

NOTICE OF VIOLATION

Childress Service Corporation
Beaver, West Virginia

Docket No. 999-90002
General License (10 CFR 31.5)
EA 93-213

During an NRC inspection conducted on July 27-28, 1993, a violation of NRC requirements was identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C, the violation is listed below:

> 10 CFR 31.5(c)(3) requires, in part, that any person who acquires, receives, possesses, uses or transfers byproduct material in a device pursuant to a general license shall assure that removal from installation involving the radioactive source, its shielding or containment, are performed: (1) in accordance with the instructions provided by the labels; or (2) by a person holding a specific license pursuant to 10 CFR Parts 30 and 32 or from an Agreement State to perform such activities.
>
> The label affixed to the licensee's Kay-Ray Model 3660 Density System, Model No. 7062BP, Serial No. 25147 (a general license device), states, in part, that installation, dismantling, or relocation of this device shall be performed by persons specifically licensed by the Nuclear Regulatory Commission or an Agreement State.
>
> Contrary to the above, on or about May 10, 1993, a licensee employee, who was not specifically licensed by the Nuclear Regulatory Commission or an Agreement State, removed a metal pipe that had attached to it the device described above which contained approximately 100 millicuries of cesium-137 from its installed position in the coal preparation line and relocated the metal pipe along with the device to a metal shed for storage.

This is a Severity level III violation (Supplement VI).

Pursuant to the provisions of 10 CFR 2.201, Childress Service Corporation is hereby required to submit a written statement or explanation to the Regional Administrator, Region II, with a copy to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555, within 30 days of the date of the letter transmitting this Notice of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each violation: (1) the reason for the violation, or, if contested, the basis for disputing the violation, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken to avoid further violations, and (4) the date when full compliance will be achieved. If an adequate reply is not received within the time specified in this Notice, an order or demand for information may be

issued as to why the license should not be modified, suspended, or revoked, or why such other action as may be proper should not be taken. Where good cause is shown, consideration will be given to extending the response time. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, this response shall be submitted under oath of affirmation.

Dated at Atlanta, Georgia
This 15th day of September, 1993

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION II
101 MARIETTA STREET, N.W.
ATLANTA, GEORGIA 30323

AUG 13 1993

Docket No. 030-03302
License No. 45-00986-01
EA 93-185

DePaul Medical Center
ATTN: Sister Ellen Eisenberger
President
150 Kingsley Lane
Norfolk, VA 23505

Dear Sister Eisenberger:

SUBJECT: NOTICE OF VIOLATION
(NRC INSPECTION REPORT NO. 45-00986-01/93-01)

This refers to the Nuclear Regulatory Commission (NRC) inspection conducted by Mr. M. Fuller of this office on June 17 and 18, 1993, at your medical facility in Norfolk, Virginia. The inspection included a review of the activities conducted under your license with respect to radiation safety and compliance with NRC regulations and the conditions of your license. At the conclusion of the inspection, the findings were discussed with Mr. Allen D. Moran, Vice President. The report documenting this inspection was sent to you by letter dated July 15, 1993. As a result of this inspection, violations of NRC requirements were identified. An enforcement conference was held on August 5, 1993, in the Region II office to discuss the violations, their cause, and your corrective actions to preclude recurrence. Enclosed are a list of enforcement conference attendees and a copy of the documents your staff provided during the enforcement conference.

Violation A in the enclosed Notice of Violation (Notice) involved your administering one hundred and six (106) radiopharmaceutical dosages consisting of quantities greater than 30 microcuries of sodium iodide I-131 to patients without a written directive or verification of that directive, as required by your quality management program (QMP). Written directives are an important component of the QMP as they were specifically devised as a means of providing appropriate safeguards to preclude a misadministration. Although a QMP had been prepared for the Nuclear Medicine Department and submitted to the NRC in January 1992, personnel in the Nuclear Medicine Department were not aware of its existence and consequently not aware of the QMP requirements for a written directive.

During the enforcement conference, your staff forthrightly discussed several causes that contributed to this violation. Among those cited was the fact that there had been a high turnover of medical physicists at your facility; over-reliance on a consultant physicist who conducted audits of the nuclear

medicine program; inadequate in-service training for the nuclear medicine staff; and an apparent lack of in-depth understanding of QMP requirements by the Radiation Safety Committee. These factors resulted in a lack of effective management oversight.

The staff recognizes that after the NRC identified this violation, immediate corrective action was taken that included immediate cessation of sodium iodide I-131 procedures in the Nuclear Medicine Department, retraining of all nuclear medicine technologists and authorized users in the QMP requirements, and providing the nuclear medicine staff with copies of policies, procedures and forms related to the administration of radiopharmaceuticals. However, the failure to meet the QMP requirement for a written directive in multiple cases is a significant regulatory concern. Therefore, this violation has been categorized at Severity Level III.

In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions" (Enforcement Policy), 10 CFR Part 2, Appendix C, a civil penalty is considered for a Severity Level III violation. However, I have decided not to propose a civil penalty in this case because, in applying the escalation and mitigation factors in the Enforcement Policy, the base civil penalty was fully mitigated based on your good corrective actions and good prior performance.

Violation B in the Notice was categorized at Severity Level IV and involved three physicians who used licensed material without being specifically authorized to do so. The three physicians were named on the license as authorized users for uptake, imaging and localization studies only. However, they routinely used licensed material for the purpose of radio-pharmaceutical therapy that included treatment of cardiac dysfunction and hyperthyroidism. Although the physicians were qualified to use licensed material for the purposes of therapy, no actions were taken to have those individuals added to the license as authorized users of licensed material for therapeutic procedures. During the enforcement conference your staff addressed this violation explaining that the problem had been identified by the consultant physicist who recommended that no action be taken to add these individuals to the license until the license renewal date so as to save the cost of a license amendment fee. The decision to wait and add the physicians to the license at the time of license renewal was misguided and might have been precluded by the diligent exercise of management oversight. Moreover, financial considerations should never take precedence over a licensee's obligation to promptly comply with regulatory requirements once inadequacies are uncovered. Based on your staff's recognition of the impropriety of that decision as well as their forthright and candid discussion of this issue during the enforcement conference, we have concluded that there was no apparent intent to violate regulatory requirements. Nevertheless, this should serve as an important example of the need for aggressive management oversight of licensed activities.

The inspection report also identified one other apparent violation related to records of tests for leakage and/or contamination for the sealed sources of licensed material in the Nuclear Medicine Department. Prior to the enforcement conference your staff provided documentation that substantiated that appropriate tests were performed as required. Therefore, we are withdrawing this apparent violation.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. In your response, you should document the specific actions taken and any additional actions you plan to prevent recurrence. After reviewing your response to this Notice, including your proposed corrective actions and the results of future inspections, the NRC will determine whether further NRC enforcement action is necessary to ensure compliance with NRC regulatory requirements.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter and its enclosures will be placed in the NRC Public Document Room.

The responses directed by this letter and the enclosed Notice are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, Pub. L. No. 96-511.

Should you have any questions concerning this letter, please contact us.

Sincerely,

Stewart D. Ebneter
Regional Administrator

Enclosures:
1. Notice of Violation
2. List of Attendees
3. Enforcement conference handouts
4. August 6, 1993 Opening Statement

cc w/encls:
Commonwealth of Virginia

NOTICE OF VIOLATION

DePaul Medical Center
150 Kingsley Lane
Norfolk, Virginia

Docket No. 030-03302
License No. 45-00986-01
EA 93-185

During an NRC inspection conducted on June 17 and 18, 1993, violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C, the violations are listed below:

A. 10 CFR 35.32(a) requires, in part, that each licensee under this part, as applicable, establish and maintain a written quality management program to provide high confidence that byproduct material or radiation from byproduct material will be administered as directed by the authorized user.

10 CFR 35.25(a)(2) requires, in part, that a licensee that permits the use of byproduct material by an individual under the supervision of an authorized user shall require the supervised individual to follow the written quality management procedures established by the licensee.

Part 1, Section 1.1 of the licensee's policies and procedures entitled "Quality Management Program" requires that an authorized user date and sign a written directive prior to administration of any therapeutic dosage of radiopharmaceutical or any dosage of quantities greater than 30 microcuries of either sodium iodide I-125 or I-131. Section 1.3 requires the protocol for administration of byproduct material be checked against the written directive. Section 1.5 requires that a verification sheet be completed for each dosage in which a written directive is required and that this be dated, completed, and initialed or signed by the physician or technologist that administered the dosage.

Contrary to the above, between January 27, 1992 and June 17, 1993, the licensee's Nuclear Medicine Staff, individuals under the supervision of the licensee's authorized user, did not follow the written quality management procedures established by the licensee, nor did the authorized user require them to follow those procedures in that 106 radiopharmaceutical dosages consisting of greater than 30 microcuries of sodium iodide I-131 were administered without a written directive. Since no written directive was prepared, the licensee lacked the capability to identify and evaluate any unintended deviation from the written directive.

This is a Severity Level III violation (Supplement VI).

B. 10 CFR 35.11(a) requires, in part, that a person shall not possess or use byproduct material for medical use except in accordance with a specific license issued by the Commission or an Agreement State.

Condition 12 of License No. 45-00986-01 specifies who is authorized to use licensed material and the specific purposes.

Contrary to the above, as of June 17, 1993, the licensee allowed individuals to conduct procedures using licensed material for which they were not authorized. Specifically, three physicians named as authorized users for uptake, imaging, and localization studies only, routinely used licensed material for the purpose of radiopharmaceutical therapy, a purpose for which they were not specifically authorized.

This is a Severity Level IV violation (Supplement VI).

Pursuant to the provision of 10 CFR 2.201, DePaul Medical Center is hereby required to submit a written statement or explanation to the Regional Administrator, Region II, with a copy to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555, within 30 days of the date of the letter transmitting this Notice of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each violation: (1) the reason for the violation, or, if contested, the basis for disputing the violation, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken to avoid further violations, and (4) the date when full compliance will be achieved. If an adequate reply is not received within the time specified in this Notice, an order or a Demand for Information may be issued as to why the license should not be modified, suspended, or revoked, or why such other action as may be proper should not be taken. Where good cause is shown, consideration will be given to extending the response time. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, this response shall be submitted under oath or affirmation.

Dated at Atlanta, Georgia
this 3rd day of August 1993

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
799 ROOSEVELT ROAD
GLEN ELLYN, ILLINOIS 60137-5927

July 26, 1993

General Licensee
[10 CFR 150.20]
EA 93-189

E.S.C. Resources, Inc.
ATTN:Mr. Bart Moscarello
President
1603 Terri Circle
Naperville, IL 60563

Dear Mr. Moscarello

SUBJECT: NOTICE OF VIOLATION

This refers to our review of your licensed activities in non-Agreement States as authorized by 10 CFR 150.20. You volunteered information to us in June 1993 that you had unknowingly conducted licensed activities in non-Agreement States without filing the proper forms with the NRC prior to conducting these activities. On July 20, 1993, you were offered the opportunity for an enforcement conference but declined.

Based on the information which you provided to us verbally at the Region III offices in June, and followup written information in letters dated June 3, 1993, and July 12, 1993, the NRC learned that E.S.C. Resources, Inc, an Agreement State licensee with the State of Illinois, had performed licensed activities in non-Agreement States and had not complied with the reciprocity requirements of 10 CFR 150.20. Specifically, E.S.C. Resources failed to provide proper notification to the NRC (via Form 241) on five occasions between 1991 and 1993 that it was performing licensed work in non-Agreement States. This work normally consisted of a combination of repairing or replacing the wiring, limit switches, shutter air cylinders, and shutter assemblies for source devices. You do not possess nor work directly with radioactive sources. The violation of 10 CFR 150.20 is described in the enclosed Notice of Violation and is categorized at Severity Level III in accordance with the "Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy) 10 CFR Part 2, Appendix C.

The root cause of the violation and the subsequent corrective actions were discussed with you on June 3, 1993, when you visited the Region III offices, and in several subsequent telephone conversations. Initially, you had called Region III on June 1, 1993, to notify the NRC of the potential violation. During that

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

conversation you were informed that you are required to file the required reciprocity forms. As a result of that call, you personally visited the Region III office on June 3 and delivered the approved forms in addition to the required fees. The major factor contributing to the violation appeared to be your misunderstanding or lack of knowledge of the conditions of your State of Illinois specific license pertaining to temporary job sites and the reciprocity process. The NRC recognizes that you immediately corrected the violation and that you plan to inform us of regularly scheduled visits to NRC non-Agreement States and also update us of your schedule changes.

The NRC relies on Agreement State licensees to notify us whenever licensed activities are performed in non-Agreement States. It is incumbent on such licensees to be aware of these reporting requirements and to be responsible for making the reports. Failure to report is a serious matter because it denies the NRC the opportunity to inspect licensed activities while the work is being done and thereby removes the NRC's ability to perform its function of verifying that licensed activities are performed in a safe manner. Therefore, to emphasize the need of the importance to adhere to regulatory requirements, I am issuing the enclosed Notice of Violation for this Severity Level III violation.

In accordance with the Enforcement Policy a civil penalty is considered for a Severity Level III violation. However, I have been authorized not to propose a civil penalty in this case because you identified the violation and were forthright in promptly notifying the NRC; you visited the Region III offices to personally discuss the issue with the NRC technical staff. During this visit you also filed the proper reciprocity forms and paid the required fees. Your forthrightness is to be commended.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice of Violation (Notice) when preparing your response. In your response, you should document the specific actions taken and any additional actions you plan to take to prevent recurrence. After reviewing your response to this Notice, including your proposed corrective actions and the results of future inspections, the NRC will determine whether further NRC enforcement action is necessary to ensure compliance with NRC regulatory requirements.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter and its enclosure will be placed in the NRC Public Document Room.

The responses directed by this letter and the enclosed Notice are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, Pub. L. No. 96-511.

Sincerely,

John B. Martin
Regional Administrator

Enclosure:
Notice of Violation

cc w/enclosure:
DCD/DCB(RIDS)
State of Illinois, Department
of Nuclear Safety

NOTICE OF VIOLATION

E.S.C. Resources, Inc.
Naperville, IL

General Licensee
EA 93-189

During an NRC inspection conducted on July 14, 1993, a violation of NRC requirements was identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C, the violation is listed below:

10 CFR 150.20(b)(1) requires that, when engaging in activities in non-Agreement States under the general license granted by 10 CFR 150.20(a), four copies of Form NRC-241 (revised) and four copies of the Agreement State specific license be filed with the Director of the appropriate Nuclear Regulatory Commission Office at least three days prior to engaging in such activity.

Contrary to the above, on five occasions since 1991, the licensee engaged in licensed activities in non-agreement states without filing the required forms.

This is a Severity Level III violation. (Supplement VI)

Pursuant to the provisions of 10 CFR 2.201, E.S.C. Resources, Inc. is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555 with a copy to the Regional Administrator, Region III, within 30 days of the date of the letter transmitting this Notice of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for the violation: (1) the reason for the violation, or, if contested, the basis for disputing the violation, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken to avoid further violations, and (4 the date when full compliance will be achieved. If an adequate reply is not received within the time specified in this Notice, an order or a Demand for Information may be issued to show cause why the license should not be modified, suspended, or revoked, or why such other action as may be proper should not be taken. Where good cause is shown, consideration will be given to extending the response time.

Under the authority of Section 182 of the Act, 42 U.S.C. 2232, this response shall be submitted under oath or affirmation.

Dated at Glen Ellyn, Illinois
this 26 day of July, 1993.

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
799 ROOSEVELT ROAD
GLEN ELLYN, ILLINOIS 60137-5927

August 20, 1993

Docket No. 030-29977
License No. 34-24957-01
EA 93-208

Hull and Associates
ATTN: John H. Hull
President
2726 Monroe Street
Toledo, Ohio 43606

Dear Mr. Hull:

SUBJECT: NOTICE OF VIOLATION
(NRC INSPECTION REPORT NO. 030-29977/93001)

This refers to the special safety inspection conducted on August 3 and 4, 1993, to review the circumstances surrounding damage to a soil moisture/density gauge containing licensed material. The report documenting the inspection was telefaxed and mailed to you by letter, dated August 16, 1993. A significant violation of NRC requirements was identified during the inspection, and on August 19, 1993, an enforcement conference was held by telephone.

By letter, dated July 9, 1993, you informed us that on June 17, 1993, a Campbell Pacific Nuclear (CPN) Model MC-3 soil moisture/density gauge containing licensed materials (sealed sources of nominally 10 millicuries of cesium-137 and 50 millicuries of americium-241) was damaged at a sanitary landfill near Geneva, Ohio. The inspection disclosed that the gauge technician left the device unattended, walking approximately 100 meters away from it, in order to speak with the site foreman. A soil compactor was operating in the area of the gauge at the time, and while the technician and the foreman spoke, the compactor ran over the gauge. Mild damage was sustained to the gauge case, but the radioactive source rod remained intact and in the shielded position.

The violation identified during the inspection is fully described in the enclosed Notice of Violation (Notice) and is considered significant because the technician failed to secure or maintain constant surveillance of the gauge while at a temporary job site. The violation demonstrates a significant failure to control licensed material and is categorized at Severity Level III in accordance with the "Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy) 10 CFR Part 2, Appendix C.

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

The root cause of the violation and the subsequent corrective actions were discussed during the August 19, 1993, telephone enforcement conference. The major factors contributing to the violation were attributed to human error and the technician's failure to understand and implement all aspects of the radiation safety program. The NRC recognizes that corrective actions consisted, but were not limited to, disciplining and retraining the technician involved in the incident and providing a written reminder to the other technicians of their responsibility to maintain constant surveillance or control of NRC licensed materials.

The NRC entrusts responsibility for radiation safety to the management of your organization; therefore, the NRC expects effective management oversight of its licensed programs. Incumbent upon each NRC licensee is the responsibility to protect the public health and safety, including the health and safety of its employees, by assuring that all NRC requirements are met. The violation demonstrates ineffective training and insufficient oversight of your radiation safety program at temporary job sites.

In accordance with the Enforcement Policy a civil penalty is usually assessed with a Severity Level III violation in order to emphasize the need for strict control of access to licensed material. However, after considering the civil penalty adjustment factors set forth in the NRC Enforcement Policy, I have decided that a civil penalty will not be assessed. Full mitigation of the civil penalty was appropriate because of your prompt and comprehensive corrective measures (as described above) and your past good performance.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. In your response, you should document the specific actions taken and any additional actions you plan to prevent recurrence. After reviewing your response to this Notice, including your proposed corrective actions and the results of future inspections, the NRC will determine whether further NRC enforcement action is necessary to ensure compliance with NRC regulatory requirements.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter, its enclosure, and your responses will be placed in the NRC Public Document Room.

The responses directed by this letter and the enclosed Notice are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, Public Law No. 96-511.

Sincerely,

Edward G. Greenman /acting for

John B. Martin
Regional Administrator

Enclosure:
Notice of Violation

cc w.enclosure:
DCD/DCB(RIDS)
State of Ohio

NOTICE OF VIOLATION

Hull and Associates
Toledo, Chio

Docket No. 030-29977
License No. 34-24957-01
EA 93-208

During an NRC inspection conducted on August 3 and 4, 1993, a violation of NRC requirements was identified. In accordance with the "Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C, the violation is listed below:

> 10 CFR 20.207(a) requires that licensed materials stored in an unrestricted area be secured against unauthorized removal from the place of storage. 10 CFR 20.207(b) requires that licensed materials in an unrestricted area and not in storage be tended under constant surveillance and immediate control of the licensee. As defined in 10 CFR 20.3(a)(17), an unrestricted area is any area access to which is not controlled by the licensee for purposes of protection of individuals from exposure to radiation and radioactive materials.
>
> Contrary to the above, on June 17, 1993, licensed material (nominally 10 millicurie cesium-137 and 50 millicurie of americium-241 sealed sources in a Campbell Pacific Nuclear Model MC-3 soil moisture/density gauge) was located at a sanitary landfill near Geneva, Ohio, an unrestricted area, was not secured against unauthorized removal, and was not under constant surveillance and immediate control of the licensee.
>
> This is a Severity Level III violation (Supplement IV).

Pursuant to the provisions of 10 CFR 2.201, Hull and Associates (Licensee) is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555 with a copy to the Regional Administrator, Region III, 799 Roosevelt Road, Glen Ellyn, Illinois 60137, within 30 days of the date of the letter transmitting this Notice of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each violation: (1) the reason for the violation, or, if contested, the basis for disputing the violation, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken to avoid further violations, and (4) the date when full compliance will be achieved. If an adequate reply is not received within the time specified in this Notice, an order or a demand for information may be issued as to why the license should not be modified, suspended, or revoked, or why such other action as may be proper should not be taken. Where good cause is shown,

consideration will be given to extending the response time. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, this response shall be submitted under oath or affirmation.

Dated at Glen Ellyn, Illinois
the 20th day of August 1993

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PENNSYLVANIA 19406-1415

AUG 20 1993

Docket No. 030-29116
License No. 29-02234-03
EA No. 92-256

Mr. James Ferrell, Administrative Director
Diagnostic Imaging
Jersey Shore Medical Center
1945 Route 33
Neptune, New Jersey 07753

Dear Mr. Ferrell:

Subject: NOTICE OF VIOLATION
(NRC Inspection Report No. 030-29116/92-002)

This letter refers to the NRC special inspection conducted on December 21, 1992, at Jersey Shore Medical Center, Neptune, New Jersey, of activities authorized by NRC License No. 29-02234-03. The inspection report was sent to you on January 7, 1993. The inspection was conducted to review the circumstances associated with a therapeutic misadministration of a patient undergoing teletherapy treatment at the facility from October 28, 1992 to November 11, 1992. On January 14, 1993, an enforcement conference was conducted with you and other members of your staff to discuss the apparent violation, its causes and your corrective actions. A copy of the Enforcement Conference Report was sent to you on January 22, 1993.

The misadministration involved a patient for whom the initial prescription was 23 treatments, consisting of a radiation dose of 180 rads per treatment to the chest. As a result of a calculational error by the Teletherapy Physicist (TP), the patient was initially administered a radiation dose of 300 rads per treatment for the first five treatments. The misadministration was identified when, after the fifth treatment, the Radiation Therapy Technician (RTT) treating the patient noticed that the treatment time appeared longer than that expected for the prescribed dose.

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RETURN RECEIPT REQUESTED

The NRC commends the technical inquisitiveness of the RTT who questioned whether the length of time of each treatment was too long, given the required dose, and who promptly requested that the TP perform a recheck of the calculations. Nonetheless, the failure to establish a particular procedure, pursuant to the quality management program (QM program), contributed to the misadministration. Specifically, the QM program in place at your institution did not specify a procedure to verify, prior to initiation of patient treatment, that: (1) the final plans for treatment and related calculations for teletherapy treatments were in accordance with the respective written directive, and (2) that each administration was in accordance with the written directive. Your written QM program stated, "Before administering each teletherapy dose, verify the treatment site and dose per fraction;" however, the procedure did not state who was supposed to complete this task or how it was to be performed. This violation is classified at Severity Level III in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy) 10 CFR Part 2, Appendix C.

The NRC recognizes that subsequent to this event, actions were taken to correct the violations and preclude recurrence. These actions, which were described during the inspection and at the enforcement conference, included, but were not limited to: (1) retraining of the RTTs in the requirements of your QM program; (2) revision to the weekly patient chart check procedures to increase the likelihood of detection of errors prior to the initial treatment; and (3) generation of a memorandum to the staff requiring a verification procedure for TP calculations, and incorporating that requirement as a QM procedure.

Notwithstanding these corrective actions, the NRC considered issuance of a civil penalty in this case to emphasize the importance of proper conduct of licensed activities at the facility, including strict adherence to regulatory requirements, to ensure that such activities are conducted safely and in accordance with the requirements. However, after consideration of the escalation/mitigation factors in this case, the NRC has decided that it is appropriate to mitigate the penalty in its entirety, because of your identification of the violation, and your prior good enforcement history.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. In your response, you should document the specific actions taken and any additional actions you plan to prevent recurrence. After reviewing your response to this Notice, including your proposed corrective actions, and the results of future inspections, the NRC will determine whether further NRC enforcement action is necessary to ensure compliance with NRC regulatory requirements.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter and its enclosure will be placed in the NRC Public Document Room.

AUG 20 1993

The responses directed by this letter and the enclosed Notice are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, Pub. L. 96-511.

Sincerely,

Thomas T. Martin
Regional Administrator

Enclosure: Notice of Violation

cc w/encl:
Public Document Room (PDR)
Nuclear Safety Information Center (NSIC)
State of New Jersey

ENCLOSURE

NOTICE OF VIOLATION

Jersey Shore Medical Center
Neptune, New Jersey 07753

Docket No. 030-29116
License No. 29-02234-03
EA 92-256

During a special NRC inspection conducted on December 21, 1992, a violation of NRC requirements was identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C, the violation is set forth below:

> 10 CFR 35.32(a) states, in part, that each licensee shall establish and maintain a written quality management program to provide high confidence that byproduct material or radiation from byproduct material will be administered as directed by the authorized user. Pursuant to 10 CFR 35.32(a)(3) and (4), the quality management program must, in part, include written policies and procedures to meet specific objectives: that final plans of treatment and related calculations for teletherapy are in accordance with the respective written directives, and each administration is in accordance with the written directive.
>
> Contrary to the above, as of December 21, 1992, the licensee's written quality management program did not include a procedure that required the licensee to verify prior to initiation of the treatment, that: (1) final plans of treatment and related calculations for teletherapy were in accordance with the respective written directives, and (2) each administration was in accordance with the written directive. The licensee's written QM program stated, "Before administering each teletherapy dose, verify the treatment site and dose per fraction;" however, the procedure did not state who was supposed to complete this task or how it was to be performed.
>
> This is a Severity Level III violation (Supplement VI).

Pursuant to the provisions of 10 CFR 2.201, the Jersey Shore Medical Center is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555, with a copy to the Regional Administrator, Region I, within 30 days of the date of the letter transmitting this Notice of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each violation: (1) the reason for the violation, or, if contested, the basis for disputing the violation, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken to avoid further violations, and (4) the date when full compliance will be achieved. If an adequate reply is not received within the time specified in this Notice, an order or a Demand for Information may be issued as to why the license should not be modified, suspended, or revoked, or why such other action as may be proper should not be taken. Where good cause is shown, consideration will be given to extending the response time. Under the authority of Section 182 of the Atomic Energy Act, 42 U.S.C. 2232, this response shall be submitted under oath or affirmation.

Dated at King of Prussia, Pennsylvania
this 31 day of August 1993

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PENNSYLVANIA 19406-1415

August 4, 1993

Docket No. 030-01879
License No. 20-05766-02
EA No. 92-258

Mr. Douglas Harding, Senior
Vice President
Lahey Clinic Foundation
41 Mall Road
Burlington, Massachusetts 01805

Dear Mr. Harding:

Subject: NOTICE OF VIOLATION
(NRC Inspection Report No. 030-01879/92-001)

This letter refers to the NRC special inspection conducted on December 3, 23, and 29, 1992, at Lahey Clinic Foundation, Burlington, Massachusetts, of activities authorized by NRC License No. 20-05766-02. The inspection report was sent to you on January 12, 1993. The inspection was conducted, in part, to review the circumstances associated with a therapeutic misadministration involving a patient undergoing brachytherapy treatment at the facility, as well as a violation of the Quality Management (QM) program requirements that contributed to the misadministration. During the inspection, other violations of NRC requirements were identified. On January 21, 1993, an open enforcement conference was conducted with you and other members of your staff to discuss the apparent violations, their causes and your corrective actions. A copy of the Enforcement Conference Report was sent to you on February 4, 1993.

The misadministration involved a patient who was initially prescribed to receive three treatments to the right main stem bronchus with a High Dose Rate (HDR) remote afterloader. Each treatment was to consist of a radiation dose of 700 rads. The afterloader utilized a 5.7 curie iridium-192 source. The misadministration occurred when, just prior to the second of the three treatments, a physicist involved with the administration of the dose made an error while entering the offset distance, a predetermined input parameter, into the treatment computer. Specifically, the physicist entered 7 millimeters rather than 70 millimeters for the offset distance, which is the distance that the source is "backed out" of the catheter after reaching the end of the catheter. As a result, the source was not backed out of the catheter as far as it should have been, resulting in 90% of the prescribed radiation dose of 700 rads being delivered to an unintended area in the right main stem bronchus.

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RETURN RECEIPT REQUESTED

The misadministration was identified when the physicist reviewed the computer printout documenting the treatment parameters after the administration occurred. In reviewing that document, which automatically "prints out" after the administration is completed, the physicist noticed that the offset distance had been entered incorrectly and he promptly informed the attending physician.

The NRC is concerned that a failure in your QM program, a program intended to provide high confidence that radiation from byproduct material will be administered to the patient in accordance with the written directive from the authorized user, contributed to the misadministration. Specifically, your written QM program did not specify a procedure to ensure that treatment parameters were entered correctly at the console of the HDR unit, including who should complete this task and how it should be performed. This failure constitutes a violation of the QM program requirements and is classified at Severity Level III in accordance with the revised "General Statement of Policy and Procedure for NRC Enforcement Actions" (Enforcement Policy), 10 CFR Part 2, Appendix C.

The NRC recognizes that subsequent to this event, actions were taken to correct the QM violation and preclude recurrence. These actions, which were described during the inspection and at the enforcement conference, included, (1) initiation of a requirement that a second physicist verify the information on the computer screen prior to institution of the treatment to ensure that the parameters have been properly incorporated; (2) establishment of a written procedure to incorporate the above requirement; and (3) prompt training of all authorized users and physicists shortly after the event to preclude a recurrence of this event.

Notwithstanding these corrective actions, the NRC considered issuance of a civil penalty in this case to emphasize the importance of proper conduct of licensed activities at the facility, including strict adherence to regulatory requirements, to ensure that such activities are conducted safely and in accordance with the requirements. However, after consideration of the escalation/mitigation factors in this case, the NRC has decided that it is appropriate to mitigate the penalty in its entirety, because of your identification of the misadministration and contributing violation, your prompt and comprehensive corrective actions, and your prior good enforcement history.

The five other violations identified during the inspection are also described in the enclosed Notice and are classified at either Severity Level IV or V.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice of Violation (Notice) when preparing your response. In your response, you should document the specific actions taken and any additional actions you plan to prevent recurrence. After reviewing your response to this Notice, including your proposed corrective actions, and the results of future inspections, the NRC will determine whether further NRC enforcement action is necessary to ensure compliance with NRC regulatory requirements.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter and its enclosure will be placed in the NRC Public Document Room.

The responses directed by this letter and the enclosed Notice are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, Pub. L. 96-511.

Sincerely,

Thomas T. Martin
Regional Administrator

Enclosure: Notice of Violation

ENCLOSURE

NOTICE OF VIOLATION

Lahey Clinic Foundation
Burlington, Massachusetts 01805

Docket No. 030-01879
License No. 20-05766-02
EA 92-258

During an NRC inspection conducted on December 3, 23, and 29, 1992, violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C, the violations are set forth below:

I. VIOLATIONS ASSOCIATED WITH A MISADMINISTRATION

A. 10 CFR 35.32(a) states, in part, that each licensee shall establish and maintain a written quality management program to provide high confidence that byproduct material or radiation from byproduct material will be administered as directed by the authorized user. Pursuant to 10 CFR 35.32(a)(4), the quality management program must, in part, include written policies and procedures to meet the specific objective: that each administration is in accordance with the written directive.

Contrary to the above, as of October 14, 1992, the licensee's written quality management program (QM program) did not include a procedure which required the licensee to verify that each administration of radiation from byproduct material used in a High Dose Rate (HDR) remote afterloader brachytherapy unit was in accordance with the written directive. Specifically, the licensee's written QM program did not include a procedure to ensure that treatment parameters were entered correctly at the console of the HDR unit, or who should complete this task and how it should be performed.

This is a Severity Level III violation (Supplement VI).

B. 10 CFR 35.33(a)(1) requires that a licensee notify by telephone the NRC Operations Center no later than the next calendar day after discovery of the misadministration.

Contrary to the above, on October 14, 1992, the licensee discovered that a therapeutic misadministration occurred at the facility involving a patient who received an underdose to the right main bronchus stem, as well as a dose to unintended areas of that location, and the NRC Operations Center was not notified until October 19, 1992, rather than by October 15, 1992.

This is a Severity Level IV violation (Supplement VI).

II. OTHER VIOLATIONS OF NRC REQUIREMENTS

A. 10 CFR 19.12 requires, in part, that all individuals working in or frequenting any portion of a restricted area be instructed in health protection problems associated with exposure to radioactive materials or radiation, and in precautions or procedures to minimize exposure.

Contrary to the above, some individuals working in a portion of a restricted area were not instructed in health protection problems associated with exposure to radioactive materials or radiation, and in precautions or procedures to minimize exposure. Specifically, on September 3, 1992, a code team was sent to a brachytherapy patient's room, a restricted area, to revive the patient, and some members of the team had not been provided radiation safety training as of that date.

This is a Severity Level IV violation (Supplement VI).

B. 10 CFR 35.50(c) requires, in part, that a licensee perform appropriate checks for geometry dependence required by 10 CFR 35.50(b) following repair of the dose calibrator.

Contrary to the above, the dose calibrator was put back in use to measure radiopharmaceutical doses, on September 15, 1992, following repairs, and as of December 3, 1992, the licensee did not perform a test for geometry dependence.

This is a Severity Level IV violation (Supplement VI).

C. 10 CFR 35.70(a) requires that a licensee survey with a radiation detection survey instrument at the end of each day of use all areas where radiopharmaceuticals are routinely prepared for use or administered.

Contrary to the above, on September 12, 1992, the licensee did not survey with a radiation detection instrument at the end of the day certain areas where radiopharmaceuticals were routinely prepared for use or administered (namely, the hot lab, injection area, and scanning room).

This is a Severity Level IV violation (Supplement VI).

D. 10 CFR 20.102(a) requires, in part, that each licensee require any individual, prior to the first entry of the individual into the licensee's restricted area during each employment or work assignment under such circumstances that the individual will receive or is likely to receive in any period of one calendar quarter an occupational dose in excess of 25 percent of the applicable standards specified in 10 CFR 20.101(a) and 10 CFR 104(a), to disclose in a written signed statement, either: (1) that the individual had no prior occupational dose during the current calendar quarter, or (2) the nature and amount of any occupational dose which the individual may have received during that specifically identified calendar quarter.

Contrary to the above, as of December 3, 1992, the licensee did not require an individual prior to first entry into the restricted area during each employment or work assignment under such circumstances that the individual would receive or would be likely to receive in any period of one calendar quarter an occupational dose in excess of 25 percent of the applicable standards specified in 10 CFR 20.101(a) and 10 CFR 20.104(a), to disclose in a written signed statement, either: (1) that the individual had no prior occupational dose during the current calendar quarter, or (2) the nature and amount of any occupational dose which the individual may have received during that identified calendar quarter. Specifically, a nuclear medicine technologist was employed in 1991, but the licensee did not require the technologist to disclose her dose history in a written signed statement for the calendar quarter during which this individual was initially employed by the licensee and required to work in a restricted area.

This is a Severity Level V violation (Supplement IV).

Pursuant to the provisions of 10 CFR 2.201, the Lahey Clinic Foundation is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555, with a copy to the Regional Administrator, Region I, within 30 days of the date of the letter transmitting this Notice of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each violation: (1) the reason for the violation, or, if contested, the basis for disputing the violation, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken to avoid further violations, and (4) the date when full compliance will be achieved. If an adequate reply is not received within the time specified in this Notice, an order or a Demand for Information may be issued as to why the license should not be modified, suspended, or revoked, or why such other action as may be proper should not be taken. Where good cause is shown, consideration will be given to extending the response time. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, this response shall be submitted under oath or affirmation.

Dated at King of Prussia, Pennsylvania
this 4th day of August 1993

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PENNSYLVANIA 19406-1415

August 27, 1993

Docket No. 030-17246
License No. 29-19269-01
EA No. 93-196

Mr. David Antes, Vice President,
Geotechnical Department
Paulus, Sokolowski and Sartor, Inc.
67A Mountain Boulevard Extension
Warren, New Jersey 07060

Dear Mr. Antes:

SUBJECT: NOTICE OF VIOLATION (NRC Inspection Report No. 030-17246/93-001)

This letter refers to the routine NRC safety inspection conducted on July 21 and 22, 1993, at the above mentioned facility in Warren, New Jersey and your job site in Jersey City, New Jersey, of activities authorized by the above NRC License, authorizing you to possess and use four nuclear gauges. During the inspection, NRC reviewed the circumstances associated with the loss, from your job site, of a nuclear gauge containing approximately 10 millicuries of cesium-137 and 50 millicuries of americium-241. The loss of this gauge was identified by your staff and reported to the NRC on July 15, 1993. The inspection report was provided to you on August 6, 1993. On August 11, 1993, an enforcement conference was conducted, by telephone with you and other members of your staff to discuss the loss, the related violation, its causes and your corrective actions. A report on this enforcement conference is enclosed (enclosure 2).

The nuclear gauge was lost on July 15, 1993, when a technician left the gauge, which was out of its storage box, unattended at the job site during an afternoon break to talk to the construction manager at a trailer. When he returned, after approximately 15 minutes, the gauge was gone. You indicated that even considering the fenced-in nature of the job site with only one open gate, the technician erred in concluding that the gauge was secure.

The NRC recognizes that you immediately notified the NRC and initiated actions to locate the gauge, once you recognized that the gauge was missing. The State of New Jersey and the local police were notified, and you offered a reward and distributed fliers. Further, although you are maintaining close contact with the local authorities, your efforts have not yet been successful in locating the gauge.

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Notwithstanding your efforts to locate the gauge, the NRC is concerned with the lack of proper security and attention to the gauge that contributed to its loss. Although, the potential for radiation exposure to the general public is small as long as the radioactive source in the gauge is in its shielded container and the handle is locked, any tampering of the source could result in substantial exposure to the general public and radioactive contamination could occur if the source is broken. The failure to maintain control of licensed material constitutes a violation of NRC requirements and is described in the enclosed Notice. This violation is categorized at Severity Level III in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy) 10 CFR Part 2, Appendix C.

The NRC further recognizes that subsequent to the event, prompt and extensive actions were initiated to prevent recurrence. These actions, which were described during the inspection and also at the enforcement conference, included: (1) reinstructing all gauge users in the proper methods for securing and maintaining proper surveillance of the gauge; (2) reinforcing the policy of maintaining control over the gauges; and (3) revising the management policy to require disciplinary action upon recurrence of the event.

Normally, a civil penalty is issued for such a violation in order to emphasize the importance of implementing long-lasting corrective actions to ensure that: (1) licensed activities are conducted safely and in accordance with requirements; and (2) licensed materials are properly controlled to prevent their loss, disposal, or transfer to a person not holding a specific license. However, after consideration of the escalating and mitigating factors in this case, I have been authorized to issue the enclosed Notice of Violation without a civil penalty.

The base civil penalty for such a violation of your license is $500. As you were given adequate prior notice in several NRC Information Notices (IN) regarding the need for maintaining control over nuclear gauges (e.g., IN 93-18, Portable Moisture-Density Gauge User Responsibilities During Field Operation, dated March 10, 1993; and IN 88-02, Lost or Stolen Gauges, dated February 2, 1988), a consideration of this factor resulted in 50% escalation of the base civil penalty. (Full 100% escalation on this factor was not applied because you stated that a system, albeit informal, had been established by the RSO to review and distribute the applicable notifications, and IN 93-18 was appropriately reviewed by the RSO and was distributed to the gauge handlers. In addition, the NRC inspector's interview of the technician involved in the event also indicated that he was aware of the importance of maintaining continuous control over the gauge thus indicating familiarity with the subject of these Notices; however, he made an error in judgement when he left the gauge unattended for a short duration.) In view of your identification of this self-disclosing violation, your prompt and comprehensive corrective actions, as well as your past good enforcement history, the base penalty was also mitigated by 175%. No further adjustment resulted from the other escalation and mitigation factors. Therefore, after consideration of all the escalation and mitigation factors a basis exists, on balance, to mitigate the penalty in its entirety. The NRC emphasizes, however, that any similar violations in the future may result in escalated enforcement action.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice of Violation when preparing your response. In your response, you should document the specific actions taken and any additional actions you plan to prevent recurrence. After reviewing your response to this Notice, including your proposed corrective actions, and the results of future inspections, the NRC will determine whether further NRC enforcement action is necessary to ensure compliance with NRC regulatory requirements.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter and its enclosures will be placed in the NRC Public Document Room.

The responses directed by this letter and Enclosure 2 are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, Pub. L. 96-511.

Sincerely,

Thomas T. Martin
Regional Administrator

Enclosures:
1. Notice of Violation
2. Enforcement Conference Summary Report

ENCLOSURE 1

NOTICE OF VIOLATION

Paulus, Sokolowski and Sartor, Inc.
Warren, New Jersey 07060

Docket No. 030-17246
License No. 29-19269-01
EA No. 93-196

During an NRC inspection conducted on July 21 and 22, 1993, a violation of NRC requirements was identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C, the violation is listed below:

> 10 CFR 20.207(a) requires that licensed materials stored in an unrestricted area be secured against unauthorized removal from the place of storage. 10 CFR 20.207(b) requires that licensed materials in an unrestricted area and not in storage be tended under constant surveillance and immediate control of the licensee. As defined in 10 CFR 20.3(a)(17), an unrestricted area is any area access to which is not controlled by the licensee for purposes of protection of individuals from exposure to radiation and radioactive materials.
>
> Contrary to the above, on July 15, 1993, a nuclear gauge containing licensed material (consisting of approximately 10 millicuries of cesium-137 and 50 millicuries of americium-241), located at a job site in Jersey City, New Jersey, an unrestricted area, was not secured against unauthorized removal, and was not under constant surveillance and immediate control of the licensee.
>
> This is a Severity Level III violation (Supplement IV).

Pursuant to the provisions of 10 CFR 2.201, Paulus, Sokolowski & Sartor, Inc. is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555, with a copy to the Regional Administrator, Region I, within 30 days of the date of the letter transmitting this Notice of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each violation: (1) the reason for the violation, or, if contested, the basis for disputing the violation, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken to avoid further violations, and (4) the date when full compliance will be achieved. If an adequate reply is not received within the time specified in this Notice, an order or a Demand for Information may be issued as to why the license should not be modified, suspended, or revoked, or why such other action as may be proper should not be taken. Where good cause is shown, consideration will be given to extending the response time. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, this response shall be submitted under oath or affirmation.

Dated at King of Prussia, Pennsylvania
this 27th day of August 1993

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
799 ROOSEVELT ROAD
GLEN ELLYN, ILLINOIS 60137-5927

August 23, 1993

General Licensee
[10 CFR 150.20]
EA 93-211

Radiation Protection Services, Ltd.
ATTN: Mr. Ronald Edwards
Radiation Physicist
1604 Mirror Lake Drive
Naperville, IL 60563

Dear Mr. Edwards

SUBJECT: NOTICE OF VIOLATION

This refers to our review of your licensed activities in non-Agreement States as authorized by 10 CFR 150.20. In April 1993 you became aware that before conducting such licensed activities you must first request reciprocity from the NRC. You then submitted the request with the appropriate fee. Based on this request, the NRC became aware that you had previously conducted licensed activities in non-Agreement States without filing the proper forms with the NRC prior to conducting the activities. When requested to do so, you also submitted letters on June 14, 1993, and July 30, 1993, with additional information on these activities. On August 18, 1993, you were offered the opportunity for an enforcement conference but declined.

Based on the information which you provided to us the NRC learned that Radiation Protection Services, Ltd., an Agreement State licensee with the State of Illinois, had performed licensed activities in non-Agreement States on at least 20 occasions between 1992 and 1993 and had not complied with the reciprocity requirements of 10 CFR 150.20. Specifically, you failed to provide proper notification to the NRC of these activities via NRC Form 241. The activities normally consisted of a combination of calibrating dose calibrators and conducting leak tests. The violation of 10 CFR 150.20 is described in the enclosed Notice of Violation and is categorized at Severity Level III in accordance with the "Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy) 10 CFR Part 2, Appendix C.

The root cause of the violation and the subsequent corrective actions were discussed with you during several telephone conversations. The major factor contributing to the violation appeared to be your misunderstanding or lack of knowledge of the conditions of your State of Illinois specific license pertaining to temporary job sites and the reciprocity process. The NRC

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RETURN RECEIPT REQUESTED

recognizes that you immediately corrected the violation and that you plan to inform us of regularly scheduled visits to NRC non-Agreement States and also update us of your schedule changes.

The NRC relies on Agreement State licensees to notify us whenever licensed activities are performed in non-Agreement States. It is incumbent on such licensees to be aware of these reporting requirements and to be responsible for making the reports. Failure to report is a serious matter because it denies the NRC the opportunity to inspect licensed activities while the work is being done and thereby removes the NRC's ability to perform its function of verifying that licensed activities are performed in a safe manner. Therefore, to emphasize the need of the importance to adhere to regulatory requirements, I am issuing the enclosed Notice of Violation for this Severity Level III violation.

In accordance with the Enforcement Policy a civil penalty is considered for a Severity Level III violation. However, I have been authorized not to propose a civil penalty in this case because you identified the violation and were forthright in promptly notifying the NRC. You also promptly corrected the problem.
You are required to respond to this letter and should follow the instructions specified in the enclosed Notice of Violation (Notice) when preparing your response. In your response, you should document the specific actions taken and any additional actions you plan to take to prevent recurrence. After reviewing your response to this Notice, including your proposed corrective actions and the results of future inspections, the NRC will determine whether further NRC enforcement action is necessary to ensure compliance with NRC regulatory requirements.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter and its enclosure will be placed in the NRC Public Document Room.

The responses directed by this letter and the enclosed Notice are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, Pub. L. No. 96-511.

Sincerely,

John B. Martin
Regional Administrator

Enclosure: Notice of Violation

cc w/enclosure:
DCD/DCB(RIDS)
State of Illinois, Department
of Nuclear Safety

NOTICE OF VIOLATION

Radiation Protection Services, Ltd.
Naperville, IL

General Licensee
EA 93-211

During an NRC evaluation conducted on August 11, 1993, a violation of NRC requirements was identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C, the violation is listed below:

10 CFR 150.20(b)(1) requires that, when engaging in activities in non-Agreement States under the general license granted by 10 CFR 150.20(a), four copies of Form NRC-241 (revised) and four copies of the Agreement State specific license be filed with the Director of the appropriate Nuclear Regulatory Commission Office at least three days prior to engaging in such activity.

Contrary to the above, on at least 20 occasions since 1992, the licensee engaged in licensed activities in non-agreement states without filing the required forms.

This is a Severity Level III violation. (Supplement VI)

Pursuant to the provisions of 10 CFR 2.201, Radiation Protection Services, Ltd., is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555 with a copy to the Regional Administrator, Region III, within 30 days of the date of the letter transmitting this Notice of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for the violation: (1) the reason for the violation, or, if contested, the basis for disputing the violation, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken to avoid further violations, and (4) the date when full compliance will be achieved. If an adequate reply is not received within the time specified in this Notice, an order or a Demand for Information may be issued to show cause why the license should not be modified, suspended, or revoked, or why such other action as may be proper should not be taken. Where good cause is shown, consideration will be given to extending the response time.

Under the authority of Section 182 of the Act, 42 U.S.C. 2232, this response shall be submitted under oath or affirmation.

Dated at Glen Ellyn, Illinois
this 23rd day of August, 1993.

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION IV
611 RYAN PLAZA DRIVE, SUITE 400
ARLINGTON, TEXAS 76011-8064

JUL - 9 1993

Docket No. 030-03235
License No. 40-01683-01
EA 93-081

Sacred Heart Hospital
ATTN: Dennis Sokol, President
501 Summit
Yankton, South Dakota 57078-9967

SUBJECT: NOTICE OF VIOLATION (NRC INSPECTION REPORT NO. 30-03235/93-01)

This refers to the inspection conducted on April 1, 1993, at the Sacred Heart Hospital, Yankton, South Dakota. A report describing the results of this inspection was issued on May 12, 1993. On May 24, 1993, you and other hospital representatives participated in a telephonic enforcement conference with the NRC to discuss the hospital's failure to establish and maintain a Quality Management Program as required by 10 CFR 35.32. A list of the participants in that enforcement conference is enclosed (Enclosure 2).

The NRC determined prior to the inspection that Sacred Heart Hospital had not developed and submitted a Quality Management Program (QMP). A Confirmatory Action Letter was issued to you on March 12, 1993, to document your commitment to ensure immediate compliance with 10 CFR 35.32 and to develop and submit to the NRC a written QMP within 30 days. You submitted a written QMP by letter dated April 9, 1993.

As discussed during the enforcement conference, 10 CFR Part 35 was revised, effective January 27, 1992, to require NRC medical licensees to establish and maintain written QMPs to provide high confidence that byproduct material or radiation from byproduct material would be administered as directed by an authorized user. The regulation requires QMPs to include written policies and procedures to meet specific objectives for administrations of sodium iodide I-131 in quantities greater than 30 microcuries and any therapeutic administration of other radiopharmaceuticals.

The NRC's inspection confirmed that Sacred Heart Hospital had not established and maintained a written QMP as required by the rule. The inspection determined that responsible nuclear medicine personnel had conducted licensed activities requiring a written QMP, but that these individuals were not aware of the QMP requirement. Specifically, Sacred Heart Hospital had administered radiopharmaceuticals covered by this new regulation (iodine-131 and phosphorous-32) on nine occasions between January 27, 1992 and the date of the inspection without first developing and implementing written policies and procedures to address the specific objectives and requirements of the rule.

The rule requires, in part, that a written directive be prepared prior to the administration to patients of sodium iodide I-131 in quantities greater than 30 microcuries and prior to any therapeutic administration of other

radiopharmaceuticals. The inspection determined that Sacred Heart Hospital's use of written prescriptions before patient administrations of sodium iodide I-131 met the intent of the objective and definition of a written directive. However, on September 11, 1992, a written directive was not prepared prior to the patient administration of 5 millicuries of sodium iodide I-131 for a whole body scan.

In addition to not having procedures in place governing the use of written directives, Sacred Heart Hospital failed to have procedures in place to meet other important objectives of the rule, such as: the verification of patient identity by more than one method; ensuring administrations are in accordance with written directives; the identification of unintended deviations from written directives; and the conduct of periodic reviews to determine the effectiveness of the program, including a review of recordable events and misadministrations. A substantial failure to establish and maintain a QMP is of significant concern to the NRC. Therefore, in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy) 10 CFR Part 2, Appendix C, the violation in the enclosed Notice of Violation (Notice) is categorized at Severity Level III.

The NRC acknowledges that you took prompt action to restore compliance following the identification of this problem by the NRC in early March. You submitted a QMP to the NRC by letter dated April 9, 199.. In addition, you stated during the enforcement conference that you will assure greater awareness of NRC requirements by subjecting NRC correspondence to radiation safety committee review. The NRC also acknowledges that this violation does not appear to have resulted in any misadministration of radiopharmaceuticals to patients.

In accordance with the Enforcement Policy, 10 CFR Part 2, Appendix C, a civil penalty is considered for a Severity Level III violation. However, I have been authorized not to propose a civil penalty in this case. The civil penalty adjustment factors in the Enforcement Policy were considered and resulted in full mitigation of the base civil penalty of $2,500. In making this determination, the base civil penalty was escalated 50% because the violation was identified by the NRC, mitigated 50% for your prompt corrective action, and mitigated 100% as a result of your most recent good inspection history. The remaining adjustment factors were considered and no further adjustment was considered appropriate.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. In your response, you should document the specific actions taken and any additional actions you plan to prevent recurrence. In addition, the NRC specifically requests that you include in your response a description of the actions taken to ensure that responsible individuals receive instruction in the policies and procedures of your written QMP. After reviewing your response to this Notice, including your proposed corrective actions, and the results of future inspections, the NRC will determine whether further NRC enforcement action is necessary to ensure compliance with NRC regulatory requirements.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter and its enclosures will be placed in the NRC Public Document Room.

The responses directed by this letter and the enclosed Notice are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, Pub. L. No. 96-511.

Sincerely,

James L. Milhoan

James L. Milhoan
Regional Administrator

Enclosures:
1) Notice of Violation
2) List of enforcement conference participants

cc w/Enclosures: State of South Dakota

NOTICE OF VIOLATION

Sacred Heart Hospital
Yankton, South Dakota

Docket No. 030-03235
License No. 40-01683-01
EA 93-081

During an NRC inspection conducted on April 1, 1993, a violation of NRC requirements was identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C, the violation is listed below:

> 10 CFR 35.32(a) states, in part, that each licensee under this part, as applicable, shall establish and maintain a written quality management program to provide high confidence that byproduct material or radiation from byproduct material will be administered as directed by the authorized user. The quality management program must include written policies and procedures to meet specific objectives, including the objective that a written directive is prepared prior to the administration to patients of sodium iodide I-131 in quantities greater than 30 microcuries and for any therapeutic administration of a radiopharmaceutical other than sodium iodide I-131.
>
> Contrary to the above, on several occasions between January 27, 1992, and the date of the inspection, the licensee administered radiopharmaceuticals (I-131 and P-32) requiring a written quality management program and the licensee had not established and maintained a written quality management program and had not developed written policies and procedures to meet the specific objectives described in 10 CFR 35.32. In addition, the licensee administered sodium iodide I-131 to a patient on September 11, 1992, in a quantity greater than 30 microcuries and did not prepare a written directive prior to the administration.
>
> This is a Severity Level III violation (Supplement VI).

Pursuant to the provisions of 10 CFR 2.201, Sacred Heart Hospital is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555, with a copy to the Regional Administrator, Region IV, 611 Ryan Plaza Drive, Suite 400, Arlington, Texas 76011, within 30 days of the date of the letter transmitting this Notice of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each violation: (1) the reason for the violation, or, if contested, the basis for disputing the violation, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken to avoid further violations, and (4) the date when full compliance will be achieved.

If an adequate reply is not received within the time specified in this Notice, an order or a Demand for Information may be issued to show cause why the license should not be modified, suspended, or revoked, or why such other action as may be proper should not be taken. Where good cause is shown, consideration will be given to extending the response time. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, this response shall be submitted under oath or affirmation.

Dated at Arlington, Texas
this 9th day of July 1993

Enforcement Conference Participants

May 24, 1993 Enforcement Conference*

NRC Region IV representatives

L. Joseph Callan, Director, Division of Radiation Safety and Safeguards
Chuck Cain, Chief, Nuclear Materials Inspection Section, DRSS
Robert Brown, Senior Radiation Specialist, DRSS
Gary Sanborn, Regional Enforcement Officer

Sacred Heart Hospital representatives

Dennis Sokol, Chief Executive Officer
Jean Hunoff, Vice President
Kevin Pistulka, Director, Department of Radiology
Robert Ellingson, Nuclear Medicine Specialist

*Conference conducted telephonically

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PENNSYLVANIA 19406-1415

September 1, 1993

Docket No. 030-14993
License No. 29-16796-02
EA 93-018

Francis Gingerelli, M.D.
Sharlin Radiological Associates
35 Pangborn Place
Hackensack, New Jersey 07601

Dear Dr. Gingerelli:

Subject: NOTICE OF VIOLATION
(NRC Inspection No. 030-14993/93-001)

This letter refers to the NRC special inspection conducted on January 21, 1993, at Sharlin Radiological Associates, Hackensack, New Jersey, of activities authorized by NRC License No. 29-16796-02. The enclosed inspection report documents the inspection.

The inspection was conducted to review the circumstances associated with a therapeutic misadministration of a patient undergoing cobalt-60 teletherapy treatment at your facility in November 1992. The misadministration involved a patient who was to receive a single dose of 700 rads to the hip during a cobalt-60 teletherapy treatment. Instead of receiving the physician's prescribed dose, the patient received 572 rads, a difference of 18% of the prescribed dose.

The misadministration occurred because a technologist incorrectly entered a treatment depth of 7 cm rather than the correct depth of 10 cm into the computer used to calculate treatment time. Apparently, one of the technologists had, from a distance, verbally instructed a second technologist to enter the proper depth at the computer console used for treatment planning, but that amount was not properly entered into the computer by the second technologist. As a result, the treatment time was calculated incorrectly. There was no verification by either technologist of the treatment parameters entered into the computer prior to initiation of the treatment. Additionally, the treatment depth was not entered on the written directive before the authorized user physician signed the written directive. By definition (10 CFR 35.2), the written directive for teletherapy must include the treatment site. Treatment depth is one of the parameters that define the treatment site. The misadministration was identified by a physicist within an hour of the occurrence when he performed a routine check of the patient's chart.

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

A failure to adhere to the requirements for establishing and maintaining a written quality management program (QM program) contributed to this misadministration in that the program did not specify a procedure to verify that final plans of treatment and related calculations for standard, fixed modality teletherapy treatment were in accordance with the written directive. The failure to review or verify the treatment time calculations or the treatment parameters as they were entered into the computer prior to the treatment, and the failure to include the treatment depth on the written directive both contributed to the error not being identified and the misadministration occurring. These violations are classified in the aggregate as a Severity Level III problem in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy) 10 CFR Part 2, Appendix C.

The NRC recognizes that subsequent to this event, actions were taken to correct the violation and preclude recurrence. These actions, which were discussed during the inspection, included, but were not limited to: (1) institution of a requirement that for all treatments consisting of a single fraction, the treatment time calculations will be verified by the technologist who measured the patient and that all calculations and treatment parameters be checked by the physicist before treatment is given; and (2) prompt performance of the annual review of your QM Program by you, your physicist, and your entire technical staff, including a review of this misadministration and your corrective actions.

Notwithstanding these corrective actions, the NRC considered issuance of a civil penalty in this case to emphasize the importance of proper conduct of licensed activities at the facility, including strict adherence to regulatory requirements, to ensure that such activities are conducted safely and in accordance with the requirements. However, after consideration of the escalation/mitigation factors in this case, the NRC has decided that it is appropriate to mitigate the penalty in its entirety because of your identification of the violation, your prompt and comprehensive corrective actions, and your prior good enforcement history.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. In your response, you should document the specific actions taken and any additional actions you plan to prevent recurrence. After reviewing your response to this Notice, including your proposed corrective actions, and the results of future inspections, the NRC will determine whether further NRC enforcement action is necessary to ensure compliance with NRC regulatory requirements.

In addition, in your response to this Notice, please confirm that the patient who was the subject of the misadministration has been notified in writing as required by 10 CFR 35.33(a)(4).

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter and its enclosure will be placed in the NRC Public Document Room.

The responses directed by this letter and the enclosed Notice are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, Pub. L. 96-511.

Sincerely,

Thomas T. Martin
Regional Administrator

Enclosures:
1. Notice of Violation
2. Inspection Report

cc w/encls:
Public Document Room (PDR)
Nuclear Safety Information Center (NSIC)
State of New Jersey

ENCLOSURE 1

NOTICE OF VIOLATION

Sharlin Radiological Associates
Hackensack, New Jersey

Docket No. 030-14993
License No. 29-16796-02
EA 93-018

During a special NRC inspection conducted on January 21, 1993, violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C, the violations are set forth below:

10 CFR 35.32(a) states, in part, that each licensee shall establish and maintain a written quality management program to provide high confidence that byproduct material or radiation from byproduct material will be administered as directed by the authorized user. Pursuant to 10 CFR 35.32(a)(1) and (3), the quality management program must include written policies and procedures to meet the specific objectives that: (1) prior to administration, a written directive is prepared for any teletherapy radiation dose, and (2) final plans of treatment and related calculations for teletherapy are in accordance with the written directive.

10 CFR 35.2 defines a written directive as an order in writing for a specific patient, dated and signed by an authorized user prior to the administration of radiation and containing, for teletherapy, the following information: the total dose, dose per fraction, treatment site, and overall treatment period.

Contrary to the above:

A. As of November 13, 1992, the licensee's written quality management program (QM program) did not specify a procedure to verify that final plans of treatment and related calculations for standard, fixed modality teletherapy treatment were in accordance with the written directive. Specifically, the licensee's written QM program did not specify a procedure to verify teletherapy treatment time calculations, including the treatment parameters that are entered into the computer used to calculate the teletherapy treatment time, and designating who should complete this task and how it should be performed.

B. On November 13, 1992, a written directive prepared for a standard, fixed modality teletherapy treatment did not include the depth of treatment (i.e., treatment site) prior to the administration of the treatment.

This is a Severity Level III problem (Supplement VI).

Pursuant to the provisions of 10 CFR 2.201, the Sharlin Radiological Associates is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555, with a copy to the Regional Administrator, Region I, within 30 days of the date of the letter transmitting this Notice of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each violation: (1) the reason for the violation, or, if contested, the basis for disputing the violation, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken to avoid further violations, and (4) the date when full compliance will be achieved.

If an adequate reply is not received within the time specified in this Notice, an order or a Demand for Information may be issued to show cause why the license should not be modified, suspended, or revoked, or why such other action as may be proper should not be taken. Where good cause is shown, consideration will be given to extending the response time. Under the authority of Section 182 of the Atomic Energy Act, 42 U.S.C. 2232, this response shall be submitted under oath or affirmation.

Dated at King of Prussia, Pennsylvania
this 22nd day of September 1993

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
799 ROOSEVELT ROAD
GLEN ELLYN, ILLINOIS 60137-5927

September 22, 1993

Docket No. 030-31333
License No. 21-26066-01
EA 93-221

Soil Engineers & Scientists, Inc.
ATTN: Mr. Timothy Hennessey
President
19366 Allen Road
Trenton, MI 48183

Dear Mr. Hennessey:

SUBJECT: NOTICE OF VIOLATION
(NRC INSPECTION REPORT NO. 030-31333/93001)

This refers to the special safety inspection conducted on August 18, 1993, to review the circumstances surrounding damage to a soil moisture/density gauge containing licensed material. The report documenting the inspection was telefaxed and mailed to you by letter dated September 3, 1993. A significant violation of NRC requirements was identified during the inspection, and on September 15, 1993, an enforcement conference was held by telephone.

You informed us on July 16, 1993, that a Troxler Model 3430 soil moisture/density gauge containing licensed materials (sealed sources of nominally 10 millicuries of cesium-137 and 50 millicuries of americium-241) was damaged at a temporary jobsite near Woodhaven, Michigan. The inspection disclosed that the gauge technician left the device on the ground unattended and walked approximately 15 feet away from it to his truck to prepare some paperwork for upcoming tests. While he was doing this, a foreman from another construction company stopped to talk to him. When the foreman drove away he hit the gauge, causing damage to the case but no damage to the source or the source rod.

The violation identified during the inspection is described in the enclosed Notice of Violation (Notice) and is considered significant because the technician failed to secure or maintain constant surveillance of the gauge while at a temporary job site. The violation demonstrates a significant failure to control licensed material and is categorized at Severity Level III in accordance with the "Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy) 10 CFR Part 2, Appendix C.

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

The root cause of the violation and the subsequent corrective actions were discussed during the September 15, 1993, telephone enforcement conference. The major cause of the violation was poor judgement by the technician regarding the requirement to keep licensed material under constant surveillance and immediate control. The NRC recognizes that immediate corrective actions were taken including terminating the technician involved in the incident and providing a written reminder to the other technicians of their responsibility to maintain constant surveillance and control of NRC licensed materials. You also conducted a special meeting with all gauge users to discuss the incident and the operating procedures. You also improved and formalized the already existing audit program which now includes a monthly, unannounced audit of each gauge user by the Radiation Safety Officer.

The NRC entrusts responsibility for radiation safety to the managers of your organization; therefore, the NRC expects effective management oversight of its licensed programs. Incumbent upon each NRC licensee is the responsibility to protect the public health and safety, including the health and safety of its employees, by assuring that all NRC requirements are met. The violation demonstrates ineffective training and insufficient oversight of your radiation safety program at temporary job sites.

In accordance with the Enforcement Policy a civil penalty is usually assessed with a Severity Level III violation in order to emphasize the need for strict control of access to licensed material. However, after considering the civil penalty adjustment factors set forth in the NRC Enforcement Policy, I have decided that a civil penalty will not be assessed. Full mitigation of the civil penalty was appropriate because of your prompt and comprehensive corrective measures (as described above) and your past good performance.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. In your response, you should document the specific actions taken and any additional actions you plan to prevent recurrence. After reviewing your response to this Notice, including your proposed corrective actions and the results of future inspections, the NRC will determine whether further NRC enforcement action is necessary to ensure compliance with NRC regulatory requirements.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter, its enclosure, and your responses will be placed in the NRC Public Document Room.

The responses directed by this letter and the enclosed Notice are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, Public Law No. 96-511.

Sincerely,

John F. Martin
Regional Administrator

Enclosure:
Notice of Violation

cc w.enclosure:
DCD/DCB(RIDS)
State of Michigan

NOTICE OF VIOLATION

Soil Engineers & Scientists, Inc.
Trenton, MI

Docket No. 030-31333
License No. 21-26066-01
EA 93-221

During an NRC inspection conducted on August 18, 1993, a violation of NRC requirements was identified. In accordance with the "Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C, the violation is listed below:

> 10 CFR 20.207(a) requires that licensed materials stored in an unrestricted area be secured against unauthorized removal from the place of storage. 10 CFR 20.207(b) requires that licensed materials in an unrestricted area and not in storage be tended under constant surveillance and immediate control of the licensee. As defined in 10 CFR 20.3(a)(17), an unrestricted area is any area access to which is not controlled by the licensee for purposes of protection of individuals from exposure to radiation and radioactive materials.
>
> Contrary to the above, on July 16, 1993, licensed material (nominally 10 millicurie cesium-137 and 50 millicurie of americium-241 sealed sources in a Troxler Model 3430 soil moisture/density gauge) was located at a temporary job site (an unrestricted area) near Trenton, Michigan, was not secured against unauthorized removal, and was not under constant surveillance and immediate control of the licensee.
>
> This is a Severity Level III violation (Supplement IV).

Pursuant to the provisions of 10 CFR 2.201, Soil Engineers & Scientists, Inc. (Licensee) is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555 with a copy to the Regional Administrator, Region III, 799 Roosevelt Road, Glen Ellyn, Illinois 60137, within 30 days of the date of the letter transmitting this Notice of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each violation: (1) the reason for the violation, or, if contested, the basis for disputing the violation, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken to avoid further violations, and (4) the date when full compliance will be achieved. If an adequate reply is not received within the time specified in this Notice, an order or a demand for information may be issued as to why the license should not be modified, suspended, or revoked, or why such other action as may be proper should not be taken. Where good cause is shown,

consideration will be given to extending the response time. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, this response shall be submitted under oath or affirmation.

Dated at Glen Ellyn, Illinois
this 22nd day of September 1993

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
799 ROOSEVELT ROAD
GLEN ELLYN, ILLINOIS 60137-5927

July 28, 1993

Docket No. 030-19555
License No. 13-17793-02
EA 93-132

St. John's Medical Center
ATTN: James Moore, Vice President
Clinical Services
2015 Jackson Street
Anderson, IN 46014

Dear Mr. Moore:

SUBJECT: NOTICE OF VIOLATION
(NRC INSPECTION REPORT NO. 030-19555/92001(DRSS))

This refers to the inspection conducted on November 24, 1992, at St. John's Medical Center. The inspection included a review of the circumstances surrounding a teletherapy misadministration which your staff identified on November 12, 1992. You reported the event to the NRC Operations Center on November 13, 1993. Subsequently, you submitted a written report dated November 20, 1992. The report documenting this inspection was sent to you by letter dated December 24, 1992. During this inspection a violation of NRC requirements was identified.

An enforcement conference was held on June 4, 1993, to discuss the violation, its causes, and your corrective actions. The report documenting this conference was sent to you by letter dated June 15, 1993.

On November 6, 1992, a treatment plan was finalized which required a dose of 3000 centigray (rads) to be given to the whole brain of a patient in 10 fractions, delivering 300 centigray per fraction. Treatment began on November 6, 1992. By the fifth day of treatment, a medical physicist identified that the patient had received a weekly cumulated dose of 2550 centigray rather than the weekly prescribed dose of 1500.

The dosimetrist had measured the patient lateral cranial thickness as 16 centimeters and determined the midline treatment depth of the brain to be 8 centimeters. However, the dosimetrist had entered 16 centimeters as the midline treatment depth on the patient data sheet. As a result of this error, a treatment time of 2.56 minutes was calculated for each port rather than the correct time of 1.51 minutes.

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

One violation is described in the enclosed Notice of Violation (Notice). The violation involves a failure of the radiation oncologist to identify an incorrect treatment depth while checking the dose calculations.

There were several other contributing causes for this event. First, there was the initial error by the dosimetrist. Second, prior to administering the first fractional dose, two teletherapy technologists questioned the long treatment time but did not share their concerns with the authorized user or other supervisory staff. Third, the senior medical physicist normally reviews all treatment calculations within 24 to 48 hours of the calculation but was on leave during this event. No one was assigned this task in her absence. Finally, the medical physicist reviewed patient charts in the absence of the senior medical physicist on the day that the second fractional dose was administered. However, the chart of the patient involved in this event was not in the chart rack and therefore, was not reviewed.

The violation and associated contributing causes described above resulted in a misadministration which potentially could have had residual consequences. Therefore, this violation has been categorized at Severity Level III.

The NRC requires you to establish and maintain an effective quality management program to ensure that the final plans of treatment and related calculations for teletherapy are in accordance with the written directives. Teletherapy misadministrations have a significant potential for adverse health effects to a patient. Incumbent upon you is the responsibility to protect public health and safety by ensuring that all NRC requirements are met.

We acknowledge your corrective actions which included, but were not limited to, a change to your procedures to add an additional independent check of the dose calculation, and shortening the time of this review from three to two days when administering more than three fractions. When either the medical physicist or the physician is not available to check the calculation, a qualified member of your staff will be assigned this responsibility.

Other corrective actions included instruction of teletherapy technologists to alert appropriate personnel whenever questions are raised concerning any parameter of treatment, assignment of the responsibility of reviewing all treatment calculations to the medical physicist in the absence of the senior medical physicist, and tracking of patients by the dosimetrist to ensure that dose calculations are checked by a physicist.

In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy) 10 CFR Part 2,

Appendix C, a civil penalty is considered for a Severity Level III violation to emphasize the need for adequate implementation of the quality management program. However, I have been authorized not to propose a civil penalty in this case because you identified the violation, your corrective actions taken to prevent recurrence of this event were timely and comprehensive, and your past performance has been good.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. In your response, you should document the specific actions taken and any additional actions you plan to prevent recurrence. After reviewing your response to this Notice, including your proposed corrective actions and the results of future inspections, the NRC will determine whether further NRC enforcement action is necessary to ensure compliance with NRC regulatory requirements.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter and its enclosure will be placed in the NRC Public Document Room.

The responses directed by this letter and the enclosed Notice are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, Pub. L. No. 96-511.

Sincerely,

John B. Martin
Regional Administrator

Enclosure:
Notice of Violation

cc/enclosure:
Indiana State Board of Health

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

St. John's Medical Center
Anderson, Indiana

Docket No. 030-19555
License No. 13-17793-02
EA 93-132

During an NRC inspection conducted on November 24, 1992, a violation of NRC requirements was identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C, the violation is listed below:

10 CFR 35.32(a)(3) requires, in part, that each licensee under this part establish and maintain a written quality management program to provide high confidence that radiation from byproduct material will be administered as directed by the authorized user. The quality management program must include written policies and procedures to meet the following objective: That the final plans of treatment and related calculations for teletherapy are in accordance with the written directives.

The licensee's Quality Management Program dated December 30, 1991, with an effective date of January 27, 1992, requires in paragraph 8 that if the prescribed dose is to be administered in more than three fractions, the dose calculations will be checked within three working days after administering the first teletherapy fractional dose. Computer generated dose calculations should be checked by examining the computer printout to verify that the correct data for the patient were used in the calculations. Alternately, the dose will be manually calculated to a single key point and the results compared to the computer-generated dose calculation.

Contrary to the above, on November 10, 1992, the licensee's quality management program did not meet the objective that final plans of treatment and related calculations for teletherapy are in accordance with the written directives. Specifically, three working days after a teletherapy treatment began, a radiation oncologist checked the dose calculation but failed to identify that the treatment depth was incorrect. An alternate manual calculation to compare the results to the computer generated dose calculation was not performed during the review.

This is a Severity Level III violation (Supplement VI).

Pursuant to the provisions of 10 CFR 2.201, St. John's Medical Center is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555, with a copy to the Regional Administrator, Region III, 799 Roosevelt Road, Glen Ellyn, IL 60137, within 30 days of the date of the letter

transmitting this Notice of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each violation: (1) the reason for the violation, or, if contested, the basis for disputing the violation, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken to avoid further violations, and (4) the date when full compliance will be achieved. If an adequate reply is not received within the time specified in this Notice, an order or a Demand for Information may be issued to show cause why the license should not be modified, suspended, or revoked, or why such other action as may be proper should not be taken. Where good cause is shown, consideration will be given to extending the response time. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, this response shall be submitted under oath or affirmation.

Dated at Glen Ellyn, Illinois
this 28 day of July 1993

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PENNSYLVANIA 19406-1415

JUL 21 1993

Docket Nos. 030-01972
030-14517
030-32590
License Nos. 20-13758-01
20-13758-02
20-13758-03
EA 93-177

Aaron Lazare, M.D.
Chancellor/Dean
University of Massachusetts
55 Lake Avenue North
Worcester, Massachusetts 01605-2397

Dear Dr. Lazare:

Subject: NOTICE OF VIOLATION (Combined NRC Inspection Report Nos. 030-01972/93-001; 030-14517/93-001 and 030-32590/93-001)

This letter refers to the routine NRC safety inspection conducted on June 14-16, 1993, at your facility in Worcester, Massachusetts, of activities authorized by NRC License Nos. 20-13758-01, 20-13758-02, and 20-13758-03. The inspection report was sent to you on July 7, 1993. During the inspection, three violations of NRC requirements were identified and discussed with you at the exit meeting. On July 14, 1993, an enforcement conference was conducted by telephone with you and other members of your staff to discuss the violations, their causes, and your corrective actions. A copy of the enforcement conference report is enclosed. The three violations are described in the enclosed Notice of Violation.

One of the three violations involved the failure to maintain constant surveillance and immediate control of a cobalt-60 teletherapy unit at the facility. Although the teletherapy unit had been secured in the locked teletherapy suite since patient treatment with this device was discontinued in July 1992, the keys to the suite were provided to contractor personnel on November 24, 1992, to permit removal of equipment and furniture from the teletherapy suite, without any instructions as to the controls required over accessibility to the suite, or the required supervision of personnel permitted into the area. At the same time that contractor personnel were in the suite, the key to the teletherapy console was left unsecured in an unlocked drawer in the suite. Although the machine was not activated while contractor personnel were in the room, allowing such personnel

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

into the area without any instructions or supervision, for the distinct purpose of removing equipment from the area, created a potential for a significant overexposure at the facility. A significant overexposure may have occurred if attempts had been made to dismantle the teletherapy machine since the teletherapy unit contained 4,000 curies of cobalt-60.

The NRC recognizes that this condition was identified by your Radiation Safety Officer on December 4, 1992, and he initiated immediate actions to enhance the security of the teletherapy unit and to preclude any additional unauthorized entry. These actions included locking of the teletherapy suite, addition of an elaborate alarm system, and disconnecting the teletherapy machine to preclude any unauthorized entry or activation of the machine. Nonetheless, the NRC is concerned with the lack of proper security of the teletherapy machine which created the potential for a serious exposure at the facility and which represented a significant failure to control licensed material. This lack of control constitutes a violation of NRC requirements and is described in the enclosed Notice. This violation is classified at Severity Level III in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy) 10 CFR Part 2, Appendix C.

Normally, a civil penalty is issued for such a violation in order to emphasize the importance of implementing long-lasting corrective actions to ensure that: (1) licensed activities are conducted safely and in accordance with requirements; and (2) licensed materials are properly controlled to prevent unnecessary radiation exposures. However, after consideration of the escalating and mitigating factors in this case, I have been authorized to issue the enclosed Notice of Violation without a civil penalty in view of your identification of the issue, your prompt and comprehensive corrective actions, and your past good enforcement history. The NRC emphasizes, however, that any similar violations in the future also may result in escalated enforcement action.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice of Violation when preparing your response. In your response, you should document the specific actions taken and any additional actions you plan to prevent recurrence. After reviewing your response to this Notice, including your proposed corrective actions, and the results of future inspections, the NRC will determine whether further NRC enforcement action is necessary to ensure compliance with NRC regulatory requirements.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter and its enclosures will be placed in the NRC Public Document Room.

The responses directed by this letter and the enclosed Notice are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, Pub. L. 96-511.

Sincerely,

Thomas T. Martin
Regional Administrator

Enclosures:
1. Notice of Violation
2. Enforcement Conference Report

cc w/encls:
Public Document Room (PDR)
Nuclear Safety Information Center (NSIC)
Commonwealth of Massachusetts (2)

ENCLOSURE 1

NOTICE OF VIOLATION

University of Massachusetts, Worcester
Worcester, Massachusetts

Docket Nos. 030-01972
030-14517
030-32590
License Nos. 20-13758-01
20-13758-02
20-13758-03
EA 93-177

During an NRC inspection conducted on June 14-16, 1993, violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy) 10 CFR Part 2, Appendix C, the violations are set forth below:

A. 10 CFR 20.207(a) requires that licensed materials stored in an unrestricted area be secured against unauthorized removal from the place of storage.

10 CFR 20.207(b) requires that licensed materials in an unrestricted area and not in storage be tended under constant surveillance and immediate control of the licensee. As defined in 10 CFR 20.3(a)(17), an unrestricted area is any area access to which is not controlled by the licensee for purposes of protection of individuals from exposure to radiation and radioactive materials.

Contrary to the above, on November 24, 1992, licensed material consisting of a cobalt-60 sealed source (approximately 4,000 curies) within a teletherapy unit located in the teletherapy treatment room, an unrestricted area, was not secured against unauthorized removal, and was not under constant surveillance and immediate control of the licensee.

This is a Severity Level III violation (Supplement IV).

B. 10 CFR 35.25(a)(1) requires that a licensee that permits the receipt, possession, use, or transfer of byproduct material by an individual under the supervision of an authorized user as allowed by 10 CFR 35.11(b) shall instruct the supervised individual in the principles of radiation safety appropriate to that individual's use of byproduct material and in the licensee's written quality management program.

Contrary to the above, as of June 14, 1993, the licensee did not instruct supervised individuals in the licensee's written medical quality management program. Specifically, supervised individuals in the Radiation Oncology Department received no training on the licensee's written quality management program for brachytherapy and teletherapy.

This is a Severity Level IV violation (Supplement VI).

C. 10 CFR 35.315(a)(8) requires, in part, that a licensee measure the thyroid burden of each individual who helped prepare or administer dosages of iodine-131 in amounts that required the patient to be hospitalized for compliance with 10 CFR 35.75, and that the measurements be performed within three days after the administration of the dosage.

Contrary to the above, from July 8, 1992 until June 3, 1993, the licensee administered doses ranging from 98 to 150 millicuries of iodine-131 to ten patients, dosages which require hospitalization for compliance with 10 CFR 35.75, and (1) on seven occasions, the licensee did not measure the thyroid burden of the nuclear medicine technologists who helped prepare or administer these dosages within three days of the administration; and (2) on three occasions, no measurement of the thyroid burden was made at all.

This is a Severity Level IV violation (Supplement VI).

Pursuant to the provisions of 10 CFR 2.201, University of Massachusetts (Licensee) is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555, with a copy to the Regional Administrator, Region I, within 30 days of the date of the letter transmitting this Notice of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each violation: (1) the reasons for the violation, or if contested, the basis for disputing the violation, (2) the corrective steps that have been taken and the results achieved, and (3) the corrective steps that will be taken to avoid further violations, and (4) the date when full compliance will be achieved. If an adequate reply is not received within the time specified in this Notice, an order or a demand for information may be issued as to why the license should not be modified, suspended, or revoked, or why such other action as may be proper should not be taken. Where good cause is shown, consideration will be given to extending the response time. Under the authority of Section 182 of the Atomic Energy Act, 42 U.S.C. 2232, this response shall be submitted under oath or affirmation.

Dated at King of Prussia, Pennsylvania
this 21st day of July 1993

III. INDIVIDUAL ACTIONS

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

May 4, 1993

IA 93-001

Mr. Richard J. Gardecki
(Address)

Dear Sir:

SUBJECT: ORDER PROHIBITING INVOLVEMENT IN CERTAIN NRC-LICENSED ACTIVITIES (EFFECTIVE IMMEDIATELY)

The enclosed Order is being issued because of your violations of 10 CFR 40.10 of the Commission's regulations as described in the Order.

Failure to comply with the provisions of this Order may result in civil or criminal sanctions.

Questions concerning this Order should be addressed to Mr. James Lieberman, Director, Office of Enforcement, who can be reached at (301) 504-2741.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice", a copy of this letter and the enclosures will be placed in the NRC's Public Document Room.

Sincerely,

Hugh L. Thompson, Jr.
Deputy Executive Director
for Nuclear Materials Safety,
Safeguards and Operations
Support

Enclosure: As stated

cc: Allied-Signal, Inc.
All Agreement States
SECY

UNITED STATES
NUCLEAR REGULATORY COMMISSION

In the Matter of	)	
	)	IA 93-001
Richard J. Gardecki	)	
	)	

ORDER PROHIBITING INVOLVEMENT IN CERTAIN
NRC-LICENSED ACTIVITIES
(EFFECTIVE IMMEDIATELY)

I

Richard J. Gardecki was recently employed by Allied-Signal, Inc., Metropolis, Illinois. Allied-Signal, Inc. (Licensee) holds License No. SUB-526 issued by the Nuclear Regulatory Commission (NRC or Commission) pursuant to 10 CFR Part 40. The license authorizes possession and conversion of uranium in accordance with the conditions specified therein. Mr. Gardecki was employed by the Licensee from about June 1991 through December 1992 in the position of Assistant Health Physicist, with responsibilities involving compliance with NRC requirements for radiation protection. Under the Licensee's organization and qualifications requirements, as specified in License Condition No. 9, an Assistant Health Physicist is required to hold a bachelor's degree. Failure to have a bachelor's degree holder in that position constitutes a violation of License Condition No. 9.

II

On October 5-7, 1992, an inspection was conducted at the Licensee's facility at Metropolis, Illinois, as a result of concerns raised within the NRC staff as to the education and experience of Richard J. Gardecki. As a result of information

developed in that inspection, an investigation was conducted in November and December 1992 by the Office of Investigations (OI). The inspection and investigation revealed that Mr. Gardecki intermittently took courses at the University of Delaware between 1962 and 1967 and in 1978, but did not accumulate sufficient credits to earn a bachelor's degree. While employed at the University of Delaware between 1977 and 1981, Mr. Gardecki prepared a transcript that falsely reflected sufficient hours of credit at that University to entitle him to a Bachelor of Science degree.

Mr. Gardecki subsequently used the false transcript to obtain employment at the University of Nebraska in about 1983, at Westinghouse Radiological Services Division in about 1985, at Environmental Testing Inc., in 1988, and at the Licensee in about June 1991. In each of these positions, Mr. Gardecki was involved in activities licensed by the NRC or an Agreement State, pursuant to an agreement with the NRC under section 274 of the Atomic Energy Act of 1954, as amended.

In addition, Mr. Gardecki obtained employment as a Radiation Specialist at the NRC in 1987 by submitting a Standard Form 171 (SF171), Application for Federal Employment, which contained the same false information regarding a bachelor's degree at the University of Delaware. He was allowed to resign his NRC employment following identification of the falsehood. Also,

during the OI investigation, he admitted that he had provided false information to the NRC regarding prior employment by General Dynamics in Denver, Colorado.

Further, in a transcribed sworn statement on December 1, 1992, Mr. Gardecki deliberately provided false information to OI investigators when he stated that he graduated from the University of Delaware in 1961. When asked about the University records indicating that he had not received a degree, Mr. Gardecki fabricated a story about the University having mixed his record with that of his brother. He also deliberately provided false information as to the accuracy of a University of Delaware transcript that he had submitted to the Licensee. In a transcribed, sworn statement to OI investigators on December 14, 1992, Mr. Gardecki admitted that he had provided false information in his sworn statements previously given to OI investigators on December 1, 1992 concerning his academic record and applications for employment.

III

Based on the above, Mr. Gardecki engaged in deliberate misconduct, which through his employment (from about June 1991 through December 1992) in a position with educational requirements that Mr. Gardecki did not meet, caused the Licensee to be in violation of the organization and qualifications

requirements of License Condition No. 9. This is a violation of 10 CFR 40.10. Mr. Gardecki also deliberately provided to NRC investigators information that he knew to be inaccurate and was in some respects material to the NRC which also constitutes a violation of 10 CFR 40.10. As an Assistant Health Physicist for the Licensee, Mr. Gardecki was responsible for performance of required surveys and keeping of required records, all of which provide evidence of compliance with Commission requirements. The NRC must be able to rely on the Licensee and its employees to comply with NRC requirements, including the requirement to provide information and maintain records that are complete and accurate in all material respects. Mr. Gardecki's deliberate actions in causing this Licensee to be in violation of License Condition No. 9, a violation of 10 CFR 40.10, and his violation of 10 CFR 40.10 caused by his deliberate misrepresentations to the NRC have raised serious doubt as to whether he can be relied upon to comply with NRC requirements and to provide complete and accurate information to the NRC or to an employer. Mr. Gardecki's misconduct (repeated on several occasions over several years with several employers) caused this Licensee to violate a Commission requirement; and his false statements to Commission officials demonstrate conduct that cannot and will not be tolerated.

Consequently, I lack the requisite reasonable assurance that licensed activities in NRC jurisdiction can be conducted in

compliance with the Commission's requirements and that the health and safety of the public will be protected, if Mr. Gardecki were permitted at this time to be named as a Radiation Safety Officer (RSO) on an NRC license or permitted to supervise licensed activities (i.e., being responsible in any respect for any individual's performance of any licensed activities) for an NRC licensee or an Agreement State licensee while conducting licensed activities in NRC jurisdiction pursuant to 10 CFR 150.20. Therefore, the public health, safety and interest require that Mr. Gardecki be prohibited from being named on an NRC license as an RSO or from supervising licensed activities (i.e., being responsible in any respect for any individual's performance of any licensed activities) for an NRC licensee or an Agreement State licensee while conducting licensed activities in NRC jurisdiction pursuant to 10 CFR 150.20 for a period of five years from the date of this Order. In addition, for the same period, Mr. Gardecki is required to give notice of the existence of this Order to a prospective employer engaged in licensed activities, described below (Section IV, paragraph 2), to assure that such employer is aware of Mr. Gardecki's previous history. Mr. Gardecki is also required to notify the NRC of his employment by any person engaged in licensed activities, described below (Section IV, paragraph 2), so that appropriate inspections can be performed. Furthermore, pursuant to 10 CFR 2.202, I find that the significance of the conduct described above is such that the

public health, safety and interest require that this Order be immediately effective.

IV

Accordingly, pursuant to sections 61, 81, 103, 161b, 161i, 182 and 186 of the Atomic Energy Act of 1954, as amended, and the Commission's regulations in 10 CFR 2.202, 10 CFR 40.10, and 10 CFR 150.20, IT IS HEREBY ORDERED, EFFECTIVE IMMEDIATELY, THAT:

1. Richard J. Gardecki is prohibited for five years from the date of this Order from being named on an NRC license as a Radiation Safety Officer or from supervising licensed activities (i.e., being responsible in any respect for any individual's performance of any licensed activities) for an NRC licensee or an agreement state licensee while conducting licensed activities in NRC jurisdiction pursuant to 10 CFR 150.20.
2. Should Richard J. Gardecki seek employment with any person engaged in licensed activities during the five year period from the date of this Order, Mr. Gardecki shall provide a copy of this Order to such person at the time Mr. Gardecki is soliciting or negotiating employment so that the person is aware of the Order prior to making an employment decision. For the

purposes of this paragraph licensed activities include licensed activities of 1) an NRC licensee, 2) an Agreement State licensee conducting licensed activities in NRC jurisdiction pursuant to 10 CFR 150.20, and 3) an Agreement State licensee involved in distribution of products that are subject to NRC jurisdiction.

3. For a five year period from the date of this Order, Richard J. Gardecki shall provide notice to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, DC 20555, of the name, address, and telephone number of the employer, within 72 hours of his acceptance of an employment offer, involving licensed activities described in paragraph 2, above.

The Director, Office of Enforcement, may, in writing, relax or rescind any of the above conditions upon demonstration by Mr. Gardecki of good cause.

V

In accordance with 10 CFR 2.202, Richard J. Gardecki must, and any other person adversely affected by this Order may, submit an answer to this Order, and may request a hearing on this Order, within 20 days of the date of this Order. The answer may consent to this Order. Unless the answer consents to this Order, the

answer shall, in writing and under oath or affirmation, specifically admit or deny each allegation or charge made in this Order and shall set forth the matters of fact and law on which Richard J. Gardecki or other person adversely affected relies and the reasons as to why the Order should not have been issued. Any answer or request for a hearing shall be submitted to the Secretary, U.S. Nuclear Regulatory Commission, Attn: Chief, Docketing and Service Section, Washington, DC 20555. Copies also shall be sent to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, DC 20555, to the Assistant General Counsel for Hearings and Enforcement at the same address, to the Regional Administrator, NRC Region III, 799 Roosevelt Rd., Glen Ellyn, IL 60137, and to Richard J. Gardecki, if the answer or hearing request is by a person other than Richard J. Gardecki. If a person other than Richard J. Gardecki requests a hearing, that person shall set forth with particularity the manner in which his or her interest is adversely affected by this Order and shall address the criteria set forth in 10 CFR 2.714(d).

If a hearing is requested by Richard J. Gardecki or a person whose interest is adversely affected, the Commission will issue an Order designating the time and place of any hearing. If a hearing is held, the issue to be considered at such hearing shall be whether this Order should be sustained.

Pursuant to 10 CFR 2.202(c)(2)(i), Richard J. Gardecki, or any other person adversely affected by this Order, may, in addition to demanding a hearing, at the time the answer is filed or sooner, move the presiding officer to set aside the immediate effectiveness of the Order on the ground that the Order, including the need for immediate effectiveness, is not based on adequate evidence but on mere suspicion, unfounded allegations, or error.

In the absence of any request for hearing, the provisions specified in Section IV above shall be final 20 days from the date of this Order without further order or proceedings. AN ANSWER OR A REQUEST FOR HEARING SHALL NOT STAY THE IMMEDIATE EFFECTIVENESS OF THIS ORDER.

FOR THE NUCLEAR REGULATORY COMMISSION

Hugh L. Thompson, Jr.
Deputy Executive Director
for Nuclear Materials Safety,
Safeguards and Operations Support

Dated at Rockville, Maryland
this 4th day of May 1993

NRC FORM 335 (2-89) NRCM 1102, 3201, 3202

U.S. NUCLEAR REGULATORY COMMISSION

BIBLIOGRAPHIC DATA SHEET

(See instructions on the reverse)

1. REPORT NUMBER (Assigned by NRC. Add Vol., Supp., Rev., and Addendum Numbers, if any.)

NUREG-0940
Vol. 12, No. 3

2. TITLE AND SUBTITLE

Enforcement Actions: Significant Actions Resolved
Quarterly Progress Report
July - September 1993

3. DATE REPORT PUBLISHED

MONTH	YEAR
December	1993

4. FIN OR GRANT NUMBER

5. AUTHOR(S)

Office of Enforcement

6. TYPE OF REPORT

Technical

7. PERIOD COVERED *(Inclusive Dates)*

8. PERFORMING ORGANIZATION – NAME AND ADDRESS *(If NRC, provide Division, Office or Region, U.S. Nuclear Regulatory Commission, and mailing address; if contractor, provide name and mailing address.)*

Office of Enforcement
U.S. Nuclear Regulatory Commission
Washington, DC 20555

9. SPONSORING ORGANIZATION – NAME AND ADDRESS *(If NRC, type "Same as above"; if contractor, provide NRC Division, Office or Region, U.S. Nuclear Regulatory Commission, and mailing address.)*

Same as above

10. SUPPLEMENTARY NOTES

11. ABSTRACT *(200 words or less)*

This compilation summarizes significant enforcement actions that have been resolved during one quarterly period (July - September 1993) and includes copies of letters, Notices, and Orders sent by the Nuclear Regulatory Commission to licensees with respect to these enforcement actions. It is anticipated that the information in this publication will be widely disseminated to managers and employees engaged in activities licensed by the NRC, so that actions can be taken to improve safety by avoiding future violations similar to those described in this publication.

12. KEY WORDS/DESCRIPTORS *(List words or phrases that will assist researchers in locating the report.)*

Technical Specifications, Radiographers, Quality Assurance, Radiation Safety Program, Safety Evaluations

13. AVAILABILITY STATEMENT

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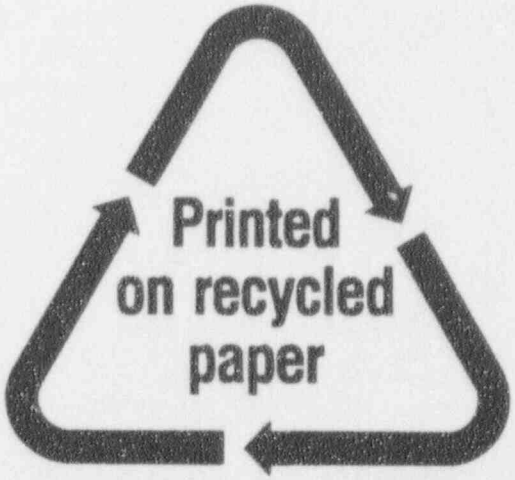

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