NUREG-0940
Vol. 12, No. 4

Enforcement Actions: Significant Actions Resolved

Quarterly Progress Report
October–December 1993

U.S. Nuclear Regulatory Commission

Office of Enforcement

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U.S. Nuclear Regulatory Commission
Washington, DC 20555–0001

ABSTRACT

This compilation summarizes significant enforcement actions that have been resolved during one quarterly period (October - December 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

October - December 1993

INTRODUCTION

This issue of NUREG-0940 is being published to inform NRC licensees about significant enforcement actions and their resolution for the fourth 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 fourth 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 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.

Future issues of this NUREG will be issued quarterly as three separate publications:

NUREG 0940, PART 1-REACTORS
NUREG 0940, PART 2-MEDICAL
NUREG 0940, PART 3-INDUSTRIAL

The purpose of this change is to focus licensee's attention on enforcement actions associated with their licensed activities.

I. REACTOR LICENSEES

A. Civil Penalties and Orders

Arizona Public Service Company, Phoenix, Arizona (Palo Verde Nuclear Generating Station), Supplement VII, EA 92-139

A Notice of Violation and Proposed Imposition of Civil Penalties in the amount of $130,000 was issued September 30, 1992, to emphasize the importance of maintaining an environment in which employees are free to provide information or raise safety concerns without fear of retaliation or discrimination. The action was based on two separate violations of the employee protection provisions of the Commission's regulations, 10 CFR 50.7 which involved two separate findings by two ALJs of the U.S. Department of Labor that Arizona Public Service Company discriminated against two of its employees for raising safety concerns. The licensee responded July 31, 1993 and paid the civil penalty for Item B of the Notice of Violation. On October 14, 1993, the licensee paid the remaining $50,000.

Commonwealth Edison Company, Downers Grove, Illinois (Zion Nuclear Generating Station, Units 1 and 2), EA 93-064

A Notice of Violation and Proposed Imposition of Civil Penalty in the amount of $50,000 was issued September 9, 1993, to emphasize the need for management to be more aggressive in the control of activities affecting safety-related systems, the importance of understanding the design basis of the licensee's facility, and the need to ensure that the facility, as described in the FSAR, is changed only in accordance with the provisions of 10 CFR 50.59. The action was based on the failure in August 1989 to perform a 10 CFR 50.59 safety evaluation for a change to the facility as described in the FSAR. The change consisted of maintaining open, for an extended period, an auxiliary building missile door, rendering the building ventilation system incapable of maintaining the design negative pressure relative to the outdoors. In August 1992, a safety evaluation was performed, but the evaluation was technically deficient, and the problem went uncorrected until December 1992. The licensee responded and paid the civil penalty on October 12, 1993.

Commonwealth Edison Company, Downers Grove, Illinois
(Quad Cities Station, Units 1 and 2) Supplement I, EA 93-210

A Notice of Violation and Proposed Imposition of Civil Penalty in the amount of $125,000 was issued September 21, 1993, to emphasize the need for management involvement and oversight of activities affecting safety-related systems, and appropriate prioritization and resolution of identified problems. The action was based on violations identified as a result of the followup of the bursting of a rupture disc in the Unit 1 High Pressure Coolant Injection System during testing conducted on June 9, 1993. During the event five workers were contaminated and injured by the resulting steam release. The licensee responded and paid the civil penalty on October 21, 1993.

Commonwealth Edison Company, Downers Grove, Illinois
(LaSalle County Station, Unit 2), Supplement IV, EA 93-235

A Notice of Violation and Proposed Imposition of Civil Penalty in the amount of $112,500 was issued November 17, 1993, to emphasize the need for management involvement and oversight of the radiation safety program. The action was based on radiation protection violations that occurred during the disassembly of the Unit 2 reactor vessel head. The violations resulted in a number of plant personnel receiving measurable intakes of radioactive material. The licensee responded and paid the civil penalty on December 17, 1993.

Consumers Power Company, Jackson, Michigan
(Big Rock Point), Supplement I, EA 93-233

A Notice of Violation and Proposed Imposition of Civil Penalty in the amount of $50,000 was issued November 9, 1993, to emphasize the need for increased management attention to licensed activities. The action was based on a breakdown in controls over significant plant activities at the facility, as evidenced by (1) a breach in primary containment integrity while changing modes from cold shutdown to refueling, and (2) exceeding the pressure limit while performing a hydrostatic test of the primary coolant system. The licensee paid the civil penalty on November 16, 1993 and responded on December 8, 1993.

GPU Nuclear Corporation, Forked River, New Jersey
(Oyster Creek Nuclear Generating Station), Supplement IV, EA 93-136

A Notice of Violation and Proposed Imposition of Civil Penalty in the amount of $75,000 was issued on

August 17, 1993, to emphasize the importance of adherence to the proper radiological control requirements and procedures as well as the communications necessary to implement those requirements and procedures. The action was based on five radiological controls violations that were identified as the result of two entries made into a highly contaminated high radiation area without proper radiological controls. The licensee responded on September 20, 1993, and paid $50,000 of the civil penalty and requested in the response that the remainder of the civil penalty be withdrawn. After considering the response, an Order Imposing a Civil Monetary Penalty in the amount of $25,000 was issued on November 9, 1993. The licensee paid the remaining amount on December 7, 1993.

Nebraska Public Power District, Columbus, Nebraska (Cooper Nuclear Station), Supplement I, EA 93-137

A Notice of Violation and Proposed Imposition of Civil Penalties in the amount of $200,000 was issued October 12, 1993, to emphasize the significance that the NRC attaches to the violations and the importance of the licensee's efforts to resolve deeply rooted and fundamental weaknesses in employee attitudes toward identifying and resolving problems. The action was based on violations involving three separate regulatory concerns. The first involved a number of corrective action violations. The second involved a violation for the inoperability of both trains of the containment hydrogen/oxygen analyzer system. The third concern involved the failure to include required portions of the service water and reactor equipment cooling systems in the inservice inspection program. The licensee responded and paid the civil penalties on November 12, 1993.

Northeast Nuclear Energy Company, Hartford, Connecticut (Millstone Nuclear Power Station) Supplement I, EA 93-130

A Notice of Violation and Proposed Imposition of Civil Penalty in the amount of $50,000 was issued September 20, 1993, to emphasize the importance of adequate and continuing management attention to the Licensed Operator Requalification Training program, so as to assure all training requirements are completed in a timely manner, and appropriate audits are performed to verify completion. The action was based on two violations associated with the licensed operator requalification program. The first involved the licensee's failure to ensure that individual licensed operators completed all necessary aspects of the requalification program which is a condition of the licensed operators' licenses. The second violation

involved the failure over the past six years of the licensee's Nuclear Review Board to comprehensively audit the licensed operator qualification/requalification programs as required by the Technical Specifications despite the fact that during 1991 and 1992 the NRC found the requalification program for Unit 1 to be unsatisfactory. The licensee responded and paid the civil penalty on October 19, 1993.

Washington Public Power Supply System, Richland, Washington (Washington Nuclear Projects No. 2) Supplement I, EA 93-191

A Notice of Violation and Proposed Imposition of Civil Penalty in the amount of $75,000 was issued November 10, 1993, to emphasize the importance the NRC attaches to the proper operation of safety systems and the need for procedural compliance. The action was based on the licensee's failure to follow procedural requirements with regard to simultaneously placing both trains of the residual heat removal system in the suppression pool cooling mode while the plant was in operation. The licensee responded and paid the civil penalty on December 10, 1993.

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

Commonwealth Edison Company, Downers Grove, Illinois (Dresden Station) Supplement III, EA 93-223

A Notice of Violation was issued November 26, 1993, based on violations involving an inadequate search which allowed a facsimile of a firearm to enter the protected area. A civil penalty was not proposed because the licensee identified the event and took good corrective actions, including initiating an investigation into the cause of the event, removing and retraining the individuals responsible for the event, instituting proficiency testing of the guard force, and implementing enhanced drills with the x-ray machine.

Commonwealth Edison Company, Downers Grove, Illinois (LaSalle County Station) Supplement VII, EA 93-283

A Notice of Violation was issued December 27, 1993, based on violations involving the granting of unescorted access to an individual who had not successfully passed fitness for duty testing. A civil penalty was not proposed because of the self-disclosing nature of the event and the licensee's initiative in identifying its root cause, the licensee's prompt and extensive corrective actions, and the licensee's SALP 1 performance in security at the LaSalle County Station.

Entergy Operations, Inc., Russellville, Arkansas
(Arkansas Nuclear One) Supplement I, EA 93-278

A Notice of Violation was issued December 14, 1993, based on the licensee's failure to ensure that the reactor building sump screens in both units were designed, installed and maintained in accordance with design specifications described in the FSAR. A civil penalty was not proposed because the problems relating to the sump screens were identified by the licensee, corrective actions following the identification of the problem was prompt and comprehensive, and the licensee's performance in safety assessment/quality verification and overall performance in identifying and correcting historical problems had been good.

GPU Nuclear Corporation, Middletown, Pennsylvania
(Three Mile Island Nuclear Station) Supplement III,
EA 93-193

A Notice of Violation was issued October 20, 1993, based on the failure to promptly take required actions following declaration of a Site Area Emergency on February 7, 1993. A civil penalty was not proposed because the licensee identified the violation, the corrective actions were prompt and comprehensive, and the licensee's performance in the area of emergency preparedness had been good as evidenced by Category 1 ratings in SALP.

New York Power Authority, White Plains, New York
(Indian Point 3) Supplement I, EA 93-180

A Notice of Violation was issued November 30, 1993, based on three violations related to the preventive maintenance program. These involved (1) the failure to perform manufacturer recommended preventive maintenance on the emergency diesel generator as required by the plant technical specifications, (2) the failure to maintain operable three of the five containment fan cooler units over an indeterminate period of time during which the reactor was above the cold shutdown condition, and (3) the failure to identify and correct in a timely manner the degraded condensate storage tank diaphragm. The other violations related to the Quality Assurance program and involved (1) a breakdown in the licensee's corrective action process, (2) failure of the plant safety review committee to perform audits as required, and (3) the failure to forward the reports of audits performed to the appropriate management positions. A civil penalty was not proposed because of the licensee's changes at the facility and (1) the licensee shut down

the plant in response to previously identified deficiencies and generally poor performance over a long period of time, (2) the licensee had developed an extensive improvement program to correct the existing deficiencies, (3) the licensee would obtain NRC agreement before restart of the facility, (4) the violations were not higher then Severity Level III, (5) the violations were not willful, and (6) the violations occurred prior to the shutdown.

Wisconsin Public Service Corporation, Green Bay, Wisconsin (Kewaunee Nuclear Plant) Supplement III, EA 93-224

A Notice of Violation was issued December 15, 1993, based on a violation involving the storing of safeguards information in an unlocked and unattended storage cabinet. A civil penalty was not proposed because the licensee identified the event, the licensee took comprehensive corrective actions, and the licensee had a record of good past performance.

II. MATERIALS LICENSEES

A. Civil Penalties and Orders

Ball Memorial Hospital, Muncie, Indiana
EA 93-215

A Confirmatory Order Modifying License was issued October 20, 1993. The action was based on the results of an on-going investigation of circumstances in which licensee nuclear medicine technologists, including the supervisory technologist, administered dosages of radiopharmaceuticals to patients that exceeded the established dosage ranges at that institution. The licensee terminated one employee and suspended another. The licensee subsequently allowed the suspended individual to return to non-NRC licensed activities.

Chemetron Corporation, Providence, Rhode Island
EA 93-068

A Confirmatory Order Modifying License was issued October 25, 1993. The action was based on a failure to fully comply with the license condition that required submission by October 1, 1993 of a Site Remediation Plan for two sites in Newburgh Heights, Ohio.

City of Columbus, Columbus, Ohio
Supplement VI, EA 92-132

A Notice of Violation and Proposed Imposition of Civil Penalty in the amount of $2,000 was issued April 6, 1993, to emphasize the significance that NRC attaches to deliberate violations of Commission regulations and license requirements, and to emphasize that senior managers and supervisors must involve themselves in the radiation safety program. This action is based on the present Radiation Safety Officer (RSO) and two former RSOs removal of source rods in moisture density gauges for cleaning, when the individuals were not authorized. The licensee responded May 19, 1993, requesting mitigation of the civil penalty. After reviewing the licensee's response, an Order Imposing Civil Monetary Penalty in the amount of $2,000 was issued July 13, 1993. The licensee paid the civil penalty October 18, 1993.

Como Plastics, Inc., Columbus, Indiana
Supplement VI, EA 93-261

A Notice of Violation and Proposed Imposition of Civil Penalty in the amount of $750 was issued November 10, 1993, to emphasize the need for effective management of radiation safety matter. The action was based on the improper transfer of two static eliminator devices each containing nominally 10 millicuries of polonium-210. The licensee responded and paid the civil penalty on November 22, 1993.

Edwards Pipeline Testing, Inc.
Supplement VI, EA 93-015

A Notice of Violation and Proposed Imposition of Civil Penalty in the amount of $12,000 was issued September 1, 1993, to emphasize the unacceptability of the licensee's electing to remain in noncompliance with a requirement that is important to safety, and to assure that the licensee's corrective actions are lasting. The action was based on repetitive willful failures to perform quarterly audits on radiography personnel. The licensee responded on September 28, 1993, requesting mitigation of the civil penalty. After consideration of the licensee's response, an Order Imposing Civil Monetary Penalty in the amount of $12,000 was issued December 6, 1993. The licensee paid the civil penalty on December 31, 1993.

Glendive Medical Center, Glendive, Montana
Supplement VI, EA 93-231

A Notice of Violation and Proposed Imposition of Civil Penalty in the amount of $2,500 was issued October 21, 1993, to emphasize the importance of ensuring that licensed activities are supervised and monitored in accordance with NRC regulations and in the interest of assuring safety. The action was based on the hospital conducting nuclear medicine activities without either an authorized user or radiation safety officer. The licensee responded and paid the civil penalty on November 16, 1993.

Hahnemann University, Philadelphia, Pennsylvania
Supplement IV and VI, EA 93-249

A Notice of Violation and Proposed Imposition of Civil Penalties in the amount of $6,250 was issued November 17, 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. The actions were based on two violations which involved (1) a substantial failure to implement the Quality Management Program, and (2) the failure of the RSO to ensure certain specific requirements were met, representing a breakdown in the control of licensed activities at the facility. The licensee responded and paid the civil penalties on November 24, 1993.

Ingham Medical Center Corporation, Lansing, Michigan
Supplement VI, EA 93-209

A Notice of Violation and Proposed Imposition of Civil Penalties in the amount of $11,250 was issued September 9, 1993, to emphasize the need for strict adherence to all NRC regulations and the specific requirements of the licensee's medical quality management (QM) program. The action was based on (1) a Severity Level I problem that led to a misadministration and that involved the licensee's failure to prepare a written directive as required by the licensee's QM program, and (2) a Severity Level III problem for violations associated with misadministration reporting requirements. The licensee responded and paid the civil penalties October 7, 1993.

Mallinckrodt Medical, Incorporated, St. Louis, Missouri
Supplement V, EA 93-140

A Notice of Violation and Proposed Imposition of Civil Penalty in the amount of $1,000 was issued July 6, 1993,

to emphasize the importance of assuring that all regulatory requirements are met when transporting radioactive material. The action was based on a violation involving the failure to meet transportation requirements of NRC and DOT in that the removable beta/gamma contamination level on the outside surface of a package shipped by the licensee was approximately 28 times the limit. The licensee responded in two letters dated July 16, 1993, requesting mitigation of the civil penalty. After consideration of the licensee's responses, the staff concluded that 50% mitigation should be given because of the licensee's good past performance. An Order Imposing Civil Monetary Penalty in the amount of $500 was issued December 13, 1993. The licensee paid the civil penalty on December 27, 1993.

N.V. Enterprises, Casper, Wyoming
Supplement IV, 93-033

A Notice of Violation and Proposed Imposition of Civil Penalty in the amount of $4,000 was issued May 7, 1993, to emphasize the importance of taking immediate action upon discovering a violation to restore compliance with NRC requirements, and the importance of maintaining an awareness of all NRC requirements, particularly those that are designed to ensure the safety of radiography personnel and the public. The action was based on a Severity Level II violation involving the deliberate failure of the licensee to comply with the requirement that radiography personnel wear alarm ratemeters at all times during radiographic operations. The licensee responded to the Notice of Violation in a letter dated June 1, 1993, and requested termination of its license on July 27, 1993. A Confirmatory Order was signed by the licensee and the NRC in November 1993 and the civil penalty was withdrawn.

Schnabel Engineering Associates, Inc., Richmond, Virginia
Supplement IV, EA 93-219

A Notice of Violation and Proposed Imposition of Civil Penalty in the amount of $375 was issued September 29, 1993, to emphasize the importance of maintaining constant surveillance and control of licensed material and ensuring that operational activities are conducted safely and in accordance with requirements. The action was based on the failure of the licensee to maintain constant surveillance and immediate control of licensed

material in a moisture/density gauge that resulted in the gauge being damaged by a bulldozer on July 11, 1993. The radioactive source in the gauge was not damaged. The licensee responded and paid the civil penalty on October 19, 1993.

Tulsa Gamma Ray, Inc., Tulsa, Oklahoma
Supplement IV, EA 93-172

A Notice of Violation and Proposed Imposition of Civil Penalty in the amount of $5,000 was issued July 28, 1993, to emphasize the importance of maintaining control of radioactive material and the importance of effecting lasting corrective actions to prevent incidents of this type. The action was based on the loss of a radiography camera from a licensee vehicle. The camera was recovered by a member of the public and returned to the licensee within an hour of the incident. The licensee responded in a letter dated September 7, 1993, requesting mitigation. After considering the licensee's response, the staff concluded that mitigation was not warranted and an Order Imposing Civil Monetary Penalty in the amount of $5,000 was issued November 24, 1993. The licensee paid the civil on December 29, 1993.

Twins Falls Clinic and Hospital, Twin Falls, Idaho
Supplement VI, EA 93-082

A Notice of Violation and Proposed Imposition of Civil Penalty in the amount of $5,000 was issued May 20, 1993, to emphasize the importance of implementing a Quality Management Program (QMP) and the importance of maintaining an awareness of current requirements. The action was based on a violation involving the licensee's failure to establish and maintain a QMP in accordance with 10 CFR 35.32(a). The licensee responded in a letter dated May 21, 1993, requesting mitigation of the penalty. After considering the licensee's response, the staff concluded that mitigation was not warranted. An Order Imposing Civil Monetary Penalty was issued August 6, 1993. The licensee requested a hearing on August 11, 1993. A Joint Motion for Order Approving and Incorporating Stipulation for Settlement of Proceeding was signed November 22, 1993 mitigating the civil penalty by 50%. The licensee paid the civil penalty on December 14, 1993.

Veterans Administration Medical Center, Dallas, Texas
Supplement VI, EA 93-217

A Notice of Violation and Proposed Imposition of Civil Penalty in the amount of $3,750 was issued September 30, 1993, to emphasize the importance of ensuring compliance

with the licensee's medical quality management (QM) program for teletherapy treatments. The action was based on the failure of the licensee to adhere to the requirements of the QM Program between February 1992 and May 1992, when the licensee discontinued its Cobalt-60 teletherapy program. The licensee responded and paid the civil penalty on October 25, 1993.

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

Bronson Methodist Hospital, Kalamazoo, Michigan
Supplement VI, EA 93-263

A Notice of Violation was issued November 30, 1993, based on violations of NRC requirements. Specifically, the Quality Management Program (QMP) did not specify that the authorized user must sign written directives, that the QMP did not assure that changes to written directives were documented and signed by the authorized users, and that the QMP did not include procedures to conduct and evaluate representative samples of patient administrations. A civil penalty was not issued because of the licensee's good corrective actions which included immediately changing the licensee's procedures to require the authorized user to sign all written directives and promptly resubmitting the licensee's revised QMP to the NRC. The licensee has also had good past performance.

Department of the Navy, Washington, D.C.
Supplement VI, EA 93-134

A Notice of Violation was issued November 18, 1993, based on an incident that was initially identified by the Navy in June 1990 involving the falsification of personnel dosimetry records. The Navy completed an investigation and after reviewing the thoroughness of this investigation, NRC determined not to conduct its own investigation. Numerous weaknesses were identified in the licensee's radiation safety program. A civil penalty was not proposed because the licensee identified the violation and took extensive corrective actions which included (1) disciplining the responsible Radiation Health Program Representative and removing the individual from radiation safety activities, (2) replacing the Radiation Health Program Coordinator responsible for supervising local radiation health programs, (3) clarifying and strengthening the oversight and audit of the branch radiation health program by, in part, establishing direct full time responsibilities at

each level, (4) establishing a dosimetry tracking system, (5) auditing the Navy Dosimetry Center, (6) directing all navy hospitals in the United States to review their branch radiation health programs, correct identified deficiencies and provide a status report to the Navy Bureau of Medicine, and (7) adding dosimetry program reviews of hospital radiological health programs to the audits conducted by the BUMED Inspector General.

St. Luke's Medical Center, Cleveland, Ohio
Supplement V, EA 93-229

A Notice of Violation was issued October 16, 1993, based on a violation involving the transportation of 250 millicuries of cesium-137 without the proper shipping requirements being met. Specifically, the shipment was packaged as limited quantity whereas it should have been packaged as type A quantity which would have required special handling and labeling. A civil penalty was not proposed because of the licensee's good prior compliance history and the licensee's corrective actions, which included a commitment not to ship any more radioactive material except by a licensed broker. The licensee also had good past performance.

Summit Testing and Inspection Company, Akron, Ohio
Supplement IV, EA 93-246

A Notice of Violation was issued October 27, 1993, based on an incident in which a soil moisture/density gauge, containing licensed material was damaged. The authorized user had left the gauge unattended, walking approximately 150 feet to inspect a concrete placement. A bulldozer, operating in the area, ran over and damaged the gauge. As a result, the source rod was broken and the Cs-137 source capsule was dislodged. A civil penalty was not proposed because of the licensee's prompt corrective actions, which consisted of remedial training of all the licensee users on their responsibilities while using gauges, development and distribution of an employee disciplinary policy specifically addressing the consequences of leaving a gauge unattended, and implementation of a new system to track and document the completion of the required periodic leak testing of sealed sources. The licensee also had good past performance.

Syncor Corporation, Glastonbury, Connecticut
Supplement IV, EA 93-286

A Notice of Violation was issued December 7, 1993, based on violations involving licensed material--iodine-131--located in the iodine compounding room, an unrestricted

area, not being secured against unauthorized removal, and not being under constant surveillance and immediate control of the licensee. A civil penalty was not proposed because of the licensee's prompt and comprehensive corrective actions and the licensee's prior good performance.

Wheaton Glass Company, Millville, New Jersey
Supplements IV and VI, EA 93-225

A Notice of Violation was issued October 7, 1993, based on violations involving (1) radiation levels in the vicinity of the "P" furnace of the licensee's facility, an unrestricted area, such that if an individual were continuously present he could have received a dose in excess of two millirems in any one hour and (2) the failure to follow emergency procedures in an emergency when major damage to the Kay-Ray lead shielding was identified by the licensee. Specifically, the area was not immediately roped off, all unauthorized personnel were not removed from the area, and the RSO was not notified. A civil penalty was not proposed because of the licensee's identification of the event, its corrective actions, and prior good performance.

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.

George D. Shepherd IA 93-002

An Order Prohibiting Involvement in Certain NRC-Licensed Activities was issued October 27, 1993 to the above individual. The Order was based on the individual deliberately failing to wear an alarm ratemeter, failing to post boundaries, and failing to perform radiation surveys of the exposure device and guide tube during the performance of radiographic operations on July 1, 1992.

The Order prohibits the individual for a period of two years from performing, supervising, or engaging in any way in licensed activities under an NRC license, or an Agreement State license when activities under that license are conducted in areas of NRC jurisdiction. For a period of two years after the prohibition the individual shall be required to notify the NRC of his employment by any person engaged in licensed activities under an NRC or Agreement State license, so that appropriate inspections can be performed. During that same period the individual shall also be required to provide a copy of the Order to any person employing him and who holds an NRC license or an Agreement State license and performs licensed activities in an NRC jurisdiction.

I.A. REACTOR LICENSEES, CIVIL PENALTIES AND ORDERS

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION V

1450 MARIA LANE
WALNUT CREEK, CALIFORNIA 94596-5368

SEP 30 1992

Docket Nos. 50-528, 50-529, and 50-530
License Nos. NPF-41, NPF-51, and NPF-74
EA 92-139

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

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTIES - $130,000
(U.S. Department of Labor Case Nos. 89-ERA-19 and 91-ERA-9)

This letter refers to the results of two administrative proceedings conducted by the U.S. Department of Labor (DOL), each proceeding consisting of an investigation and hearing, regarding complaints filed October 21, 1988 and September 24, 1990, respectively, by Sarah C. Thomas and Linda E. Mitchell, employees at the Palo Verde Nuclear Generating Station (PVNGS). In each case, a DOL Administrative Law Judge (ALJ) has issued a Recommended Decision and Order (1) finding that Arizona Public Service Company (APS) discriminated against Ms. Thomas and Ms. Mitchell because they engaged in protected activity, in violation of Section 210 of the Energy Reorganization Act, and (2) directing APS to take specific actions to remedy that discrimination. In each case, APS has filed an appeal with the Secretary of Labor.

Based on the two decisions, the NRC finds that violations of the Commission's regulations have occurred. On September 17, 1992, you notified me that APS had waived the opportunity to have an enforcement conference regarding this matter.

The violations described in the enclosed Notice of Violation and Proposed Imposition of Civil Penalties concern two findings of discrimination in violation of 10 CFR 50.7, "Employee Protection." Specifically, according to the ALJ decision, shortly after Ms. Thomas engaged in protected activity, her supervisor retaliated against her because of that activity. According to the other ALJ decision, APS management failed to take prompt, effective remedial action regarding a number of actions that created a "hostile work environment" for Ms. Mitchell after she identified safety concerns to the NRC.

Under 10 CFR 50.7, discrimination by a Commission licensee against an employee for engaging in certain protected activities is prohibited. The activities protected include raising safety concerns to higher levels of plant and corporate management, providing the Commission information about possible violations of requirements imposed under either the Atomic Energy Act or the Energy Reorganization Act, requesting the Commission to institute enforcement action against his or her employer for the administration or enforcement of these requirements, or testifying in any Commission proceeding.

The violation concerning Ms. Thomas has been categorized as a Severity Level III violation. The violation concerning Ms. Mitchell has been categorized as a Severity Level II violation primarily because of the actions of the person who was at that time the Director of Quality Assurance (QA). Those actions are of particular concern because as Director of QA, this person was responsible for the employee concerns program and for protecting those persons who raised safety concerns from harassment and intimidation.

Both situations are significant because discrimination may create a chilling effect which could discourage individuals from raising safety issues. Such an environment cannot be tolerated if licensees are to fulfill their responsibility to protect the public health and safety. Thus, licensee management must avoid actions that discriminate against individuals for raising safety concerns, and must promptly and effectively remedy actions that constitute discrimination.

Therefore, to emphasize the importance of maintaining an environment in which employees are free to provide information or raise safety concerns without fear of retaliation or discrimination, I have been authorized, after consultation with the Director, Office of Enforcement, and the Deputy Executive Director for Nuclear Reactor Regulation, Regional Operations & Research, to issue the enclosed Notice of Violation and Proposed Imposition of Civil Penalties in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions" (Enforcement Policy), 10 CFR Part 2, Appendix C.

The base value of a civil penalty for a Severity Level III violation is $50,000. The base value for a Severity Level II violation is $80,000. The escalation and mitigation factors in the Enforcement Policy were considered and no adjustment of the base civil penalty was deemed appropriate.

The NRC has proposed a combined total Civil Penalty of $130,000 for the Thomas and Mitchell cases. However, payment of each civil penalty may be deferred until 30 days after a final decision by the Secretary of Labor on each of the respective appeals now pending. Therefore, you are not required to provide a formal response pursuant to 10 CFR 2.201 and 2.205 until 30 days after the Secretary has issued a final decision in each of these respective cases. However, notwithstanding your past corrective actions documented in your response of June 8, 1989, to our "chilling effect" letter dated May 12, 1989, regarding the actions against Ms. Thomas, please inform me in writing within thirty days of additional actions you may have taken to minimize any potential chilling effect arising from the circumstances related to Mmes. Thomas and Mitchell that might inhibit or prevent your employees or contractors from raising safety concerns to either your own organization or the NRC. Further, in this written response, please address the actions you have taken to assess the extent to which your employees harbor reservations about raising safety concerns, and the actions you have taken to eliminate or minimize those reservations.

In accordance with 10 CFR 2.790 of the Commission's regulations, a copy of this letter, the enclosures, and your responses, will be placed in the NRC Public Document Room.

Sincerely,

John B. Martin
Regional Administrator

Enclosure: Notice of Violation and
Proposed Imposition of Civil Penalties

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTIES

Arizona Public Service Company
Palo Verde Nuclear Generating Company

Docket Nos. 50-528, 50-529 and 50-530
License Nos. NPF-41, NPF-51, and NPF-74
EA-92-139

Based on the results of investigations and hearings conducted by the U.S. Department of Labor (DOL) (DOL cases 89-ERA-19 and 91-ERA-9) and the resulting decisions by DOL Administrative Law Judges (ALJs) dated April 13, 1989 and July 2, 1992, respectively, the NRC has determined that violations of its regulations occurred. 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:

10 CFR 50.7 prohibits discrimination by a Commission licensee, permittee, an applicant for a Commission license or permit, or a contractor or subcontractor of a Commission licensee, permittee, or applicant against an employee for engaging in certain protected activities. Discrimination includes discharge and other actions that relate to compensation, terms, conditions, and privileges of employment. The protected activities include, but are not limited to, providing the NRC or licensee information about possible violations of NRC requirements.

A. Contrary to the above, Sarah C. Thomas, who was employed by APS as an engineering technician, was unlawfully discriminated against as described in the DOL ALJ Recommended Decision and Order issued April 13, 1989, 89-ERA-19. Specifically, Ms. Thomas was reassigned to another position, was denied a promotion, was treated differently from another employee in being considered for another promotion, was required to complete unnecessary training, and had her certifications for certain procedures suspended, all in retaliation for engaging in protected activities. The protected activities included raising safety concerns to licensee management and the NRC regarding problems with a computer system and the testing of certain valves.

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

B. Contrary to the above, Linda E. Mitchell, who was employed by APS as an Electrical Engineer II, was unlawfully discriminated against as described in the DOL ALJ Recommended Decision and Order issued July 2, 1992, 91-ERA-9. Specifically, Ms. Mitchell was subjected to a series of actions which comprised a hostile work environment in retaliation for engaging in certain protected activities. The protected activities included raising various safety concerns to licensee management and the NRC, including concerns regarding problems with emergency lighting at Palo Verde.

This is a Severity Level II violation (Supplement VII).
Civil Penalty - $80,000

Pursuant to the provisions of 10 CFR 2.201, APS is hereby required to submit a written statement or explanation in response to this Notice of Violation and Proposed Imposition of Civil Penalties (Notice) to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, within 30 days of the date of a final decision of the Secretary of Labor on each of the respective cases. A separate response is required for each case. Each 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 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, each response shall be submitted under oath or affirmation.

Within the same period 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 the civil penalties, in whole or in part, by a written answer addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission. Again, a separate response is required for each case. Should the licensee fail to answer within the time specified, an order imposing the respective civil penalty 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 in 10 CFR Part 2, Appendix C should be addressed. Any written answer in accordance with 10 CFR 2.205 should be set forth separate 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. A separate response is required for each case. 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 responses noted above (Reply to Notice of Violation, letter with payment of civil penalties, and Answer to 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 U.S. Nuclear Regulatory Commission, Regional Administrator, Region V, 1450 Maria Lane, Walnut Creek, California 94596-5368, and a copy to the NRC Resident Staff at the Palo Verde Nuclear Generating Station.

FOR THE NUCLEAR REGULATORY COMMISSION

John B. Martin
Regional Administrator

Dated at Walnut Creek, California
this 30 day of September 1992

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

OCT 26 1993

Dockets No. 50-528, 50-529, and 50-530
Licenses No. NPF-41, NPF-51, and NPF-74
EA 92-139

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

SUBJECT: PARTIAL PAYMENT OF PROPOSED IMPOSITION OF CIVIL PENALTY (U.S. Department of Labor Cases No. 89-ERA-19 and 91-ERA-9).

Gentlemen:

Thank you for your letter dated July 31, 1993 transmitting your Reply and Answer to Violation B of our Notice of Violation and Proposed Imposition of Civil Penalties (Notice) dated September 30, 1992. With your letter, you forwarded a check for $80,000 in payment of the proposed civil penalty for Item B of that Notice of Violation, while denying that there was any basis for the penalty.

Specifically, you argued, in part, that because two of the five incidents relied upon by the Administrative Law Judge (ALJ) had been investigated by the NRC and the NRC investigative conclusions weakened or contradicted the bases for the ALJ's conclusions on those incidents, the NRC should not have relied on the ALJ decision in issuing its Notice of Violation. We were aware of the results of the NRC investigation at the time that the subject enforcement action was proposed. Notwithstanding the fact that APS continues to deny this violation, the NRC believes the Notice is supported and we see no basis to reconsider the action.

Further, we recognize your desire "to bring this matter to a close and enable management to focus attention on assuring current employees feel free to raise concerns rather than on the litigation of old issues." Thus, we accept your check in payment for the violation that has since resulted in final action before the Department of Labor (DOL).

With respect to the second violation cited in the Notice, we are aware that the Secretary of Labor ruled on September 17, 1993 that discrimination occurred and that you have recently submitted your response to the Notice. We will address your response to this second violation in separate correspondence.

You requested that Enclosure 4 to your letter -- the "Answer to Proposed Civil Penalty Based Upon Violation B of Notice of Violation EA-92-139" -- be withheld from public disclosure and not be placed in the Public Document Room (PDR) based on your assertion that the disclosure would constitute an unwarranted invasion of personal privacy. The NRC has reviewed that request and, with the exception of the NRC/IG reports and a copy of the DOL compliance officer's narrative summary enclosed in your response as well as some names and personal identifying information, we believe that there is no basis to withhold the response itself and other enclosures.

The NRC has redacted this document to remove limited personal privacy-related information, and has removed the NRC/IG reports and the DOL compliance officer's narrative summary. A copy of the redacted document is enclosed for your information. The NRC intends to release, and place in the Public Document Room, a copy of this redacted version of your response 20 days from the date of this letter.

Sincerely,

Joseph R. Gray, Deputy Director
Office of Enforcement

Enclosure: As Stated

cc: B. Faulkenberry, RV

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

NOV 16 1993

Dockets No. 50-528, 50-529, and 50-530
Licenses No. NPF-41, NPF-51, and NPF-74
EA 92-139

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

SUBJECT: FINAL PAYMENT OF PROPOSED IMPOSITION OF CIVIL PENALTY (U.S. Department of Labor Cases No. 89-ERA-19 and 91-ERA-9).

Gentlemen:

Thank you for your letter dated October 14, 1993 transmitting your Reply and Answer to Violation A of our Notice of Violation and Proposed Imposition of Civil Penalties (Notice) dated September 30, 1992. With your letter, you forwarded a check for $50,000 in payment of the proposed civil penalty for Item A of that Notice of Violation, while continuing to deny the violation.

In Enclosure 2 of your letter, you stated that APS does not believe that the events cited in the April 14, 1989 Recommended Decision and Order (RDO) of the Department of Labor Administrative Law Judge (ALJ) constitute a violation of 10 CFR 50.7. You also stated that the basis for this position had been previously transmitted to the NRC in a letter from W. F. Conway, APS, to J. B. Martin, NRC, on June 8, 1989. However, that June 8, 1989 letter merely restated APS' assertion of "the lack of any prohibited or discriminatory activity." We were aware of those assertions at the time that Violation A was issued. At this point, we continue to believe that the findings in the Notice are supported and we see no basis to reconsider the action.

We recognize your desire "to bring this matter to a close and enable management to focus attention on assuring employees currently feel free to raise concerns rather than to focus on litigation of events which occurred almost five (5) years ago." Thus, we accept your check in payment for the violation that has

since resulted in final action before the Department of Labor (DOL).

Sincerely,

Joseph R. Gray, Deputy Director
Office of Enforcement

cc: B. Faulkenberry, RV

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

September 9, 1993

Docket Nos. 50-295 and 50-304
License Nos. DPR-37 and DPR-48
EA 93-064

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 - $50,000
(INSPECTION REPORT NOS. 50-295/93009; 50-304/93009 AND 50-295/93014; 50-304/93014)

This refers to the special inspection conducted from July 27, 1992 through March 23, 1993 at Zion Nuclear Generating Station, Units 1 and 2. The inspection included a review of the circumstances surrounding, and related issues emerging from, the opening of auxiliary building missile door L-10. The report documenting this inspection was sent to you by letter dated April 6, 1993. During the inspection, violations of NRC requirements were identified.

An enforcement conference was held on April 16, 1993 to discuss the apparent violations identified in the original report, their causes, and your corrective actions. The report summarizing the enforcement conference was sent to you by letter dated May 3, 1993. A follow-up inspection was conducted on June 24, 1993, and additional violations were identified which were discussed at an exit meeting. The report documenting the follow-up inspection was sent to you by letter dated August 5, 1993.

In August 1989, you set up an on-site laundry facility, located in two semi-trailers next to auxiliary building missile door L-10, to support a refueling outage. To gain access to the facility, the missile door was periodically opened. The open door created a potential unmonitored release path, and the size of the opening (approximately 144 ft^2) was sufficient to prevent the

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

ventilation system from keeping the auxiliary building at its required negative pressure relative to the outside environment. At that time, however, you failed to evaluate the significance of this facility change (as required by 10 CFR 50.59), and therefore failed to recognize it as an unreviewed safety question, as discussed below. In July 1991, you performed a 10 CFR 50.59 safety evaluation prior to installing a penetration sleeve assembly through the auxiliary building wall near the missile door (to pass supply and drain piping between the auxiliary building and the external laundry). This evaluation recognized the potential for a release path through the penetration, but did not consider the open missile door as a potential release pathway, and concluded that no unreviewed safety question existed.

In the Fall of 1991, a new trailer was installed next to the missile door, and in February 1992, the missile door was continually left open due to the failure of the electrical door actuators. Again, in taking these actions, you failed to recognize that the open missile door was a change to the facility as described in the Updated Final Safety Analysis Report (UFSAR) that required a 10 CFR 50.59 safety evaluation to be performed.

In August 1992, after the NRC inspector raised concerns in this matter, you completed a 10 CFR 50.59 safety evaluation that was technically deficient. In brief, the evaluation rested on the faulty assumption that, with the missile door open, the auxiliary building ventilation system could maintain a negative pressure (relative to the outside) of ¼-inch of water. The inspector questioned this assumption, and his concerns were verified by a December 1992 test which demonstrated that the auxiliary building ventilation system could not maintain the design negative pressure in the auxiliary building with the missile door open.

At the enforcement conference, in addressing the technical significance of the violation and its reportability, you contended that maintaining the auxiliary building at a nominal negative pressure with respect to the outdoors, as described in the UFSAR, is not part of the design basis. We disagree with your contention, because a failure to maintain this parameter invalidates your calculated dose estimates for the UFSAR-postulated accident that involves dropping a spent fuel assembly onto the spent fuel pool floor. For this accident, with the auxiliary building not maintained at a nominal negative pressure relative to the outdoors, actual doses at the site boundary could be higher. Because the previously evaluated consequences of this UFSAR-postulated accident could be increased in this manner, the facility change occasioned by maintaining the missile door open constituted an unreviewed safety question.

Section I of the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice) presents these failures as a violation of 10 CFR 50.59, in that the August 1989 facility change involving an unreviewed safety question was conducted without performing a safety evaluation, and the safety evaluation eventually performed in August 1992 was deficient.

The root cause of the violation was a poor understanding by your engineering

staff of the design basis of the auxiliary building structure and ventilation system. Your handling of this issue reflects major weaknesses in engineering activities at Zion and highlights 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. NRC is also concerned that your management was not aggressive in resolving the issue once a potential safety concern regarding the open doors was identified. The failure to perform adequate safety evaluations and obtain Commission approval prior to modifying an important structure (i.e., the Zion auxiliary building) is of significant regulatory concern.

As such, this violation represents 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, the violation has been categorized at Severity Level III.

To emphasize the need for management to be more aggressive in the control of activities affecting safety-related systems, the importance of understanding the design basis of your facility, and the need to ensure that the facility, as described in the UFSAR, is changed only 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 in the amount of $50,000 for the Severity Level III violation.

The base value of a civil penalty for a Severity Level III violation is $50,000. The adjustment factors in the Enforcement Policy were considered. The civil penalty was increased by 50% because the NRC identified the violation. The civil penalty was mitigated 50% for the comprehensive corrective actions you took after the violation was identified, as presented at the enforcement conference. The other adjustment factors in the policy were considered and no further adjustment to the base civil penalty was considered appropriate.

Section II of the Notice describes four violations not assessed a civil penalty involving (1) inadequate procedures, (2) failure to report a condition that could prevent the fulfillment of a safety function, (3) failure to promptly identify and correct conditions adverse to quality, and (4) failure to calibrate required instrumentation. Each of these violations has been characterized at a Severity Level IV, in keeping with their respective levels of safety significance.

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 is 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)
R. Tuetken, Site Vice President
L. DelGeorge, Vice President,
Nuclear Oversight and Regulatory
Services
A. Broccolo, Station Manager
S. Kaplan, Regulatory Assurance Supervisor
D. Farrar, Nuclear Regulatory
Services Manager
OC/LFDCB
Resident Inspectors, Zion, Braidwood,
Byron
R. Hubbard
J. McCaffrey, Chief, Public Utilities
Division
Mayor, City of Zion
Licensing Project Manager, NRR
R. Newmann, Office of Public Counsel,
State of Illinois Center
R. Thompson, Administrator, Wisconsin
Division of Emergency Government
State Liaison Officer
Chairman, Illinois Commerce Commission

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

Commonwealth Edison Company
Zion Station
Units 1 and 2

Docket Nos. 50-295; 50-304
License Nos. DPR-39; DPR-48
EA 93-064

During NRC inspections conducted from July 27, 1992 through March 23, 1993, and on June 24, 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:

I. Violation 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 safety analysis report (SAR), without prior Commission approval, unless the proposed change involves an unreviewed safety question or a change to the license technical specifications. A proposed change is deemed to involve an unreviewed safety question if, among other things, the consequences of an accident previously evaluated in the SAR may be increased.

10 CFR 50.59 also requires that the licensee maintain records of changes to the facility, including a written safety evaluation which provides the bases for determining that the proposed change does not involve an unreviewed safety question.

Final SAR Section 9.10.2, "Auxiliary Building Ventilation System Design and Operation," and, subsequently, Updated Final Safety Analysis Report (UFSAR) Section 9.4.3.2, "Auxiliary Building Ventilation System Description," state that the exhaust fans for the auxiliary building are controlled to maintain the auxiliary building at a nominal ¼-inch of water of negative pressure with respect to the outdoors.

Contrary to the above:

A. In August 1989, without prior Commission approval, the licensee made a facility change that involved an unreviewed safety question, and a written safety evaluation was not performed. Specifically, the licensee kept the auxiliary building missile door L-10 open for an extended period, rendering the exhaust fans incapable of maintaining a nominal ¼-inch of water of negative pressure with respect to the outdoors, and thereby increasing the potential consequences of a previously evaluated accident (i.e., increasing the off-site doses that could result from dropping a spent fuel assembly onto the spent fuel floor).

B. On August 24, 1992, the licensee completed a 10 CFR 50.59 safety

evaluation of keeping the auxiliary building missile door L-10 open, and the evaluation failed to provide the bases for determining that this change did not involve an unreviewed safety question. Specifically, the evaluation incorrectly assumed that the auxiliary building exhaust fans could maintain a nominal ¼-inch of water of negative pressure relative to the outside with door L-10 open, and failed to consider the effect of the open door on a previously evaluated accident (i.e., increasing the off-site doses that could result from dropping a spent fuel assembly onto the spent fuel pool floor).

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

II. Violations Not Assessed a Civil Penalty

A. 10 CFR 50, Appendix B, Criterion V states:

> Activities affecting quality shall 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. 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:

1. As of March 23, 1993, the licensee had failed to prescribe by procedure that auxiliary building missile door L-10 should be normally closed, an activity affecting quality (in protecting safety-related equipment against loss of function due to flooding, as prescribed by UFSAR Section 2.4.5.3).

2. As of March 23, 1993, Procedure TSGP-35, Revision 1, dated May 18, 1990, "Cubicle Differential Pressure Surveillance," a procedure affecting quality, failed to use appropriate quantitative or qualitative acceptance criteria to ensure that potentially contaminated cubicles or pipe chases would be maintained at a nominal negative pressure of ¼-inch of water relative to the auxiliary building (as prescribed by UFSAR Section 9.4.3.1).

3. As of March 23, 1993, Procedure PT-0, Revision 6, dated June 21, 1992, "Surveillance Checklist and Periodic Test," a procedure affecting quality, failed to use appropriate quantitative or qualitative acceptance criteria to ensure that the auxiliary building would be maintained at a nominal

negative pressure of ¼-inch of water relative to the outdoors (as prescribed by UFSAR Section 9.4.3.2).

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

B. 10 CFR 50.73(a)(2)(v)(D) requires that the licensee report within 30 days of discovery any event or condition that alone could have prevented the fulfillment of the safety function of structures or systems that are needed to mitigate the consequences of an accident.

Contrary to the above, as of June 24, 1993, the licensee had failed to report that missile door L-10 being in the full open position resulted in the auxiliary building ventilation system test failure on December 9, 1992, a condition which could increase the actual off-site doses for the postulated accident involving dropping of a spent fuel assembly onto the spent fuel pool floor (UFSAR Section 15.7.4.1.5), and therefore could have alone prevented fulfillment of a safety function of a structure needed to mitigate the consequences of an accident.

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

C. 10 CFR 50, Appendix B, Criterion XVI, states, in part, that measures shall be established to assure that conditions adverse to quality are promptly identified and corrected.

Contrary to the above:

1. After becoming aware of a condition adverse to quality in September 1992, when the inspector identified that the 10 CFR 50.59 safety evaluation dated August 24, 1992 used an invalid assumption (that the auxiliary building ventilation system could maintain a nominal ¼-inch of water of negative pressure with respect to the outdoors with door L-10 open), the licensee failed to promptly correct the condition adverse to quality (it was not corrected until December 9, 1992, when door L-10 was partially closed to the half open position).

2. As of April 29, 1993, the licensee had failed to promptly identify and correct a condition adverse to quality, in that nine auxiliary building cubicle differential pressure gauges (used in activities affecting quality) had been inoperable for periods ranging from 6 to 18 months.

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

D. 10 CFR 50, Appendix B, Criterion XII, "Control of Measuring and Test Equipment," requires, in part, that measures be established

to assure that gauges used in activities affecting quality are properly calibrated and adjusted at specified periods to maintain accuracy within necessary limits.

Contrary to the above, as of June 24, 1993, the licensee had not specified a calibration frequency for the auxiliary building individual cubicle differential pressure gauges, gauges used in activities affecting quality. Further, five gauges had not been calibrated since 1978.

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 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 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 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 III, 799 Roosevelt Road, Glen Ellyn, Illinois 60137, and with a copy to the NRC Resident Inspector at the Zion Station.

Dated at Glen Ellyn, Illinois
this 9th day of September 1993

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

September 21, 1993

Docket Nos. 50-254 and 50-265
License Nos. DPR-29 and DPR-30
EA 93-210

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 - $125,000
(NRC INSPECTION REPORT NO. 50-254/265/93017(DRS))

This refers to the special safety inspection conducted during the period of June 9 through August 12, 1993, at Quad Cities Station, Units 1 and 2. The purpose of the inspection was to review the circumstances surrounding the Unit 1 High Pressure Coolant Injection (HPCI) system rupture disc burst event on June 9, 1993. The report documenting this inspection was sent to you by letter dated August 13, 1993. You reported this event to the NRC Operations Center on June 9, 1993, and subsequently reported the reactor shutdown on June 18, 1993. You submitted a Licensee Event Report on July 9, 1993, and a letter addressing your corrective actions on August 20, 1993.

On June 9, 1993, while performing the Unit 1 quarterly HPCI pump operability test, water was expelled from the HPCI turbine casing bursting the 20 year old rupture discs and releasing steam into the HPCI room. The water had accumulated in the casing because of a faulty steam drain level switch. The event damaged the HPCI turbine thrust bearing, a set of fire doors, and both sets of secondary containment doors. Five workers were contaminated and injured as a result of the steam release, one of whom required hospitalization for burns for several days.

The failed Unit 1 HPCI steam drain system was not an isolated case. Inspections after the June 9, 1993, event identified that the steam drain systems on Unit 2 HPCI, and Unit 2 reactor core

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isolation cooling (RCIC) systems were also not functioning properly.

Four violations were identified as described in the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice). The violations involve: (1) failure to correct deficiencies with the HPCI turbine steam inlet and exhaust level switches despite recurring work requests, industry notifications, a HPCI reliability centered maintenance (RCM) report recommendation, and a Site Quality Verification (SQV) audit; (2) failure to make personnel near the HPCI turbine aware of an impending test and the potential for leaking steam; (3) failure to conduct a briefing prior to a test; and (4) an inadequate procedure for draining moisture from the HPCI turbine inlet steam line.

The root cause of the event was Commonwealth Edison Company (CECo) management's failure to properly control activities associated with the safety related HPCI system. The most significant failure was that engineering personnel did not fully understand the system's design and vulnerabilities, and did not insist that steam drain system problems were properly addressed. These failures existed even though there were long-standing, uncorrected problems with the steam drain system, and industry and CECo documents, such as General Electric Service Information Letter No. 531 dated February 7, 1991, which were not acted on in a timely manner.

Contributing to the problem were the facts that operations' personnel failed to control system testing; maintenance personnel failed to evaluate recurring steam drain system failures; quality verification personnel failed to follow up on identified issues; and an assessment of the potential HPCI vulnerabilities in November 1992 failed to consider relevant available documents that could have led to the earlier discovery of the problems with the system.

While the issues discussed above specifically relate to the June 9, 1993 event, data indicates that your management effectiveness in maintaining safety system reliability has been poor at Quad Cities. The number of safety system failures at Quad Cities in the last several years has been abnormally high. For the HPCI system alone, LER data shows that there have been 27 system failures since 1989. I am particularly concerned that recent discussions with your supervisory and staff personnel revealed a general lack of knowledge of the poor performance of such safety systems, and little appreciation of the significance of the safety system failures.

The violations represent a breakdown in the control of licensed activities and a significant lack of attention towards 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, the violations are classified in the aggregate as a Severity Level III problem.

To emphasize the need for management involvement and oversight of activities affecting safety related systems, and appropriate prioritization and resolution of identified problems, 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 $125,000 for the 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.

The base civil penalty was escalated 50 percent because the NRC identified the program breakdown during the follow-up of the event. We acknowledge your comprehensive corrective actions for the HPCI event itself, as identified in your letter dated August 20, 1993. However, the corrective actions did not address the broader issues of engineering and management effectiveness. This was underscored by a recent event in which the HPCI system engineer inappropriately directed valve manipulations which resulted in the HPCI drain float switch being isolated. Therefore, no adjustment to the base civil penalty was made for corrective action. The base civil penalty was escalated 100 percent for your poor past performance. As previously discussed, the number of safety system failures at Quad Cities has been abnormally high. Furthermore, two other escalated actions were recently issued (EA 93-127 and EA 93-162) for failure to implement fire protection and safe shutdown requirements; and inoperability of the diesel generators due to an original plant design error, and an incorrectly installed oiler. 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 150 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, 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
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 Liaison Officer
H. J. Miller, Region III

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

Commonwealth Edison Company
Quad Cities Station
Units 1 and 2

Docket Nos. 50-254 and 50-265
License Nos. DPR-29 and DPR-30
EA 93-210

During an NRC inspection conducted from June 9 through August 12, 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 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:

1. As of June 9, 1993, recurring significant conditions adverse to quality existed with the High Pressure Coolant Injection (HPCI) turbine steam inlet drain level high alarm as documented in eight work requests dated between April 17, 1986, and September 18, 1992, and the cause of the condition was not determined and corrective action was not taken to preclude repetition.

2. As of June 9, 1993, the licensee failed to promptly correct an identified condition adverse to quality. Specifically, the licensee received a General Electric Service Information Letter (SIL) No. 531, "HPCI and Reactor Core Isolation Cooling (RCIC) Magnetrol Level Switches," which was issued on February 7, 1991. The SIL recommended the installation of an improved level switch in high temperature applications. Although the SIL directly applied to the HPCI and RCIC system drain level switches, the licensee took no action regarding the recommendations.

3. As of June 9, 1993, the licensee failed to promptly correct an identified condition adverse to quality. Specifically, the final report of the HPCI system

reliability centered maintenance study dated December 31, 1991, recommended calibration and functional testing of the HPCI turbine inlet and exhaust drain pot high level switches at 18 month intervals. The licensee did not include this activity in its preventative maintenance program. Furthermore, Site Quality Verification Audit No. 04-93-01 dated March 10, 1993, identified that the torus high level switches had not been tested as recommended by the reliability centered maintenance study, and concluded that the station did not adequately review the reliability centered maintenance report.

B. 10 CFR 50, Appendix B, Criterion V, "Instructions, Procedures, and Drawings," states that activities affecting quality shall 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. Procedure QCOS 2300-5, Revision 3, dated December 11, 1992, "Quarterly HPCI Pump Operability Test," Step F.4, requires ensuring that personnel near the HPCI turbine are aware of the impending test and the potential for steam leaking around the turbine.

   Contrary to the above, on June 9, 1993, personnel near the HPCI turbine were not made aware of the impending test and the potential for steam leaking around the turbine.

2. Procedure QAP 300-2, Revision 36, dated May 1993, "Conduct of Operations," Step C.13.j, "Responsibilities of all Operating Department personnel licensed by the Nuclear Regulatory Commission as Reactor Operators or Senior Reactor Operators," requires that briefings be conducted by cognizant personnel for individuals involved in an evolution that is to be performed. The detail of the briefing is dependent on the degree of complexity, routineness, logistics, or number of people involved.

   Step C.14.i, "Responsibilities of all Operating Department personnel licensed by the Nuclear Regulatory Commission as Senior Reactor Operators," requires that briefings be conducted by the Shift Engineer, or his designee, for individuals involved in an evolution that is to be performed. The detail of the briefing is dependent on the degree of complexity, routineness, logistics, or number of people involved.

The individual who is to perform the activity is responsible to adequately review the procedure, to fully understand what he is doing, and to be cognizant of all limitations, precautions, and requirements.

Evolutions involving many individuals, especially from two or more departments or disciplines, may require large formal briefings or preplanning sessions. If the evolution is complex and involves close coordination, the briefing session shall be coordinated by the Operating Engineer or his designee and should include:

(1) a review of the appropriate section of the procedure by key parties;

(2) examination of each individual's specific involvement and responsibility;

(3) discussion of expected results or performance; review of limitations, hold points, emergency action to be taken if contingencies arise; and

(4) assurance that everyone understands the interface and communications required.

Contrary to the above, on June 9, 1993, Operating Department personnel licensed by the NRC did not conduct a briefing prior to performance of the Quarterly HPCI Pump Operability Test, an evolution involving many individuals drawn from two or more departments and requiring close coordination among the participants.

3. Procedure QCOS 2300-5, Revision 3, dated December 11, 1992, "Quarterly HPCI Pump Operability Test," Step I.22, for draining moisture from the HPCI inlet steam line specified a time limit of 10 seconds as the criterion for closing drain valves AO 1(2)-2301-64 and AO 1(2)-2301-65.

Contrary to the above, as of June 9, 1993, Procedure QCOS 2300-5, Revision 3 was determined to be inappropriate for the circumstances because Step I.22 should have specified the observation of steam from the sump as the criterion for closing the drain valves in order to ensure that all moisture had been properly drained.

This is a Severity Level III problem (Supplement I).
Civil Penalty - $125,000.

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 21st day of September 1993

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

November 17, 1993

Docket No. 50-374
License No. NPF-18
EA 93-235

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

Dear Mr. Wallace:

SUBJECT: LASALLE COUNTY STATION - UNIT 2
NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY - $112,500
(NRC INSPECTION REPORT NO. 50-374/93025(DRSS))

This refers to the special safety inspection conducted during the period of September 8 through 14, 1993, at LaSalle County Station, Unit 2. The purpose of the inspection was to review a significant radioactive contamination event which occurred during reactor vessel disassembly on September 7, 1993. The report documenting this inspection was sent to you by letter dated September 27, 1993. During the inspection, violations of NRC requirements were identified.

An enforcement conference was held on October 5, 1993, to discuss the apparent violations, their causes and your corrective actions. The report summarizing the conference was sent to you by letter dated October 13, 1993.

On September 7, 1993, three crews (eight workers) were assigned to the Unit 2 reactor cavity to disassemble the reactor vessel head with pneumatic tools. A pre-job meeting which included the maintenance foreman, workers and three radiation protection technicians (RPTs) assigned to cover the job was held. However, the discussion of radiological controls was limited. Initially, two RPTs were covering the job from the refueling floor. The RPTs did not enter the cavity and air sampling of the reactor cavity was not performed. Even though contamination levels exceeded 100,000 dpm/100cm^2 in what should have been considered the work area, the workers were not wearing respirators as required by procedure for work areas with such contamination levels. In addition, engineering controls were not used to limit airborne radioactivity in the cavity.

A third RPT relieved one of the RPTs (RPT #1) on the refueling floor, and noticed that one of two continuous air monitors on the floor was alarming. About the same time, RPT #1 notified the refueling floor that his face was contaminated. Operations had previously secured the Unit 2 Reactor Building ventilation system to perform a scheduled surveillance approximately 15 minutes earlier.

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The workers were notified and exited the refueling floor, and the refueling floor coordinator requested Operations to restart the ventilation system. Shortly thereafter, contamination was detected in various levels of the Unit 2 reactor building due to air flow through gaps in the refueling floor equipment hatch. In total, 22 workers were contaminated during the event, 17 of whom received measurable intakes of radioactive material.

Three violations were identified as described in the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice). The violations involve: (1) failure to adequately evaluate the job and make necessary surveys of the reactor cavity while the job was in progress; (2) failure to use engineering controls to limit airborne radioactivity in the reactor cavity; and (3) failure of the workers to wear respirators in accordance with radiation protection procedures.

The root causes of the event included inadequate planning which resulted in the failure to adequately evaluate the radiological hazards associated with the reactor vessel disassembly. The ALARA review for the job was cursory and did not consider the potential changing radiological conditions in the cavity. There was a clear lack of management and first line supervisory oversight of the RPTs. Contributing factors included ineffective training of the RPTs and radiation workers, the lack of a questioning attitude of RPTs and workers concerning the work environment, poor communications, a lack of understanding of how the reactor building ventilation system's operation affects radiological conditions, and an inadequate review of Information Notice 92-75.

The root causes of this event are similar to those associated with the failure to make appropriate surveys which resulted in administrative overexposures on December 17, 1991 (EA 92-003). Your corrective actions documented in your February 1992 response to the enforcement conference and Notice of Violation were ineffective in preventing recurrence, and a lack of management involvement allowed inconsistent performance of the radiological controls program to persist. I am particularly concerned because I brought to your attention at the August 20, 1993, public Systematic Assessment of Licensee Performance (SALP) meeting, clear precursors of poor radiation protection program performance. These included the lack of management and supervisory oversight illustrated by the station Radiation Protection Manager not entering the radiologically controlled area during the first eight months of 1993, recent radioactive waste spills, and continued observations of poor radiation worker performance.

furthermore, we are concerned that performance after this event has continued to be poor. Specifically, we continue to see disturbing radiation protection work practices during our plant tours, including two cases of radiation workers not following specific job instructions to contact radiation protection before commencing work. We are concerned that this continuing poor performance may stem from your underestimating the depth and breadth of the underlying problems as illustrated by what appeared to be an overly optimistic portrayal of the present situation at the enforcement conference. It appears that the continuing problems are due, in part, to poor individual performance by RPT' and other radiation workers; these problems raise fundamental questions about the attitude of station workers towards radiation hazards.

This situation requires sustained and intensive management oversight and involvement in radiation work activities.

We acknowledge your corrective actions for the violations, which included but were not limited to: implementation of the lead technician program for the refuel floor by a qualified manager, ensuring continuity is provided when new programs are implemented, conducting one-on-one discussions with the RPTs to review the event and management expectations, developing an administrative controls guide for the refuel floor, reconsidering the need for localized ventilation units during reactor vessel disassembly, and extensive actions to address programmatic and radiation protection attitude issues. However, we are concerned that you apparently underestimated the scope of the problems that you face, your training initiatives were not sufficiently comprenensive in that no feedback mechanism was included to assess effectiveness, and you did not address improvements for reviewing NRC information notices.

We recognize that the radiation doses received by the workers during the event were within regulatory limits. Nevertheless, based on the concerns discussed above, 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," (Enforcement Policy) 10 CFR Part 2, Appendix C.

To emphasize the need for management involvement and oversight of the 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 Penalty (Notice) in the amount of $112,500 for the three violations that constitute a 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.

The base civil penalty was mitigated 25 percent because your staff demonstrated initiative in identifying the root causes of the violations resulting in this self-disclosing event. In particular, the immediate actions of the involved radiation protection personnel in pursuing the initial indications of the problem demonstrated a questioning attitude. The base civil penalty was not mitigated for your corrective actions because we had concerns in this area, as discussed above.

The base civil penalty was escalated 50 percent for your poor past performance. A number of problems have been identified in the last two years including a contaminated area posting being cut down and discarded (8/93), three liquid radioactive waste spills which resulted in the significant spread of contamination (6/93 and 8/93), a violation for workers not adhering to a radiation work permit (11/92), and the administrative overexposures discussed above (12/91).

The base civil penalty was escalated 100 percent for prior opportunity to identify. NRC Information Notice 92-75 was issued in November 1992 and alerted licensees to unplanned personnel intakes of radioactive materials because of inadequate radiological, engineering, and procedural controls for contaminated areas. The Information Notice emphasized the need for vigilance in conducting maintenance activities that could significantly increase

airborne radioactive material. Furthermore, as noted earlier, clear precursors of poor radiation protection program performance were brought to your attention at the SALP meeting.

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 125 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, 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

See Attached Distribution

Distribution:

cc w/enclosure:
L. DelGeorge, Vice President,
Nuclear Oversight and Regulatory
Services
W. Murphy, Site Vice President
J. Schmeltz, Acting Station Manager
J. Lockwood, Regulatory Assurance
Supervisor
D. Farrar, Nuclear Regulatory
Services Manager
OC/LFDCB
Resident Inspectors, LaSalle,
Clinton, Dresden, Quad Cities
R. Hubbard
J. W. McCaffrey, Chief, Public
Utilities Division
Licensing Project Manager, NRR
R. Newmann, Office of Public Counsel
State Liaison Officer
Chairman, Illinois Commerce
Commission

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

Commonwealth Edison Company
LaSalle County Station
Unit 2

Docket No. 50-374
License No. NPF-18
EA 93-235

During an NRC inspection conducted from September 8 through 14, 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 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 determine that individuals would not be exposed to airborne concentrations exceeding the limits specified in 10 CFR 20.103. Specifically, on September 7, 1993, while performing work in the Unit 2 reactor cavity, breathing zone air surveys were not performed to evaluate the extent of the radiation hazards present during reactor vessel head stud removal. Furthermore, during evaluation of the job the licensee failed to recognize that radiological conditions would likely change in the cavity due to the exhaust of three pneumatic tools. (01013)

B. 10 CFR 20.103(b)(1) states that the licensee shall, as a precautionary procedure, use process or other engineering controls, to the extent practicable, to limit concentrations of radioactive materials in air to levels below those which delimit an airborne radioactivity area as defined in § 20.203(d)(1)(ii).

Contrary to the above, on September 7, 1993, while performing work in the Unit 2 reactor cavity, the licensee did not use engineering controls such as high efficiency particulate air filter ventilation or pneumatic tool air exhaust diffusers to limit concentrations of radioactive materials in air to levels below those which delimit an airborne radioactivity area. (01023)

C. Technical Specification 6.2.B states, in part, that radiation control procedures shall be adhered to.

Procedure LRP-1310-4, Revision 12, dated August 17, 1992, "Selection,

Issuance, and Control of Radiological Respiratory Protective Equipment," Section F.1.a, requires Radiation Protection personnel to evaluate the respiratory protection requirements based on air sampling data and/or contamination surveys per Attachment B. Attachment B states, in part, that smearable levels of greater than 100,000 dpm/100cm² for beta-gamma emitters will require the use of a full face mask pending air sample results which may relax the requirement.

Contrary to the above, on September 7, 1993, while performing work in the Unit 2 reactor cavity which had contamination levels greater than 100,000 dpm/100cm² for beta-gamma emitters in the primary work area, workers did not use full face masks and air samples were not taken. (01033)

This is a Severity Level III problem (Supplement IV).
Civil Penalty - $112,500.

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 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 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 LaSalle County Station.

Dated at Glen Ellyn, Illinois
this 17 day of November 1993

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

November 9, 1993

Docket No. 50-155
License No. DPR-6
EA 93-233

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

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY - $50,000 (INSPECTION REPORT 50-155/93015(DRP))

Dear Mr. Hoffman,

This refers to the special inspection conducted from August 24 through September 14, 1993 at your Big Rock Point facility. The inspection reviewed circumstances surrounding two recent events, and identified several related violations. The first event, which you identified and reported in Licensee Event Report (LER) 93-002, was the existence of a primary containment breach while changing modes from Cold Shutdown to Refueling. The second event was a primary coolant system (PCS) hydrostatic pressure test that inadvertently pressurized the PCS beyond the procedural limit, thus lifting a steam safety relief valve. The report documenting this inspection was sent to you by letter dated October 5, 1993.

On October 12, 1993, we held an enforcement conference in the Region III office with you and other Consumers Power Company representatives to discuss the apparent violations, their causes, and your corrective actions. The enforcement conference summary was sent to you by letter dated October 15, 1993.

The violations in the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice) involve the loss of control over these two plant evolutions. In the first case, containment integrity was breached on June 27, 1993 by performing a switching and tagging order. The order, developed to drain the feedwater line, failed to convey its effect on containment integrity due to inadequate attention to detail both by the preparer and the subsequent reviewer, the shift supervisor. The shift supervisor authorized implementing the order without determining its effect on plant conditions.

Two days later, with containment integrity still breached, shift supervision approved performing a surveillance test that changed the plant operational mode from Cold Shutdown to Refueling, a change requiring containment

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integrity. Only after completing this test was the containment integrity breach identified.

A contributing cause to this event was your lack of effective corrective actions for past events. The root cause analysis for a December 1991 containment integrity breach was narrowly focused. Similarly, the corrective actions implemented for a 1992 inadequate switching and tagging order event were narrowly focused on the event specifics. Your corrective actions for these events failed to adequately address program weaknesses and plant configuration control weaknesses.

The second evolution was a hydrostatic pressure test of the PCS. During the test, your personnel lost control of the evolution and pressurized the PCS to a level where one of the steam safety valves opened, rupturing four rupture discs. Review of the event found inadequate job briefings, inadequate job planning, shift supervision becoming overly involved in troubleshooting which caused a loss of focus on overall plant status, inadequate communications between the job site and control room, inadequate work practices during the test performance, and insufficient understanding of solid plant operations.

The fundamental problem was a pervasive lack of sensitivity to the potential for a pressure excursion, which engendered a lax approach to conducting the test. Related weaknesses found during review included problems with test configuration (no relief valve at the pump), inadequate maintenance of the public address system, and procedure weaknesses. Management expectations and policy regarding such an evolution were also not effectively understood. As a result, a test that was performed only once per outage and that involved an abnormal solid plant operating condition, was treated as "routine" and implemented without sufficient preparation.

The enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice) describes six violations. These violations represent a breakdown in the controls essential for safe conduct of important activities. Although this particular case had minor safety consequences, similar performance under other circumstances might have resulted in more significant consequences.

Furthermore, the disorganized manner in which the hydrostatic pressure test was conducted is unacceptable for nuclear power plant operations. We are concerned that the underlying causes of this event are essentially identical to the causes of a recent Palisades event, for which we held a previous enforcement conference with you on August 10, 1993. After the Palisades control rod withdrawal event, the lessons to be learned were published at Big Rock Point. Given that the Palisades event occurred in June 1993, corrective actions for Consumers Power should have been developed and implemented to preclude similar events at Big Rock Point. We are also concerned that neither your line management nor your Nuclear Performance Assessment Department (NPAD) contributed significantly to ensuring that these types of events do not recur.

Collectively, the violations in the enclosed Notice represent a potentially significant lack of attention 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.

Your corrective actions included improving visual aids for the containment isolation valves; notifying operations procedure sponsors of the potential for breaching containment integrity and instructing them to add caution statements in applicable procedures; improving administrative controls for containment isolation valve operations and mode switch manipulation; and improving the man-machine interface for future PCS pressure tests (by modifying the pressure test equipment and the containment paging system). In addition, you specified generic corrective actions, including increased backshift management during abnormal evolutions (refueling outages, all reactivity events, infrequently performed tests and evolutions, etc.); more staff training in human performance evaluation methodology; and better guidance on using the infrequently performed test and evolution process to identify other evolutions for which the process is mandatory.

To emphasize the need for increased management attention to licensed activities, 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. Partial mitigation (25%) was warranted for your identification and reporting of the events. You identified and correctly reported the loss of containment integrity event. The hydrostatic pressure test event was self-disclosing. NRC initiative was required to identify the numerous other contributing violations. In addition, full mitigation (50%) was warranted for your comprehensive corrective actions.

Partial escalation (50%) was assessed for past performance based upon your most recent Systematic Assessment of Licensee Performance (SALP) ratings, more recent inspection findings, and the sometimes narrow scope and ineffectiveness of previous corrective actions. Specifically, at a July 9, 1992 enforcement conference, we discussed violations associated, in part, with inadequate configuration control during the implementation of a switching and tagging order. Additionally, for a 1991 LER involving a previous breach of containment integrity, your corrective actions were narrow in scope and insufficiently implemented. Partial escalation (25%) was also warranted for the prior opportunity to identify, based on your ineffective short-term implementation of the lessons learned from the recent Palisades control rod event.

The remaining factors in the Enforcement Policy were considered and no further adjustments were considered appropriate. Therefore, based on the above, the civil penalty remained unchanged.

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 each of the violations and to resolve the general weakness in your plant configuration management program. After reviewing your response to this Notice 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,

J. B. Martin,
Regional Administrator

Enclosure:
Notice of Violation

cc w/enclosure:
Patrick Donnelley, Plant Manager
Big Rock Point Nuclear Plant
OC/LFDCB
Resident Inspector, RIII
James R. Padgett, Michigan Public
Service Commission
Michigan Department of
Public Health
SRI, Palisades
L. Olshan, LPM, NRR
B. Jorgensen, RIII
W. Dean, PDIII-1, NRR

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

Consumers Power Company
Big Rock Point Nuclear Plant

Docket No. 50-155
License No. DPR-6
EA 93-233

During an NRC inspection conducted from August 24 to September 14, 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 Part 50, Appendix B, Criterion V, requires, in part, that activities affecting quality be prescribed in documented instructions, procedures, or drawings of a type appropriate to the circumstances, and be accomplished in accordance with these instructions, procedures, or drawings.

Technical Specification 3.6 requires, in part, that containment sphere integrity shall be maintained during shutdown, refueling, and cold shutdown, except as specified by a system of procedures or controls to be established for occasions containment must be breached during cold shutdown.

Surveillance Procedure TR-96/T7-29, "Control Rod Withdrawal Interlocks Test," Revision 7, Step 3.0.a, requires as a prerequisite to initiating the surveillance that plant conditions be such that the mode switch may be placed in REFUEL or RUN.

Surveillance Procedure TV-10, "Pressure Test of Nuclear Steam Supply System," Revision 46, Step 2.2.3.b requires in part that when flange and wall temperatures are above 130°F, hydrostatic test pressure shall not exceed 1535 psig.

1. Contrary to the above, draining of the feedwater line, an activity affecting quality, was performed on June 27, 1993 using Switching and Tagging Order 93-0375. This order was an instruction not appropriate to the circumstances, in that it caused containment sphere integrity to be inadvertently breached when the plant was in cold shutdown, and established no controls for such a breach. (01013)

2. Contrary to the above, as of September 14, 1993, the licensee's surveillance for containment isolation, an activity affecting quality, was prescribed by Procedure O-TGS-1, Checklist A-9, Revision 24. This procedure was not appropriate to the circumstances, in that it failed to identify valve VFW-185 as a containment isolation valve required to be closed or capped to effect containment integrity. (01023)

3. Contrary to the above, on June 29, 1993, the control rod withdrawal interlocks test, an activity affecting quality, was not accomplished in accordance with Procedure TR-96/T7-29, in that the surveillance was initiated and performed with containment integrity breached, a plant condition that did not permit the mode switch to be placed in REFUEL. (01033)

4. Contrary to the above, at 1:00 a.m. on August 24, 1993, the hydrostatic test of the primary coolant system, an activity affecting quality, was not accomplished in accordance with Procedure TV-10 in that, with the flange and wall temperature approximately 249°F throughout the test, the hydrostatic test pressure was permitted to reach 1570 psig. (01043)

B. 10 CFR Part 50, Appendix B, Criterion XVI, requires, in part, that the cause of a significant condition adverse to quality be promptly identified and corrective action taken to preclude repetition.

Contrary to the above, the licensee failed to take corrective actions to preclude repetition of a significant condition adverse to quality, in that, after a January 10, 1992 failure caused by a shift supervisor release of work procedures without determining the resultant effect on plant conditions, and a May 6, 1992 loss of DC power caused by implementing an inadequate switching and tagging order (together resulting in a July 22, 1992 NRC Notice of Violation), the licensee's corrective actions failed to prevent a similar failure. Specifically, an inadequate switching and tagging order was implemented on June 27, 1993, without determining the resultant effect on plant conditions. (01053)

C. 10 CFR Part 50, Appendix B, Criterion II, requires, in part, that training and indoctrination shall be provided as necessary to personnel performing activities affecting quality to assure that suitable proficiency is achieved and maintained.

Contrary to the above, on August 13, 1993, due to insufficient training and indoctrination, suitable proficiency had not been maintained by personnel performing the hydrostatic test of the primary coolant system, an activity affecting quality, in that they were not aware of the rapid effects of a running hydrostatic test pump on solid plant pressure. In addition, the auxiliary operator assigned to the pump was not proficient in the ability to establish a blowdown pathway, if necessary, to reduce pressure. (01063)

These violations represent 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 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.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 III, 799 Roosevelt Road, Glen Ellyn, Illinois 60137, and with a copy to the NRC Resident Inspector at the Big Rock Point Nuclear Plant.

Dated at Glen Ellyn, Illinois
this 9th day of November 1993

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

AUG 17 1993

Docket No. 50-219
License No. DPR-16
EA 93-136

Mr. John J. Barton
Vice President and Director
GPU Nuclear Corporation
Oyster Creek Nuclear Generating Station
Post Office Box 388
Forked River, New Jersey 08731

Dear Mr. Barton:

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY - $75,000
(NRC Inspection Report No. 50-219/93-07)

This letter refers to the NRC safety inspection conducted on May 17 and 18, 1993, at the Oyster Creek Nuclear Generating Station, Forked River, New Jersey. The inspection was conducted to review the events associated with entry and work in the fill aisle batch tank pit of the Oyster Creek New Radwaste Building on May 7 and 11, 1993. The specific events were identified by your staff and reported to the NRC resident staff, even though such reporting was not required. The inspection report, which was transmitted to you on May 31, 1993, identified five apparent violations of NRC requirements, two of which were originally identified by your staff. On June 24, 1993, an open enforcement conference was conducted in the Region I office with you and other members of your staff to discuss the apparent violations, their causes and your corrective actions. An enforcement conference summary report was sent to you by separate correspondence on July 9, 1993.

On May 7, 1993, two contractor workers and a Radiological Controls Technician (RCT) providing coverage for the job entered the New Radwaste Building fill aisle, a locked high radiation area, to preview a task of decontaminating the fill aisle. The RCT was not aware that the task involved entry into the highly contaminated batch tank pit, as the radiation work permit (RWP) did not clearly define the scope of the task, and there were communication problems between the RCT and the Group Radiological Controls Supervisor (GRCS) and between the RCT

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and the workers. Although the GRCS was involved in the pre-job discussion with the workers and was aware of the planned entry into the pit, this discussion was not attended by the RCT and the results of the discussion were not communicated adequately to her. As a result, no survey of this area was done and no instructions regarding radiological hazards in this area were provided to the workers before the entry to the batch tank pit. When one of the workers entered the pit, his alarming dosimeter indicated a much higher dose rate than expected, and he immediately left the area, thereby averting a large unplanned exposure.

Subsequently, on May 11, 1993, another entry was made into the pit to perform decontamination work. The fact that no air sampling was performed prior to this entry is a concern to the NRC. Not only did your staff fail to take air samples prior to the entry on May 11, 1993, but also failed to take samples on the previous day when making the decision about the proper respirator selection for the upcoming entry. Also, based on your determination that a group entry was volved, only one of the two workers entering the pit was provided with a breathing zone nalyzer (BZA). However, the workers entered and worked in the pit individually and may have worked in air contaminated at different concentrations. In any case, the BZA results obtained after completion of the task indicated that the negative pressure full face respirators provided to the workers did not have an adequate protection factor. Therefore, the air sampling for the decontamination entry made on May 11, 1993, was inadequate.

The specific violations are described in the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice), and consist of (1) failure to initiate a radiation work permit (RWP) that clearly defined the scope of the work; (2) failure to survey the work area and provide adequate instructions to workers; (3) failure to perform air sampling required to select proper respiratory protection equipment; (4) failure to conduct appropriate air sampling during the work; and (5) failure to maintain an adequate as low as is reasonably achievable (ALARA) review procedure. The five violations of NRC requirements represent a significant continuing problem in your radiological safety program and a lack of adequate attention to NRC requirements.

At the enforcement conference you denied the last three violations. With respect to Items C and D of the enclosed Notice, you stated that respirators were selected based on expected air activity, and that the two workers were performing similar tasks in the same area on May 11 for similar periods of time, albeit, at different times, resulting in good correlation between the whole body count (WBC) and air sample for both workers. Notwithstanding your contentions, the NRC maintains that these two violations occurred because (1) prior to the May 11 entry, your staff failed to verify by air sampling that their assumptions about the radiological conditions were corr and (2) since the workers were performing decontamination work that could change the ological working conditions and were not entering together, both workers should have been p vided with BZA samplers.

With respect to Item E of the enclosed Notice, you denied the apparent violation presented in the inspection report that dealt with your failure to perform a review to assure that radiation exposures for the work were maintained ALARA. Your denial of the violation was based on an interpretation by the radiological engineer that the work would not cause further spread of contamination and that the airborne concentration was not expected to exceed a factor of 50 times the limits specified in 10 CFR 20, Appendix B, Table 1. As a result of this interpretation of the criteria provided in your procedure, the engineer chose not to perform an ALARA review. After reviewing this information, we have determined that a violation for failure to follow your procedural requirement to perform an ALARA review did not occur in that the engineer chose not to perform an ALARA review in literal compliance with the criteria in your procedure. Nevertheless, an ALARA review was clearly warranted in this situation and the fact that the criteria in your procedure did not require an ALARA review in this situation demonstrates that the procedure was inadequate. In particular, the procedure permits the engineer to decide whether or not an ALARA review is warranted for a highly contaminated system or component without providing additional standards against which the engineer is to make a determination on the need for an ALARA review. If such a review had been performed it is likely that the violations associated with the May 11, 1993 entry being cited would not have occurred. We are concerned that neither your short-term nor long-term corrective actions presented at the enforcement conference proposed a solution for this problem. In your response to this letter, please provide your corrective actions in this area.

The NRC is particularly concerned by certain similarities between the May 7, 1993 event and an event that occurred at Oyster Creek in 1991 (Reference: EA No. 91-056) for which escalated enforcement (Severity Level III violation) was taken. The May 7 event involved poor job planning as related to communicating all relevant information to the involved parties. During the 1991 event, a licensed operator entered a locked high radiation (LHR) area without appropriate monitoring instrumentation, and before a survey was done and before instructions were given to the operator regarding the radiological hazards. During that event, the RWP did not include the entry to the LHR area in the scope of the work, and due to poor communication during the job planning stage, neither the possibility of this entry, nor the prohibition against it, was clearly articulated. It appears that the corrective actions taken for the 1991 event, to emphasize clear communication between the parties involved and to ensure adequacy of monitoring instruments when group entries are made into radiation areas, were not effective in preventing the recent violations.

The NRC recognizes that the radiation doses received by workers in these two incidents were, in each case, well within the regulatory limits. Nevertheless, given the continuing weakness with the communications and coordination associated with work in areas of significant radiological hazards as evidenced by these events, the violations have been categorized 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 also recognizes that subsequent to the identification of the violations, several immediate corrective actions were taken. These corrective actions included, but were not limited to, reviews of the events and issuance of various guidance to appropriate plant personnel. The guidance included requiring complete information on the job scope before an RWP could be issued; interpretation of ALARA review criteria; requirements for pre-job briefings and discussions; and additional BZA sampling and additional conservatism in selection of respirators.

Notwithstanding these corrective actions, to emphasize the importance of adherence to the proper radiological control requirements and procedures as well as the communications necessary to implement those requirements and 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 of Violation and Proposed Imposition of Civil Penalty (Notice) in the amount of $75,000 for the Severity Level III problem. The base civil penalty amount for a Severity Level III violation or problem is $50,000. The escalation and mitigation factors set forth in the Enforcement Policy were considered as discussed below.

The base civil penalty was escalated 25% because your long-term corrective actions to prevent recurrence were not considered adequate or timely. In the NRC's view, the two events clearly indicated weaknesses in your radiological controls program regarding job planning and communication, especially for decontamination work in highly contaminated areas. However, as of the enforcement conference, you had not yet determined whether changes were warranted in the areas of job planning and ALARA reviews for future similar tasks. The base civil penalty was further escalated by 25% on the basis of prior performance. As discussed earlier, inadequacies in communications and coordination associated with the work on May 7 and 11, 1993, were evident in the Notice issued in June 1991. Full escalation based on this factor was not applied because of your generally improving performance in radiological controls. The other adjustment factors in the enforcement policy were considered, and no further adjustment to the base civil penalty is considered appropriate. Therefore, on balance, the base civil penalty is escalated 50%.

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. During the enforcement conference, you also indicated that a human-performance-based evaluation to determine the root causes is currently in progress. You should include, in your response, the results of this evaluation. 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

ENCLOSURE

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

GPU Nuclear Corporation
Oyster Creek Nuclear Generating Station

Docket No. 50-219
License No. DPR-16
EA 93-136

During an NRC inspection conducted on May 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 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. Plant Technical Specification (TS) 6.11 requires, in part, that procedures for personnel radiation protection be prepared consistent with the requirements of 10 CFR Part 20 and shall be approved, maintained and adhered to for all operations involving personnel radiation exposure.

Licensee radiation safety procedure 9300-ADM-4110.04, Rev. 8, "Radiation Work Permit (RWP)," paragraph 7.2.3, Block 3, Work Description, written to comply with TS 6.11 and 10 CFR Part 20, requires that sufficient detail be provided in the RWPs for Radiological Controls personnel to understand the scope of the task.

Contrary to the above, RWP 930254, prepared for decontamination work scheduled for May 7, 1993, in the New Radwaste Building fill aisle, did not provide sufficient detail for Radiological Controls personnel to understand the scope of the task. Specifically, the RWP did not indicate that personnel would enter into the batch tank pit on the 23' elevation of the New Radwaste Building. Consequently, on May 7, 1993, workers entered the batch tank pit, while neither the Radiation Controls Technician providing job coverage to the workers, nor the Radiological Engineering Department, which establishes as low as reasonably achievable (ALARA) controls and support, knew that this entry was to be made under this RWP.

B. 10 CFR 20.201(b) requires that each licensee make such surveys as (1) may be necessary to comply with the requirements of Part 20 and which (2) 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.

10 CFR 19.12 requires, in part, that all individuals working in any portion of a restricted area be kept informed of radiation in such portions of the restricted area, and be instructed in the precautions and procedures to minimize exposure to radiation. The extent of these instructions shall be commensurate with potential radiological health protection problems in the restricted area.

Contrary to the above, prior to the May 7, 1993 entry by personnel into the batch tank pit on the 23' elevation of the New Radwaste Building, a portion of the licensee's restricted area that was posted as a locked high radiation area and which required respirator usage, the licensee did not (1) survey the batch pit to assure compliance with that portion of 10 CFR 20.101 that limits total occupational dose and (2) inform individuals working in the area of radiation levels in the area and had not instructed those individuals in the precautions and procedures to minimize exposure to radiation. The floor of the batch pit had been covered with spilled powder resin from the batch tank and had contact dose rates of about 10 R/hr.

C. 10 CFR 20.103(c)(2) requires, in part, that the licensee maintain and implement a respiratory protection program that includes, as a minimum, air sampling sufficient to identify the hazard and permit proper equipment selection.

Licensee radiation safety procedure 9300-4020.03, Revision 8, "Use of Respiratory Protection Equipment," paragraph 7.9.2 requires that the protection factor (PF) for respiratory protection equipment selected be greater than the multiple by which the peak concentration of airborne radioactive materials are expected to exceed the values of Appendix B, Table I, Column I of 10 CFR Part 20 as determined by the sampling of the airborne contamination.

Contrary to the above, on May 11, 1993, the licensee did not maintain and implement a respiratory protection program in that (1) radiation workers were permitted entry into the batch tank pit on the 23' elevation of the New Radwaste Building to remove debris, without prior air sampling being conducted in the pit to identify the hazard and (2) the respiratory protection equipment (negative pressure full face respirators) worn by the workers provided a PF of 50, which was less than the required PF indicated by the air sampling conducted during the pit entry.

D. 10 CFR 20.103(a)(3), requires, in part, that for purposes of determining compliance with the requirements of 10 CFR 20.103, the licensee shall use suitable measurements of concentrations of radioactive material in air for detecting and evaluating airborne radioactivity in restricted areas.

Contrary to the above, on May 11, 1993, two radiation workers entered the batch tank pit on the 23' elevation of the New Radwaste Building, a posted restricted area requiring respiratory protection equipment for entry, and the licensee did not use suitable measurements of concentrations of radioactive material in air for detecting and evaluating airborne radioactivity. Specifically, only one person had been issued a breathing zone analyzer (BZA), despite the fact that only one person could enter the batch tank pit at a time. This resulted in a situation where the worker without the BZA could be working in higher concentrations of airborne radioactivity.

E. Plant Technical Specification 6.11 requires that procedures for personnel radiation protection be prepared consistent with the requirements of 10 CFR Part 20 and shall be approved, maintained, and adhered to for all operations involving personnel radiation exposure.

Licensee radiation safety procedure 9300-ADM-4010.02, Revision 5, "ALARA Review Procedure," Section 7.3, "ALARA Review Criteria", in part, implements the requirements of 10 CFR Part 20 by specifying the circumstances in which an ALARA review must be done.

Contrary to the above, as of May 18, 1993, procedure 9300-ADM-4010.02 did not adequately specify criteria for performing an ALARA review for highly contaminated systems and components in that such reviews were left to the discretion of Radiological Engineering without guidelines for exercising that discretion. As a consequence, Radiological Engineering waived the performance of an ALARA review for a planned decontamination task involving highly contaminated material in a locked high radiation exclusion area - a situation for which an ALARA review would normally have been warranted by sound radiological protection principles.

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

Civil Penalty - $75,000.

Pursuant to the provisions of 10 CFR 2.201, GPU Nuclear (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, 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, 475 Allendale Road, King of Prussia, Pa 10406, and a copy to the NRC Resident Inspector at Oyster Creek.

Dated at King of Prussia, Pennsylvania
this 17th day of August 1993

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

NOV 0 9 1993

Docket No. 50-219
License No. DPR-16
EA 93-136

Mr. John J. Barton, Vice President
and Director
GPU Nuclear Corporation
Oyster Creek Nuclear Generating Station
Post Office Box 388
Forked River, New Jersey 08731

Dear Mr. Barton:

SUBJECT: ORDER IMPOSING A CIVIL MONETARY PENALTY - $25,000
(NRC Inspection Report No. 50-219/93-07)

This letter refers to your letter, dated September 20, 1993, in response to the Notice of Violation and Proposed Imposition of Civil Penalty (Notice) sent to you by our letter dated August 17, 1993. Our letter and Notice described five violations of NRC radiological controls requirements, which were classified in the aggregate as a Severity Level III problem. To emphasize the importance of adherence to the proper radiological control requirements as well as the communications necessary to implement those requirements, a civil penalty in the amount of $75,000 was proposed for these violations. The base civil penalty of $50,000 was escalated by 25% based on the long term corrective action not being adequate or timely, and another 25% based on the licensee's prior performance.

In your response, you admitted the violations, and paid $50,000 of the civil penalty. However, you contended that the escalation of the base amount of the penalty was unwarranted, and you requested that it be withdrawn, for the reasons set forth in your response, as summarized in the Appendix.

After considering 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 withdrawing the remainder of the civil penalty. Accordingly, we hereby serve the enclosed Order on GPU Nuclear Corporation imposing a civil monetary penalty in the amount of $25,000.

We will review the effectiveness of your corrective actions during a subsequent inspection.

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

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's Public Document Room.

Sincerely,

James Lieberman, Director
Office of Enforcement

Enclosures: As Stated

cc w/encls:
M. Laggart, Manager, Corporate Licensing
G. Busch, Manager, Site Licensing, Oyster Creek
Public Document Room (PDR)
Local Public Document Room (LPDR)
Nuclear Safety Information Center (NSIC)
NRC Resident Inspector
K. Abraham, PAO-RI (2)
State of New Jersey

UNITED STATES
NUCLEAR REGULATORY COMMISSION

In the Matter of	)	
	)	
GPU Nuclear Corporation	)	Docket No. 50-219
Oyster Creek Nuclear Generating Station	)	License No. DPR-16
	)	
Forked River, New Jersey	)	EA 93-136

ORDER IMPOSING A CIVIL MONETARY PENALTY

I

GPU Nuclear Corporation (Licensee) is the holder of Operating License No. DPR-16 (License), issued by the U. S. Nuclear Regulatory Commission (NRC or Commission). The License authorizes the Licensee to operate the Oyster Creek Nuclear Generating Station, in accordance with the conditions specified therein.

II

An inspection of licensed activities was conducted on May 17 and 18, 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 August 17, 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 on September 20, 1993. In its response, the Licensee admitted the violations, and paid $50,000 of the $75,000 proposed. However, the licensee requested withdrawal of the remaining portion 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 portion of the civil penalty not paid by the licensee should be imposed for the violations designated in the Notice.

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 $25,000 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

James Lieberman, Director
Office of Enforcement

Dated at Rockville, Maryland
this 9th day of November 1993

APPENDIX

EVALUATION AND CONCLUSION

On August 17, 1993, a Notice of Violation and Proposed Imposition of Civil Penalty (Notice) in the amount of $75,000 was issued to the licensee for five violations identified during an NRC inspection. GPU Nuclear Corporation (Licensee) responded to the Notice on September 20, 1993. The Licensee admitted the violations, paid $50,000 of the civil penalty, but requested withdrawal of the remaining $25,000 of the civil penalty. The NRC's evaluation and conclusion regarding the licensee's requests are as follows:

1. **Restatement of Violations**

   A. Plant Technical Specification (TS) 6.11 requires, in part, that procedures for personnel radiation protection be prepared consistent with the requirements of 10 CFR Part 20 and shall be approved, maintained and adhered to for all operations involving personnel radiation exposure.

      Licensee radiation safety procedure 9300-ADM-4110.04, Rev. 8, "Radiation Work Permit (RWP)," paragraph 7.2.3, Block 3, Work Description, written to comply with TS 6.11 and 10 CFR Part 20, requires that sufficient detail be provided in the RWPs for Radiological Controls personnel to understand the scope of the task.

      Contrary to the above, RWP 930254, prepared for decontamination work scheduled for May 7, 1993, in the New Radwaste Building fill aisle, did not provide sufficient detail for Radiological Controls personnel to understand the scope of the task. Specifically, the RWP did not indicate that personnel would enter into the batch tank pit on the 23' elevation of the New Radwaste Building. Consequently, on May 7, 1993, workers entered the batch tank pit, while neither the Radiation Controls Technician providing job coverage to the workers, nor the Radiological Engineering Department, which establishes as low as reasonably achievable (ALARA) controls and support, knew that this entry was to be made under this RWP.

   B. 10 CFR 20.201(b) requires that each licensee make such surveys as (1) may be necessary to comply with the requirements of Part 20 and which (2) 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. 10 CFR 19.12 requires, in part, that all individuals working in any portion of a restricted area be kept informed of radiation in such portions of the restricted area, and be instructed in the precautions and procedures to minimize exposure to radiation. The extent of these instructions shall be commensurate with potential radiological health protection problems in the restricted area.

Contrary to the above, prior to the May 7, 1993 entry by personnel into the batch tank pit on the 23' elevation of the New Radwaste Building, a portion of the licensee's restricted area that was posted as a locked high radiation area and which required respirator usage, the licensee did not (1) survey the batch pit to assure compliance with that portion of 10 CFR 20.101 that limits total occupational dose and (2) inform individuals working in the area of radiation levels in the area and had not instructed those individuals in the precautions and procedures to minimize exposure to radiation. The floor of the batch pit had been covered with spilled powder resin from the batch tank and had contact dose rates of about 10 R/hr.

C. 10 CFR 20.103(c)(2) requires, in part, that the licensee maintain and implement a respiratory protection program that includes, as a minimum, air sampling sufficient to identify the hazard and permit proper equipment selection.

Licensee radiation safety procedure 9300-4020.03, Revision 8, "Use of Respiratory Protection Equipment," paragraph 7.9.2 requires that the protection factor (PF) for respiratory protection equipment selected be greater than the multiple by which the peak concentration of airborne radioactive materials is expected to exceed the values of Appendix B, Table I, Column I of 10 CFR Part 20 as determined by the sampling of the airborne contamination.

Contrary to the above, on May 11, 1993, the licensee did not maintain and implement a respiratory protection program in that (1) radiation workers were permitted entry into the batch tank pit on the 23' elevation of the New Radwaste Building to remove debris, without prior air sampling being conducted in the pit to identify the hazard and (2) the respiratory protection equipment (negative pressure full face respirators) worn by the workers provided a PF of 50, which was less than the required PF indicated by the air sampling conducted during the pit entry.

D. 10 CFR 20.103(a)(3), requires, in part, that for purposes of determining compliance with the requirements of 10 CFR 20.103, the licensee shall use suitable measurements of concentrations of radioactive material in air for detecting and evaluating airborne radioactivity in restricted areas.

Contrary to the above, on May 11, 1993, two radiation workers entered the batch tank pit on the 23' elevation of the New Radwaste Building, a posted restricted area requiring respiratory protection equipment for entry, and the licensee did not use suitable measurements of concentrations of radioactive material in air for detecting and evaluating airborne radioactivity. Specifically, only one person had been issued a breathing zone analyzer (BZA), despite the fact that only one person could enter the batch tank pit at a time. This resulted in a situation where the worker without the BZA could be working in higher concentrations of airborne radioactivity.

E. Plant Technical Specification 6.11 requires that procedures for personnel radiation protection be prepared consistent with the requirements of 10 CFR Part 20 and shall be approved, maintained, and adhered to for all operations involving personnel radiation exposure.

Licensee radiation safety procedure 9300-ADM-4010.02, Revision 5, "ALARA Review Procedure," Section 7.3, "ALARA Review Criteria", in part, implements the requirements of 10 CFR Part 20 by specifying the circumstances in which an ALARA review must be done.

Contrary to the above, as of May 18, 1993, procedure 9300-ADM-4010.02 did not adequately specify criteria for performing an ALARA review for highly contaminated systems and components in that such reviews were left to the discretion of Radiological Engineering without guidelines for exercising that discretion. As a consequence, Radiological Engineering waived the performance of an ALARA review for a planned decontamination task involving highly contaminated material in a locked high radiation exclusion area - a situation for which an ALARA review would normally have been warranted by sound radiological protection principles.

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

Civil Penalty - $75,000.

2. **Summary of Licensee Request for Mitigation**

The licensee, in its response, admitted the violations, and paid $50,000 of the proposed civil penalty. However, the licensee, requested withdrawal of the $25,000 escalation of the civil penalty. (The NRC had escalated the base civil penalty of $50,000 by 25% based on the long term corrective actions not being adequate or timely, and another 25% based on the licensee's prior performance). As a basis for its request, the licensee stated that prior to the enforcement conference, the Vice President/Director of the Station directed that future decontamination activities, similar to the May 7 and 11 tasks, be performed under the licensee's work management planning process. The licensee also indicated that Radiological Controls management had issued directives to define the expected interpretations of the As-Low-As-Reasonably-Achievable (ALARA) review criteria. These directives were included in the procedures shortly after the enforcement conference. Therefore, the licensee requests that the 25% escalation based on the corrective action factor be withdrawn.

With respect to the licensee's prior performance, the licensee contends that the May 1993 event and the April 1991 event, the latter being the subject of a past escalated enforcement action (Reference: EA No. 91-056), do not have similar root causes. Therefore, the licensee maintains that the two events are not indicative of the same failure, and corrective actions for the April 1991 event cannot be expected to have prevented the May 7th event. On this basis, the licensee contends that the 25% escalation of the base civil penalty on prior performance is inappropriate.

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 withdrawal of the $25,000 portion of the civil penalty attributed to the 50% escalation of the base amount.

With respect to the 25% escalation of the penalty based on corrective actions, the licensee's presentation at the June 24, 1993 enforcement conference, more than six weeks after the event, indicated that the licensee had not completed its determination on a need for clarifying the ALARA review procedure or on the need for instituting long-term corrective actions that focused on ALARA review and job planning. Weaknesses in the ALARA procedure were a major contributing factor in the root cause of the violations,

because had the procedure specified clear criteria for performing an ALARA review in this case, such a review would have provided the necessary elements of radiological planning to prevent the violations from occurring.

The NRC recognizes that the licensee's May 24, 1993, "ALARA Reviews and RWP Requirements" memorandum instructed the licensee's staff to perform reviews for a broad category of work. However, at the enforcement conference, the licensee indicated that they had not determined if these changes would be made permanent by incorporating them in the ALARA procedure. While the licensee's May 24, 1993 memorandum constituted an adequate interim corrective action, it needed to be incorporated into the radiation protection procedures to qualify as a long-term corrective action, because Technical Specification 6.11 requires that all operations involving personnel radiation exposure shall be conducted following personnel radiation protection procedures. In this case, the necessary procedure changes, including the temporary change to the ALARA review procedure, were not made until the NRC emphasized the need for permanent procedural guidance at the enforcement conference. Therefore, the NRC maintains that the licensee's long-term corrective actions were not adequate or timely and the 25% civil penalty escalation based on corrective actions was appropriate.

With respect to the 25% escalation of the penalty based on past performance, the NRC maintains that the 1991 and May 1993 events were similar in that they both indicated weaknesses in job planning and communication, and failure of personnel to ensure that radiological requirements regarding appropriate survey, instructions and monitoring were followed. For example, in 1991, one operator entered a locked high radiation area of unknown radiation intensity without appropriate survey, monitoring equipment, and instructions in precautions and procedures to minimize exposure to radiation, as required by the plant technical specifications and the regulations. In May 1993, workers entered a highly contaminated locked high radiation area of unknown radiation hazard without appropriate survey and instructions, and on one occasion, one worker entered the same area without suitable monitoring equipment for airborne radioactivity, as required by the regulations.

In addition, the 1991 event indicated a need for the licensee to enhance its procedure regarding personnel monitoring during group entry, in particular, the practice of allocating certain monitors to only one person when more than one person was entering the area. During the May 11, 1993 event, the same "group entry" criterion was applied and

resulted in not having suitable measurements of radioactive dose for one of the two workers, since they were separately entering the highly contaminated area.

When considering whether to escalate the penalty based on the licensee performance factor, a number of criteria are considered, as stated in Section VI.B.2 of the Enforcement Policy. In addition to the effectiveness of previous corrective actions for similar problems, those criteria consist of Systematic Assessment of Licensee Performance (SALP) evaluations, prior enforcement history overall as well as in the area of concern. The base civil penalty may also be escalated by as much as 100% if the current violation reflects the licensee's poor prior performance. Even if the NRC were to accept the licensee's argument that the events were not similar, a basis for partial escalation based on past performance still exists, given the licensee's prior enforcement history in the area of radiological controls, since it included the escalated enforcement action in 1991 along with several cited and non-cited violations since then. In light of the prior events, the NRC could have considered an even higher escalation, rather than the 25% applied, but chose not to because of the licensee's improving SALP rating in this area. Therefore, based on the above, the NRC maintains that 25% escalation on the factor is appropriate.

4. NRC Conclusion

The NRC concludes that the licensee has not provided an adequate basis for mitigating the escalation of the civil penalty based on the corrective action and prior performance adjustment factors. Accordingly, the NRC has determined that a monetary civil penalty in the amount of $25,000 should be imposed.

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

OCT 12 1993

Docket No. 50-298
License No. DPR-46
EA 93-137

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

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTIES - $200,000 (NRC INSPECTION REPORT NO. 50-298/93-17)

This is in reference to the inspection conducted March 29 through April 2 and May 3-7, 1993, at the Cooper Nuclear Station (CNS), Brownville, Nebraska. This inspection was conducted specifically to evaluate the effectiveness of Nebraska Public Power District (NPPD) processes for identifying and resolving deficiencies and determining the operability of systems affected by deficiencies. A report documenting the results of this inspection was issued on June 17, 1993. On August 13, 1993, you and other Nebraska Public Power District (NPPD) 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.

Based on the information developed during the inspection and the information that NPPD provided during the enforcement conference, the NRC has determined that the following significant violations of NRC requirements did occur and that civil penalties should be assessed: 1) several violations of 10 CFR 50, Appendix B, Criterion XVI, which are itemized in the enclosure and which collectively indicate a breakdown in NPPD's corrective action program ($75,000); 2) a violation of plant Technical Specifications involving inoperable containment hydrogen/oxygen analyzers ($75,000); and 3) a violation of 10 CFR 50.55a(g) involving a failure to include essential portions of the CNS service water and reactor equipment cooling systems in the required inservice inspection program ($50,000).

The circumstances surrounding these violations are described in detail in the June 17 inspection report. At the August 13 enforcement conference, NPPD characterized these violations as having minimal safety significance but acknowledged the regulatory significance of the violations taken as a whole. From the NRC's perspective, these particular violations have both regulatory and safety significance because: 1) the breakdown in NPPD's corrective action program had the potential to affect the reliability of many safety-related systems and components; 2) the failure to maintain the containment hydrogen/oxygen analyzers in an operable condition is a specific example where an important component may not have provided reliable information when it is

counted on, i.e., under accident conditions; and 3) the failure to include the service water and reactor equipment cooling systems in the inservice inspection program since initial plant operations, specifically the failure to conduct pressure testing of these systems, placed into question the long-term reliability of these systems. In addition, NPPD failed to detect this problem despite a similar violation in 1991 and a third-party review of its inservice inspection program to determine whether other nonconformances existed (Inspection Report 50-298/91-26).

With regard to the violations indicating a breakdown in NPPD's corrective action programs, the NRC recognizes that NPPD was cited on March 30, 1993, for a similar violation (EA 93-030) and that a $100,000 civil penalty was proposed and was subsequently paid. In an April 29, 1993 response to that enforcement action, NPPD noted the development of a Corrective Action Program Overview Group (CAPOG) to review the effectiveness of its programs and described its plans to have a consultant review personnel-related and management oversight issues. The NRC acknowledges that NPPD's long-term corrective actions for EA 93-030 could not have prevented the violations cited in section I.A of the enclosed Notice of Violation and Proposed Imposition of Civil Penalties, most of which occurred prior to the date of NPPD's written response. However, NPPD was clearly aware of the NRC's concerns about its corrective action programs prior to the dates of the violations in the enclosure and its employees should have been more sensitive to the need to formally document and systematically resolve problems. For example, the plant's secondary containment system failed a test on March 8, 1993, and failed an undocumented follow-up test on March 10, 1993. Despite a history of secondary containment test failures, plant personnel declared it operable on March 12, 1993, prior to determining the cause of the failures, and generated a nonconformance report documenting the test problems only after NRC inspectors questioned plant personnel. NPPD's subsequent investigation found that an error during plant construction resulted in a missing loop seal in a 10-inch pipe between the reactor building and the radwaste building. From the NRC's perspective, NPPD personnel should have been keenly aware in March 1993 of the need to document and promptly resolve such problems in that the NRC had described its concerns in a SALP report issued in March 1992 and had continued to document its concerns in inspection reports issued following the SALP report.

Additionally, the circumstances surrounding the testing of the secondary containment and the problems associated with the hydrogen/oxygen analyzers illustrate a serious NRC concern with maintenance and testing practices at CNS. Performing preventive maintenance prior to conducting a test of secondary containment and excessive draining of the filter bowls on the hydrogen/oxygen analyzers to eliminate erratic instrument readings are practices that had the potential to mask unsatisfactory system performance and to permit system problems to go undiscovered and uncorrected.

Therefore, based on the regulatory and safety significance that the NRC attaches to these particular violations, each of the above violations has been 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 results of NPPD's investigation into the causes of these violations, as well as the violations that are not being assessed civil penalties, confirm the NRC's concerns about the effectiveness of NPPD's processes for ensuring that deficiencies are identified to the proper level of management and resolved adequately and in a manner that precludes their recurrence. NPPD's investigation determined that the following causes contributed to the occurrence of these violations: a willingness to correct deficiencies without documenting them in the corrective action program, a rigid corrective action program that made its use undesirable, a lack of problem ownership, a perception that the corrective action program was an NRC program as opposed to a program that provided benefits to NPPD, a perception that corrective action documents were negative performance indicators, a perception that managers responded negatively to problems, production pressures (in one instance), and a lack of personal accountability.

While these causes are disturbing, their identification is essential to the development of an effective resolution. NRC recognizes that NPPD has initiated broad corrective action in an attempt to resolve these weaknesses in its corrective action programs. However, the NRC also recognizes that the resolution of such fundamental weaknesses will require a substantial effort for an extended period of time and that NPPD may have to take additional steps as it continues to obtain information from the efforts already underway.

To emphasize the significance that the NRC attaches to these violations and the importance that the NRC attaches to NPPD's efforts to resolve deeply rooted and fundamental weaknesses in employee attitudes toward identifying and resolving problems, 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 violations described above.

The base value of a civil penalty for a Severity Level III violation or problem is $50,000. The civil penalty adjustment factors in the Enforcement Policy were considered and resulted in the following:

1. For the breakdown in the corrective action program, the base penalty was increased by $25,000, resulting in a penalty of $75,000, because the NRC identified the individual violations that comprise this Severity Level III problem. Although these violations are an indication of continuing poor performance in this programmatic area, the NRC did not increase the penalty based on the Licensee Performance factor because a previous civil penalty (EA 93-030) for a similar violation was increased for the same reason and because NPPD had not had the opportunity to complete its long-term corrective actions in response to EA 93-030.

2. For the inoperable hydrogen/oxygen analyzers, the base penalty was increased by $25,000, resulting in a penalty of $75,000, because the NRC identified the violation and because NPPD had multiple opportunities to identify and correct this problem prior to this inspection. These increases were balanced against mitigation for NPPD's specific corrective actions.

3. For the failure to include the service water and reactor equipment cooling systems in the inservice inspection program, the base penalty was not adjusted, resulting in a penalty of $50,000. In this case, the fact that the NRC identified this violation was balanced against NPPD's specific corrective actions.

The remaining civil penalty adjustment factors were considered for each of the above civil penalties but no further adjustments were considered appropriate.

In addition to the violations discussed above, the Notice contains several Severity Level IV violations which have not been assessed a civil penalty. These violations include: 1) the failure of workers to follow the provisions of a maintenance work request; 2) the failure of a worker to follow procedures for racking out an electrical breaker, resulting in a temporary loss of shutdown cooling; 3) the failure of workers to sign a special work permit prior to entering a radiologically controlled area; 4) the failure to maintain adequate procedures for conducting functional tests of the hydrogen/oxygen analyzers; 5) the failure to have an appropriate rationale for relying on reverse-direction testing of containment isolation valves; and 6) the failure to test the internals of the hydrogen/oxygen analyzers to the required pressure.

Based on the NRC's consideration of NPPD's arguments at the enforcement conference and other relevant information, the NRC is not issuing citations for several issues which were identified as apparent violations in the inspection report. The apparent failure to identify overtime deviation requests, while a violation of procedures, is not being cited because it is not considered significant and therefore meets the criteria in Section VII.B.1 of the Enforcement Policy. The apparent failure to take adequate corrective action to address relief valve setpoint drift problems is not being cited at this time but is considered an unresolved item (298/9317-09). The NRC plans further review of this issue to determine whether NPPD efforts to resolve this problem are adequate. The remaining issues are not being cited either because the NRC has insufficient information to conclude that a violation occurred or because the circumstances do not appear to have resulted in a violation of requirements. Those issues are: 1) the apparent failure to maintain compliance with the Technical Specifications regarding secondary containment integrity; 2) the apparent failure to proceduralize steps necessary to restore power to containment radiation monitors; 3) the apparent failure to properly log the status of critical plant components; and 4) the apparent failure to have adequate procedures for integrated leak rate testing.

NPPD is required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing its response. In its response, NPPD should document the specific actions taken and any additional actions it plans to prevent recurrence. After reviewing NPPD's response to this Notice, including its 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 w/Enclosure:
Nebraska Public Power District
ATTN: G. D. Watson, General Counsel
P.O. Box 499
Columbus, Nebraska 68602-0499

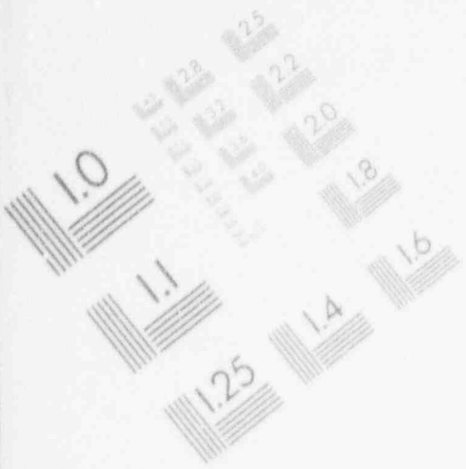
Cooper Nuclear Station
ATTN: John M. Meacham, Site Manager
P.O. Box 98
Brownville, Nebraska 68321

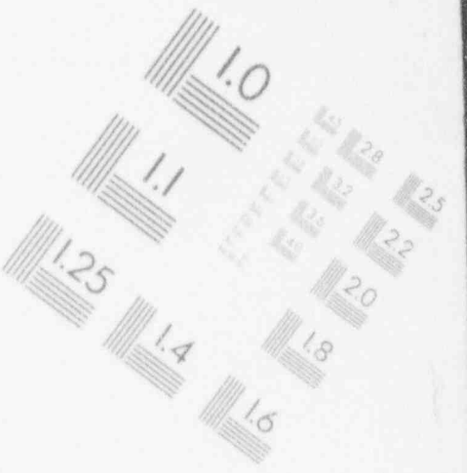
Nebraska Department of Environmental
Control
ATTN: Randolph Wood, Director
Box 98922
Lincoln, Nebraska 68509-8922

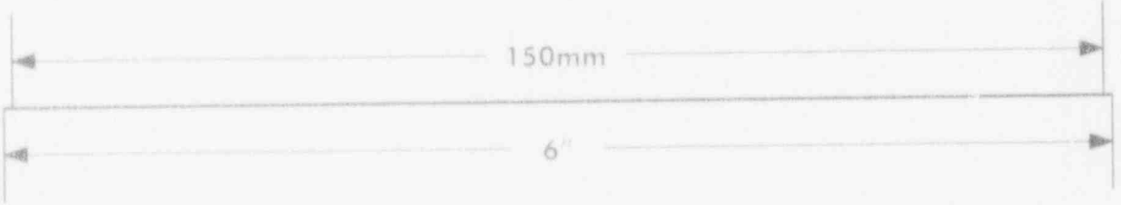
Nemaha County Board of Commissioners
ATTN: Richard Moody, Chairman
Nemaha County Courthouse
1824 N Street
Auburn, Nebraska 68305

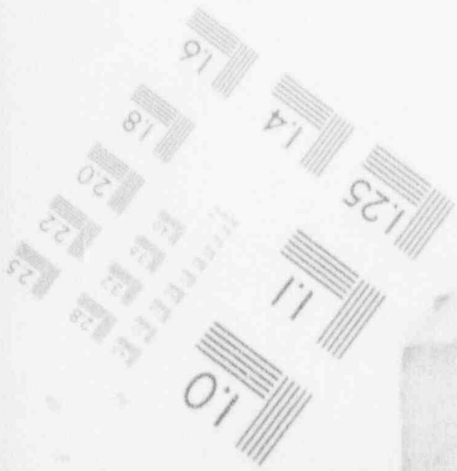
1

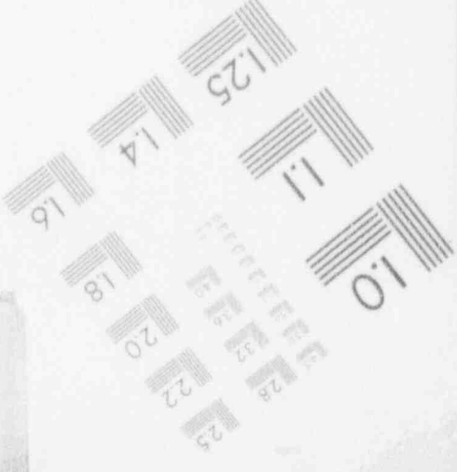
IMAGE EVALUATION
TEST TARGET (MT-3)

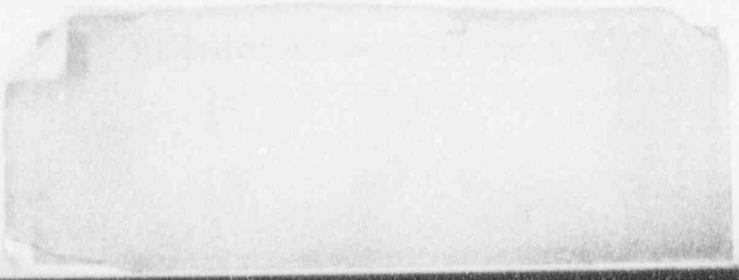












1

IMAGE EVALUATION TEST TARGET (MT-3)

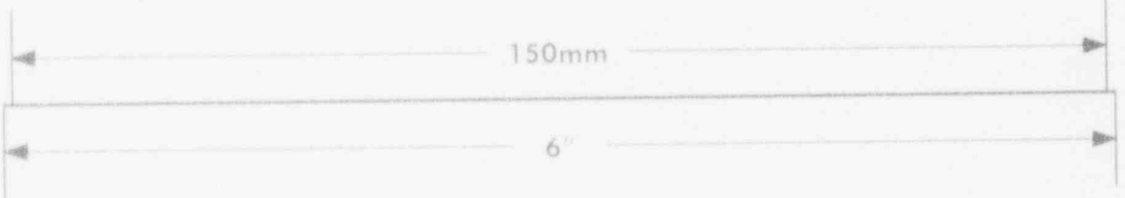


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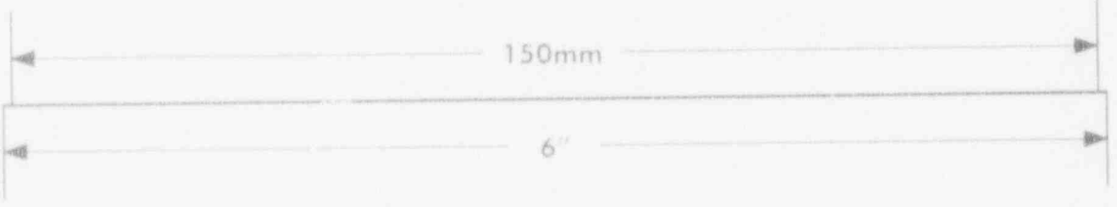
IMAGE EVALUATION TEST TARGET (MT-3)



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 93-137

During an NRC inspection conducted March 29 through April 2 and May 3-7, 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 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. Appendix B to 10 CFR Part 50, Criterion XVI requires that measures shall 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.

1. Contrary to the above, on March 12, 1993, the secondary containment was declared operable without promptly identifying and correcting a significant condition adverse to quality which contributed to the secondary containment failure to meet its integrity test on March 8, 1993. It was subsequently identified that a loop seal had not been established in a pipe from the reactor building to the radwaste building because of a construction deficiency. This condition created a direct leakage path between the reactor and radwaste buildings. (01013)

2. Contrary to the above, on November 16, 1992, the licensee did not promptly identify and correct emergency diesel generator Fuel Oil Tanks A and B particulate concentrations which exceeded the limit established in Station Procedure 6.3.12.3, Revision 13, "Diesel Fuel Oil Quality Test." Measures to correct the high particulate concentrations were not implemented until after April 2, 1993. The emergency diesel generators were required to be operable from November 16, 1992, until the plant was shut down for a refueling outage on March 6, 1993. (01023)

3. Contrary to the above, on May 1, 1992, after identifying primary system leakage past the inboard and outboard shutdown cooling suction isolation Valves RHR-MO-18 and -17, the licensee did not establish measures to promptly correct the condition. On March 29, 1993, the licensee identified that a significant condition adverse to quality existed in that Valve RH-MO-18 failed the 10 CFR Part 50, Appendix J local leak rate test. It was found that five cracks existed in the valve seat and disc. (01033)

4. Contrary to the above, on March 30, 1993, it was determined that the licensee had not promptly identified and corrected a significant condition adverse to quality for paint blistering in the Emergency Condensate Storage Tanks A and B. An inspection of Tanks A and B, as authorized by Maintenance Work Request 93-1271, had identified blistering of the tank interior coating; however, the results of the inspection were not documented in the maintenance work request and no other corrective action measure was initiated to evaluate and correct this condition. (01043)

These violations represent a Severity Level III problem (Supplement I).
Civil Penalty - $75,000

B. Technical Specification Table 3.2.H states that the primary containment Hydrogen Concentration Analyzers PC-AN-H_2/O_2 -I and -II are required to be operable at all times except when the reactor is in cold shutdown or in the REFUEL mode during a refueling outage.

Contrary to the above, from April 1990 until March 6, 1993, with the reactor not in cold shutdown or REFUEL mode during a refueling outage (at various times), primary containment Hydrogen Concentration Analyzers PC-AN-H_2/O_2 -I and -II were not operable. Specifically, it was identified that the inline sample line filter canisters and the sample line slopes resulted in the accumulation of moisture, which resulted in erratic readings and unreliable analyzer operation. (01053)

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

C. 10 CFR 50.55a(g)(1) requires, in part, for boiling, water-cooled nuclear power facilities with construction permits issued prior to January 1, 1971, that safety-related components that are not part of the reactor coolant pressure boundary meet the requirements of 10 CFR 50.55a(g)(4) and (5).

10 CFR 50.55a(g)(4) requires, in part, that throughout the service life of a boiling, water-cooled nuclear power facility, components (including supports), which are classified as ASME Code Class 1, 2, and 3, must meet the requirements, except design and access provisions and preservice examination requirements, set forth in Section XI of the ASME Boiler and Pressure Vessel Code and Addenda.

10 CFR 50.55a(g)(5)(i) requires, in part, that the inservice inspection (ISI) program for a boiling, water-cooled nuclear power facility, must be revised by the licensee, as necessary, to meet the requirements of 10 CFR 50.55a(g)(4).

Contrary to the above, the licensee, which had received a construction permit prior to January 1, 1971, did not include the safety-related components of the service water and reactor equipment cooling systems in

the initial licensed ISI program and did not update the requirements relative to these systems to ASME Section XI equivalency. This condition had existed since initial plant operation in 1974. Since February 12, 1976, when the revisions to 10 CFR 50.55a(g) went into effect, the licensee did not include the essential portions of the service water and reactor equipment cooling systems in the ASME Section XI ISI Program. (01063)

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

II. Violations Not Assessed A Civil Penalty

A. Appendix B to 10 CFR Part 50, Criterion V, Instructions, Procedures, and Drawings, states that activities affecting quality shall 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. Contrary to the above, on April 10, 1993, craft personnel failed to implement Step 5 of Maintenance Work Request 93-3021 which required a system engineer to inspect the inside of the two No. 1 emergency diesel generator aftercoolers prior to cleaning. The craft personnel proceeded to clean the left aftercooler (Step 7) prior to the system engineer conducting the required inspection.

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

2. Contrary to the above, on March 6, 1993, a station operator failed to implement the requirement of Operating Procedure 2.2.18, Revision 33, "4160V Auxiliary Power Distribution," Step 8.1.4 to rack out the Core Spray Pump A breaker. Instead, the station operator proceeded to rack out the breaker to a safety-related substation, by first tripping the breaker, and caused a loss of shutdown cooling.

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

3. Contrary to the above, on March 8, 1993, two contract mechanical maintenance personnel entered the special work permit area surrounding the drywell without reading and signing the special work permit as required by Health Physics Procedure 9.1.1.4, Sections 8.4.3.1 and 8.4.3.5.

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

4. Contrary to the above, as of March 29, 1993, the licensee had not established appropriate quantitative acceptance criteria in Procedures 6.3.1.13, Revision 9, "Division I H_2/O_2 Analyzer Calibration and Functional/Functional Test," and 6.3.1.14,

Revision 10, "Division II H_2/O_2 Analyzer Calibration and Functional/Functional Test," to verify operability of the hydrogen/oxygen analyzer heat tracing. The heat tracing is required to be operable to support operability of the hydrogen/oxygen analyzers as required by Technical Specification Table 3.2.H, POST-ACCIDENT MONITORING INSTRUMENTATION REQUIREMENTS.

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

B. Appendix J to 10 CFR Part 50, Section III.C, states, in part, for valve local leak rate tests that the test pressure shall be applied in the same direction as that applied when the valve would be required to perform its safety function, unless it can be determined that the results from the tests for a pressure applied in a different direction will provide equivalent or more conservative results.

Contrary to the above, since initial plant operation in 1974, the licensee performed reverse direction testing of 26 containment isolation valves without the local leak rate test results being equivalent or more conservative.

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

C. Technical Specification 4.7.A.2 requires integrated leak rate testing to verify primary containment integrity at 58 psig.

Contrary to the above, since installation of the hydrogen/oxygen analyzers in April 1988, the licensee had not tested the cabinet internals at 58 psig. The cabinet internals constitute a primary containment boundary during a design basis event.

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

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 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 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 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 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 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 Cooper Nuclear Station.

Dated at Arlington, Texas
this 12th day of October 1993

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

September 20, 1993

Docket Nos. 50-245, 50-336 and 50-423
License Nos. DPR-21, DPR-65 and NPF-49
EA 93-130

Mr. John F. Opeka
Executive Vice President - Nuclear
Northeast Nuclear Energy Company
Post Office Box 270
Hartford, Connecticut 06141-0270

Dear Mr. Opeka:

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY - $50,000
(NRC INSPECTION REPORT NOS. 50-245, 50-336, AND 50-423/93-80)

This letter refers to the NRC inspection conducted between April 14 through 23 and on May 12, 1993, at the Millstone Nuclear Power Station, Units 1, 2 and 3, Waterford, Connecticut, to review the status and implementation of your licensed operator requalification training (LORT) program. The inspection report was sent to you on June 7, 1993. During the inspection, two apparent violations of the NRC requirements were identified. In addition, the NRC also identified several deviations from commitments you made to the NRC. On July 1, 1993, an enforcement conference was conducted with you and members of your staff to discuss the apparent violations and deviations, their causes and your corrective actions.

The violations are described in the enclosed Notice, and involve: (1) numerous licensed operators, at Units 1 and 2, not fully completing the LORT program for the 1991 and 1992 requalification training period that ended on December 31, 1992; and (2) the failure of the facility Nuclear Review Board (NRB), for the last six years, to either perform, or perform adequately, audits of training, retraining, qualification, and performance of the operations staff in Units 2 and 3, as required by the facility Technical Specifications and the Quality Assurance Plan commitment to ANSI 18.7-1976. The second violation was previously identified by the NRC in February 1993 for Unit 1. During the April-May inspection, the NRC determined that the NRB has not adequately audited these programs for any of the three units during the past six years. While some audits were performed during this time period that did cover certain aspects of these programs, auditing had not been performed in many essential program areas. This violation is particularly significant since there was a two year period in which the NRC found your licensed operator requalification program to be unsatisfactory at Unit 1.

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

The causes of the first violation included lack of a clearly articulated policy on attendance at LORT classes, including classroom instruction, simulator sessions, and job performance tasks, which resulted in a situation where expectations for attendance by staff license holders were lower than those for attendance by operating crew license holders; inadequate priority given by management and staff to timely attendance; and ineffective monitoring of the program. The causes for the second violation included lack of formal procedural controls for NRB audits, and weak implementation of audit requirements.

In addition to the two violations, the NRC identified several deviations from your commitments made to the NRC in your October 7 and November 11, 1991 letters that addressed corrective actions for previously identified LORT program weaknesses, after your requalification program was found to be unsatisfactory in 1991. These deviations involved: (1) not completing management observations of operating crew performance on simulators at the required frequency; and (2) not developing written standards of performance for operating crews by February 28, 1992. The fact that these deviations continued after your requalification program at Unit 1 again was found unsatisfactory in 1992, indicates a lack of effective corrective action and inadequate management oversight and control of the requalification program at your facility.

The NRC's concern about the first violation is in no way diminished by the fact that staff, versus operating crew, license holders were responsible for much of the missed training. It is important that such individuals, some of whom supervised and managed the control room staffs, stay completely current with the required training, even though they are not regularly at the controls of the reactor. The NRC recognizes that the potential safety consequences of both violations was lessened by the fact that all the licensed operators who missed the training did demonstrate proficiency and overall knowledge in subsequent periodic and annual evaluations. Nevertheless, the NRC is concerned that despite your Unit 1 requalification training program being determined to be unsatisfactory by the NRC in 1991, the corrective actions taken at the time to improve the program were not effective in precluding the violations and did not prevent the program from being found unsatisfactory in 1992. Further, the corrective actions taken after the program was again found unsatisfactory in 1992 did not ensure that commitments made to the NRC were satisfactorily implemented.

The violations and the deviations appear to be symptomatic of the significant program weakness that led to your requalification training program being found unsatisfactory in 1991 and 1992. Therefore, despite the fact that the violations identified occurred during the two previous requalification training cycles, the NRC has determined that these weaknesses in the management oversight and control of the LORT program represent a significant regulatory concern. 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 in the aggregate as a Severity Level III problem.

The NRC recognizes that a number of corrective actions were taken to improve the LORT program after the September 1992 unsatisfactory requalification program and again when these violations were most recently identified. These actions included improvements in the accountability, leadership, and partnership between the Operations and Training departments; a change in certain management personnel; addition of a human behavior specialist to the training staff; communication of management expectations on training and performance to the staff via a revised policy statement and meetings between management and staff; conduct of various workshops and training sessions with your staff; and the monitoring of performance on a periodic basis at the executive Vice President level. The above corrective actions, the positive appraisal of many aspects of your LORT program contained in the inspection report, and your frank, self-critical evaluation of the findings of our inspection which you presented at the enforcement conference are encouraging actions. The NRC emphasizes the importance of proper implementation and completion of these actions to preclude recurrence of the violations; and to ensure the requalification programs at your facilities in the future are not found to be unsatisfactory.

Notwithstanding those actions, to emphasize the importance of adequate and continuing management attention to the LORT, so as to assure all training requirements are completed in a timely manner, and appropriate audits are performed to verify completion (particularly in light of two successive unsatisfactory determinations by the NRC of your requalification program), 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 violation or 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 these violations were identified. However, the base civil penalty was also escalated 50% because the NRC identified the violations. The other adjustment factors in the Policy were considered and no further adjustment to the base civil penalty was considered appropriate. Therefore, on balance, no adjustment to the base civil penalty resulted.

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 to responding to the violations you should address the actions you have taken or will take to ensure commitments made to the NRC are properly implemented. 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 are requested to make copies of this action available to all individuals at your facility who hold NRC licenses. While this action focuses on your overall administration of the licensed operator requalification program and the oversight of the program, each of your NRC licensed operators should be reminded that they are also individually responsible for compliance with the conditions of their licenses.

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:
W. Romberg, Vice President - Nuclear, Operations Services
S. Scace, Vice President, Millstone Station
H. Haynes, Nuclear Unit Director
G. Bouchard, Nuclear Unit Director
F. Dacimo, Nuclear Unit Director
R. Kacich, Director, Nuclear Licensing
J. Solymossy, Director of Quality Services
G. Garfield, Esquire
N. Reynolds, Esquire
K. Abraham, PAO-RI (2)
Public Document Room (PDR)
Local Public Document Room (LPDR)
Nuclear Safety Information Center (NSIC)
NRC Resident Inspector
State of Connecticut SLO

ENCLOSURE

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

Northeast Nuclear Energy Company
Millstone Nuclear Power Plant

Docket Nos. 50-245/50-336/50-423
License Nos. DPR-21/DPR-65/NPF-49
EA 93-130

During an NRC inspection conducted on April 14-23, and May 12, 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 Section 6.4.1 requires a Licensed Operator Requalification Training (LORT) program that meets or exceeds 10 CFR 55.59. 10 CFR 55.59(a)(1) requires a licensee (licensed operator) to successfully complete the facility's requalification program and 10 CFR 55.53 (h) makes completion of the requalification program a condition of the licenses for licensed operators and senior licensed operators. 10 CFR 50.54 (i) requires, except as provided in 10 CFR 55.13, that the facility licensee only allow operators and senior operators licensed pursuant to 10 CFR Part 55 to manipulate the controls of the reactor.

Contrary to the above, during the 1991 - 1992 LORT program, the facility licensee failed to ensure that all personnel licensed pursuant to 10 CFR Part 55 to operate or supervise the operation of Units 1 and 2, had successfully completed the requalification program, which is a condition of their licenses. Specifically, numerous licensed personnel for Unit 1 and Unit 2 missed at least one requalification training session (simulator, job performance measure, or class room instruction) and did not makeup the missed program content elements.

B. Technical Specification 6.5.3.7.b. requires that the Nuclear Review Board perform audits that encompass the performance, training, and qualifications of the unit staff at least once per 12 months.

Contrary to the above, between January 1, 1987 and January 1, 1993, the facility licensee audits of the unit staff for Units 2 and 3 either were not performed, or did not include adequate audits of the programs for performance, training, and qualification of the licensed operators.

The above 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, Northeast Nuclear Energy 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 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. 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 Millstone Station.

Dated at King of Prussia, Pennsylvania
this 20th day of September 1993

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION V

1450 MARIA LANE
WALNUT CREEK, CALIFORNIA 94596-5368

November 10, 1993

Docket No. 50-397
License No. NPF-21
EA 93-191

Washington Public Power Supply System
Post Office Box 968
Richland, Washington 99352

Attention: Mr. W. C. Counsil
Managing Director

Subject: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY -- $75,000
(NRC INSPECTION REPORT NOS. 50-397/93-18, 50-397/93-24, AND 50-397/93-29)

This refers to the inspections conducted by Messrs. R. C. Barr, D. L. Proulx, K. E. Johnston, and W. L. Johnson of this office on May 3 through August 2, 1993, at the Washington Nuclear Project No. 2 (WNP-2). The results of these inspections were documented in the referenced NRC inspection reports, which were transmitted to you on July 27, August 30, and August 17, 1993. These issues were discussed with you during an enforcement conference held in the Region V Office on September 22, 1993. The enforcement conference was summarized in Meeting Report No. 50-397/93-37, transmitted to you on October 15, 1993.

The enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice) refers to the use of the residual heat removal (RHR) system in the suppression pool cooling (SPC) mode during power operation, and to several recent procedure violations. The Washington Public Power Supply System (Supply System) identified the use of the RHR system in the SPC mode as part of an engineering review begun in late 1992 and documented the finding in Licensee Event Report (LER) 50-397/93-01, Revision 1, dated June 11, 1993. These SPC mode concerns were evaluated for potential enforcement action during a special inspection documented in Inspection Report No. 50-397/93-29, dated August 17, 1993.

On three separate occasions, operators failed to comply with a procedure that prohibited the use of two trains of the RHR system in the SPC mode during power operation. The procedure requirement was put in place in September 1990 after your staff determined that a train of RHR operating in the SPC mode could partially drain following a loss of offsite power (LOP) and incur a severe water hammer if the RHR pump automatically restarted in response to a loss-of-coolant accident (LOCA). A LOP coincident with a LOCA is a design basis event for WNP-2. Operators placed two trains of the RHR system in the SPC mode on September 30, 1991, for almost 3 hours; on July 6, 1992, for over 6 hours; and on July 11, 1992, for over 2 hours. These three instances,

identified by your staff, occurred during low power safety/relief valve (SRV) testing.

As stated in the LER, your staff initially determined that placing a train of RHR in the SPC mode rendered it inoperable since calculations showed that it would not be able to perform its design function following a LOCA coincident with a LOP. However, your review also concluded that these events did not significantly increase the overall core damage frequency (CDF). This conclusion was based on the limited time that the RHR trains were in the SPC mode and the low probability of a LOCA coincident with a LOP. In addition, at the enforcement conference you stated that the initial operability determination is being evaluated further, based on your belief that the initial operability determination was too conservative, as evidenced by the position other licensees have taken on this issue. Nevertheless, we have concluded that the condition in which two trains of RHR were in the SPC mode constitutes an instance wherein a system designed to prevent or mitigate a serious safety event was degraded to the extent that a detailed evaluation is required to determine operability.

Additionally, the RHR procedure violations are considered significant in light of WNP-2's history of procedure compliance problems as documented below and later in this letter. Specifically, several operator requalification failures between February and June 1991 resulted largely from a prevalent operator attitude that plant procedures, including the emergency operating procedures, were issued for guidance and did not require strict compliance. In addition, the January 1992 Electrical Distribution System Functional Inspection (EDSFI) identified eleven separate examples of failure to follow procedures, and the July 1992 Testing Team inspection identified eight examples. An enforcement conference was held with you following the EDSFI; however, these items were subsequently cited as Severity Level IV violations. Overall, between September 1991 and August 1993, the NRC has identified more than 60 examples of procedure violations, resulting in over thirty Level IV violations. While the Supply System management team has repeatedly concurred with the NRC's concerns regarding inadequate procedure compliance, and a number of corrective actions have been taken, the NRC continues to identify numerous instances of procedure non-adherence.

In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions" (Enforcement Policy), 10 CFR Part 2, Appendix C, the three procedure violations involving the use of the RHR system in the SPC mode during power operation have been classified as a Severity Level III problem.

To emphasize the importance the NRC attaches to the proper operation of safety systems and the need for procedure compliance, 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 in the amount of $75,000. The base value of a civil penalty for a Severity III problem is $50,000. The escalation and mitigation factors in the Enforcement Policy were considered as described below.

With respect to identification, the Supply System identified this violation as a result of apparently improved rigor in the pursuit of engineering issues, while investigating a problem concerning suppression pool air space temperatures. Accordingly, 50% mitigation for identification is warranted.

The corrective actions proposed in LER 93-01, which documented this problem, were not aggressive, and appeared indicative of an assessment that this issue was of minor significance. The LER merely referenced training on procedure compliance which had already been provided to operators, and established the LER as required operator reading. Only after submittal of the LER and the issuance of Special Inspection Report No. 50-397/93-29 did the Supply System take additional corrective actions to revise operating procedures so that they more clearly define the requirements applicable to the SPC mode of operation, and to revise administrative procedures regarding the use of procedure caution statements. Your staff appears to have focused primary corrective actions on procedure quality improvements, and did not take full advantage of problems such as the RHR procedure violations to effectively emphasize the importance of strict procedure adherence. Based on these considerations, we have concluded that 50% escalation is warranted for corrective action.

The Supply System's performance in the area of procedure compliance has been of concern for several years and has been so noted in each SALP report since 1988. These procedure adherence weaknesses have resulted in the numerous violations mentioned above and the weaknesses were discussed in management meetings in February, May and October of 1992, and in March 1993. In part, the problems with procedural adherence have been caused by the Supply System's inconsistency in holding personnel accountable for procedural compliance. However, the procedure adherence violations at issue here occurred in the Plant Operations area, a functional area which has shown some improvement in the recent past. This was evidenced in a generally well-managed refueling outage (April - June 1993) and good plant operational performance since that time. The Plant Operations area was also awarded a SALP Category 2 rating earlier this year (improved from a Category 3 the previous SALP period). Therefore, on balance, we have escalated the proposed civil penalty by 50% rather than by 100% for licensee performance.

The other adjustment factors in the Enforcement Policy were considered, and no further adjustment to the base civil penalty is considered appropriate. Based on the above, the base civil penalty has been increased by 50%.

One violation originally considered for inclusion in the enclosed Notice concerned the Supply System's failure to take adequate corrective actions in response to industry information regarding the use of the SPC mode of RHR. Although this deficiency may have contributed to the 1990 instance when both loops of the RHR system were operated in the SPC mode, your staff did ultimately address the problem by making an appropriate procedure revision later in 1990. Your staff identified this violation, and has taken appropriate corrective actions to address it. Since the criteria of Section VII.B(2) of 10 CFR Part 2, Appendix C, were met, this violation is not being cited.

The enclosed Notice also includes a number of examples of less significant procedure violations (cited in the Notice as Severity Level IV violations not assessed a civil penalty) that resulted from the apparent violations documented in Inspection Reports 50-397/93-18 and 93-24. While these violations do not directly relate to the RHR issues discussed above, they do demonstrate a continued lack of attention to detail by Supply System workers when performing procedures, a willingness to work around inadequate procedures, and a lack of adequate supervisory review of performance related to procedures. In this regard, we note that your September 8, 1993, letter discussed the root causes and your planned corrective actions to address these violations. We strongly encourage your management to take appropriate and effective measures to improve your staff's performance regarding procedure adherence.

One other apparent violation identified in Inspection Report No. 50-397/93-18 involved the approval of overtime for operators after WNP-2 returned to operation, on other than an individual basis, contrary to the requirements of TS 6.2.e.4. As documented in that inspection report, your staff committed to take appropriate corrective actions for this violation. Since the criteria of Section VII.B(1) of 10 CFR Part 2, Appendix C, were met, this violation also 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. You may include by reference, where this is applicable, portions of your September 8, 1993 letter which addressed the procedure violations. 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,

B. H. Faulkenberry
Regional Administrator

Enclosure: Notice of Violation and
Proposed Imposition of Civil Penalty

cc w/encl: See Next Page

Mr. J. V. Parrish, Assistant Managing Director for Operations, WPPSS
Mr. J. C. Gearhart, Director, Quality Assurance, WPPSS
Mr. J. H. Swailes, WNP-2 Plant Manager
G. E. C. Doupe, Esq., WPPSS
Mr. Warren A. Bishop, Chairman, Energy Facility Site Evaluation Council
Mr. Alan G. Hosler, Licensing Manager, WPPSS
Chairman, Benton County Board of Commissioners
M. H. Philips, Jr., Esq., Winston & Strawn

NOTICE OF VIOLATION
AND PROPOSED IMPOSITION OF CIVIL PENALTY

Washington Public Power Supply System
Washington Nuclear Project No. 2 (WNP-2)

Docket No. 50-397
License No. NPF-21
EA 93-191

During NRC inspections conducted on May 3 through August 2, 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

Section 6.8.1 of the Technical Specifications states, in part, that written procedures shall be established, implemented, and maintained covering the applicable procedures recommended in Appendix A of Regulatory Guide 1.33, Revision 2, February 1978.

Appendix A of Regulatory Guide 1.33, Section 4.e. recommends procedures for operation of the Shutdown Cooling System.

WNP-2 Operating Procedure PPM 2.4.2, "Residual Heat Removal," Revision 16 (applicable from October 8, 1990, to June 17, 1992), stated in Paragraph 5.22 under the heading "Limitations:" "During non-emergency conditions, do not align more than one RHR [Residual Heat Removal] loop in the suppression pool cooling mode at a time."

PPM 2.4.2, Revision 17 (applicable from June 18, 1992, to November 1, 1992), stated in Paragraph 4.23 under the heading "Precautions and Limitations:" "During non-emergency conditions, do not align more than one RHR loop in the Suppression Pool Cooling mode at one time."

Contrary to the above, on September 30, 1991, and on July 6 and 11, 1992, during non-emergency conditions, operators placed two loops of RHR in the Suppression Pool Cooling Mode.

This is a Severity Level III violation (Supplement I).
Civil Penalty - $75,000. (01013)

II. Violations Not Assessed a Civil Penalty

A. Section 6.8.1 of the Technical Specifications states, in part:

"Written procedures shall be established, implemented and maintained covering the activities referenced below:

a. The applicable procedures recommended in Appendix A of Regulatory Guide 1.33, Revision 2, February 1978.

c. Refueling operations. ...

g. Fire Protection Program implementation."

Appendix A of Regulatory Guide 1.33 recommends the following procedures:

- Section 1.c recommends a procedure for equipment control (e.g., locking and tagging).
- Section 8.a recommends a procedure to ensure that tools, gauges, instruments, and other measuring and testing devices are properly controlled, calibrated, and adjusted at specified periods to maintain accuracy.
- Section 8.b.(2)(a) recommends a procedure for containment and penetration leak-rate tests

1. WNP-2 refueling procedure PPM 6.3.2, "Fuel Shuffling and/or Offloading and Reloading", Revision 7, required:

   - In Step 6.1, that the Refueling Floor Operator perform the steps, in order, listed on the Nuclear Component Transfer List.
   - In Attachment 8.4, "Bridge Manipulations During Refueling," that control rod blade guides be oriented with spacer buttons facing the control rod blades.
   - In Step 6.1.3, that the Refueling Floor Operator verify the identity of each fuel assembly by orientation and location on the Nuclear Components Transfer List as it is loaded.

   Contrary to the above:

   a. On May 9, 1993, the Refueling Floor Operator did not perform the steps, in order, listed on the Nuclear Component Transfer List, in that Step 250 was performed before Step 249.

   b. As of May 12, 1993, during refueling, several blade guides were not oriented with spacer buttons facing the control rod blades.

c. As of May 12, 1993, the orientation of a fuel bundle had not been properly verified as it was loaded in that it was found misoriented 90 degrees.

d. As of May 23, 1993, the orientation of a fuel bundle had not been properly verified as it was loaded in that it was found misoriented 180 degrees.

2. WNP-2 Administrative Procedure PPM 1.3.10, Revision 12, "Fire Protection Program," in Section 6.1, "Fire Protection System Impairments," states:

"6.1.1.c. Examples of PLANNED impairments include ... Propping a normally closed fire door in the open position.

6.1.1.d A fire protection system impairment permit is not required ... provided ALL of the following conditions can be met: ... The impaired component must be attended (within line of sight).

6.1.2.c. Impairments involving passive fire protection components (i.e., fire doors, dampers and penetrations): ... Must be documented by use of a Fire Impairment Checklist, unless the requirements of 6.1.1.d are met."

Section 6.3.5.a states:

"... Combustible liquids must be removed and put into storage at the end of the job or at the end of the shift if the job is not continuous between consecutive shifts."

Section 6.3.8.a states in part:

"... When removal is not possible, a Transient Combustible Permit is required if the combustibles are to be left unattended for any length of time (i.e., breaks, lunch)"

Contrary to the above:

a. On May 27, 1993, the fire door to the Division 1 battery charger room was propped open. This impairment was unattended, as no licensee personnel were present at the door or within line of sight, and this impairment was not documented by a Fire Impairment Checklist.

b. On July 19, 1993, combustible liquids were present in the Residual Heat Removal A pump room, having been left unattended since July 17, 1993, but no Transient Combustible Permit had been obtained.

3. WNP-2 Administrative Procedure PPM 1.3.29, Revision 18, "Locked Valve Checklist," states in section 4.1, "All locked valves greater than or equal to 2 inches shall be fixed in place using a shackle lock and chain."

   Contrary to the above, on June 1, 1993, valves RRC-V-51A and RRC-V-51B (2-inch valves) were required by PPM 1.3.29 to be locked closed, but were not fixed in place by a lock and chain in that the handwheels secured by the locking device were not attached to the valves.

4. WNP-2 Administrative Procedure PPM 1.5.4, Revision 16, "Control of Measuring and Test Equipment - Transfer Standards," Step 6.1.5.a, requires that personnel using measuring and test equipment (M&TE) ensure that each piece of M&TE is properly checked out from the M&TE Tool Crib.

   Contrary to the above, on May 8, 1993, personnel used an M&TE gauge to perform a pressure test of Diesel Generator No. 2, engine B, cylinder 20, in accordance with Maintenance Work Request AP-1184, Step 2.40, which had not been checked out from the M&TE Tool Crib.

5. WNP-2 Surveillance Test Procedure PPM 7.4.6.1.2.4, Revision 7, "Containment Isolation Valve and Penetration Leak Test Program," Step 2.1.6, states the following:

   > "Containment penetration components undergoing maintenance/repairs which could alter the leakage rate shall require ... as-found ... testing during the outage period in which the maintenance is performed, unless determined not required by the LLRT [local-leak rate test] test coordinator."

   Contrary to the above, on May 3, 1993, containment penetration valves RHR-V-16B and RHR-V-17B underwent maintenance activities which could have altered the leakage rate and no as-found testing was performed nor determination made by the LLRT coordinator that the test was not required.

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

B. Section 6.8.1.k of the Technical Specifications states that written procedures shall be established, implemented and maintained covering Health Physics/Chemistry Support.

   Section 6.12.1 of the Technical Specifications states in part that "each high radiation area in which the intensity of radiation is greater than 100 mrems/h but less than 1000 mrems/h shall be barricaded and conspicuously posted as a high radiation area."

Section 3.1.7.4.1 of the WNP-2 Health Physics Program Description (HPPD), Revision 34, states, "An area shall be posted as a radiation area where there exists radiation at such levels that a major portion of the body could receive in any one hour a dose of 2.5 millirem."

WNP-2 Administrative Procedure PPM 1.11.11, Revision 2, "Entry Into, Conduct In and Exit from Radiologically Controlled Areas," Paragraph 4.6, states that "Persons entering a radiologically controlled area shall return barriers, altered for access, to their original position after passing."

Contrary to the above,

1. On May 28, 1993, an area on the 522-foot elevation of the reactor building contained radiation levels greater than 100 mrem/hour, but was not conspicuously posted at all entrances to the area as a "High Radiation Area." Specifically, an 18-inch gap behind the instrument rack on the 522-foot elevation provided access to the High Radiation Area, but was not posted.

2. On May 19, 1993, in an area of the 548-foot elevation of the reactor building where a major portion of the body could receive in any one hour a dose of 2.5 millirem, radiation levels were greater than 5 mrem/hour, but the area was not conspicuously posted as a radiation area.

3. On May 27, 1993, personnel who entered a radiation area at the entrance to the offgas preheater room on the 441-foot elevation of the turbine building altered a barrier for access to a radiologically controlled area, but they did not return the barrier to its original position when exiting.

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

C. 10 CFR Part 50, Appendix B, Criterion V, requires activities affecting quality to be prescribed by appropriate procedures and accomplished in accordance with those procedures.

1. WNP-2 Administrative Procedure PPM 1.3.9, "Temporary Modifications," states in Paragraph 6.3, "Restoration of a TM [temporary modification] via TMR,"

"6.3.6 Upon authorization from the Shift Manager, the Work Supervisor, or designee shall: ...

c. Account for all TMR tags. Return all the TMR tags to the Control Room. Tags that cannot be returned because they are lost or contaminated shall be noted in the TMR form COMMENTS section.

d. Ensure the individuals performing the removal sign the Restoration Performed by and Verified by steps on the original TMR form.

e. Inform the Shift Manager ... the TM restoration is complete ..."

"6.3.7 The Shift Manager shall:

a. Review the original TMR form to ensure all the TMR tags are accounted for, returned tags are discarded, and all the required steps are signed. ...

c. Ensure any restoration testing specified on the TMR is complete.

d. Ensure documents changed and/or special instructions issued ... are corrected and operating personnel on his shift have been briefed.

e. Sign the Restoration Complete and note any unexpected, or unusual events in the Comments section...

f. File the TMR in the Completed section of the TMR log.

g. Make the appropriate date entry in the TMR Log Index under Restored Date."

Contrary to the above, on June 20, 1993, the hardware associated with temporary modification request TMR-93-017 was removed but the TMR tags were not returned to the control room or accounted for; the signatures for restoration by the craft or Shift Manager were not obtained; the Shift Manager was not notified; Operations personnel were not briefed on the restoration; the TMR log index was not updated; and TMR-93-017 was left in the Active section of the TMR log.

2. WNP-2 Administrative Procedure PPM 1.17.2, Revision 1, "Procurement Engineering Reviews," required in Paragraph 7.4 that substitute items that are not identical to the original

item have substitution evaluations performed to determine their suitability for use in safety-related applications.

Contrary to the above, as of June 9, 1993, the licensee had replaced safety-related carbon steel hydraulic control unit accumulators with new stainless steel accumulators of a different size, weight, and pressure and temperature rating without performing a substitution evaluation to ensure the suitability of the new design.

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

Pursuant to the provisions of 10 CFR 2.201, the Washington Public Power Supply System (the 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 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. 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, and a copy to the NRC Resident Inspector at WNP-2.

Dated at Walnut Creek, California
This 10th day of November, 1993

I.B. REACTOR 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

November 26, 1993

Docket Nos. 50-10; 50-237; 50-249
License Nos. DPR-02; DPR-19; DPR-25
EA 93-223

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

Dear Mr. Wallace:

SUBJECT: DRESDEN STATION - UNITS 1, 2 AND 3
NOTICE OF VIOLATION (NRC INSPECTION REPORT NOS. 50-10/93003(DRSS), 50-237/93025(DRSS); and 50-249/93025(DRSS))

This refers to the reactive security inspection conducted on August 25, 1993, at Dresden Station, Units 1, 2 and 3. The inspection included a review of an event on August 16, 1993 involving an inadequate search which allowed a facsimile of a firearm to enter the protected area. The report documenting this inspection was sent to you by letter dated September 9, 1993. During this inspection a violation of NRC requirements was identified.

An enforcement conference was held on September 16, 1993, to discuss the proposed violation, its causes, and your corrective actions. The report summarizing the conference was sent to you by letter dated September 27, 1993. After the conference, your staff was requested by the NRC to reinvestigate the circumstances surrounding this event. You subsequently submitted by letter dated October 4, 1993, an Investigative Report prepared by Corporate Security.

On August 16, 1993, at approximately 6:55 a.m., a station employee unknowingly brought a facsimile of a firearm into the Dresden protected area. The facsimile was in the employee's duffle bag and was not detected by the security officer during x-ray ingress screening. The facsimile remained in the employee's locked locker inside the protected area until the end of the day. At approximately 4:00 p.m., the employee discovered in the parking lot that the facsimile was in his duffle bag. At approximately 5:30 p.m., the employee called the Plant Manager from offsite and reported the event.

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Your investigation concluded that the circumstances of the event could not be corroborated or disproved. Furthermore, you concluded that there was no intent by the employee in bringing the facsimile into the protected area, and no documentation or substantial information was obtained to question the employee's trustworthiness or reliability.

One violation is described in the enclosed Notice of Violation (Notice) involving an inadequate search of a package. The root cause of the violation appears to have been an isolated error by the security officer.

Although the potential for exploitation of the facsimile was minimal, the violation represents an inadequate search which resulted in the introduction of the facsimile of a firearm into the protected area. 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 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, I have been authorized, after consultation with the Director, Office of Enforcement, and the Deputy Executive Director for Nuclear Reactor Regulation, Region\ Operations and Research, not to propose a civil penalty in his case. In reaching this decision, the NRC considered the adjustment factors in the Enforcement Policy, and determined that full mitigation of the base civil penalty was appropriate for your identification of the event and your good corrective actions, including initiating an investigation into the cause of the event, removing and retraining the individuals responsible for the event, instituting proficiency testing of the guard force, and implementing enhanced drills with the x-ray machine.

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 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,

JGMiller for

John B. Martin
Regional Administrator

Enclosure: Notice of Violation

cc w/enclosure:
M. Lyster, Site Vice President
L. DelGeorge, Vice President,
Nuclear Oversight and Regulatory
Services
G. Spedl, Station Manager
J. Shields, Regulatory Assurance
Supervisor
D. Farrar, Nuclear Regulatory
Services Manager
OC/LFDCB
Resident Inspectors, Dresden
LaSalle, Quad Cities, Clinton
Richard Hubbard
J. McCaffrey, Chief, Public
Utilities Division
R. Newmann, Office of Public
Counsel, State of Illinois Center

NOTICE OF VIOLATION

Commonwealth Edison Company
Dresden Station
Units 1, 2 and 3

Docket Nos. 50-10; 50-237; 50-249
License Nos. DRP-02; DPR-19; DPR-25
EA 93-223

During an NRC inspection conducted on August 25, 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:

Amendments 42 and 38 of facility operating license numbers DPR-02, DPR-19, and DPR-25 require that the licensee have and maintain a Station Security Plan.

Technical Specification 6.2.A requires written procedures to be implemented covering the Station Security Plan.

Section D.1 of Security Post Order No. 1, Revision 13, dated January 1993 which implements the Station Security Plan requires, in part, the security officer to visually examine the contents of all packages that are conveyed through the x-ray machine, and to control and assure the physical search of any packages containing items which, viewed on the x-ray monitor, are unidentifiable or seem suspicious. This type of item is termed an "indiscernible mass."

Contrary to the above, on August 16, 1993, at approximately 6:55 a.m., a security officer did not adequately examine, control and assure the physical search of a package containing an indiscernible mass when viewed on the x-ray monitor prior to its entry into the protected area. This indiscernible mass was a facsimile of a firearm. (01013)

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

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 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, and a copy to the NRC Resident Inspector at the Dresden Station, 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 may 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 November 1993

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
801 WARRENVILLE ROAD
LISLE, ILLINOIS 60532-4351

DEC 27 1993

Dockets No. 50-373; 50-374
Licenses No. NPF-11; NPF-18
EA 93-283

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

Dear Mr. Wallace:

SUBJECT: NOTICE OF VIOLATION
(INSPECTION REPORT 50-373/93033; 50-374/93033)

This refers to the reactive security inspection conducted on November 4, 1993, at the LaSalle County Station to review the circumstances surrounding the granting of unescorted access to an individual who had not successfully passed fitness for duty testing. The report documenting this inspection was mailed to you by letter, dated November 22, 1993. A significant violation of NRC requirements was identified during the inspection, and on November 30, 1993, an enforcement conference was held in the Region III office. Attending the enforcement conference were Mr. W. Murphy, Site Vice President for the LaSalle County Station, Mr. W. L. Axelson, Director, Division of Radiation Safety and Safeguards, and other members of our respective staffs. A copy of the enforcement conference report was mailed to you on December 7, 1993.

The violation is described in the enclosed Notice of Violation and concerns a failure to fully evaluate information obtained from the fitness for duty program, implemented pursuant to 10 CFR 26.24(a), prior to authorizing an individual to receive a photo identification badge and unescorted access to the LaSalle County Station. 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 because the failure of an individual responsible for implementing the fitness for duty program caused an individual to be improperly granted unescorted access to the LaSalle County Station.

The root causes of the violation and the subsequent corrective actions were discussed during the enforcement conference. The major factors contributing to the violations appeared to be inadequate training of a clerical employee and personnel error on the part of the Commonwealth Edison employee responsible for implementing the fitness for duty program at the LaSalle County Station. The NRC recognizes that immediate corrective actions were taken when the violation was identified. Corrective actions included, but were not limited to: withdrawing site access for the individual who failed the fitness for duty test; disciplinary action, against the assistant station security supervisor; reassignment of a person with previous experience in the

area of fitness for duty to administer the fitness or duty program; and independent verification of fitness for duty and access authorization information prior to fabricating a security badge. Also, each Commonwealth Edison Company Station was provided with the details of this event and the Directors of Station Support Services at each of the other five nuclear plants operated by the Commonwealth Edison Company were requested to perform a self assessment of the security badging process at their respective facility.

The NRC acknowledges that, in this instance, it was a c' rical employee who, through improper training in the responsibilities associated with completing documents for the fitness for duty program, was responsible for the violation. However, the Assistant Station Security Supervisor failed to discharge his responsibilities concerning the fitness for duty program by not checking that all actions, including the duty fitness of the employee, were successfully completed and all supporting data were present prior to granting the individual unescorted access to the LaSalle County Station.

The NRC recognizes that this was the first failure of the fitness for duty program after performing 5,561 pre-access drug tests. Nonetheless, an individual failed a fitness for duty test, but was still issued a photo identification badge and permitted unescorted access to a nuclear power plant, the very action that 10 CFR Part 26, "Fitness for Duty" was intended to prevent.

A civil penalty is usually considered for a Severity Level III violation. However, 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, not to propose a civil penalty in this case. In reaching this decision, we considered the adjustment factors in the NRC Enforcement Policy and determined that full mitigation of the base civil penalty was appropriate. Full mitigation was permitted because of the self-disclosing nature of the event and your initiative in identifying its root cause; your prompt and extensive corrective actions, as discussed above; and your SALP 1 performance in security at the LaSalle County Station. The remaining factors in the enforcement policy were also 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. 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:
W. Murphy, Site Vice President
L. DelGeorge, Vice President
Nuclear Oversight and
Regulatory Services
J. Schmeltz, Acting Station Manager
J. Lockwood, Regulatory Assurance
Supervisor
D. Farrar, Nuclear Regulatory
Services Manager
Resident Inspectors LaSalle,
Dresden and Quad Cities
Richard Hubbard
J. McCaffrey, Chief, Public
Utilities Division
Licensing Project Manager, NRR
Robert Newmann, Office of Public
Counsel
Chairman, Illinois Commerce
Commission

NOTICE OF VIOLATION

Commonwealth Edison Company
LaSalle County Station
Units 1 and 2

Dockets No. 50-373; 50-374
Licenses No. NPF-11; NPF-18
EA No. 93-283

During an NRC inspection conducted on November 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, the violation is listed below:

10 CFR 26.24(a)(1) requires that a licensee provide a means to deter and detect substance abuse by implementing chemical testing programs for persons subject to this part. The program shall include testing within 60 days prior to the initial granting of unescorted access to protected areas or assignment to activities within the scope of this part.

Paragraph 5.5 of the Licensee's "Corporate Nuclear Security Guideline No. 224," Revision 0, July 1991, (which implements 10 CFR 26.24 in part) requires in part that each nuclear station shall assure that a negative pre-access test result has been received for each individual prior to issuing a photo identification badge.

Contrary to the above, on October 18, 1993 the licensee failed to assure that a negative pre-access test result had been received for an individual prior to issuing a photo identification badge and granting unescorted access to protected areas. Specifically, an individual, who had tested positive for a controlled substance, was issued a photo identification badge and was granted unescorted access to protected areas. (01013)

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

Pursuant to the provisions of 10 CFR 2.201, the Commonwealth Edison 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 III, 801 Warrenville Road, Lisle, Illinois 60532-4351, and a copy to the NRC Resident Inspector at the LaSalle County Station, 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 Lisle, Illinois
the 21st day of December 1993

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

DEC 14 1993

Docket Nos. 50-313; 50-368
License Nos. DPR-51; NPF-6
EA 93-278

Entergy Operations, Inc.
ATTN: J. W. Yelverton
Vice President Operations
Arkansas Nuclear One
Route 3, Box 137G
Russellville, Arkansas 72801

SUBJECT: NOTICE OF VIOLATION
(NRC INSPECTION REPORT NO. 50-313/93-31; 50-368/93-31)

This is in reference to the inspection conducted October 21-25, 1993, at the Arkansas Nuclear One (ANO) nuclear power plant, Units 1 and 2. This inspection was conducted to review the circumstances surrounding Entergy Operations, Inc.'s discovery on October 1, 1993, that the ANO Unit 1 reactor building sump did not meet design criteria. Plant personnel found unscreened openings into the sump and tears in the existing screening material that covered the sump. On October 22, 1993, plant personnel found unscreened openings associated with the ANO Unit 2 reactor building sump. Entergy Operations submitted licensee Event Reports on November 12 and 22, 1993, describing the results of its findings with respect to ANO Units 1 and 2, respectively. A report documenting the results of our inspection was issued on November 16, 1993. On November 23, 1993, you and other Entergy Operations, Inc. 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 had occurred.

Based on the NRC's review of information developed during the inspection and the information exchanged during the enforcement conference, the NRC has concluded that Entergy Operations violated 10 CFR Part 50, Appendix B, Criterion III, "Design Control," by failing to assure that the reactor building sump screens in both units were designed, installed and maintained in accordance with design specifications described in the Final Safety Analysis Reports. Criterion III states, in part, that measures shall be established to assure that applicable regulatory requirements and the design basis are correctly translated into specifications, drawings, procedures and instructions.

As described in more detail in the inspection report and the LERs submitted by Entergy Operations, plant personnel found numerous unscreened openings into the sumps and openings in existing screens that would have permitted debris to bypass the screens and enter the reactor building sumps. Many of these openings had existed since initial plant construction due to an apparent failure to assure that design basis requirements were followed during construction. The violations described in the enclosed Notice of Violation

are considered significant because the sumps provide a long-term source of cooling water for various Emergency Core Cooling and safety systems following an accident and the screens are designed to prevent debris from interfering with the operation of these systems. During the enforcement conference, Entergy Operations described the results of its evaluations and concluded that, at worst, the screen integrity problems could have degraded the operation of safety systems following various Loss of Coolant Accidents (LOCAs) but would not have resulted in a loss of system function. Based on this conclusion and the results of the NRC's independent analysis, which does not disagree substantially with that performed by Entergy Operations, the violations involving ANO Unit 1 and 2 have been 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, Supplement I, C.2.(b).

While the NRC commends Entergy Operations personnel for identifying and correcting these problems at this time, we also conclude that Entergy Operations had several opportunities to identify and correct this condition earlier. In addition to the many opportunities during physical inspections of the reactor building sumps at the conclusion of each refueling outage, the NRC provided specific notice of potential sump screen problems in Information Notice 89-77, "Debris in Containment Emergency Sumps and Incorrect Screen Configurations." Although this notice alerted all licensees to the potential for gaps in screens, missing screens and damaged screens, as well as the potential for debris in sumps, Entergy Operations' response to this notice focused only on the need to assure that the sumps were free of debris and failed to focus on the need to assure the integrity and proper configuration of the screens.

NRC recognizes that Entergy Operations took prompt corrective action to repair and restore the reactor building sump screens to their design basis and has taken or developed actions to address potential weaknesses revealed by this discovery. Other actions include an assessment of other components vulnerable to the same errors in design and construction, a review of discrepancies discovered during the ongoing design basis reconstitution process to assure no immediate safety concerns, a review of the plant's current design control processes, and a review of the processes for responding to NRC information notices.

In accordance with the Enforcement Policy, a civil penalty is considered for a Severity Level III problem. However, 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, not to propose a civil penalty in this case based on the application of the civil penalty adjustment factors discussed in Section VI.B.2 of the Enforcement Policy. This determination was based on the following considerations: 1) The problems related to the sump screens were identified by Entergy Operations personnel (minus 50%); 2) Entergy Operations' corrective actions following the identification of these problems were prompt and

comprehensive (minus 50%); 3) Entergy Operations' performance in safety assessment/quality verification and overall performance in identifying and correcting historical problems has been good (minus 100%); and 4) Entergy Operations had several earlier opportunities to have identified the specific problems in this case (plus 100%). The remaining civil penalty adjustment factors were considered but no further adjustments were deemed appropriate.

Entergy Operations, Inc. is required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing its response. In its response, Entergy Operations, Inc. should document the specific actions taken and any additional actions it plans to prevent recurrence. After reviewing Entergy Operations' response to this Notice, including its 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

cc w/Enclosure:
Entergy Operations, Inc.
ATTN: Harry W. Keiser, Executive
Vice President & Chief Operating Officer
P.O. Box 31995
Jackson, Mississippi 39286-1995

Entergy Operations, Inc.
ATTN: John R. McGaha, Vice President
Operations Support
P.O. Box 31995
Jackson, Mississippi 39286

Wise, Carter, Child & Caraway
ATTN: Robert B. McGehee, Esq.
P.O. Box 651
Jackson, Mississippi 39205

Honorable C. Doug Luningham
County Judge of Pope County
Pope County Courthouse
Russellville, Arkansas 72801

Winston & Strawn
ATTN: Nicholas S. Reynolds, Esq.
1400 L Street, N.W.
Washington, D.C. 20005-3502

Arkansas Department of Health
ATTN: Ms. Greta Dicus, Director
Division of Radiation Control and
Emergency Management
4815 West Markham Street
Little Rock, Arkansas 72201-3867

B&W Nuclear Technologies
ATTN: Robert B. Borsum
Licensing Representative
1700 Rockville Pike, Suite 525
Rockville, Maryland 20852

Admiral Kinnaird R. McKee, USN (Ret)
214 South Morris Street
Oxford, Maryland 21654

ABB Combustion Engineering
ATTN: Charles B. Brinkman
Manager, Washington
Nuclear Operations
12300 Twinbrook Parkway, Suite 330
Rockville, Maryland 20852

NOTICE OF VIOLATION

Entergy Operations, Inc.
Arkansas Nuclear One
Units 1 and 2

Docket Nos. 50-316; 50-368
License Nos. DPR-51; NPF-6
EA 93-278

During an NRC inspection conducted October 21-25, 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, the violations are listed below:

10 CFR Part 50, Appendix B, Criterion III, states, in part, that measures shall be established to assure that applicable regulatory requirements and the design basis are correctly translated into specifications, drawings, procedures, and instructions.

Unit 1 Safety Analysis Report Section 9.5.2.2 and the Unit's design basis Upper Level Document ULD-1-SYS-04, which specify the design basis for the reactor building sump, state in part that the sump is covered with a screen of 0.132 inch by 0.132 inch mesh. These documents also state that all of the components in the decay heat removal system, which are used when the system is in the recirculation mode, are capable of operating in the presence of any debris which may pass through this screen without plugging.

Unit 2 Safety Analysis Report Section 6.2.2.2 and the Unit's design basis Upper Level Document ULD-2-SYS-04, which specify the design basis for the reactor building sump, state in part that a series of screens and supports completely covers the sump to prevent floating debris and high density particles from entering, and that the inner screen has a maximum diagonal opening of 0.09 inch.

Contrary to the above, as of October 1, 1993, the licensee did not assure that the design basis was correctly translated into specifications, drawings, procedures and instructions. Specifically:

1. On October 1, 1993, 22 openings (6 inches in diameter by 3 inches high) in the curb around the Unit 1 reactor building sump were identified which were not screened and which would have allowed the passage of debris larger than 0.132 inches by 0.132 inches into the reactor building sump.

2. On October 1, 1993, several openings around conduit penetrations through the Unit 1 reactor building sump screens, two tears in the screening material, and floor drains that were not screened were identified which would have allowed the passage of debris larger than 0.132 inches by 0.132 inches into the reactor building sump.

3. On October 22, 1993, several penetrations were identified along the lower structural support of the Unit 2 reactor building sump which bypassed the screens and provided a pathway for debris

larger than 0.09 inch by 0.09 inch to be swept into the sump. (01013)

These violations represent a Severity Level III problem (Supplement I).

Pursuant to the provisions of 10 CFR 2.201, Entergy Operations, 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 IV, 611 Ryan Plaza Drive, Suite 400, Arlington, Texas 76011, and a copy to the NRC Resident Inspector at Arkansas Nuclear One, 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 14th day of December 1993

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

October 20, 1993

Docket No. 50-289
License No. DPR-50
EA 93-193

Mr. T. Gary Broughton
Vice President and Director, TMI-1
GPU Nuclear Corporation
Three Mile Island Nuclear Station
Post Office Box 480
Middletown, Pennsylvania 17057-0191

Dear Mr. Broughton:

SUBJECT: NOTICE OF VIOLATION (NRC INSPECTION 50-289/93-08)

This letter refers to the NRC Incident Investigation Team (IIT) inspection conducted on February 9-19, 1993, as well as the subsequent Region I inspection conducted on June 7-11, 1993, to review, in part, the emergency response actions taken when an unauthorized vehicle and unauthorized individual intruded into the Three Mile Island facility on February 7, 1993. The event resulted in your declaration of a Site Area Emergency. During the follow-up NRC inspection in June 1993, two apparent violations of NRC requirements were identified, one of which was sent to you in a Notice of Violation issued with the related inspection report on August 11, 1993. The other violation was discussed with you and members of your staff at an enforcement conference on August 24, 1993, conducted to review the violation, its causes, and your corrective actions.

In responding to the event, the control room doors were locked because of the uncertainty regarding the threat to personnel safety that may have existed as a result of the intrusion. The emergency procedures, however, did not address the possibility of locking the control room doors, nor did these procedures describe alternate means of access to the auto-dial pager system for executing the emergency response callout and response team mobilization in the event that the control room doors were locked. This procedural inadequacy hampered the onshift personnel in adequately responding to the event and resulted in the violation discussed at the enforcement conference, i.e., a delay of approximately 47 minutes by onshift personnel in calling out the emergency response organization. That delay contributed, in part, to the Emergency Operations Facility and Technical Support Center not being activated until approximately three hours after the declaration of the Site Area Emergency.

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

The NRC recognizes that concern for personnel safety was a factor in the decision to maintain the doors locked which, in turn, led to the delay in callout of the emergency response organization. The NRC also recognizes that the actual safety significance of the violation in this specific instance was minimized by the fact that: (1) callouts were eventually made, albeit late; (2) the capabilities existed onsite for evaluation of dose assessment, managing the emergency response, and making protective action recommendations (there was only a reduction in the engineering support during the delay) had they been necessary; and (3) this event could have been classified at a lower emergency event level, namely, an alert. Nonetheless, the NRC is concerned that adequate compensatory measures were not taken for an event perceived to be a Site Area Emergency to ensure that the emergency callouts were made promptly as contemplated and required by your Emergency Plan for this class of emergency. Had this incident also involved a sabotage-induced equipment or system degradation, your delay in mobilizing your emergency response organization could have adversely impacted the effectiveness of your emergency response. To reflect the potential seriousness with which we view your delay and violation, we have classified the violation 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 prompt and comprehensive corrective actions were taken, including, but not limited to: (1) revision of the procedure for callout of emergency personnel to include alternate methods of callout; and (2) providing instructions on the procedure changes to appropriate personnel. Although a civil penalty was considered for this Severity Level III violation, 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 not propose a civil penalty in this case because the violation was identified by you, the corrective actions were prompt and comprehensive, and your performance in the area of emergency preparedness has been good, as evidenced by Category 1 ratings in this area during the last two SALP rating periods. Any similar violations of this nature in the future could 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 (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

ENCLOSURE

NOTICE OF VIOLATION

GPU Nuclear Corporation
Three Mile Island Nuclear Station

Docket No. 50-289
License No. DPR-50
EA 93-193

During an NRC inspection conducted on June 7-11, 1993, an apparent violation of NRC requirements was identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 Part CFR 2, Appendix C, the violation is listed below:

10 CFR 50.54(q) states that a licensee authorized to possess and operate a nuclear power reactor shall follow and maintain in effect emergency plans which meet the standards in 10 CFR 50.47(b) and the requirements in Appendix E of this part.

General Public Utilities Nuclear Corporation (GPUNC) Emergency Plan, maintained to comply with 10 CFR 50.54(q), Section 4.1, specifies that each emergency classification is associated with a particular set of immediate actions that include mobilization of the applicable portion of the emergency organizations to cope with the situation and continue accident assessment functions, and that activation and mobilization must occur if a prescribed emergency level is declared.

GPUNC Emergency Plan, Section 4.1.3, specifies that, for a Site Area Emergency, all Emergency Plan related actions (notifications, etc.) will be carried out in parallel with the remainder of the Operating Procedures.

GPUNC Emergency Plan, Table 7A, lists the actions to be taken for each class of emergency, and specifies that emergency response facilities will be activated for a Site Area Emergency.

Contrary to the above, on February 7, 1993, when a Site Area Emergency (SAE) was declared at Three Mile Island Unit 1, the licensee did not take immediate action to mobilize the applicable portion of the emergency organization in that the licensee did not immediately call out the Emergency Response Organization. Specifically, there was a delay of about 47 minutes in initiating the required callout. (01013)

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

Pursuant to the provisions of 10 CFR 2.201, GPU Nuclear Corporation 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, and a copy to the NRC Resident Inspector, 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 King of Prussia, Pennsylvania
this 28th day of October 1993

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

November 30, 1993

Docket No. 50-286
License No. DPR-64
EA 93-180

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

Dear Mr. Beedle:

SUBJECT: NOTICE OF VIOLATION
(NRC Inspection Reports No. 50-286/93-04, 93-08 and 93-80)

This letter refers to three NRC inspections, including one team inspection, conducted from February 21 to May 31, 1993, at Indian Point Unit 3, Buchanan, New York. The inspection reports were sent to you on May 21, July 21, and July 23, 1993. During the inspections, six violations of NRC requirements were identified. On August 25, 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 (Notice) (Enclosure). The first three violations are described in Section I of the Notice and involve deficiencies related to the preventive maintenance program at the facility. The first violation involves the failure to perform manufacturer recommended preventive maintenance (PM) on the emergency diesel generators as required by the plant technical specifications. Specifically, for certain significant PM activities related to emergency diesel overhaul, the manufacturer recommended frequency was extended from once every six years to once every 12 years without agreement from the manufacturer. Additionally, some of the PM activities (with either a manufacturer recommended or licensee extended 12 year frequency) were several years overdue since they have not been performed in 17 years. The NRC has also determined that you have not incorporated the commitments made in your response to a similar violation issued in 1988 regarding the emergency diesel generator manufacturer recommended PM schedule.

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The second violation related to the PM program involves the failure to maintain operable, as required by your technical specifications, three of the five containment fan cooler units (FCUs), over an indeterminate period of time during which the reactor was above the cold shutdown condition. During a surveillance test on April 14, 1993, bypass dampers of three of the five FCUs, which were last successfully tested on May 30, 1992, were found to be mechanically bound and incapable of being operated from the control room. This condition resulted from a lack of an appropriate PM program for the FCUs in that the manufacturer recommended PM activities were neither included in the program nor performed on the dampers.

The third violation related to the PM program involves the failure to identify and correct in a timely manner the degraded condensate storage tank (CST) diaphragm. An inspection done by your staff on April 7, 1993, identified that the diaphragm was degraded in that it had sunk below the surface of the water. The NRC is concerned that the CST diaphragm was not included in your surveillance or PM program, even though: (1) the service life of the diaphragm had been exceeded by approximately 10 years; (2) indications and early notice of potential problems were evident via increased oxygen levels in the CST since November 13, 1991; and (3) NRC Information Notice 91-82, "Problems with Diaphragms in Safety Related Tanks" which directly related to this problem was issued on December 18, 1991.

The NRC recognizes that the emergency diesel generators were available to perform their safety function even though not all of the manufacturer recommended preventive maintenance was performed. In addition, your analysis indicated that even with the FCU bypass dampers inoperable, the radiation doses to the general public would likely not have exceeded the regulatory limits under the worst case design basis accident scenario. Furthermore, the degraded CST diaphragm did not affect the auxiliary feedwater supply. Nevertheless, the deficiencies in the PM program that resulted in these violations are of significant concern to the NRC since they resulted in a reduced margin of safety and because certain safety equipment, required by the plant TS, was not operable. Therefore, in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions" (Enforcement Policy), 10 CFR Part 2, Appendix C, these three violations are classified in the aggregate as a Severity Level III problem.

The other three violations, related to your Quality Assurance (QA) program, are described in Section II of the enclosed Notice, and involve: (1) a breakdown in your corrective action process with respect to QA audit findings in that QA audits identified numerous deficiencies at the facility, yet timely and effective actions were not taken to correct the deficiencies; (2) the failure of the plant Safety Review Committee (SRC) to perform audits of the facility staff performance as required by the technical specifications; and (3) the failure to forward the reports of audits performed under the cognizance of the SRC to appropriate management positions, including the Executive Vice President, within 30 days of completion of the audit as required by the technical specifications.

The NRC also recognizes that on an individual basis the potential safety consequences of these QA program violations were low. Nevertheless, assurance of quality of activities is important to nuclear safety and provides an element of defense in depth by providing independent assessments to senior management. The NRC is concerned that the violations collectively represent a significant lack of attention toward licensed responsibilities and ineffective implementation of the QA program, due to a lack of management oversight and involvement in the QA Program. Such ineffective QA program implementation has been an ongoing problem at Indian Point 3. Therefore, in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions" (Enforcement Policy), 10 CFR Part 2, Appendix C, these three violations related to the QA program implementation also are classified in the aggregate as a Severity Level III problem.

During the enforcement conference, you indicated that a plant management philosophy had existed to perform maintenance on equipment only when broken, that there was a narrow approach taken in understanding and resolving problems, and that these then-existing management philosophies were the root causes for the PM program deficiency. In addition, you indicated that QA had a diminished role at the plant as a result of long-term management neglect towards the QA function, which in turn fostered a similar attitude in plant staff. You noted that as a result, although sometimes a short-term closure of an audit finding was obtained, the broader underlying performance issues were not addressed.

The recent enforcement history at Indian Point 3, has included the issuance of numerous civil penalties in the cumulative amount of $762,500 in the past two years. The most recent was a $300,000 civil penalty issued on July 21, 1993. In your August 27, 1993 response to that recent civil penalty, you acknowledged that broad-based problems have existed at Indian Point 3, including failure to follow procedures, inattention to detail, management's failure to correct problems, and inadequate quality assurance oversight. You also indicated that numerous changes in plant management personnel and the plant staff's awareness of management's high expectations and accountability policies are expected to resolve these broad based problems. The NRC also expects proper implementation of these actions to ensure improvements in PM and QA programs in particular, and the operation and maintenance of the facility in general. The NRC also notes that you have developed and are presently implementing an extensive improvement program to correct identified deficiencies.

Therefore, although civil penalties normally are proposed for Severity Level III violations or problems, I have decided, after consultation with the Director, Office of Enforcement, the Deputy Executive Director for Nuclear Reactor Regulation, Regional Operations and Research, and the Commission, to exercise discretion in accordance with the guidance set forth in Section VII.B.(3) of the Enforcement Policy, and not propose a civil penalty for these violations. This decision is based on your changes at the facility, and the facts that (1) you shut down the plant on your own initiative in February 1993, in response to the previously identified deficiencies and generally poor performance over a long period of time; (2) you have developed and are in the process of implementing an extensive improvement program to correct the existing deficiencies;

(3) as noted in Confirmatory Action Letter 1-93-009, issued on June 17, 1993, you indicated that you would obtain the agreement of the NRC prior to the restart of the facility; (4) the violations are categorized not higher than Severity Level III; (5) the violations were not willful; and (6) the subject violations are based upon activities occurring prior to the shutdown. Nonetheless, the NRC emphasizes, that any similar violations in the future resulting from the failure to effectively implement your improvement plan could result in additional escalated enforcement action.

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

ENCLOSURE

NOTICE OF VIOLATION

New York Power Authority
Indian Point Unit 3

Docket No. 50-286
License No. DPR-64
EA 93-180

During three NRC inspections conducted from February 21 to May 31, 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:

I. Violations Related to the Preventive Maintenance (PM) Program

A. Indian Point 3 (IP3) Technical Specification 4.6.A.4 requires that each emergency diesel generator (EDG) be inspected and maintained following the manufacturer's recommendations for this class of standby service. The manufacturer's recommendations for this class of standby service include certain preventive maintenance (PM) activities on air start system components and certain periodic inspection and PMs every six and 12 years.

Contrary to the above, as of May 10, 1993, the licensee failed to inspect and maintain the EDGs at IP3 following the manufacturer's recommendations for this class of standby service. Specifically, the licensee extended the manufacturer recommended frequency for certain PMs related to EDG overhaul from once every six years to once every 12 years, without agreement from the manufacturer; failed to incorporate manufacturer recommendations, including other PM activities to be performed every six and 12 years, into the PM program for the EDGs; failed to perform these six-year and 12-year activities on schedule; and failed to include portions of the air start system in the PM program as recommended by the manufacturer. (01013)

B. IP3 Technical Specification 3.3.B.1, in part, requires that five containment fan cooler units (FCUs) be operable whenever the reactor is brought above the cold shutdown condition. IP3 Technical Specification 3.3.B.2 allows one FCU to be inoperable any time the reactor is above cold shutdown provided that specified conditions are met.

Contrary to the above, for an indeterminate period of time between May 30, 1992 and March 7, 1993, the reactor was operated above the cold shutdown condition, with only two of the five FCUs operable. Specifically, three of the FCUs (Nos. 32, 34, and 35) were inoperable in that the bypass dampers of these FCUs were mechanically bound and incapable of being operated from the control room. (01023)

C. 10 CFR Part 50, Appendix B, Criterion XVI, "Corrective Action" requires that measures be established to assure that conditions adverse to quality, such as deficiencies and nonconformances are promptly identified and corrected.

Contrary to the above, as of April 7, 1993, the licensee failed to establish measures to ensure conditions adverse to quality are promptly identified and corrected. Specifically, the licensee failed to implement a PM program for periodic inspection and replacement of the condensate storage tank (CST) diaphragm and failed to promptly identify and correct the degraded CST diaphragm despite: (1) having information about the limited service life of the diaphragm; (2) having received NRC Information Notice 91-82 "Problems with Diaphragms in Safety Related Tanks" dated December 18, 1991; and (3) the indications of a potential problem provided by increased levels of oxygen in the CST that existed since November 1991. (01033)

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

II. Violations Related to the QA Program

A. 10 CFR Part 50, Appendix B, Criterion XVI, "Corrective Action", in part, requires that measures be established to assure that conditions adverse to quality, such as deficiencies and nonconformances are promptly identified and corrected. In cases of significant conditions adverse to quality, the measures shall assure that corrective actions are taken to preclude repetition.

10 CFR Part 50, Appendix B, Criterion XVIII, "Audits" requires, in part, that audits be performed to verify the compliance with all aspects of the quality assurance program and to determine the effectiveness of the program. Audit results shall be documented and follow-up action taken where indicated.

The NYPA Quality Assurance Procedures Manual Section 16.1, "Corrective Action", Section 18.1 "Quality Assurance Audit Program", and Section 18.4, "Technical Specifications Required Audits" were established pursuant to the above to implement the requirements of 10 CFR Part 50 for IP3.

Contrary to the above, as of April 1993, the audits of IP3 facility activities have revealed numerous findings of conditions adverse to quality that the licensee failed to promptly correct. Specifically, as detailed by the examples below, prompt corrective actions were not taken for a number of corrective action requests (CARs) as evidenced by the fact that subsequent CARs were submitted on the same issues. For example:

- Material Traceability and Control of Equipment Returned to Vendors, CAR 91-04-04 - Subsequent CARs 92-624, 645, 657;

- Setpoints, CAR 90-14-05 - Subsequent CARs 91-595, 92-663;

- LER Submittals, CAR 92-720 - Subsequent CAR 93-799;

- Fire Protection, CAR 92-685 - Subsequent CARs 743, 93-792.

Additionally, as of April 1993, Cooperative Management Audit Program (CMAP) audits performed in 1991 and 1992 had identified various deficiencies that were not promptly corrected as required. These deficiencies included Recommendations 14 and 16 of Audit No. 91-13 and Recommendation 4 of Audit No. 92-15, each of which documented problems with QA procedures and practices. (02013)

B. Technical Specification 6.5.2.8.b, "Safety Review Committee Audits", requires, in part, that audits of facility activities be performed under the cognizance of the Safety Review Committee (SRC), and shall encompass the performance of the facility staff at least once per 12 months.

Contrary to the above, since at least October 1988, audits of facility staff performance have not been performed annually under the cognizance of the SRC. (02023)

C. Technical Specification 6.5.2.10.c, "Safety Review Committee Records" requires that audit reports encompassed by Specification 6.5.2.8 (i.e. those audits of facility activities performed under the cognizance of the SRC) be forwarded to the Executive Vice President - Nuclear Generation and to the management positions responsible for the areas audited within 30 days after the completion of the audit.

Contrary to the above, as of April 1993, numerous audit reports of facility activities including IP3 audits 92-12, 92-16, 92-17, 92-19, 92-20, 92-22, 92-24, 92-30, 92-37 and Corporate audits 91-05, 91-14, 92-13, 92-34, performed under the cognizance of the SRC were not forwarded to the Executive Vice President - Nuclear Generation and to the management positions responsible for the areas audited within 30 days after the completion of the audit. (02033)

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

Pursuant to the provisions of 10 CFR 2.201, New York Power Authority 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 1, and a copy to the NRC Resident Inspector at Indian Point 3, 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 King of Prussia, Pennsylvania
this 30th day of November 1993

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
801 WARRENVILLE ROAD
LISLE, ILLINOIS 60532-4351

December 15, 1993

Docket No. 50-305
License No. DPR-43
EA 93-224

Wisconsin Public Service
Corporation
ATTN: Mr. C. R. Steinhardt
Senior Vice President -
Nuclear Power
700 North Adams
Post Office Box 19002
Green Bay, WI 54307-9002

Dear Mr. Steinhardt:

SUBJECT: NOTICE OF VIOLATION
(NRC INSPECTION REPORT NO. 50-305/93018(DRSS))

This refers to the inspection conducted during the period of August 23-31, 1993, at the corporate office of Wisconsin Public Service Corporation, to review the circumstances surrounding safeguards information which was stored in an unlocked and unattended storage cabinet. During this inspection a violation of NRC requirements was identified, and on September 23, 1993, an enforcement conference was held by telephone.

The report documenting the inspection was sent to you by letter dated September 10, 1993. The report summarizing the conference was sent to you by letter dated September 23, 1993.

On July 1, 1993, a clerk opened a cabinet containing safeguards information to file documents and forgot to return the locking bar prior to locking the padlock. The cabinet is located in a single-person office in Wisconsin Public Service Corporation's corporate offices assigned to the Assistant to Nuclear Licensing and Systems Superintendent who was out of the office at that time. Upon returning to his office on July 6, 1993, the Assistant to the Nuclear Licensing and Systems Superintendent identified the unlocked cabinet and immediately notified the Kewaunee Security Operations Supervisor.

Your investigation determined that a nuclear department employee, who periodically used the office while his own was occupied, entered the office where the cabinet was located on July 1, 1993, noticed the unlocked cabinet and assumed that the cabinet no

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longer contained safeguards information. You concluded that the employee had a reasonable basis for his assumption because he was not trained in the protection of safeguards information, and his work does not involve safeguards information. Your planned revisions to the General Employee Training sessions, in response to this issue, should emphasize the need for employees to be more proactive when observing questionable or unusual conditions although they may be outside their area of expertise.

The violation, which is described in the enclosed Notice of Violation (Notice), concerns a failure to store unattended safeguards information in a locked cabinet. The root cause of the violation was an isolated error by the clerk.

The safeguards information stored in the cabinet included copies of the Kewaunee Security Manual, the Security Contingency Plan, and written security procedures. The violation represents a failure to protect or control safeguards information considered to be significant while the information was outside the Kewaunee protected area and was accessible to those not authorized access to the protected area. 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 has been categorized at Severity Level III.

A civil penalty is considered for a Severity Level III violation. However, 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, not to propose a civil penalty in this case. In reaching this decision, we considered the adjustment factors in the Enforcement Policy and determined that full mitigation of the base civil penalty was appropriate for your identification of the event, your comprehensive corrective actions, and your good past 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 and its enclosure 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, PL 96-511.

Sincerely,

John B. Martin
Regional Administrator

Enclosure:
Notice of Violation

cc w/enclosure:

C. A. Schrock, Manager -
Nuclear Engineering
Mark L. Marchi, Plant Manager
OC/LFDCB
Resident Inspector, RIII
Licensing Project Manager, NRR
Virgil Kanable, Chief, Boiler Section
Cheryl L. Parrino, Wisconsin
Public Service Commission
Robert M. Thompson, Administrator
WI Division of Emergency Government

NOTICE OF VIOLATION

Wisconsin Public Service Corporation
Kewaunee Nuclear Plant

Docket No. 50-305
License No. DPR-43
EA 93-224

During an NRC inspection conducted on August 23-31, 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 73.21(d)(2) requires, in part, that Safeguards Information be stored in a locked security storage container while unattended.

The Kewaunee Security Manual, Security Contingency Plan, and written physical security procedures are considered Safeguards Information as described in 10 CFR 73.21(b)(1).

Contrary to the above, from approximately 1:00 p.m., July 1, 1993, until approximately 7:30 a.m., July 6, 1993, a security storage container containing Safeguards Information consisting of copies of the Kewaunee Security Manual, Security Contingency Plan, and written security procedures was unlocked and unattended. (01013)

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

Pursuant to the provisions of 10 CFR 2.201, Wisconsin Public Service Corporation (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, 801 Warrenville Road, Lisle, Illinois 60532-4351, and a copy to the NRC Resident Inspector at the Kewaunee Nuclear Plant, 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 may 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 Lisle, Illinois
this 15th day of December 1993

II.A. MATERIALS LICENSEES, CIVIL PENALTIES AND ORDERS

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

OCT 20 1993

Docket No. 030-01586
License No. 13-00951-03
EA 93-215

Ball Memorial Hospital
ATTN: Mitchell C. Carson
Vice President of Operations
2401 West University Avenue
Muncie, Indiana 47303

Dear Mr. Carson:

SUBJECT: CONFIRMATORY ORDER MODIFYING LICENSE

This refers to the special safety inspection conducted by the U. S. Nuclear Regulatory Commission (NRC) from July 21 to August 9, 1993, and the subsequent investigation conducted by the NRC Office of Investigations (OI) at Ball Memorial Hospital, Muncie, Indiana. While investigation activities are still ongoing, significant violations of NRC requirements have already been identified by both the NRC inspection and investigation and by your internal investigation.

On July 19, 1993, the NRC Region III office received information that nuclear medicine technologists at Ball Memorial Hospital had increased the dosages of radiopharmaceuticals used in diagnostic studies in order to reduce the imaging time and had falsified required records of the dosages administered. On June 15, 1993, one technologist was interviewed by managers of Ball Memorial Hospital. The technologist stated that without authorization from a physician, dosages were increased to minimize a patient's discomfort, to reduce the duration of a study of a critically ill patient, or to enhance the clarity of the image for a study performed on an obese patient, and the records of the administered dosage were falsified.

The NRC commenced an inspection and confirmed that since at least 1988, nuclear medicine technologists increased radiopharmaceutical dosages by as much as 40 percent above the approved dosage ranges for imaging studies and entered false information about the dosages in NRC-required records. The dosages were increased for imaging studies of the lung, liver, bone and gastrointestinal tract using technetium-99(m) and xenon-133. As a result of the NRC inspection, Confirmatory

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Action Letter No. RIII-93-012, dated July 26, 1993, was issued to the Licensee. At this time, the NRC is not aware of any medical misadministrations, as defined in 10 CFR 35.2, as a result of the increased dosages of radiopharmaceuticals. Nevertheless, the increase in dosages of radiopharmaceuticals without the approval of an authorized user and apparently deliberate falsification of information in NRC-required records are both significant regulatory concerns.

The enclosed Confirmatory Order Modifying License confirms the commitments made to the NRC by Ball Memorial Hospital in letters dated August 5 and August 13, 1993, and modifies NRC Byproduct Material License No. 13-00951-03 to include these commitments. Failure to comply with the provisions of this Order may result in civil or criminal sanctions. Ball Memorial Hospital has agreed to the issuance of this Confirmatory Order.

Questions concerning the Confirmatory Order Modifying License may be addressed to Patricia Santiago, Assistant Director for Materials, Office of Enforcement. Ms. Santiago can be reached at telephone number (301) 504-3055.

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:
DCB/DCD(RIDS)
State of Indiana, Director,
Department of Public Health

UNITED STATES
NUCLEAR REGULATORY COMMISSION

In the Matter of	)	Docket No. 030-01586
Ball Memorial Hospital	)	License No. 13-00951-03
Muncie, Indiana	)	EA 93-215

CONFIRMATORY ORDER MODIFYING LICENSE

I

Ball Memorial Hospital (Ball or Licensee) is the holder of Byproduct Material License No. 13-00951-03 issued by the Nuclear Regulatory Commission (NRC or Commission) pursuant to 10 CFR Parts 30 and 35. The license authorizes the use of byproduct material for medical purposes pursuant to 10 CFR Part 35 (e.g., as radiopharmaceuticals identified in 10 CFR 35.100, 35.200 and 35.300; as brachytherapy sources identified in 10 CFR 35.400; as sealed sources identified in 10 CFR 35.500; and as prepackaged in vitro kits identified in 10 CFR 31.11). The facility where licensed materials are authorized for use and storage is located at 2401 University Avenue, Muncie, Indiana. The license, originally issued on August 19, 1958, was last amended on July 20, 1993, and is due to expire on December 31, 1993.

II

On July 19, 1993, the NRC Region III office received information that the Licensee was investigating an allegation that it received on June 4, 1993. Allegedly, nuclear medicine technologists in its employ had increased the dosages of

radiopharmaceuticals used in diagnostic studies in order to reduce the imaging time and had falsified required records of the dosages administered. On June 15, 1993, as related to NRC by Licensee officials, one technologist told Licensee officials that without approval from an authorized user, dosages were increased to minimize a patient's discomfort, to reduce the duration of a study of a critically ill patient, or to enhance the clarity of the image for a study performed on an obese patient, and the records of the administered dosages did not reflect the dosage increase.

The NRC commenced an inspection on July 21, 1993, and based on interviews of the nuclear medicine technologists, the NRC confirmed the information provided by the Licensee on July 19, 1993. The NRC learned that since at least 1988 nuclear medicine technologists have increased the dosages of radiopharmaceuticals by as much as 40 percent above the approved dosage ranges for imaging studies and false information about the administered dosage was entered in the records (i.e., dosages within the approved range were indicated in the records even though the actual administered dosages were higher). As a result of the NRC inspection, the NRC issued to the Licensee Confirmatory Action Letter No. RIII-93-012, dated July 26, 1993, in which the Licensee agreed to, among other things:

A. Immediately reaffirm to the nuclear medicine technologists that diagnostic dosages cannot exceed the prescribed dosage limits without authorized user approval.

B. Immediately take action to perform a two-person verification of patient dosages as described in the July 26, 1993 Confirmatory Action Letter.

C. Within 30 days, conduct the first of a series of quarterly audits of the nuclear medicine program to be conducted by an auditor independent of the hospital.

D. Within two weeks, increase the coverage by the Radiation Safety Officer (RSO) of the nuclear medicine department to at least two days per week.

E. Within two weeks, provide to the NRC Region III office a description of actions the Licensee has taken, or plans to take, to assure Licensee management that its nuclear medicine program is being operated according to NRC requirements.

Although the NRC inspection and investigation activities are continuing, the following significant violations have been identified to date:

A. Apparently deliberate violation of 10 CFR 35.25(a)(2) in that the nuclear medicine technologists failed to follow the instructions of the supervising authorized users as contained in the Licensee's procedure, entitled "Approved Dose Ranges of Radiopharmaceutical Use." That procedure specifies the radioisotope, procedures and dosage ranges to be used. Specifically, the nuclear medicine technologists intentionally increased the dosage beyond the range prescribed by the procedure.

B. Apparently deliberate violation of License Condition No. 16 which requires the Licensee to implement the model safety rules published in NRC Regulatory Guide 10.8, Appendix I, Item 14, prohibiting the use of a dosage if it varies by more than 10 percent from the prescribed dosage. Specifically, nuclear medicine technologists increased dosages 10% - 40% in order to decrease the scan time for the procedure being performed.

C. Apparently deliberate violation of 10 CFR 35.53(c) which requires that records of the measurement of radiopharmaceutical dosages contain certain information, including the prescribed dosage and the activity of the dosage at the time of measurement and violation of 10 CFR 30.9(a) which requires that records maintained by a licensee be complete and accurate in all material respects. More specifically, from approximately 1988 to June 15, 1993, the activity of some radiopharmaceutical dosages was beyond the approved dosage range and this deviation in the patient dosage was not reflected in patient dosage records.

The Licensee conducted an internal investigation and based on the results of its investigation, the Licensee initially suspended two nuclear medicine technologists from all NRC-licensed activities. Subsequently, the Licensee terminated one of the two individuals and the other individual returned to duties that do not involve NRC-licensed activities.

III

To preclude recurrence of any of the violations described above and to improve its oversight of its licensed nuclear medicine activities, the Licensee committed to a number of corrective

actions in its letters dated August 5 and August 13, 1993, responding to the NRC's July 26, 1993 Confirmatory Action Letter. The principal actions to which it agreed included, but were not limited to: (A) assigning a pharmacist or a radiologist to verify all radioisotope dosages prior to administration until such time that the unit dose system is fully operational; (B) implementing a unit dose system for all patients with the exception of add-on and on-call patient examinations when the radiopharmaceutical will be obtained from a generator. Dosages obtained from a generator will be verified by a pharmacist or a radiologist; (C) installing a printer for the dose calibrator; (D) obtaining the services of an Assistant Radiation Safety Officer (ARSO) to work in the Nuclear Medicine Section at least 16 hours per week, with the responsibilities of the ARSO described in Attachment V to the Licensee's letter dated August 5, 1993; (E) contracting for the services of a qualified individual to perform an independent audit of the Licensee's Nuclear Medicine Section, with the scope of such audit described in Attachment IV to the Licensee's letter dated August 5, 1993; (F) providing to the NRC a copy of the Licensee's internal investigation report; (G) notifying the NRC prior to permitting certain individuals to return to work in licensed activities; and (H) conducting monthly and quarterly audits of the Nuclear Medicine Section for at least one year, with the scope of those

audits as outlined in Attachments I and II of the Licensee's letter dated August 13, 1993.

I find that the Licensee's commitments, as set forth in its letters of August 5 and August 13, 1993, are acceptable and necessary and conclude that, with these commitments, the public health and safety is reasonably assured. In view of the foregoing, I have determined that public health and safety require that the commitments made by the Licensee in the letters dated August 5 and August 13, 1993, be confirmed by this Order. The Licensee has agreed to this action in telephone conversations held on October 8, 1993 between B. J. Holt, NRC Region III, and Mitchell C. Carson, Vice President of Operations, Ball Memorial Hospital, and on October 13, 1993 between Roy J. Caniano, NRC Region III, and Mitchell C. Carson, Vice President of Operations, Ball Memorial Hospital.

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 35, IT IS HEREBY ORDERED, THAT LICENSE NO. 13-00951-03 IS MODIFIED AS FOLLOWS:

A. A unit dose system shall be implemented for the Nuclear Medicine Section and such unit dosages shall be obtained from an outside radiopharmacy with the exception of add-on and on-call patient examinations when the radiopharmaceutical may be obtained from a generator. All unit dose and generator orders for radiopharmaceuticals will be made by an authorized user named on the NRC license or the Assistant Director of Radiology or his designee, and the designee will not be a nuclear medicine technologist or an employee of the Nuclear Medicine Section.

B. For add-on and on-call patient examinations when the radiopharmaceutical is obtained from a generator, the Licensee will develop and implement a system for independent verification of the dosage. Such verification will be performed by a person who is not a nuclear medicine technologist or associated with the Licensee's Nuclear Medicine Section, with the exception that an authorized user may perform the independent verification of the dosage assay.

C. The Licensee shall use the printer installed for the dose calibrator to automatically provide a record of

each dosage measured and to maintain such records for NRC inspection for a period of at least five years.

D. The Licensee shall obtain the services of an Assistant Radiation Safety Officer (ARSO) who will work in the Licensee's Nuclear Medicine Section for at least 16 hours per week. The ARSO will perform assigned duties for a minimum of a 1 year period from the date of initial assignment. The duties of the ARSO shall be as described in Attachment V to the Licensee's letter dated August 5, 1993 and duties as described within Section IV. E of this Order.

E. Dosage records will be reviewed on a weekly basis to assure that all dosages administered were within the approved dosage ranges. This review will be performed by the RSO or ARSO. Any identified deviation from the approved dosage ranges that had not received prior approval of the physician authorized user must be immediately brought to the attention of the Vice President of Operations, Ball Memorial Hospital, and NRC Region III. A record of these reviews will be prepared and maintained for NRC inspection for a period of at least 5 years.

F. The Licensee shall obtain the services of a qualified Radiation Safety Officer, employed outside of the Licensee's organization, to perform an independent radiation safety and compliance audit of the Licensee's Nuclear Medicine Section. The scope of the audit shall be as described in Attachment IV to the Licensee's letter dated August 5, 1993. The audit which commenced on September 20, 1993 can serve to address this condition.

G. The Licensee shall inform the NRC Region III office when the Licensee's internal investigation has been completed and provide the complete report of that investigation to the NRC Region III office and, additionally, a version with all personal privacy-related information redacted, suitable for placement in the NRC Public Document Room.

H. The Licensee shall conduct monthly and quarterly radiation safety and compliance audits of the Nuclear Medicine Section. These audits will be performed for at least one year from the date of this Order. The scope of such audits shall be as outlined in Attachments I and II to the Licensee's letter dated August 13, 1993. A complete copy of each monthly and

quarterly audit report shall be sent to the NRC Region III office within 10 working days of the completion of each audit.

The Regional Administrator, Region III, may, in writing, relax or rescind any of the above conditions upon demonstration by the Licensee of good cause.

V

In accordance with 10 CFR 2.202, any person adversely affected by this Confirmatory Order, other than the Licensee, 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, 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, and to the Regional Administrator, Region III, U. S. Nuclear Regulatory Commission, 799 Roosevelt Road, Glen Ellyn, Illinois 60137, and to the Licensee. If such a person 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 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.

In the absence of any request for a hearing, the provisions specified in Section IV above shall be effective and final 20 days from the date of this Order without further order or proceedings.

FOR THE NUCLEAR REGULATORY COMMISSION

James Lieberman, Director
Office of Enforcement

Dated at Rockville, Maryland
this 20th day of October 1993

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

OCT 26 1993

Docket No. 40-8724
License No. SUB-1357
EA 93-068

Chemetron Corporation
ATTN: Mr. David R. Sargent
President
1 Citizens Plaza
Providence, Rhode Island 02903

Gentlemen:

SUBJECT: CONFIRMATORY ORDER MODIFYING LICENSE

The enclosed Confirmatory Order Modifying License is being issued to establish dates for the submittal of three sections which were not included in Chemetron's October 1, 1993, Site Remediation Plan for the Bert Avenue and Harvard Avenue sites but were required to be submitted by Condition 12 of your license. This Order modifies License No. SUB-1357 by adding a new license condition 14 that requires Chemetron to submit the Planned Final Radiation Survey section of the Site Remediation Plan by November 1, 1993, and the Safety Analysis and the Radiological Assessment sections by November 15, 1993. Issuance of this Confirmatory Order does not preclude enforcement action for violation of the existing requirement in Condition 12 that a complete plan be submitted by October 1, 1993. The failure to meet Condition 12 will be the subject of separate correspondence.

The NRC expects and demands Chemetron's compliance with the enclosed Order. The requirements in the Order to submit the identified sections of the Site Remediation Plan are continuing requirements. Accordingly, each day beyond the initial deadline stated in the Order that Chemetron fails to submit a required section would constitute a separate violation. Failure by the Licensee to fully comply with this Order will be cause for NRC consideration of civil enforcement sanctions. You should be aware that the NRC is authorized to impose a civil penalty for each separate violation of up to a maximum of $100,000 per day. In this case, should Chemetron violate the Order, the NRC intends to impose substantial civil penalties for each item submitted late or which contains substantial technical inadequacies, until those items are submitted or the inadequacies are remedied.

In accordance with 10 C.F.R. § 2.790 of the NRC's Rules of Practice, Part 2, Title 10, Code of Federal Regulations, a copy of this letter and the enclosed Confirmatory Order Modifying License will be placed in the NRC's Public Document Room.

Sincerely,

James Lieberman, Director
Office of Enforcement

Enclosure: Confirmatory Order Modifying License

cc:
Chemetron Distribution List

Chemetron Distribution List

cc:
Senator Metzenbaum
Senator Glenn
Robert E. Owen, ODH
Donald Schregardus, OEPA
Kathryn Jones, OEPA
Sylvia Lowrance,USEPA
Henry Longest, USEPA
James R. Williams, OEMA
Michael D. Dawson, OH Gov. Office
Todd Brady, Cuyahoga BoH
Kathleen Edwards, Mayor
of Newburgh Heights
Lou Bacci, Mayor of
Cuyahoga Heights
The Earth Day Coalition
Mark J. Wetterhahn, Esq.

UNITED STATES
NUCLEAR REGULATORY COMMISSION

In the matter of	)	Docket No. 40-08724
	)	License No. SUB-1357
Chemetron Corporation	)	EA 93-068
Providence, RI 02903	)	
	)	
(Bert Avenue and Harvard Avenue Remediation)	)	

CONFIRMATORY ORDER MODIFYING LICENSE

I

Chemetron Corporation (Licensee) is the holder of Source Material License No. SUB-1357 (License) originally issued on June 12, 1979, by the Nuclear Regulatory Commission (NRC or Commission) pursuant to 10 C.F.R. Parts 30, 31, 32, 33, 34, 35, 40, and 70, for possession only of depleted uranium contamination in a facility located at 2910 Harvard Avenue, Newburgh Heights, Ohio (the Harvard Avenue site). The License was modified on October 1, 1987, to authorize the Licensee to possess the radioactive material at the McGean-Rohco site located between 28th and 29th Streets at Bert Avenue, Newburgh Heights, Ohio (the Bert Avenue site). The License was last renewed on January 10, 1990, and was due to expire on October 31, 1990. On October 1, 1990, Chemetron filed a timely license renewal application with NRC. Pursuant to 10 C.F.R. § 40.43(b), the License is continuing in effect.

II

License Condition 12, which became effective May 25, 1993, required the final remediation plan for the Licensee's Harvard Avenue and Bert Avenue sites to be submitted by October 1, 1993.

On October 1, 1993, Chemetron submitted its Site Remediation Plan for the Harvard Avenue and Bert Avenue sites, indicating in its cover letter that the submittal was "[i]n fulfillment of condition 12 of the referenced license . . . ." Chemetron, however, did not include in the Site Remediation Plan three sections critical to the NRC's health and safety review of the plan; rather, the Site Remediation Plan stated that Chemetron would submit these three sections at a later date. The sections of the Site Remediation Plan that Chemetron failed to submit were the Planned Final Radiation Survey, the Safety Analysis, and the Radiological Assessment. Chemetron representatives gave no prior notice to the NRC staff, or indication in their remediation plan transmittal letter, that these sections would not be submitted or that these sections would be submitted at a later time, nor did they seek an extension of this date.

The Commission's regulation in 10 C.F.R § 40.42(c)(2)(iii) specifies the contents required in a decommissioning plan. The Planned Final Radiation Survey section is one of the components of the decommissioning plan required under 10 C.F.R. § 40.42(c)(2)(iii)(C). This section of the Site Remediation Plan would provide the Licensee's planned final survey procedures to demonstrate that the Site Remediation Plan accomplished its planned objectives in compliance with the decontamination criteria approved by the NRC for the site. The Safety Analysis is required under 10 C.F.R. § 40.42(c)(2)(iii)(B), which requires the description of methods used to assure protection of workers and the environment against radiation hazards during decommissioning. The Safety Analysis evaluates the doses from routine operations and accidents during the remediation activities as discussed in Section 2.1.2 in Regulatory

Guide 3.65, "Standard Format and Content of Decommissioning Plans for Licensees Under 10 CFR Parts 30, 40, and 70."

In the Chemetron Site Remediation Plan, Chemetron is proposing to use onsite disposal in accordance with 10 C.F.R. § 20.302. An application for Commission approval of proposed procedures to dispose of licensed material pursuant to 10 C.F.R. § 20.302, as required by that section, should include "an analysis and evaluation of pertinent information as to the nature of the environment, including topographical, geological, meteorological, and hydrological characteristics; usage of ground and surface waters in the general area; the nature and location of other potentially affected facilities; and procedures to be observed to minimize the risk of unexpected or hazardous exposures." The required analysis and evaluation would include a radiological assessment that discusses the doses to the public from various exposure pathways.

In summary, the Licensee's October 1, 1993, Site Remediation Plan is incomplete in that it lacks a Planned Final Radiation Survey and a Safety Analysis (required by 10 C.F.R. § 40.42(c)(2)(iii)) and a Radiological Assessment (required by 10 C.F.R. § 20.302(a)). Without the Planned Final Radiation Survey, the Safety Analysis, and the Radiological Assessment, the NRC staff cannot evaluate the health and safety aspects of the Site Remediation Plan as required under the regulations for the proposed decommissioning actions. Specifically, the NRC staff is unable to determine whether the health and safety of the public and workers and the environment will be protected during decommissioning and whether Chemetron's Site Remediation Plan will ultimately provide adequate protection of the public

health and safety if properly implemented. Consequently, the Licensee is in violation of License Condition 12. Having violated the previous required schedule, it is now necessary to establish a date to bring the Licensee into compliance and to preclude recurrence of the violation described above.

III

During a telephone call on October 19, 1993 between Dr. Barry Koh, Chemetron, and Mr. T. Johnson, NRC, it was agreed that Chemetron would submit:

1. A technically complete Planned Final Radiation Survey section for the Site Remediation Plan for the Harvard Avenue and Bert Avenue sites by November 1, 1993;

2. A technically complete Safety Analysis section for the Site Remediation Plan for the Harvard Avenue and Bert Avenue sites by November 15, 1993; and

3. A technically complete Radiological Assessment section for the Site Remediation Plan for the Harvard Avenue and Bert Avenue sites by November 15, 1993.

I find that the Licensee's current commitments, as set forth above, are necessary and desirable to protect the public health, safety and interest. In view of the foregoing, I have determined that the commitment made by the Licensee in the October 19, 1993 telephone conversation, should be confirmed

by this Order. In a telephone conversation held on October 25, 1993 between Mr. John Greeves, NRC, and Mr. David R. Cargent, Chemetron, the Licensee agreed to the imposition of the requirements set forth in Section IV of this Order. The issuance of this Order does not relieve the Licensee from additional enforcement action for the violation of License Condition 12.

IV

Accordingly, pursuant to Sections 62, 63, 161b, 161c, 161i, 161o, 182 and 186 of the Atomic Energy Act of 1954, as amended, and the Commission's regulations in 10 C.F.R. § 2.202 and 10 C.F.R. Part 40, IT IS HEREBY ORDERED THAT LICENSE NO. SUB-1357 IS MODIFIED BY ADDING A NEW LICENSE CONDITION NO. 14 AS FOLLOWS:

14. The Licensee shall submit final versions of (1) a technically complete Planned Final Radiation Survey section for the Site Remediation Plan for the Harvard Avenue and Bert Avenue sites by November 1, 1993; (2) a technically complete Safety Analysis section for the Site Remediation Plan for the Harvard Avenue and Bert Avenue sites by November 15, 1993; and (3) a technically complete Radiological Assessment section for the Site Remediation Plan for the Harvard Avenue and Bert Avenue sites by November 15, 1993. The obligations established by this License Condition are continuing in nature and remain in effect until the required submittals have been met and any failure by Chemetron to submit technically complete and final versions of the three items required to be submitted by this License Condition shall give rise to a new deadline for Chemetron to

submit technically complete and final versions of those items on the day following the prior deadline.

The Director, Office of Nuclear Material Safety and Safeguards, may, in writing, relax or rescind any of the above conditions upon the Licensee's showing, in writing, of good cause.

V

In accordance with 10 C.F.R. § 2.202, any person adversely affected by this Confirmatory Order, other than the Licensee, 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, 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 and the Director, Office of Nuclear Material Safety and Safeguards, at the same address, and to the Regional Administrator, Region III, U. S. Nuclear Regulatory Commission, 799 Roosevelt Road, Glen Ellyn, Illinois 60137, and to the Licensee. If such a person 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 C.F.R. § 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.

On the basis of the Licensee's consent to Section IV of this Order, this Order is effective upon issuance.

FOR THE NUCLEAR REGULATORY COMMISSION

James Lieberman, Director
Office of Enforcement

Dated at Rockville, Maryland
this 26th day of October 1993

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

April 6, 1993

Docket No. 030-11722
License No. 34-13103-02
EA 92-132

City of Columbus
Division of Construction Inspection
ATTN: Mr. Richard Cummins
Manager of Testing
1129 Morse Road, 2nd Floor
Columbus, Ohio 43229

Dear Mr. Cummins:

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY - $2,000
(NRC INSPECTION REPORT NO. 030-11722/91001)
(NRC INVESTIGATION REPORT NO. 3-91-012)

This refers to the routine safety inspection conducted on July 23 and 25, 1991, and the subsequent investigation at the City of Columbus, Division of Construction Inspection. The report documenting this inspection and a copy of the synopsis of the investigation report were mailed to you by letter, dated December 30, 1992. A significant violation of NRC requirements was identified during the inspection and investigation, and on January 6, 1993, an enforcement conference was held by telephone. A copy of the enforcement conference report was mailed to you on January 15, 1993.

The safety inspection was conducted to review the radiation safety program associated with your possession of four Troxler soil moisture-density gauges which are used to test road construction material. Each of those gauges contains NRC-licensed sealed sources of cesium-137 and americium-241. The inspection disclosed that your current Radiation Safety Officer and his predecessors routinely removed the source rod to clean mud from the four gauges even though they were not authorized by License Condition No. 19 to perform that activity. Subsequent to the inspection, the NRC Office of Investigations (OI) conducted an investigation and determined that two former Radiation Safety Officers knew that the NRC license prohibited anyone from removing the source rod from the gauge unless that person was specifically authorized to do so; therefore, their actions were

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

deliberate. The investigation also showed that your current Radiation Safety Officer also performed the same maintenance activity as his predecessors, but he was not aware of License Condition 19.

The violation is fully described in the enclosed Notice of Violation (Notice), Enclosure 1, and concerns the deliberate performance of licensed activities by unauthorized individuals.

Therefore, the violation is categorized at Severity Level III in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C (1991) (Enforcement Policy).

Deliberate violations of NRC regulations and license conditions are of particular concern to the NRC because the regulatory program is based on licensees, their contractors, employees, and agents acting with integrity. Such violations will not be tolerated by the Commission and must not be tolerated by a licensee. The deliberate violation committed by your previous Radiation Safety Officers, and the lack of awareness of the license requirement on the part of your current Radiation Safety Officer, are especially significant because the Radiation Safety Officer is your technical expert on the conditions of the NRC license and the NRC regulations. Notwithstanding the deliberateness of these acts, which is a cause for concern itself, the removal of source rods could have serious consequences if performed improperly. The manufacturer, Troxler, states that the gamma dose rate at direct surface contact is >20 rem/hr. The dose rate at a distance of 1.2 inches is 3.5 rem/hr. Thus there is a potential for significant exposure if the source is improperly handled or controlled.

The root causes of the violation and the subsequent corrective action were discussed during the January 6, 1993, enforcement conference. The major factors contributing to the violation appeared to be a lack of appreciation for safety regulations by your Radiation Safety Officers who were ineffective in implementing the radiation safety program. Also, there was an overall lack of management oversight of your Radiation Safety Officer. The NRC recognizes that your corrective actions were prompt and extensive.

Therefore, to emphasize the significance that NRC attaches to deliberate violations of Commission regulations and license requirements, and to emphasize that senior managers and supervisors must involve themselves in the radiation safety program, I have been authorized, after consultation with the Commission 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 value of a civil penalty for a Severity Level III violation is $500. The base civil penalty was initially increased 50 percent because the NRC identified the violation. It was escalated an additional 100 percent for the multiple times that the violation occurred. However, the base civil penalty was reduced 50 percent for your prompt and extensive corrective action. The remaining factors in the enforcement policy were also considered and no further adjustment to that civil penalty is considered appropriate. In addition, the base civil penalty is being increased 200 percent because Radiation Safety Officers, whom you specifically designated to ensure compliance with NRC regulatory requirements were involved in willful violations. This increase in the civil penalty emphasizes the unacceptability of involvement of Radiation Safety Officers in willful violations. On balance, the base civil penalty was increased 300 percent.

Each of the individuals involved with removing the source rod from the various gauges remains in your employ and is involved or could be involved in activities authorized by your NRC license. Therefore, in order to determine whether additional regulatory action is needed, you are hereby required, pursuant to sections 161c, 161o, 182, and 186 of the Atomic Energy Act of 1954, as amended, and the Commission's regulations in 10 CFR 2.204 and 10 CFR 30.32(b), to provide in writing, under oath or affirmation within 30 days of the date of this letter, the basis for your belief that the present Radiation Safety Officer fully understands his responsibilities and obligations under the NRC license and regulations. Since the previous Radiation Safety Officers may become involved in licensed activities in the future, you are also required to provide within 30 days written assurance under oath or affirmation that they understand the responsibilities and obligations of being involved in licensed activities.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice of Violation and Proposed Imposition of Civil Penalty when preparing your response. In your response, you should document the specific actions taken, including disciplinary action, if any, against the employees involved in this matter, and any additional actions you plan to prevent recurrence. After reviewing your response to this Notice, including your proposed corrective actions, your written assurance that certain employees understand their obligations and responsibilities, 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 July 23 and 25, 1991, inspection also identified a number of other violations of NRC requirements and license conditions that

are specifically described in Enclosure 2. The violations include: failure to evaluate extremity exposures of individuals handling source rods; failure to perform quarterly safety checks; overnight storage of licensed materials at unauthorized locations; failure to list an emergency response telephone number and other required information on a shipping paper; and failure to make shipping papers properly accessible. Each violation was individually categorized at Severity Level IV in accordance with the NRC Enforcement Policy (1991). These violations have been corrected and those actions were reviewed during an inspection on August 17, 1992 and documented in Inspection Report 92-001. Therefore, a response with respect to the violations described in Enclosure 2 is not required.

Three additional violations, each categorized at Severity Level V were identified during the inspection. These violations included the failure to: (1) maintain a record of qualifications and training for an individual authorized to use byproduct material; (2) include all required information on shipping papers; and (3) post required documents and notices at the licensee's facility. These violations are not cited because each met the criteria of Paragraph V.A of the NRC Enforcement Policy (1991) for the use of enforcement discretion.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter, its enclosures, 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

Enclosures:
1. Notice of Violation and Proposed Imposition of Civil Penalty
2. Notice of Violation (no response required)

cc/enclosures:
DCD/DCB (RIDS)

Enclosure 1

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

City of Columbus
Division of Construction Inspection
Columbus, Ohio

Docket No. 030-11722
License No. 34-13103-02
EA 92-132

During an NRC inspection conducted on July 23 and 25, 1991, and a subsequent investigation, 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 (1991), 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:

License Condition No. 14 which was in effect from June 4, 1981, until it was superseded by License Condition No. 19 on December 12, 1990, prohibited the licensee from removing sealed sources containing licensed material from gauges. License Condition No. 19 which was in effect from December 12, 1990, until the license was renewed in its entirety on March 24, 1992, required that any cleaning, maintenance or repair of gauges that requires removal of the source rod shall be performed only by the manufacturer or by other persons specifically licensed by the Commission or an Agreement State to perform such services.

Contrary to the above, from approximately 1982 to July 21, 1991, licensee employees routinely removed source rods in order to clean and maintain the gauges, but these employees were not representatives of the manufacturer and were not specifically licensed by the Commission or an Agreement State to perform such services. Specifically, from 1982 to November 1990, one individual removed source rods at least twice a year to clean the gauges; from at least December 12, 1990, to July 21, 1991, another individual removed the source rods from at least three gauges on a monthly basis to clean and maintain the gauges; and on at least one occasion from December 12, 1990, to July 21, 1991, a third individual removed the source rod from one moisture-density gauge to clean and maintain the gauge.

This is a Severity Level III violation (Supplement VI).
Civil Penalty - $2,000.

Pursuant to the provisions of 10 CFR 2.201, the City of Columbus, Division of Construction Inspection (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 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 (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

A. Bert Davis
Regional Administrator

Dated at Glen Ellyn, Illinois
this 6 day of April 1993

NOTICE OF VIOLATION

City of Columbus
Division of Construction Inspection
Columbus, Ohio

Docket No. 030-11722
License No. 34-13103-02

As a result of the inspection conducted on July 23 and 25, 1991, and in accordance with the "Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C (1991) (Enforcement Policy), the following violations were identified:

A. 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. 10 CFR 20.101 limits the radiation dose to a worker's extremity to 18.75 rems per calendar quarter.

Contrary to the above, as of July 23, 1991, the licensee did not make surveys (evaluations) to assure compliance with that part of 10 CFR 20.101 that limits the radiation dose to a worker's extremity to 18.75 rems per calendar quarter. Specifically, the license did not evaluate the radiation hazards that may be present to show compliance with 10 CFR 20.101 when sources rod were removed in order to clean and maintain the gauges.

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

B. License Condition No. 17, effective June 26, 1986, which was in effect until December 12, 1990, when License Amendment No. 6 was issued, required that licensed material be possessed and used in accordance with the statements, representations, and procedures contained in certain referenced documents, including the license application dated March 4, 1981, and a letter dated May 1, 1986. Amendment No. 6, License Condition No. 17, dated December 12, 1990, was in effect until the license was renewed in its entirety on March 24, 1992, and required that licensed material be possessed and used in accordance with the statements, representations, and procedures contained in certain referenced documents, including the license application dated March 4, 1981, and letters dated May 1, 1986, and November 8, 1990.

1. Item 15.(4) of the March 4, 1981, license application required, in part, that the Division Superintendent or his designated representative make a quarterly physical safety check covering security, personnel monitoring, records and reports, incidents, emergency procedures and transportation by private motor vehicle.

   Contrary to the above, from June 26, 1986 through July 25, 1991, the Division Superintendent or his designee did not make any quarterly physical safety checks.

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

2. Item 13 of the letter dated May 1, 1986, required, in part, that gauges will not be stored at temporary job sites.

   The letter dated November 8, 1990, required the overnight storage of nuclear gauges on the second floor of the licensee's facility at 1120 Morse Road, Columbus, Ohio.

   Contrary to the above, as of July 23, 1991, nuclear gauges were not always stored in the storage area located on the second floor of the licensee's facility at 1120 Morse Road, Columbus, Ohio. Specifically, the Radiation Protection Officer stated that gauges are routinely stored in automobiles parked overnight at the homes of the authorized users and are occasionally removed from the vehicles for recharging in the authorized users' garages.

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

C. 10 CFR 71.5(a) requires that licensees who transport licensed material outside the confines of their plants 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.

Pursuant to 49 CFR 172.101, radioactive material is classified as a hazardous material.

1. 49 CFR 172.604(a)(3) requires, in part, that a person who offers a hazardous material for transportation must provide a 24-hour emergency response telephone number on the shipping paper for use in the event of an emergency involving the hazardous material.

Contrary to the above, on July 23, 1991, the licensee offered for transportation and transported a package containing approximately 0.04 curies of americium-241 and 0.008 curies of cesium-137, hazardous materials, outside the confines of its plant, and the licensee did not provide a 24-hour emergency response telephone number on the shipping paper.

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 required by 49 CFR 177.817(a) is readily available to, and recognizable by, authorities in the event of accident or inspection. The driver shall store the shipping paper as follows: 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.

Contrary to the above, on July 23, 1991, the licensee transported approximately 0.04 curies of americium-241 and 0.008 curies of cesium-137 in special form radioactive material, a hazardous material, outside the confines of its plant and the driver of the vehicle did not ensure that the shipping paper was readily available in the driver's compartment, as required. Specifically, the shipping paper was stored behind the driver's seat while the driver was not at the controls of the vehicle.

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

3. 49 CFR 172.400(a) requires each person who offers a package containing a hazardous material for transportation shall label it as specified in 49 CFR 172.101. 49 CFR 172.101, "Hazardous Material Table," shows that the identification number for special form radioactive material is UN 2974.

Contrary to the above, on July 23, 1991, the licensee offered for transportation and transported a package containing approximately 0.04 curies of americium-241

and 0.008 curies of cesium-137, special form radioactive material, which is also a hazardous material, outside the confines of its plant, and the package was not labelled with the correct identification number as specified in 49 CFR 172.101. Specifically, the package was labelled "NA 9182," rather than "UN 2974," as specified in 49 CFR 172.101.

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

An inspection on August 17, 1992, showed that steps have been taken to correct the identified violations and to prevent recurrence. Consequently, no reply to the violations is required and we have no further questions regarding this matter.

FOR THE NUCLEAR REGULATORY COMMISSION

A. Bert Davis
Regional Administrator

Dated at Glen Ellyn, Illinois
this 6 day of April 1993

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

JUL 13 1993

Docket No. 030-11722
License No. 34-13103-02
EA 92-132

City of Columbus
Division of Construction Inspection
ATTN: Mr. Richard Cummins
Manager of Testing
1800 East 17th Avenue
Columbus, Ohio 43219

Dear Mr. Cummins:

SUBJECT: ORDER IMPOSING CIVIL MONETARY PENALTY - $2,000

This refers to your letter dated May 19, 1993, in response to the Notice of Violation and Proposed Imposition of Civil Penalty (Notice) sent to you as Enclosure 1 to our letter dated April 6, 1993. Our letter also described six other violations which were not assessed a civil penalty and for which your corrections had been reviewed at an inspection on August 17, 1992. Thus, they will not be discussed further in this correspondence.

To emphasize the need for effective management and oversight of NRC licensed activities and the significance that NRC attaches to deliberate violations of NRC requirements, a civil penalty of $2,000 was proposed on April 6, 1993.

Your response neither admits nor denies the violation and requests that the penalty be mitigated to $1,000. After considering your response, we have concluded, for the reasons given in the Appendix attached to the enclosed Order Imposing Civil Monetary Penalty, that you did not provide an adequate basis for modifying or withdrawing the violation, reducing the Severity Level, or remission of $1,000 of the civil penalty. Accordingly, we hereby serve the enclosed Order Imposing Civil Monetary Penalty on the City of Columbus, Division of Construction Inspection, Columbus, Ohio (Licensee) imposing a civil monetary penalty in the amount of $2,000. We will review the effectiveness of your corrective actions concerning this violation during a subsequent inspection.

The NRC letter of April 6, 1993, which forwarded the Notice, required the City of Columbus to provide "... the basis for your

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belief that the present Radiation Safety Officer fully understands his responsibilities and obligations under the NRC license and regulations." Your response stated: "That as the duly appointed Testing Section Manager who directly supervises the personnel that operate the gauges as well as the current Radiation Safety Officer, Affiant fully understands the responsibilities and obligations of such position under the City's NRC license and regulations." This addresses the Section Manager's understanding, not that of the Radiation Safety Officer, as required by our letter. Please submit within 30 days of the date of this letter, under oath or affirmation, written information that provides the specific basis for your belief that the Radiation Safety Officer fully understands his responsibilities and obligations. It should be more than a simple, conclusionary statement that you believe it to be true. Failure to provide the requested information may result in an order precluding him from being involved in licensed activities.

Finally, we emphasize that willful violations will not be tolerated. It is not acceptable to violate requirements to save costs. Future similar violations may result in criminal sanctions and license revocation. If you have any questions concerning this matter, please contact me 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,

James Lieberman, Director
Office of Enforcement

Enclosures:
1. Order Imposing Civil Monetary Penalty
2. Appendix - Evaluations and Conclusion

cc w/enclosures:
DCD/DCB (RIDS)
Daniel W. Drake, Chief Environmental and Utilities Attorney, City of Columbus

UNITED STATES
NUCLEAR REGULATORY COMMISSION

In the Matter of	)	
	)	Docket No. 030-11722
CITY OF COLUMBUS	)	License No. 34-13103-02
Division of Construction Inspection	)	EA 92-132
Columbus, Ohio	)	

ORDER IMPOSING CIVIL MONETARY PENALTY

I

The City of Columbus, Division of Construction Inspection, Columbus, Ohio (Licensee) is the holder of Byproduct License No. 34-13103-02 first issued by the Nuclear Regulatory Commission (NRC or Commission) on June 4, 1981, and renewed in its entirety on March 24, 1992. The license is due to expire on March 31, 1997. The license authorizes the Licensee to use sealed sources of cesium-137 not to exceed 10 millicuries (Troxler Drawing No. A 102112) and sealed sources of americium-241 not to exceed 50 millicuries each (Troxler Drawing No. A-102451) in Troxler Model 3400 Series surface/moisture density gauges in accordance with the conditions specified therein. Licensed material may be stored at the Licensee's facility located at 1800 East 17th Avenue, Columbus, Ohio, or at temporary job sites of the Licensee anywhere in the United States where the U. S. Nuclear Regulatory Commission maintains jurisdiction for regulating the use of licensed material.

II

An inspection of the Licensee's activities was conducted on July 23 and 25, 1991, and the NRC Office of Investigations subsequently conducted an investigation of certain apparently deliberate actions. The results of the inspection and investigation 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 as Enclosure 1 to the NRC's letter dated April 6, 1993. The Notice stated the nature of the violation, the provision of the NRC's requirements that the Licensee had violated, and the amount of the civil penalty proposed for the violation. The Licensee responded to the Notice by letter dated May 19, 1993. In its response, the Licensee did not specifically admit or deny the violation and requested a $1,000 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 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 $2,000 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 Secretary, U.S. Nuclear Regulatory Commission and 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 the Notice referenced in Section II above, and

(b) whether, on the basis of such violation, this Order should be sustained.

FOR THE NUCLEAR REGULATORY COMMISSION

James Lieberman, Director
Office of Enforcement

Dated at Rockville, Maryland
this 13th day of July 1993

APPENDIX
EVALUATION AND CONCLUSIONS

On April 6, 1993, a Notice of Violation and Proposed Imposition of Civil Penalty (Notice) was issued for a violation identified during an NRC inspection on July 23 and 25, 1991, and a subsequent investigation concerning the violation conducted by the NRC Office of Investigations. The City of Columbus, through its Chief Environmental and Utilities Attorney, responded to the Notice by letter dated May 19, 1993. In its response, the Licensee did not specifically admit or deny the violation, and requested remission of the civil penalty by $1,000. The NRC's evaluation and conclusions regarding the Licensee's request are as follows:

Restatement of Violation

License Condition No. 14 which was in effect from June 4, 1981, until it was superseded by License Condition No. 19 on December 12, 1990, prohibited the Licensee from removing sealed sources containing licensed material from gauges. License Condition No. 19 which was in effect from December 12, 1990, until the license was renewed in its entirety on March 24, 1992, required that any cleaning, maintenance or repair of gauges that requires removal of the source rod (sealed sources) shall be performed only by the manufacturer or by other persons specifically licensed by the Commission or an Agreement State to perform such services.

Contrary to the above, from approximately 1982 to July 21, 1991, Licensee employees routinely removed source rods in order to clean and maintain the gauges and they were not representatives of the manufacturer or were not specifically licensed by the Commission or an Agreement State to perform such services. Specifically, from 1982 to November 1990, one individual removed source rods at least twice a year to clean the gauges. From at least December 12, 1990, to July 21, 1991, another individual removed the source rods from at least three gauges on a monthly basis to clean and maintain the gauges. A third individual removed the source rod from one moisture density gauge on at least one occasion from December 12, 1990, to July 21, 1991, to clean and maintain the gauge.

Restatement of Licensee's Response to Violation

The Division's first gauge operator and Radiation Safety Officer (RSO) stated that during his initial training classes with Troxler Electronics, he was instructed in the removing and cleaning of the gauge source rod using the lead shield. He was advised of the necessary safety precautions to follow, and was led to believe that the exposure level, once the rod was removed, was minimal and not a safety hazard.

The sole purpose that this RSO and gauge user and successive RSOs and gauge operators gave for continued removal and cleaning of the source was not a deliberate attempt to violate NRC regulations or to intentionally disregard the NRC's authority, but to keep maintenance costs and periods of time without the much needed gauges to a minimum.

Prior to the City's contracting with an outside contractor for cleaning, the Division's only option was to send the gauges back to the manufacturer's headquarters in North Carolina. Services from the City's present contractor were not available locally at that time, and service by the manufacturer itself entailed lost time and expense.

NRC's Evaluation of Licensee's Response

The NRC recognizes that the manufacturer may have demonstrated to Licensee personnel safe methods to clean and maintain a soil moisture density gauge. The NRC acknowledges that the two previous RSOs routinely removed source rods to clean gauges in an attempt to save money for the City of Columbus, and they were not instructed by their supervisors or managers to perform this unauthorized maintenance. Nonetheless, their training and activities did not relieve the Licensee from the condition of the license that prohibited the removal of source rods by other than a specifically authorized individual.

This case is of particular concern because the RSOs, the technical experts in the safe handling of these nuclear gauges with responsibility for ensuring that Licensee employees satisfy the conditions in the license, were the individuals who exposed and removed the source rods. The NRC expects RSOs to be aware of regulatory requirements and follow them, particularly if the requirement is specifically stated in a license condition. Individuals who are specifically authorized to perform maintenance are not only trained in the proper maintenance procedures, but also receive radiation safety training specific to the job. Furthermore, an authorized person is issued specific extremity dosimetry in order to show the radiation exposure to the hands during source rod removal. This specialized training and dosimetry were not available to any of your employees who performed this maintenance. The only dosimetry available to them was a personnel dosimeter (film badge), which is not sufficient for this specific type of work; therefore, it cannot be conclusively shown that the employees did not receive a radiation exposure to the extremities. The NRC acknowledges that no individual's personnel dosimeter showed a significant exposure.

The Licensee points out that such maintenance services were not locally obtainable at the time of the violation and that the devices would have had to be sent to the manufacturer for

maintenance at considerable loss of time and expense to the City. However, the City of Columbus had the option of amending its NRC license to allow this maintenance by an employee who had received the necessary radiation safety training and who used proper dosimetry.

As to the willfulness of the violations and the Licensee's request for $1000 remission of the civil penalty, in sworn, transcribed testimony, two of the previous RSOs stated that they knew the NRC prohibited the removal of the source rods (sealed sources), and in fact discussed that point between themselves. Regardless of their motive to save money for the City of Columbus, these RSOs, the technical experts who are expected to set the example for the safe use of the nuclear gauge to other gauge users, knew the NRC prohibited the removal of source rods by other than specifically authorized personnel, yet performed this unauthorized maintenance practice for many years. The NRC concludes that the violations were willful.

As stated in the NRC's letter, dated April 6, 1993, the civil penalty adjustment factors described in the NRC Enforcement Policy were considered in arriving at the base civil penalty. That letter stated that the civil penalty was increased an additional 200 percent "because your Radiation Safety Officers, whom you specifically designated to ensure compliance with NRC regulatory requirements were involved in willful violations. This increase in the civil penalty emphasizes the unacceptability of involvement of Radiation Safety Officers in willful violations." The Licensee's letter of May 19, 1993, in response to the Notice, does not challenge any or all of the NRC's explanation for arriving at the $2,000 civil penalty.

NRC Conclusion

The NRC staff has concluded that the information provided in the Licensee's response does not provide an adequate basis for mitigation of the civil penalty. The substance of the Licensee's May 19, 1993, response to the Notice centers around an attempt to keep maintenance costs as low as possible for the City. Employees who were specifically charged with handling nuclear gauging devices in a safe manner and were the Licensee's technical experts in the safe use of the devices, purposely ignored a condition of the NRC license. License Conditions are established not only for the safety of the Licensee's employees, but also for the public health and safety. The disregard of NRC regulations and license conditions cannot be tolerated by the NRC and should not be excused by the City of Columbus as a way to save money. The only argument the Licensee makes for remission of $1,000 of the proposed civil penalty is to save tax money. The NRC's Enforcement Policy in 10 CFR Part 2, Appendix C, does not provide for remission of a civil penalty on this basis and

the staff has determined that remission is not appropriate in this case.

The NRC has concluded that this violation occurred as stated and no adequate basis for either reduction of the severity level or for mitigation of the civil penalty was provided by the licensee. Consequently, the proposed civil penalty in the amount of $2,000 should be imposed.

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

November 10, 1993

General License
(10 CFR 31.5)
EA 93-261

Como Plastics, Inc.
Attn: Ms. Melinda Ford
Plant Manager
Post Office Box 387
Columbus, Indiana

Dear Ms. Ford:

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY - $750 (INSPECTION REPORT 99990003/93036)

This refers to the safety inspection conducted at your facility on September 28, 1993, concerning the loss of static eliminator devices containing nominally 10 millicuries of polonium-210 which you possessed under a General License issued pursuant to 10 CFR 31.5. The report documenting the inspection is enclosed with this letter. The inspection identified a significant violation of NRC requirements and a copy of the inspection report is enclosed. On October 25, 1993, you were contacted by Mr. Cameron of this office and offered the opportunity to further discuss the issues surrounding the violations at an enforcement conference. You declined the invitation based on your belief that all pertinent facts were known and had previously been discussed.

On February 17, 1992, Como Plastics informed NRC Region III that two static eliminator devices had been lost. One of the devices was subsequently located. An inventory was conducted during the NRC inspection and an additional device could not be located.

The violation is fully described in the enclosed Notice of Violation and concerns the failure to control access to licensed materials for radiation purposes as specified by NRC requirements. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy) 10 CFR Part 2, Appendix C, the violation is categorized at Severity Level III.

The root cause of the violation appears to be a lack of management oversight of the radioactive materials in the possession of Como Plastics.

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The NRC recognizes the low safety significance of the loss of the static eliminator devices because of the form of the material. Nevertheless, the loss of byproduct material possessed under a General License represents a potential hazard to the health and safety of the general public and indicates a serious lack of control over licensed material. The loss also demonstrates a significant lack of management involvement in the oversight of the use of radioactive materials.

The general license under which Como Plastics, Incorporated, possessed nuclear materials requires that radiation safety be managed effectively. Incumbent on Como Plastics is the responsibility to protect the health and safety of employees and the public by assuring that all requirements of the NRC general license are met. Therefore, I have decided to issue the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice) in the amount of $750 for the Severity Level III violation.

The base value of a civil penalty for a Severity Level III violation is $500. The civil penalty adjustment factors in the Enforcement Policy were considered. The civil penalty was mitigated 50 percent because of the corrective action (i.e. returning all nuclear materials to the manufacturer). However, the base civil penalty was escalated 100 percent for your poor past performance in maintaining control of byproduct materials. On July 29, 1988, you reported the loss of three static eliminator devices, containing polonium-210. On February 17, 1992, you reported the loss of two more such devices, but subsequently reported that one of these had been located. Then, during our special inspection conducted on September 28, 1993, an inventory disclosed that a fifth device was missing. Therefore, no credit was given for the civil penalty adjustment factor for identification. The remaining factors in the Enforcement Policy were also considered and no further adjustment to the base civil penalty is considered appropriate. On balance the amount of the civil penalty was increased 50 percent.

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

Enclosures:
1. Notice of Violation and Proposed
2. Inspection Report No. 99990003/93036 Imposition of Civil Penalty

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

Como Plastics, Inc.
Columbus, Indiana

General License
(10 CFR 31.5)
EA 93-261

During an NRC inspection conducted on September 28, 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 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 is set forth below:

10 CFR 31.5(c)(8) requires, in part, that any person who acquires, receives, possesses, uses, or transfers byproduct material in a device pursuant to a general license shall, except as provided in 10 CFR 31.5(c)(9) which is not pertinent here, transfer or dispose of the device containing byproduct material only by transfer to persons holding a specific license pursuant to 10 CFR Parts 30 and 32 or from an Agreement State to receive the device.

Contrary to the above, as of September 28, 1993, the licensee disposed of two Nuclear Radiation Development, Inc., Model P2051 generally licensed static eliminator devices each containing nominally 10 millicuries of polonium-210, and the disposals were not made to a person holding a specific license issued pursuant to 10 CFR Parts 30 or 32 or from an Agreement State to receive the devices. Specifically, the devices were transferred to an unlicensed sanitary landfill for disposal. (01013)

This is a Severity Level III violation (Supplement VI).
Civil Penalty - $750.

Pursuant to the provisions of 10 CFR 2.201, Como Plastics, 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 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.

Dated at Glen Ellyn, Illinois
this 10th day of November 1993

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

SEP 1 1993

Docket No. 030-28835
License No. 35-23193-01
EA 93-015

Edwards Pipeline Testing, Inc.
ATTN: Don Earl Edwards
President
P.O. Box 470978
Tulsa, Oklahoma 74147

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY - $12,000 (NRC INSPECTION REPORT NOS. 92-01 AND 93-01; NRC INVESTIGATION CASE NO. 4-92-028)

This is in reference to NRC inspections conducted on August 26, 1992, in Tulsa, Oklahoma, and on February 10, 1993, at radiography field sites in Idaho. A report describing the results of these inspections was issued on June 23, 1993. On July 19, 1993, you and other representatives of Edwards Pipeline Testing, Inc., and its parent company, International Testing Services, Inc., attended an enforcement conference in the NRC's Arlington, Texas office to discuss potentially significant violations of NRC requirements discovered during these inspections. A list of enforcement conference participants is enclosed (Enclosure 2).

The violations in the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Enclosure 1) include: 1) a failure to comply fully with the requirement to audit the performance of all radiography personnel at least quarterly; and 2) a failure on the part of one radiographer to wear an alarm ratemeter at all times during radiographic operations.

The August 26, 1992, inspection found that Edwards Pipeline Testing was not complying fully with the requirement to audit the performance of radiography personnel at least quarterly, a violation for which your company had been cited following NRC inspections in 1989 and 1990. An investigation conducted by the NRC's Office of Investigations (OI) following the August 1992 inspection and completed in April 1993 determined that you had knowingly remained in noncompliance with this requirement. You informed the NRC's investigator that the reasons for this noncompliance could be summarized as "logistics, time and money." During the enforcement conference, you stated that the company's original license condition, which relied on the radiation safety officer to perform these audits, was flawed because the company employed radiography personnel at temporary job sites all over the country.

Following the NRC inspection in 1990, Edwards Pipeline Testing submitted a license renewal application to the NRC which proposed allowing certain senior

radiography personnel to conduct the required audits. On December 17, 1990, the NRC informed Edwards Pipeline Testing in writing that compliance with the original license condition was required while this application was pending. The NRC acknowledges that it conducted another inspection on September 20, 1991, and despite the fact that Edwards Pipeline Testing was not yet in full compliance, did not issue a citation or take enforcement action. This fact does not excuse noncompliance with the requirement. You stated at the enforcement conference that the NRC's 1991 inspection led you to believe that the NRC was satisfied with the progress you were making toward full compliance, but that at no time did you believe that compliance was not required.

The requirement to conduct quarterly audits of radiography personnel was enacted to provide assurance that these individuals -- who are handling radioactive sources with a substantial potential for harm -- are following all requirements necessary to assure the safety of radiography personnel and members of the public. The NRC's representatives emphasized during the enforcement conference that NRC licensees do not have the authority to choose, for economic or other reasons, which requirements they will follow and which they will not. Your statements at the enforcement conference indicated that you recognize the significance of this requirement and the seriousness with which the NRC views these violations, and that you have established a program to ensure compliance in the future, notwithstanding its impact on business considerations. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy) 10 CFR Part 2, Appendix C, the repetitive and willful failure to comply fully with this requirement is classified at Severity Level II.

The NRC acknowledges that, in response to the NRC's concerns following the August 26, 1992, inspection, Edwards Pipeline Testing took action to amend its license to increase the number of individuals who could perform these required audits. However, in February 1993, the NRC felt it necessary to obtain a further commitment from you to audit all radiography personnel and you agreed to complete audits of all personnel who had not been audited within the previous 90 days. This commitment was described in a February 3, 1993, Confirmatory Action Letter issued by the NRC. On February 5 1993, you replied in writing that all required audits had been done.

To emphasize the significance of Edwards Pipeline Testing selecting to remain in noncompliance with a requirement that is important to safety, and to assure that your corrective actions are lasting, 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 $12,000 for the Severity Level II violation discussed above. The base value of a civil penalty for a Severity Level II violation is $8,000. The civil penalty adjustment factors in the Enforcement Policy were considered and resulted in an increase of $4,000. In making this increase, the NRC determined that a 50-percent increase was warranted because

you failed to take prompt and effective corrective actions to assure full compliance despite a recognition of the audit violation in 1990 and a recognition since that time that not all personnel were being audited at the required intervals, and because the audits had not been completed as of February 2, 1993, several months after the 1992 inspection. The other adjustment factors in the Enforcement Policy were considered but no further adjustment to the base civil penalty was considered appropriate. The NRC notes in particular that no adjustment was made under the "Licensee performance" factor, despite good prior performance in all other respects, because of the significance that the NRC attaches to a decision made by a company president to remain in noncompliance over an extended period of time.

As discussed above, the NRC's February 10, 1993, inspection of field radiography sites in Idaho found one radiographer who was not wearing an alarm ratemeter while performing radiographic operations. The requirement to wear alarm ratemeters was enacted to provide radiography personnel an audible warning of unexpected high radiation levels and to prevent unnecessary radiation exposures to radiographers and members of the public. In this instance, the radiographer had been wearing the ratemeter during radiographic operations all day, but failed to put it back on when, after reviewing the films, it was decided to repeat two exposures. The failure to wear an alarm ratemeter, even if the failure appears isolated as in this case, is considered a significant violation and has been classified at Severity Level III in accordance with the Enforcement Policy. While a civil penalty is normally proposed for a Severity Level III violation, I have been authorized not to propose a civil penalty in this case because you took prompt corrective action, including disciplinary action against the involved radiographer, and developed effective corrective action to prevent a recurrence, which together warrant 50 percent mitigation, and because with the exception of the audit violations discussed above, Edwards Pipeline Testing has consistently been found in compliance with NRC requirements, which warrants 100 percent mitigation. Accordingly, the civil penalty that normally would have been proposed is 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 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,

for James L. Milhoan
Regional Administrator

Enclosures:
1. Notice of Violation and Proposed Imposition of Civil Penalty
2. Enforcement Conference Attendees

cc w/Enclosures: State of Oklahoma

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

Edwards Pipeline Testing, Inc.
Tulsa, Oklahoma

Docket No. 030-28[illegible]05
License No. 35-23193-01
EA 93-015

During NRC inspections conducted on August 26, 1992, and February 10, 1993, and an investigation completed in April 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. Violation Assessed a Civil Penalty

10 CFR 34.11(d)(1) requires, in part, that an applicant have an inspection program that requires the observation of the performance of each radiographer and radiographer's assistant during an actual radiographic operation at intervals not to exceed three months.

License Condition 19 (as it existed at the time of the violation) incorporated the inspection program containing the requirements stated in 10 CFR 34.11(d)(1), as submitted in the licensee's application dated August 5, 1985, and subsequent letter and enclosure received September 30, 1985, into License No. 35-23193-01.

Item 4 of the September 30, 1985, letter references internal inspection procedures contained in Section III, Item 14, of the licensee's operating procedures manual ("manual") enclosed with that letter.

Item 14.3 of the manual states that field inspections shall be performed on each radiographer and radiographer's assistant at least once each quarter. Item 14.4 further states that any radiographer or radiographer's assistant who has not worked for at least 3 months shall be subject to a field inspection performed during the first job (radiography) which they perform.

Contrary to the above, between August 30, 1990, and August 26, 1992, the licensee had not observed each radiographer and radiographer's assistant during actual radiographic operations, at least once each quarter. Specifically, based on information provided by the licensee during the inspection and at the enforcement conference, a substantial number of radiographers and radiograpner's assistants were engaged in radiographic operations but were not audited through a field inspection during actual radiographic operations at the required frequency.

This is a Severity Level II violation (Supplement VI).
Civil Penalty - $12,000

B. Violation Not Assessed a Civil Penalty

10 CFR 34.33(a) requires, in part, that a licensee not permit any individual to act as a radiographer or a radiographer's assistant unless, at all times during radiographic operations, the individual wears a direct reading pocket dosimeter, an alarm ratemeter, and either a film badge or a thermoluminescent dosimeter.

Contrary to the above, on February 10, 1993, a radiographer employed by the licensee did not wear an alarm ratemeter while conducting radiographic operations at a temporary field site location near Pocatello, Idaho.

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

Pursuant to the provisions of 10 CFR 2.201, Edwards Pipeline Testing, 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 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 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 1st day of September 1993

Enclosure 2

Enforcement Conference Attendance List

Licensee: Edwards Pipeline Testing, Inc., Tulsa, Oklahoma
Time/Date: 1 p.m. CDT July 19, 1993
Location: NRC Region IV, Arlington, Texas
EA No.: EA 93-015

Edwards Pipeline Testing, Inc.

John B. Connally III, President, International Testing Services, Inc.
Don Earl Edwards, President, Edwards Pipeline Testing, Inc.
T. D. Reeder, Radiation Safety Officer, Edwards Pipeline Testing, Inc.
Larry Lake, Asst. Radiation Safety Officer, Edwards Pipeline Testing, Inc.

Nuclear Regulatory Commission

John M. Montgomery, Deputy Regional Administrator, Region IV (RIV)
William L. Brown, Regional Counsel, RIV
L. Joseph Callan, Director, Division of Radiation Safety & Safeguards, RIV
Charles L. Cain, Chief, Nuclear Materials Inspection Section, DRSS, RIV
Linda L. Kasner, Senior Radiation Specialist, NMIS, DRSS, RIV
Mark R. Shaffer, Radiation Specialist, NMIS, DRSS, RIV
Gary F. Sanborn, Enforcement Officer, RIV
Geoffrey D. Cant, Enforcement Specialist, Office of Enforcement

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

DEC 0 1 1993

Docket No. 030-28835
License No. 35-23193-01
EA 93-015

Edwards Pipeline Testing, Inc.
ATTN: Don Earl Edwards, President
Post Office Box 470978
Tulsa, Oklahoma 74147

SUBJECT: ORDER IMPOSING CIVIL MONETARY PENALTY - $12,000

This refers to Edwards Pipeline Testing, Inc.'s replies dated September 28, 1993, in response to the Notice of Violation and Proposed Imposition of Civil Penalty (Notice) sent to you by our letter dated September 1, 1993. Our letter and Notice described a willful violation of NRC requirements related to the performance of quarterly audits of radiography personnel. To emphasize the significance of Edwards Pipeline Testing remaining in noncompliance with a requirement that is important to safety, and to assure that your corrective actions are lasting, a civil penalty of $12,000 was proposed.

In your September 28, 1993 replies, which included a Reply to a Notice of Violation and an Answer to a Notice of Violation, you admitted the violation but requested that the NRC reduce the civil penalty to $8,000 based on the extenuating circumstances associated with this violation, and your assertion that you had made continuous efforts to assure full compliance. In the appendix to the enclosed Order, we have summarized the reasons for your request for reconsideration of the civil penalty and the NRC's evaluation of your reasons. We note, in response to your replies, that we continue to consider this to have been a willful violation because you knew Edwards Pipeline Testing was not in full compliance over a lengthy period and failed to take adequate steps to achieve full compliance with the audit requirement.

After consideration of your request for mitigation of the penalty, we have concluded for the reasons cited in the appendix to the enclosed Order Imposing Civil Monetary Penalty that the full amount of the penalty should be imposed by Order. Accordingly, we hereby serve the enclosed Order on Edwards Pipeline Testing, Inc., imposing a civil monetary penalty in the amount of $12,000. We will continue to review the effectiveness of your corrective actions in future inspections.

CERTIFIED MAIL
RETURN RECEIPT 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,

Hugh L. Thompson, Jr.
Deputy Executive Director
for Nuclear Materials Safety, Safeguards
and Operations Support

Enclosure: Order Imposing Civil Monetary Penalty

cc w/encl: State of Oklahoma

UNITED STATES
NUCLEAR REGULATORY COMMISSION

In the Matter of	)	
	)	
EDWARDS PIPELINE TESTING, INC.	)	Docket No. 030-28835
Tulsa, Oklahoma	)	License No. 35-23193-01
	)	EA 93-015

ORDER IMPOSING CIVIL MONETARY PENALTY

I

Edwards Pipeline Testing, Inc. (Licensee or Edwards Pipeline Testing) is the holder of NRC Byproduct Materials License No. 35-23193-01 issued by the Nuclear Regulatory Commission (NRC or Commission). The license authorizes the Licensee to possess and use sealed radioactive sources to perform industrial radiography in accordance with the conditions of the license.

II

An inspection of the Licensee's activities was conducted on August 26, 1992. The results of this inspection and a follow-up investigation conducted by the Office of Investigations (OI) 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 1, 1993. The Notice described the nature of the violation, 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 in a Reply and an Answer dated September 28, 1993. In its Reply and Answer, the Licensee admitted the violation which resulted in the proposed civil penalty, 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 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 the civil penalty in the amount of $12,000 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 Erforcement 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 violation 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 6th day of December 1993

APPENDIX

EVALUATION AND CONCLUSIONS

On September 1, 1993, a Notice of Violation and Proposed Imposition of Civil Penalty (Notice) was issued for a violation identified during an NRC inspection and a follow-up investigation conducted by the Office of Investigations. Edwards Pipeline Testing, Inc. responded to the Notice on September 28, 1993. The Licensee admitted the violation that resulted in the proposed civil penalty, but requested mitigation. A restatement of the violation, and the NRC's evaluation and conclusions regarding the Licensee's request follow:

Restatement of Violation Assessed a Civil Penalty

10 CFR 34.11(d)(1) requires, in part, that an applicant have an inspection program that requires the observation of the performance of each radiographer and radiographer's assistant during an actual radiographic operation at intervals not to exceed three months.

License Condition 19 (as it existed at the time of the violation) incorporated the inspection program containing the requirements stated in 10 CFR 34.11(d)(1), as submitted in the licensee's application dated August 5, 1985, and subsequent letter and enclosure received September 30, 1985, into License No. 35-23193-01.

Item 4 of the September 30, 1985, letter references internal inspection procedures contained in Section III, Item 14, of the licensee's operating procedures manual ("manual") enclosed with that letter.

Item 14.3 of the manual states that field inspections shall be performed on each radiographer and radiographer's assistant at least once each quarter. Item 14.4 further states that any radiographer or radiographer's assistant who has not worked for at least 3 months shall be subject to a field inspection performed during the first job (radiography) which they perform.

Contrary to the above, between August 30, 1990, and August 26, 1992, the licensee had not observed each radiographer and radiographer's assistant during actual radiographic operations, at least once each quarter. Specifically, based on information provided by the licensee during the inspection and at the enforcement conference, a substantial number of radiographers and radiographer's assistants were engaged in radiographic operations but were not audited through a field

inspection during actual radiographic operations at the required frequency.

This is a Severity Level II violation (Supplement VI).
Civil Penalty - $12,000

Summary of Licensee's Request for Mitigation

In its September 28, 1993, replies, which included a Reply to a Notice of Violation (Reply) and an Answer to a Notice of Violation (Answer), the Licensee admitted the violation but requested that the penalty be reduced to $8,000, citing several reasons. The reasons, which have been drawn from both the Reply and the Answer, are summarized below:

1. The Licensee bases its request to reduce the civil penalty on extenuating circumstances assertedly associated with this violation, including:

   a. Edwards Pipeline Testing's license consultant failed to consider the complexity of one individual performing audits simultaneously at numerous temporary field locations throughout the United States, resulting in the license containing conditions that were logistically impossible to comply with as the size of the company increased;

   b. The company experienced rapid growth which resulted in a larger number of radiography personnel and a greater turnover in personnel, both of which compounded the problem;

   c. Some employees failed to complete assigned duties related to the company's radiation safety program, such as the proper recording and filing of records related to periodic field inspections;

   d. Proposed revisions to license conditions were included in a September 30, 1990, application for license renewal, which Mr. Edwards, the Licensee's President, fully expected to be able to implement within 30-60 days; and

   e. The NRC performed an inspection on December 3, 1991, the results of which led company management to believe that corrective actions as of that date were appropriate.

2. The Licensee contends that the NRC has mistaken Mr. Edwards' knowledge of the fact that a violation was occurring to mean that he willfully decided to operate in noncompliance. The

Licensee asserts that Mr. Edwards has made continuous efforts to assure full compliance, including assertions that:

a. Mr. Edwards took immediate action following an August 1989 inspection to instruct the company's RSO to take all required steps to remedy the noncompliance;

b. In 1990, Mr. Edwards ordered an in-depth evaluation of the company's license conditions, which resulted in proposed revisions that were included in a September 30, 1990 license renewal application;

c. In July 1991, Mr. Edwards hired another employee with extensive experience to add support to the radiation safety program; and

d. In August 1992, another individual was assigned the duties of Radiation Safety Director, with responsibility for evaluating and submitting amendments to the license, and additional clerical support for the radiation safety program was obtained.

3. The Licensee argues that the NRC cited the company's otherwise impressive record and indicated that it would have mitigated the $8,000 (base) penalty except for the fact that the president of the company willfully decided to operate in noncompliance. The Licensee believes that the facts indicate that Mr. Edwards continually attempted to achieve compliance and was merely being responsive to the investigators when he stated that he thought that full compliance would not be successfully achieved until the revisions to the license were approved. The Licensee concludes that its audit history does not indicate a cavalier attitude toward safety and respectfully requests a hearing or further appropriate appeal opportunity.

NRC Evaluation of Licensee's Request for Mitigation

The NRC's evaluation of the Licensee's arguments follows:

1. The NRC was aware of all of the circumstances surrounding this violation when it proposed the penalty, including that the Licensee had come into compliance early in 1993. Had those circumstances not existed, the NRC probably would have taken a different enforcement action. In the absence of the company president's attempts to achieve compliance, the NRC almost certainly would have issued an order that would have prohibited his involvement in licensed activities.

The Licensee was aware of the need to have its license amended. At the enforcement conference, Mr. Edwards stated that he had given instructions to Licensee employees to obtain an amendment. The Licensee advices that proposed revisions to license conditions were included with the September 30, 1990, application for license renewal, which the Licensee believed it would be able to implement within 30-60 days. However, growth of the Licensee's organization does not justify departure from the existing license conditions. Furthermore, the NRC sent a letter to the Licensee on December 17, 1990, reminding the Licensee that "...the procedures presently identified in the license must be observed until the license renewal application has been reviewed and approved by NRC."

With regard to the NRC's September 1991 inspection,[1] the NRC acknowledges that its failure to take enforcement action following this inspection may have contributed to the Licensee's perception that the NRC was satisfied with its corrective actions at that time. However, while the NRC then recognized that the Licensee was moving into compliance this does not mean that there was no violation, nor does it excuse the violation. Moreover, the violation cited in this NOV existed for over a year prior to the September 1991 inspection as well as during the subsequent year. Furthermore, Mr. Edwards acknowledged in response to questioning at the enforcement conference that at no time did he believe compliance was not required.

2. The facts, which are supported by Mr. Edwards' statements at the enforcement conference, are that full compliance was not achieved and that Mr. Edwards was aware that full compliance had not been achieved. This is a willful violation because Mr. Edwards knew he was not in compliance and failed to take prompt and effective steps to achieve full compliance with the requirement. The Licensee's president made decisions that lead to the violation for business reasons, including the cost of compliance and the amount of the Licensee's employees' time needed to comply. Moreover, the Licensee was not even in compliance with its proposed audit requirement during the two-year period cited in this violation. The NRC cannot allow its licensees to make business decisions, e.g., based on cost, to override the Commission's regulatory requirements in its regulations, licenses, and orders. The long term knowledge of the existence of this violation coupled with the failure to take

[1] The inspection was performed on September 20, 1991 and the Inspection Report was issued on December 3, 1991, the date referred to in the Licensee's Reply.

effective corrective action over the same long period demonstrate the significance of the violation and the need for an appropriate sanction.

3. While we agree that Edwards' inspection history does not indicate a generally cavalier attitude toward safety, as discussed above, this was a willful violation. Based on the Licensee's prior performance in the specific area of field audits, i.e., considering that this violation continued over an extended period of time with the knowledge of the Licensee's President, as a result of the President's decision regarding the time, effort, and cost of compliance, it is not appropriate to mitigate the base penalty for the Licensee's otherwise good regulatory performance. Of significant weight in this decision is that the Licensee did not implement the new audit process that it had proposed and was eventually adopted. The Licensee's request for a hearing or appropriate appeal opportunity is premature, but can be made in response to an order imposing a civil monetary penalty.

NRC Conclusion

The Licensee has not provided any new information that the NRC was not aware of when it proposed the civil penalty. Therefore, we conclude that the Licensee has not provided an adequate basis for a reduction in the size of the proposed civil penalty. Consequently, the proposed civil penalty in the amount of $12,000 should be imposed.

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

OCT 21 1993

Docket No. 030-12470
License No. 25-17265-01
EA 93-231

Glendive Medical Center
ATTN: Paul Hanson
Chief Executive Officer
202 Prospect Drive
Glendive, Montana 59330-1999

SUBJECT: NOTICE OF VIOLATION & PROPOSED IMPOSITION OF CIVIL PENALTY - $2,500 (NRC INSPECTION REPORT NO. 30-12470/93-01)

This refers to the inspection conducted August 18, 1993, and September 8-9, 1993, of NRC-licensed activities at the Glendive Medical Center, Glendive, Montana. A report documenting the results of this inspection was issued on October 5, 1993. Based on this inspection having identified potentially significant violations of NRC requirements, an enforcement conference was conducted telephonically between medical center and NRC representatives on October 18, 1993. A list of enforcement conference participants is enclosed (Enclosure 2).

As discussed during the inspection and re-emphasized during the enforcement conference, NRC regulations in 10 CFR Part 35 require that licensed nuclear medicine activites be carried out under the supervision of approved authorized users and that a radiation safety officer (RSO) be appointed to assure that activities are carried out in accordance with all radiation safety requirements and the conditions of the license. The purpose of these requirements is to provide reasonable assurance that radioactive material used in the practice of nuclear medicine will be used safely and in a manner that maximizes the benefit to patients while at the same time minimizing radiation exposures to facility employees, patients and members of the public. In addition, in accordance with 10 CFR 35.21(b), radiation safety officers are relied upon to respond to incidents involving patient care, such as the inadvertent misadministration of a radiopharmaceutical, or incidents involving radioactive materials, such as spills or other mishaps which pose the potential for spreading radioactive contamination.

The NRC's inspection found that Glendive Medical Center's RSO and only remaining authorized user had discontinued his contract with the facility on May 31, 1993, and had not been replaced. The inspection also found that Glendive Medical Center carried out licensed activities from May 31 to September 9, 1993, without an RSO, and from May 31 to mid-July and August 22 to September 9, 1993, without an approved authorized user. On September 9, 1993, following telephone conversations with you, the NRC issued a Confirmatory Action Letter (4-93-013) to document your commitment to arrange for an RSO and authorized user. In a letter dated September 9, 1993, you reported that this matter had been resolved on an interim basis, i.e., a

physician had agreed to serve in both capacities until a permanent replacement was in place.

Glendive Medical Center's chief technologist stated during the enforcement conference that he believed that Dr. Fizzotti, the former RSO/authorized user, had agreed to continue to act as the facility's RSO despite Dr. Fizzotti's resignation to work at another facility some 200 miles from Glendive. As hospital representatives acknowledged, however, no such agreement was documented nor was Dr. Fizzotti routinely involved in many of the activities and duties of the RSO from that date forward. Dr. Fizzotti himself told the NRC inspector that he had no intention of fulfilling the responsibilities of the RSO as defined in NRC regulations, e.g., responding to incidents involving licensed material. Therefore, the NRC concludes that the hospital was, in effect, without an RSO for the period discussed above.

The violations in section I of Enclosure I include a failure to have an RSO between May 31 and September 9, 1993; a failure to assure that licensed material was used under the supervision of an authorized user between May 31 and mid-July 1993 and August 22 to September 9, 1993; and a failure to notify the NRC when the RSO/authorized user left the facility on May 31, 1993, and when other authorized users discontinued their involvement at the hospital. These violations indicate to the NRC a lack of understanding of the applicable requirements and, importantly, the reason for their existence. We note that had you informed us, as required, when the RSO resigned, we would have counseled you then on the need to seek an immediate replacement.

For the reasons discussed above, the NRC considers these violations to be significant from both a regulatory and safety perspective and has therefore classified these violations 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 acknowledges that as of September 9, 1993, Glendive Medical Center was in compliance with the requirements regarding an RSO and authorized users. In addition, you told us during the enforcement conference that your policies and procedures manual has been revised to require the hospital to obtain the services of an RSO if the RSO is unavailable for any reason, that you are arranging training for your new RSO to ensure that he is familiar with all requirements, and that you will request training on the responsibilities of the radiation safety committee from your health physics consultant.

To emphasize the importance of ensuring that licensed activities are supervised and monitored in accordance with NRC regulations and in the interest of assuring safety, 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 and resulted in no net adjustment. In examining the factors, the NRC deemed an increase warranted based on NRC identification of the violations. This increase was offset, however, by a decrease based on Glendive Medical Center's relatively good performance as a licensee of the NRC

prior to this inspection. The remaining adjustment factors were considered and no further adjustments to the base civil penalty were considered appropriate.

Section II of the enclosed Notice includes two violations which were found during this inspection but which were not considered significant. These violations have been classified at Severity Level IV and V in accordance with the Enforcement Policy and have not been assessed monetary penalties. In addition, one apparent violation discussed during the enforcement conference, an apparent failure to obtain written permission from the facility's Radiation Safety Committee prior to employing a visiting authorized user from mid-July to August 22, 1993, is not being cited because you provided us information that indicates that this physician's experience was considered and that he was approved by members of the radiation safety committee at a medical staff meeting.

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

Enclosures:
1. Notice of Violation & Proposed Imposition of Civil Penalty
2. Enforcement conference participants

cc w/Enclosures:
State of Montana Radiation Control Program Director

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

Glendive Medical Center
Glendive, Montana

Docket 030-12470
License 25-17265-01
EA 93-231

During an NRC inspection conducted on August 18 and September 8-9, 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 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 35.21(a) requires, in part, that a licensee appoint a Radiation Safety Officer responsible for implementing the radiation safety program.

Contrary to the above, from May 31, 1993, when the former Radiation Safety Officer terminated his contract with Glendive Medical Center, to September 8, 1993, the licensee did not appoint a Radiation Safety Officer (RSO) responsible for implementing the radiation safety program (01013).

B. 10 CFR 35.14 requires that a licensee notify the NRC by letter within thirty days when an authorized user, Radiation Safety Officer, or Teletherapy physicist permanently discontinues performance of duties under the license or has a name change, or when the licensee's mailing address changes.

Contrary to the above, on May 31, 1993, several of the licensee's authorized users and the Radiation Safety Officer permanently discontinued performance of duties under the license and as of August 18, 1993, the licensee had not notified NRC (01023).

C. License Condition 12 of NRC License No. 25-17256-01 specifies, in part, five physicians who are designated as authorized users of byproduct material under the license.

10 CFR 35.11(b) requires that an individual may receive, possess, use, or transfer byproduct material in accordance with the regulations of 10 CFR Part 35 under the supervision of an authorized user unless prohibited by license condition.

Contrary to the above, between May 31 and mid-July 1993, and from August 22 to September 9, 1993, the licensee permitted an individual other than the physicians who were specified as authorized users in NRC License No. 25-17256-01 to receive, possess, use, and transfer byproduct material without the supervision of an authorized user. During these periods, use of

licensed material included administration of radiopharmaceuticals to patients (01033).

These violations represent a Severity Level III problem (Supplement VI).
Civil Penalty - $2,500

II. Violations Not Assessed a Civil Penalty

A. 10 CFR 35.22(a)(1) requires, in part, that a licensee establish a Radiation Safety Committee to oversee the use of byproduct material and that the membership of the Radiation Safety Committee consist of at least three individuals and include an authorized user of each type of use permitted by the license, the Radiation Safety Officer, a representative of the nursing service, and a representative of management who is neither an authorized user nor the Radiation Safety Officer.

10 CFR 35.22(a)(3) requires that to establish a quorum and conduct business, at least on 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, from January through December 1992, the licensee's Radiation Safety Committee membership did not include a representative of the nursing service, and on October 29, 1992, the Radiation Safety Committee met and conducted business and the Radiation Safety Officer was not present.

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

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 procedures for maintaining records associated with dispensing radiopharmaceuticals from multi-dose vials are described in the application dated March 23, 1993, and were approved by License Condition No. 15.B.

The application dated March 23, 1993, states in Item 10.9 that the licensee will establish and implement the model procedure for a multi-dose vial record system as published in Appendix M.2 to Regulatory Guide 10.8 (Revision 2).

Contrary to the above, as of August 18, 1993, the licensee had not established and implemented the model procedure for a multi-dose vial record system as published in Appendix M.s to Regulatory Guide 10.8 (Revision 2). As of that date, the licensee had not maintained any record system for multi-dose vials.

This is a Severity Level V violation (Supplement VI).

Pursuant to the provisions of 10 CFR 2.201, Glendive 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 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 21st day of October 1993

Enclosure 2

ENFORCEMENT CONFERENCE PARTICIPANTS

LICENSEE: Glendive Medical Center, Glendive, Montana

TIME/DATE: 1 p.m. CDT, October 18, 1993

LOCATION: Conference conducted telephonically

EA NUMBER: 93-231

Glendive Medical Center representatives

Paul Hanson, Chief Executive Officer
Dr. K.V. Ragain, Radiation Safety Officer-designate
Tom Christensen, Chief Technologist

NRC Region 4 representatives

Charles L. Cain, Director (Acting), Division of Radiation Safety & Safeguards
Linda L. Kasner, Chief (Acting), Nuclear Materials Inspection Section
William L. Brown, Regional Counsel
Gary F. Sanborn, Enforcement Officer

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

November 17, 1993

Docket Nos. 030-02959
030-20830
License Nos. 37-00467-34
37-00467-35
EA No. 93-249

Mr. Alan Lieber, Assistant Vice President
Hahnemann University
Broad and Vine Streets
Philadelphia, Pennsylvania 19102-1192

Dear Mr. Lieber:

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTIES - $6,250
(NRC INSPECTION REPORT NOS. 030-02959/93-001 AND 030-20830/93-001)

This letter refers to the NRC inspection conducted on September 14 and 15, 1993, at your facility in Philadelphia, Pennsylvania of activities authorized by NRC Licenses 37-00467-34 and 37-00467-35. The inspection report was sent to you on October 22, 1993. During the inspection, apparent violations of NRC requirements were identified. On November 3, 1993, an 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 is enclosed.

Three violations are being cited and are described in the enclosed Notice of Violation and Proposed Imposition of Civil Penalties (Notice) (Enclosure 1). The first violation is set forth in Section I of the enclosed Notice and involved the failure to establish adequate written policies and procedures for implementing the quality management program (QMP) at your facility. As a result of this failure, understanding of QMP requirements was lacking, and written directives were either used incorrectly, were missing, or never prepared. For example, your interim Radiation Safety Officer (RSO) had acknowledged to the NRC that written directives containing the prescribed dose and signature of the authorized user were not prepared in the brachytherapy area prior to dose administration. 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.

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

The second violation being cited is described in Section II of the enclosed Notice, and involved the failure of your RSO to ensure that radiation safety activities were being performed in accordance with approved procedures and requirements. Specifically, security was not maintained at a laboratory where millicurie quantities of technetium-99m were maintained in that the laboratory was unlocked and unattended; inventories of brachytherapy and other sealed sources were not performed at a quarterly frequency; leak tests were not performed on certain reference or calibration sources for the six month period ending December 31, 1992; records of inventories and leak tests, when performed, were at times, not signed by the RSO; evidence of eating and drinking was found in certain restricted areas; and procedures established by the RSO for periodic radiation surveys (audits) of laboratories were not always followed. This violation, which you acknowledged at the enforcement conference, represents a breakdown in the control of licensed activities at the facility.

It appears that a failure to devote sufficient time and resources to radiation safety program activities contributed to these violations. This failure demonstrates a lack of management attention to, and oversight of, licensed activities at the facility, and is particularly significant since the need for, and importance of, appropriate attention to the radiation safety program were emphasized during a previous enforcement conference with you on November 30, 1992, to discuss other violations of NRC requirements. However, actions implemented at that time to upgrade the oversight of the program were not effective in preventing these recent violations.

The NRC license issued to Hahnemann University entrusts responsibility for radiation safety to the Radiation Safety Committee (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 that contributed to the failure to, at times, 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 second violation, and all of the specific examples described therein, represents a breakdown in the control of licensed activities and is also categorized at Severity Level III, as set forth in Section II of the enclosed Notice.

The NRC recognizes that prior to the recent inspection, the management of Hahnemann University recognized that concerns existed with the overall management of the radiation safety program, and had retained another, more experienced individual, as the new RSO. Further, the RSO responsibilities have been restructured in that the RSO duties are now solely dedicated to the performance of radiation safety activities. The NRC also recognizes that subsequent to the NRC inspection, actions were taken or planned to correct the violations and effect improvements in the control, oversight, and implementation of the radiation safety program. These actions, which were described at the enforcement conference, include, but are not limited to: (1) prompt development of a revised QMP plan, and submittal of the revised QMP plan and procedures at the time of the enforcement conference; (2) plans for the new RSO to perform a systematic review of the entire radiation safety program to ascertain the need for any additional improvements; (3) plans to improve record-keeping at the facility; (4) plans to increase radiation safety staff interaction with users of material; (5) plans to retain an outside consultant in approximately six months to evaluate the status of the radiation safety program and the program upgrades; and (6) installation of a lock on the door of the laboratory where material was left unsecured, as well as pertinent training to the staff. These corrective actions, with respect to both violations, were considered prompt and comprehensive.

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 cumulative amount of $6,250 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. The escalating/mitigating factors were considered, and a basis exists for (1) 50% escalation of the penalty because the violation was identified by the NRC, (2) 50% mitigation of the penalty based on your prompt and comprehensive corrective actions, and (3) no adjustment based on past performance given the limited period of time the QMP has been in effect, and the fact no prior violations were identified in this area. Therefore, on balance, no adjustment of the base civil penalty is warranted. The other escalation/mitigation factors were considered and no further adjustment is warranted.

With respect to the second violation classified at Severity Level III, the escalating/mitigating factors were considered and the base civil penalty amount has been (1) escalated by 50% because the violations were identified by the NRC; (2) mitigated by 50% because of your prompt and comprehensive corrective actions; and (3) escalated by 50% based on your overall past performance in the past two years which includes five violations and a prior enforcement conference in November 1992. Therefore, on balance, 50% escalation of the civil penalty for this Severity Level III violation is warranted. The other escalation/mitigation factors were considered and no further adjustment is considered appropriate.

A third violation is also described in Section III of the Notice and is classified at Severity Level V.

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.

Sincerely,

William T. Martin

Thomas T. Martin
Regional Administrator

Enclosures:
1. Notice of Violation and Proposed Imposition of Civil Penalties
2. Enforcement Conference Report

ENCLOSURE 1

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTIES

Hahnemann University
Philadelphia, Pennsylvania

Docket Nos. 030-02959
030-20830
License Nos. 37-00467-34
37-00467-35
EA 93-249

During an NRC inspection conducted on September 14 and 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 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) requires, in part, that each 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; the QMP must include written policies and procedures to meet the specific objectives that patient identification be verified prior to dose administration; that final plans of treatment and related calculations for brachytherapy are in accordance with a written directive; and that any unintended deviation from the written directive is identified and evaluated, and appropriate action is taken.

10 CFR 35.32(b)(1) requires, in part, that the licensee develop procedures for and conduct a review of the QMP at intervals of no greater than twelve months.

Contrary to the above, as of September 15, 1993:

1. The licensee had not established an adequate written QMP to provide high confidence that byproduct material or radiation from byproduct material would be administered as directed by the authorized user in that written policies and procedures for the QMP were not adequately established in accordance with 10 CFR 35.32 as required in that the procedures that were submitted consisted of simply one page that recounted the objectives stated in the regulations and contained no details as to how these objectives would be met; and

2. QMP policies and procedures were not established to conduct a review to verify compliance with all aspects of the QMP at intervals of no greater than twelve months.

This violation is classified at Severity Level III (Supplement VI).

Civil Penalty - $2,500

IFS Code 01013

II. Violation Representative of a Breakdown in Control of Licensed Activities

10 CFR 35.21(a) requires that the licensee, through the Radiation Safety Officer (RSO), 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, as of September 15, 1993, the licensee, through its RSO, failed to ensure that radiation safety activities were being performed in accordance with the approved procedures and regulatory requirements in the daily operation of the byproduct material program, as evidenced by the following examples.

1. Licensed material consisting of millicurie quantities of technetium-99m located in the Nuclear Cardiology Hot Lab, an unrestricted area, was not secured against unauthorized removal, and was not under constant surveillance and immediate control of the licensee, as required by 10 CFR 20.207(a) and 10 CFR 20.207(b).

2. Inventories of brachytherapy and other sealed sources were performed at a six month frequency, rather than at the quarterly frequency required by 10 CFR 35.59(g).

3. Leak tests on reference or calibration sources were not performed for the six-month period ending December 31, 1992, and no other intervals had been approved as required by 10 CFR 35.59(b)(2).

4. Procedures established by the RSO to perform periodic radiation surveys (audits) of laboratories, as required by 10 CFR 35.21(b)(2)(viii), were not followed on September 15, 1993, in that the only task performed by the Radiation Safety Technician was surveys for removable contamination, and other procedures that were part of the RSO's survey audits were omitted (e.g., checking to see film badges were worn, radioactive waste was properly stored, and having discussions with personnel to assure compliance).

5. Procedures established by the RSO prohibiting eating and drinking in restricted areas, as required by License Condition 24 and "Laboratory Safety Practices", Item 2, Page 27 of the licensee's application, dated March 24, 1987, were not followed in that on September 15, 1993, evidence of eating and drinking was observed in the Nuclear Cardiology Laboratory and one of the research laboratories. The evidence consisted of empty cans of soda, candy wrappers on bench tops and empty milk containers.

6. Records of inventories and leak tests of brachytherapy and calibration sealed sources, required to be kept pursuant to 10 CFR 35.59(d) and 10 CFR 35.59(i), were not signed by the RSO as of September 15, 1993.

This violation is classified at Severity Level III (Supplements IV and VI).

Civil Penalty - $3,750

IFS Code 02013

III. Other Violation of NRC Requirements

Condition 13 of License No. 37-00467-35 requires, in part, that sealed sources and detector cells be tested for leakage and/or contamination at intervals not to exceed six months or at such intervals as are specified by the certificate of registration referred to in 10 CFR 32.210, not to exceed three years; and that records of leak test results shall be maintained for inspection by the Commission.

Contrary to the above, as of September 15, 1993, the licensee did not maintain records for leak test results of a cesium-137 sealed source containing greater than 3,200 curies of activity for the six month period between December 31, 1992 and June 30, 1993, and no other interval was specified by the certificate of registration referred to in 10 CFR 32.210.

This violation is classified at Severity Level V (Supplement VI).

IFS Code 03015

Pursuant to the provisions of 10 CFR 2.201, Hahnemann University (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 17th day of November 1993

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

SEP 09 1993

Docket No. 030-02132
License No. 21-12826-01
EA 93-109

Ingham Medical Center Corporation
ATTN: David Kreiger
Vice President
401 West Greenlawn Avenue
Lansing, Michigan 48910

Dear Mr. Kreiger:

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTIES - $11,250
(NRC INSPECTION REPORT NO. 030-02132/93001)

This refers to the special safety inspection conducted on February 25 and 26, 1993 at Ingham Medical Center Corporation (Ingham Medical Center) to review the circumstances surrounding the administration of 9.9 millicuries of sodium iodide I-131 on May 11, 1992, to a patient who had not had a total thyroidectomy. The report documenting this inspection was mailed to you by letter dated May 14, 1993. Significant violations of NRC requirements were identified, and on May 21, 1993, an enforcement conference was held in the Region III office. Attending the enforcement conference were you, Mr. Charles E. Norelius, Director, Division of Radiation Safety and Safeguards, and other members of our respective staffs. A copy of the enforcement conference report was mailed to you on June 3, 1993.

The event occurred because of an alleged misunderstanding during telephone conversations on May 5, 1992, between a medical assistant at the referring physician's office, who thought a thyroid scan for a patient was being ordered, and a nuclear medicine technologist at Ingham Medical Center, who thought a whole body scan (thyroid carcinoma survey) was being ordered. Consequently, on May 11, 1992, 9.9 millicuries of sodium iodide I-131 was administered to the patient for a whole body scan rather than the intended administration of 10 millicuries of technetium-99(m) pertechnetate for a thyroid scan. This event resulted in a serious injury (i.e., substantial organ impairment) to a patient.

Your staff reviewed the event and verbally notified the patient through the patient's physician, and categorized the incident as a "recordable event" in accordance with 10 CFR 35.2. As defined in 10 CFR 35.2 a "recordable event" is "the administration of a radiopharmaceutical without a written directive where a written directive is required." However, the event was a

"misadministration," as defined by 10 CFR 35.2, because the wrong radiopharmaceutical was administered and involved a dosage of greater than 30 microcuries of sodium iodide I-131. In this case, the authorized user established the procedure that a thyroid carcinoma survey (iodine-131 whole body scan) could only be done after a total thyroidectomy. Since the patient had an intact thyroid, iodine-131 should not have been administered. The Licensee's procedure for a thyroid scan, which is the procedure that should have been done for an intact thyroid gland, specifies a different radio-pharmaceutical, technetium-99m pertechnetate.

The violations identified in Section I of the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice) concern: (a) the failure to have an authorized user prepare a written directive for a specific patient prior to the administration of quantities greater than 30 microcuries of sodium iodide I-131; and (b) the failure to follow the written instruction of the supervising authorized user that requires that a patient have a total thyroidectomy prior to undergoing a whole body scan. First, the NRC is most concerned about the failure to have an authorized user prepare a written directive and implement this key objective of the QMP. Both authorized users as well as the chief nuclear medicine technologist and staff technologists were not adequately knowledgeable and conversant in the Licensee's specific written QMP requirement that a written directive be prepared by an authorized user prior to any administration of quantities greater than 30 microcuries of sodium iodide I-131. Even after the event, training provided by the Licensee to the nuclear medicine staff on June 24, 1992, required the preparation of a "written order" by a referring physician prior to performing a thyroid carcinoma survey (requiring the administration of 10 millicuries of sodium iodide I-131). 10 CFR 35.32(a)(1)(iv) requires that the written directive be signed and dated by the authorized user. The written directive is intended to ensure that the authorized user, not just the referring physician, becomes involved before the radiopharmaceutical is administered to the patient. Therefore, as a result of the inadequate understanding of the Licensee's QMP, the authorized users and technologists did not ensure that a written directive was prepared by an authorized user prior to the administration of the 9.9 millicuries of sodium iodide I-131. Secondly, the NRC is concerned that the technologists failed to follow the authorized user's standing procedure for a whole body scan, titled "Thyroid Carcinoma Survey," which requires that the patient must have had a total thyroidectomy. In this case, the nuclear medicine technologists (including the Chief Technologist) did not review the "Thyroid Carcinoma Survey" procedure to ensure an adequate understanding of the necessary checks to be made before administering the sodium iodide I-131 and beginning the procedure. No one on the Licensee's staff followed the procedure

and made any inquiry of the patient, referring physician, or authorized user as to the physical status of the patient's thyroid. Additionally, in performing the whole body scan, the technologists used a checklist only intended for performing thyroid scans and uptakes, and not whole body scans.

An NRC medical consultant independently reviewed the event and concluded that the most probable effect of this radiation exposure was the development of permanent hypothyroidism; the available evidence suggested that this had already occurred to this patient. The Licensee's letter to the NRC dated April 2, 1993 explained that on May 12, 1992, the Licensee had notified the referring physician and patient of the event. The letter further stated that "...a letter consistent with 10 CFR 35.33(a)(4) has been forwarded to the patient."

The violations described in Section I of the enclosed Notice represent a significant failure to implement and follow the procedures of the medical QMP, required by 10 CFR 35.32(a), that resulted in a serious injury to a patient (i.e. the substantial impairment of an organ). Therefore, in accordance with the "Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy) 10 CFR Part 2, Appendix C (1992), the violations are classified in the aggregate as a Severity Level I problem.

The violations identified in Section II of the enclosed Notice concern the failure to make required notifications of the misadministration to the NRC Operations Center, the NRC regional office, and written notification to the patient. On May 12, 1992, the referring physician and your radiation safety officer (RSO) discussed the event, and your RSO was aware that the referring physician wanted the patient to have a thyroid scan and had not intended a whole body scan for the patient. Moreover, iodine-131 had been administered to a patient with an intact thyroid gland, whereas technetium-99m is the radionuclide specified in your procedures for such cases. Therefore, knowing that a radiopharmaceutical dosage of greater than 30 microcuries of sodium iodide I-131 involving the wrong radiopharmaceutical was used, the event should have been considered a misadministration within the definition of 10 CFR 35.2, and the notifications required by 10 CFR 35.33(a) should have been made. The failure to make the required notification to the NRC Operations Center and regional office precluded the NRC from performing an inspection contemporaneous with the event and from insuring immediate review of the event by an NRC medical consultant.

The violations described in Section II of the enclosed Notice represent a significant failure to make required notifications. Therefore, in accordance with the "Statement of Policy and

Procedure for NRC Enforcement Actions," (Enforcement Policy) 10 CFR Part 2, Appendix C (1992), the violations are classified in the aggregate as a Severity Level III problem.

The NRC recognizes that corrective actions were initiated to correct the violations and preclude recurrence. These actions, as described in the enforcement conference summary of June 3, 1993, and in your March 9, 1993 letter to the NRC, included: (1) providing training to the authorized users, technologists, and RSO on the requirements of the QMP; (2) reviewing and revising procedures for thyroid studies to ensure compatibility with the QMP; (3) assigning the Director of Radiology direct supervisory responsibility for the Nuclear Medicine Department; (4) review of all records and documentation, including the annual audits required by the QMP, by the consulting medical physicist; and (5) developing a policy for referral of any future incidents that may be interpreted as a misadministration or involve significant adverse patient outcomes to the NRC for consultation. Additionally, as discussed at the time of the enforcement conference, the Licensee was in the process of completing administrative actions to discontinue the procedure for whole body scans using sodium iodide I-131.

To emphasize the need for strict adherence to all NRC regulations and the specific requirements of your QMP, I have been authorized, after consultation with the Commission, to issue the enclosed Notice with proposed civil penalties in the cumulative amount of $11,250. The civil penalty adjustment factors in the Enforcement Policy were considered for both the Severity Level I and the Severity Level III problems.

The base amount of a civil penalty for a Severity Level I problem is $5,000. However, a civil penalty of $7,500 is proposed for this Severity Level I problem as a result of violations associated with the misadministration (Section I of the enclosed Notice). The base civil penalty was not adjusted for your identification of this self-disclosing event because a thorough root cause analysis of the event had not been performed after the event. Your staff relied solely on the recollections of your nuclear medicine technologist and a written report prepared by the technologist after the event. No attempt was made to determine why the confusion over the type of procedure being ordered was not discussed with an authorized user. Further, the root cause analysis did not establish why an authorized user had not prepared a specific written directive prior to administering the sodium iodide I-131. Finally, no attempt was made to determine why nuclear medicine procedures were not followed. The base civil penalty was increased 50 percent because of your lack of timely and effective corrective actions for this event. You did not take prompt and extensive corrective actions after discovery of the event on May 12, 1992. The failure to take

immediate actions necessary to restore compliance led to the NRC's issuance of a Confirmatory Action Letter (CAL) on March 2, 1993, to ensure that you provided training to all nuclear medicine staff members, the RSO, authorized users and technologists on the requirements of your QMP, 10 CFR Part 35, and the conditions of your NRC byproduct material license. Additionally, part of your corrective action was not appropriate. On approximately June 24, 1992, you modified the standing procedure for thyroid studies. However, the procedural change required a written order from the referring physician, not a written directive from the authorized user as required by 10 CFR 35.32(a)(1) and defined in 10 CFR 35.2. In accordance with the enforcement policy, the civil penalty for violations categorized at Severity Level I that involve a misadministration normally are not mitigated on the basis of licensee performance. The remaining factors in the enforcement policy were also considered and no further adjustment to the base civil penalty was considered appropriate for the violations described in Section I of the attached Notice.

The base amount of a civil penalty for a Severity Level III problem is $2,500. However, a civil penalty of $3,750 is proposed for this Severity Level III problem as a result of violations associated with the failure to make the required notifications and reports associated with a misadministration (Section II of the enclosed Notice). The base civil penalty was increased 50 percent for your inadequate and untimely corrective actions which required the NRC to intervene and issue a CAL on March 2, 1993, to ensure that you made the required notifications, including the written notification to the patient. While your overall past performance has been good (two violations in each of the previous two inspections), mitigation based on licensee performance is not appropriate because, even after the CAL identified that a misadministration had occurred and confirmed NRC's understanding that you would make the required notifications, you failed to make the notifications within the time specified in 10 CFR 35.33, which reflects continuing poor performance in the area of concern. The remaining factors in the enforcement policy were also considered and no further adjustment to the base civil penalty was considered appropriate for the violations described in Section II of the enclosed Notice.

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 of the violations. Finally, you should also describe what actions are being taken to ensure that, when nuclear medicine technologists have questions or concerns about the specific nuclear medicine study to be performed, appropriate action is taken to resolve the issue prior to the administration

of a radiopharmaceutical to a patient. 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,

/Hugh L. Thompson, Jr.

Hugh L. Thompson, Jr.
Deputy Executive Director for
Nuclear Materials, Safety, Safeguards,
and Operations Support

Enclosure:
Notice of Violation and Proposed
Imposition of Civil Penalties

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTIES

Ingham Medical Center Corporation
Lansing, Michigan

Docket No. 030-02132
License No. 21-12826-01
EA 93-109

During an NRC inspection conducted on February 25 and 26, 1993, and a subsequent review of the event by a medical consultant contracted by the NRC, 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 (1992), 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 Associated with the Misadministration

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 will be administered as directed by the authorized user. 10 CFR 35.32(a)(1)(iv) specifies, in part, that prior to administration, a written directive shall be prepared for any administration of quantities greater than 30 microcuries of sodium iodide 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 in quantities greater than 30 microcuries of sodium iodide I-131. The written directive shall contain the dosage.

Item 3.A.2 of the licensee's quality management program, submitted to the Commission on November 25, 1991, requires, in part, that a written directive be prepared prior to any administration of sodium iodide I-131 greater than 30 microcuries.

Contrary to the above, on May 11, 1992, the licensee administered 9.9 millicuries of sodium iodide I-131 to a patient, a dosage greater than 30 microcuries, and a written directive was not prepared prior to administration.

B. 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 instructions of the supervising authorized user.

The instructions of the supervising authorized user, entitled: "Thyroid Carcinoma Survey - All Nuclear Personnel", revised on October 1, 1989, require, in part, that the patient must have had a total thyroidectomy before performing a thyroid carcinoma survey.

Contrary to the above, on May 11, 1992, a nuclear medicine technologist working under the supervision of the licensee's authorized user, failed to follow the instructions of the authorized user and administered 9.9 millicuries of sodium iodide I-131 for a thyroid carcinoma survey to a patient with an intact thyroid.

This is a Severity Level I problem (Supplement VI).
Civil Penalty - $7,500.

II. Violations Associated with Reporting Requirements

A. 10 CFR 35.33(a)(1) requires that the licensee notify the NRC Operations Center by telephone no later than the next calendar day after discovery of a misadministration.

10 CFR 35.33(a)(2) requires that the licensee submit a written report to the NRC regional office within 15 days after discovery of a misadministration.

Contrary to the above, the licensee did not notify the NRC Operations Center by the next calendar day nor submit a written report to the NRC regional office within 15 days following discovery of a misadministration that occurred on May 11, 1992. Specifically, on May 12, 1992, the licensee became aware of a misadministration of sodium iodide I-131, but the licensee did not notify the NRC Operations Center until May 13, 1993, and did not submit a written report to the NRC Region III office until April 7, 1993.

B. 10 CFR 35.33(a)(3) requires, in part, that the licensee notify the patient of the misadministration no later than 24 hours after its discovery.

10 CFR 35.33(a)(4) requires that if the patient is verbally notified of a misadministration, the licensee shall also furnish a written report to the patient within 15 days of discovery of the misadministration.

Contrary to the above, the licensee, through the referring physician, verbally notified the patient of

the event on May 12, 1992, but did not furnish a written report of the misadministration to the patient until approximately April 2, 1993, a period greater than 15 days following the discovery of the misadministration.

This is a Severity Level III problem (Supplement VI).
Civil Penalty - $3,750.

Pursuant to the provisions of 10 CFR 2.201, Ingham Medical Center Corporation (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 cumulative 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.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 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 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.

Dated at Rockville, Maryland
this 9th day of September 1993

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

JUL 06 1993

Docket No. 030-32954
License No. 24-04206-13MD
EA 93-140

Mr. Warren K. Fadling, Director
Nuclear Medicine Division
Mallinckrodt Medical, Incorporated
Post Office Box 5840
675 McDonnell Boulevard
St. Louis, Missouri 63134

Dear Mr. Fadling:

SUBJECT: CORRECTED COPY OF NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY ISSUED ON JUNE 18, 1993

On June 18, 1993, the NRC issued to you a Notice of Violation and Proposed Imposition of Civil Penalty in the amount of $5,000 for a transportation violation associated with your Folcroft, Pennsylvania facility. The violation was classified at Severity Level III.

The base civil penalty amounts assessed by the NRC are derived using Tables 1A and 1B of the NRC Enforcement Policy, 10 CFR Part 2, Appendix C. Although $5,000 is the base civil penalty amount for most Severity Level III violations involving a nuclear pharmacy, the base amount for the type of transportation violation described in the June 18 Notice is $1,000, and the penalty assessed for that violation should have been $1,000.

Accordingly, I have enclosed a Corrected Notice of Violation and Proposed Imposition of Civil Penalty which simply revises the civil penalty amount for the violation set forth in Section I of the Notice to $1,000. The NRC apologizes for any inconvenience this error may have caused you.

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

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.

Sincerely,

Thomas T. Martin
Regional Administrator

Enclosure:
Corrected Copy of Notice of Violation and Proposed Imposition of Civil Penalty

cc w/encls:
Public Document Room (PDR)
Nuclear Safety Information Center (NSIC)
Commonwealth of Pennsylvania

R. Gilliam Facility Manager
Mallinckrodt Medical, Incorporated
19 Independence Court
Folcroft, Pennsylvania 19032

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

ENCLOSURE

JUL 06 1993

Docket No. 030-32954
License No. 24-04206-13MD
EA 93-140

Mr. Warren K. Fadling, Director
Nuclear Medicine Division
Mallinckrodt Medical, Incorporated
Post Office Box 5840
675 McDonnell Boulevard
St. Louis, Missouri 63134

Dear Mr. Fadling:

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY - $1,000
NRC Inspection Report No. 030-32954/93-001)

This refers to the NRC inspection conducted on May 14, 1993, at your Folcroft, Pennsylvania, facility to review the circumstances associated with two incidents involving your licensed activities in which packages were shipped to Mercy Catholic Medical Center, Fitzgerald Division (Fitzgerald), in Darby, Pennsylvania, without certain requirements being met. In one instance, which occurred on May 7, 1993, the external contamination levels on the surface of the package were in excess of 25 times the regulatory limit. In the second instance, which occurred on May 11, 1993, you did not properly label a package received by the Mercy Catholic Medical Center, Fitzgerald Division. During the NRC inspection, two violations of NRC requirements were identified by the NRC. The inspection report was sent to you on May 28, 1993. On June 3, 1993, an enforcement conference was held with you and members of your staff to discuss the violations, their causes, and your corrective actions. A copy of the enforcement conference summary report is enclosed (Enclosure 2).

With respect to the May 7, 1993 incident, the Radiation Safety Officer at Fitzgerald, notified the NRC Region I office and Mallinckrodt, of external contamination levels in excess of 6000 disintegrations per minute/square centimeter (dpm/cm^2) on the package that contained greater than 100 millicuries of technetium-99m in liquid form that was received from Mallinckrodt. This is a violation of the NRC and Department of Transportation (DOT) regulations which require that the external removable contamination levels on the packages be limited to 220 dpm/cm^2.

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

The NRC is particularly concerned with this incident, given the levels of external contamination that were detected on the surface of the package (reusable suitcase). Although a root cause of the external contamination was not conclusively determined, an inadequate survey of the empty package at your facility upon receipt from your customers and the failure to perform a survey of the outside surfaces of the package prior to shipment appear to have contributed to this occurrence. The NRC recognizes that the safety significance of this violation was minimized by the fact that (1) the contamination involved technetium-99m that has a half life of 6 hours, (2) you used your own driver and vehicle for the shipment and that reduced the possibility of spread of contamination in the public domain, and (3) a survey of the vehicle performed after the incident did not detect any contamination of the vehicle. Nonetheless, the possibility existed that radioactive material could have ended up uncontrolled in the public domain. 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 and is described in Section I of the enclosed Notice (Enclosure 1).

With respect to the May 11, 1993 incident, the Radiation Safety Officer at the Fitzgerald Division again contacted the NRC Region I office to report that a package was received that day from Mallinckrodt which was not properly labeled. The package was labeled with a DOT White-I label, which would require the radiation level on the surface of the package to be less than 0.5 mR/hr at all points. However, the survey of the package upon receipt revealed a radiation level of 4.0 mR/hr on the surface of the package. This constitutes a second violation of NRC and DOT requirements. This violation of the DOT labeling requirements is categorized at Severity Level IV, and is described in Section II of the enclosed Notice.

The NRC recognizes that immediate corrective actions were taken when the violations were identified. These actions included, but were not limited to, performing a prompt survey of the driver and the vehicle, revising the procedure to require wipe tests of the transportation case immediately prior to shipment, and instructing all personnel responsible for transportation surveys in proper survey techniques and importance of these surveys. In addition, since Mallinckrodt operates facilities at other locations of the country, the facility managers were notified of the contamination event via voice mail. Also, to prevent occurrence at other facilities, the event will be discussed at your upcoming managers' meeting. At the time of the enforcement conference, these corrective actions were either completed or near completion.

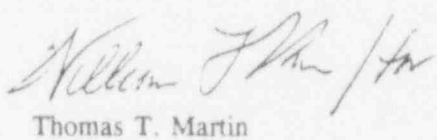
Notwithstanding the above corrective actions, to emphasize the importance of assuring that all regulatory requirements are met when transporting radioactive material, I have been authorized to issue the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice) in the amount of $1,000 for the Severity Level III violation. The base value of a civil penalty for a Severity Level III transportation violation of this type is $1,000. The civil penalty adjustment factors in the Enforcement Policy were considered, and on balance, no adjustment to the base civil penalty amount was made. Although a basis exists for escalating the penalty by 50% because the violations were identified by the NRC after being notified of the incidents by Mercy Catholic Medical Center, a basis also exists for mitigation of the penalty by 50% based on your prompt and comprehensive corrective actions. The other adjustment factors in the policy were considered and no further adjustment to the base civil penalty 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. 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

Enclosures:
1. Notice of Violation and Proposed Imposition of Civil Penalty
2. Enforcement Conference Summary Report

cc w/encls:
Public Document Room (PDR)
Nuclear Safety Information Center (NSIC)
Commonwealth of Pennsylvania

R. Gilliam, Facility Manager
Mallinckrodt Medical, Incorporated
19 Independence Court
Folcroft, Pennsylvania 19032

Enclosure 1

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

Mallinckrodt Medical, Inc.
Folcroft, Pennsylvania

Docket No. 030-32954
License No. 24-04206-13MD
EA No. 93-140

During an NRC inspection conducted on May 14, 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 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 173.443(a) requires, in part, with exceptions not applicable here, that for beta-gamma emitting contaminants, the level of non-fixed (removable) radioactive contamination on the external surfaces of each package offered for shipment, when averaged over the surface wiped, not exceed 220 disintegrations per minute per square centimeter.

Contrary to the above, on May 7, 1993, the licensee transported a package from its Folcroft facility to the Fitzgerald Division of the Mercy Catholic Medical Center, and upon arrival at the Fitzgerald Division, the package was determined to have non-fixed contamination caused by technetium-99m, a beta-gamma emitting radionuclide, of approximately 6000 disintegrations per minute per square centimeter averaged over the surface wiped.

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

Civil Penalty - $1,000

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 172.403 requires, in part, with exceptions not applicable here, that each package of radioactive material be labeled, as appropriate, with a RADIOACTIVE WHITE-I, a RADIOACTIVE YELLOW-II, or a RADIOACTIVE YELLOW-III label and that a package will be labeled with a RADIOACTIVE WHITE-I label only if the radiation level on its surface is less than or equal to 0.5 mR/hr.

Contrary to the above, on May 11, 1993, the licensee transported outside the confines of its plant technetium-99m in a package labeled with a RADIOACTIVE WHITE-I label, and the radiation level on the surface of the package was 4.0 mR/hr, which exceeded 0.5 mR/hr.

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

Pursuant to the provisions of 10 CFR 2.201, Mallinckrodt Medical Incorporated (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(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 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.

Dated at King of Prussia, Pennsylvania
this 6th day of July 1993

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

DEC 13 1993

Docket No. 030-32954
License No. 24-04206-13MD
EA 93-140

Mr. Warren K. Fadling, Director
Nuclear Medicine Division
Mallinckrodt Medical, Incorporated
Post Office Box 5840
675 McDonnell Boulevard
St. Louis, Missouri 63134

Dear Mr. Fadling:

SUBJECT: ORDER IMPOSING A CIVIL MONETARY PENALTY - $500
(NRC Inspection Report No. 030-32954/93-001)

This letter refers to your two letters, dated July 16, 1993, in response to the Notice of Violation and Proposed Imposition of Civil Penalty (Notice) sent to you by our letter dated July 6, 1993. Our letter and Notice described two violations of NRC requirements, one of which was categorized as a Severity Level III violation. The circumstances surrounding the violation were reported to the NRC by another licensee (Fitzgerald Division of the Mercy Catholic Medical Center in Darby, Pennsylvania, referred to as Fitzgerald Mercy). This violation was identified by the NRC during an inspection of your Folcroft, Pennsylvania facility on May 14, 1993, and involved radioactive contamination that was 25 times the regulatory limits on a package shipped to Fitzgerald Mercy from your Folcroft, Pennsylvania facility on May 7, 1993. To emphasize the importance of assuring that all regulatory requirements are met when transporting radioactive material, a Notice of Violation and Proposed Imposition of Civil Penalty in the amount of $1,000 was proposed for this violation.

In your reply, you admitted both of the violations. However, you requested mitigation of the $1,000 civil penalty assessed for Violation I, for the reasons set forth in your answer, as summarized in the Appendix attached to the enclosed Order Imposing a Civil Monetary Penalty.

After consideration of your responses, we have concluded, for the reasons given in the Appendix to the enclosed Order, that the civil penalty should be mitigated 50% because of your good past performance. Accordingly, we hereby serve the enclosed Order on Mallinckrodt Medical, Incorporated imposing a civil monetary penalty in the amount of $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, Jr.
Deputy Executive Director for
Nuclear Materials Safety, Safeguards
and Operations Support

Enclosure:
As Stated

cc w/encls:
Public Document Room (PDR)
Nuclear Safety Information Center (NSIC)
Commonwealth of Pennsylvania

R. Gilliam, Facility Manager
Mallinckrodt Medical, Incorporated
19 Independence Court
Folcroft, Pennsylvania 19032

UNITED STATES
NUCLEAR REGULATORY COMMISSION

In the Matter of	)	
	)	
Mallinckrodt Medical, Incorporated	)	Docket No. 030-32954
Folcroft, Pennsylvania	)	License No. 24-04206-13MD
	)	EA 93-140

ORDER IMPOSING A CIVIL MONETARY PENALTY

I

Mallinckrodt Medical, Incorporated, St. Louis, Missouri (Licensee) is the holder of Byproduct Material License No. 24-04206-13MD (License), issued by the Nuclear Regulatory Commission (NRC or Commission) on November 16, 1992, for use of licensed materials at the licensee's facility in Folcroft, Pennsylvania. The License authorizes the Licensee to manufacture, use, and transport byproduct material to area hospitals for use as nuclear pharmaceuticals in accordance with the conditions specified therein. Licensed activities conducted at the Folcroft facility consist of compounding, dispensing and/or distributing radiopharmaceuticals, redistributing of unopened molybdenum-99/technetium-99m generators and providing calibration of survey instruments for licensees authorized to use licensed materials listed in 10 CFR 35.100, 35.200, 35.300, 35.400, and 35.500. The License is scheduled to expire on August 31, 1994.

II

An inspection of the Licensee's activities at its Folcroft, PA facility was conducted by the NRC on May 14, 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 July 6, 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 Violation I.

The Licensee responded to the Notice by letters dated July 16, 1993. In its Reply, the Licensee admits both of the violations, but in its Answer requests mitigation of the civil penalty assessed for Violation I based on its prior performance history and corrective actions taken to mitigate and prevent recurrence of the violation (further described in the Appendix to this Order).

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 in the Notice; that the civil penalty proposed for Violation I designated in the Notice should be mitigated by 50% based on reconsideration of application of the Licensee

Performance factor in the Enforcement Policy; and that a civil penalty of $500 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 $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 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 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 13th day of December 1993

APPENDIX

EVALUATION AND CONCLUSION

On July 6, 1993, a Notice of Violation and Proposed Imposition of Civil Penalty (Notice) was issued for two violations identified during an NRC inspection conducted on May 14, 1993. A civil penalty was proposed for Violation I. Mallinckrodt Medical, Incorporated (licensee) in a Reply and an Answer, both dated July 16, 1993, admitted the violations, but requested mitigation of the civil penalty. The NRC's evaluation and conclusion regarding the licensee's requests are as follows:

1. Restatement of Violation 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 173.443(a) requires, in part, with exceptions not applicable here, that for beta-gamma emitting contaminants, the level of non-fixed (removable) radioactive contamination on the external surfaces of each package offered for shipment, when averaged over the surface wiped, not exceed 220 disintegrations per minute per square centimeter.

   Contrary to the above, on May 7, 1993, the licensee transported a package from its Folcroft facility to the Fitzgerald Division of the Mercy Catholic Medical Center, and upon arrival at the Fitzgerald Division, the package was determined to have non-fixed contamination caused by technetium-99m, a beta-gamma emitting radionuclide, of approximately 6000 disintegrations per minute per square centimeter averaged over the surface wiped.

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

   Civil Penalty - $1,000

2. Summary of Licensee's Request

   In its written Reply, the licensee admits the violation. However, in its Answer, the licensee requests that the penalty be mitigated in its entirety. In support of its request, the licensee notes that the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C (Enforcement Policy), Section VI.B.2(c) allows mitigation of the base civil penalty by as much as 100% if the current violation is an isolated failure that is inconsistent with a licensee's outstandingly good prior

performance. The licensee also notes that prior performance is described in the Enforcement Policy as the licensee's performance normally within the last two years or the period within the last two inspections, whichever is longer. The licensee indicated that during this period, there have been no problems identified with contamination or improper surveying of packages containing radioactive materials at the Folcroft facility, and requests that this performance history be considered in the NRC's review of the situation.

The licensee further notes that the Enforcement Policy in Section VI.B.2(b) allows for mitigation of up to 50% when a licensee takes immediate corrective actions to restore safety and compliance with the license and regulations. The Enforcement Policy states that the issues to be considered are the promptness, extensiveness and timeliness of corrective actions, and the degree of licensee initiative. The licensee indicated that the Outgoing Package procedure at its Folcroft facility was reviewed for possible deficiencies and was revised to include a wipe test on the delivery case prior to shipment. This revision was completed prior to the NRC inspection of the Folcroft facility on May 14, 1993. The licensee's corporate management later issued the change to all Mallinckrodt pharmacies nationwide for immediate implementation. Further, the licensee points out that the corrective steps taken achieved the objectives of the NRC enforcement action policy before any enforcement action had begun, thereby demonstrating the licensee's commitment to radiation safety and the protection of the public. In view of the above, the licensee requests that the NRC consider withdrawing the civil penalty.

3. NRC Evaluation of Licensee's Response

The NRC has evaluated the licensee responses and has determined that the licensee's past performance justifies some mitigation of the civil penalty. In determining the amount of the civil penalty, the NRC considered the escalation and mitigation factors set forth in the NRC Enforcement Policy. With respect to the licensee's corrective actions, the NRC considered those actions, concluded they were prompt and comprehensive, and concluded that the base civil penalty amount for this Severity Level III violation should be decreased by 50% because of those actions. This is the maximum amount of mitigation allowed by the Enforcement Policy. The Enforcement Policy allows for a 50% escalation if the NRC identifies the violation, which was applied in this case because the violation was identified when another licensee reported the contamination incident to the NRC.

With respect to the licensee's past performance, this factor was also considered in the NRC analysis. The licensee contends mitigation is warranted because there have been no problems in the area of concern. The Enforcement Policy provides, however, that consideration will be given to the licensee's prior enforcement history overall and in the area of concern. Mitigation may be granted if the violation is inconsistent with a licensee's "outstandingly good prior performance." The licensee's prior enforcement history overall included two violations during each of the last two inspections in 1992 and 1991. The NRC acknowledges that none of these four violations identified in the previous inspections were similar to the violation assessed a penalty in the July 6, 1993 Notice. While your procedures called for surveys of incoming shipments in the past, they did not require surveys of outgoing shipments. Thus it may be fortuitous that no prior incidents such as this were discovered. Thus, although the Licensee's past performance does contain some violations, the overall record is sufficiently good to justify some mitigation of the civil penalty. Therefore, the NRC concludes that 50% mitigation on this factor is warranted.

4. NRC Conclusion

The NRC has concluded that Violation I occurred as stated and that the licensee provided an adequate basis for further mitigation of the civil penalty. Consequently, the NRC has determined that a civil monetary penalty in the amount of $500 should be imposed.

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

MAY 7 1993

Docket No. 030-30082
License No. 49-26888-01
EA 93-033

N.V. Enterprises
ATTN: Wayne E. Nelson
Radiation Safety Officer
1711 E. 24th Street
Casper, Wyoming 82601

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY - $4,000 - AND DEMAND FOR INFORMATION (NRC INSPECTION REPORT NO. 030-30082/91-01 & INVESTIGATION CASE NO. 4-91-017)

This is in reference to the inspection conducted on October 22, 1991, at N.V. Enterprises in Casper, Wyoming. This inspection, which was documented in a report issued December 4, 1991, found one violation of NRC requirements, the failure to wear alarm ratemeters during the performance of industrial radiography. In a letter dated March 31, 1993, the NRC informed you that the circumstances surrounding this violation had been reviewed by the NRC's Office of Investigations (OI) to determine whether the violation was committed willfully. OI's investigation concluded that the violation was deliberate, i.e., the owner of the company at the time of the violation remained in noncompliance from approximately October 10, 1991, when he was informed of the requirement, until October 22, 1991, the date of the NRC's inspection. On April 13, 1993, N.V. Enterprises representatives participated telephonically in an enforcement conference with NRC representatives to discuss this violation. A list of enforcement conference participants is enclosed.

Since January 10, 1991, the NRC has required in 10 CFR 34.33(a) that alarm ratemeters be worn by radiography personnel at all times during radiographic operations. This requirement, which calls for the use of alarm ratemeters that will emit an audible alarm in high radiation fields, was developed to prevent inadvertent and unnecessary exposure to high radiation levels and was based on the NRC's conclusion that most radiation incidents involving radiography activities would be prevented by the use of such devices. Based on the information developed during the inspection and investigation, and the discussions that took place during the enforcement conference, N.V. Enterprises was in violation of this important requirement from January 10, 1991, until the date of the inspection in October 1991.

Although N.V. Enterprises may have been confused about the effective date of the requirement prior to October 10, 1991, the inspection and investigation revealed that you (who at the time were employed by N.V. Enterprises as a radiographer and were not the radiation safety officer) had become aware from

an equipment vendor that the radiation monitoring devices N.V. Enterprises was using did not meet NRC requirements because they were not set to alarm in a 500 millirem/hour radiation field. Although you obtained an alarm ratemeter for your own use and informed the owner of the company (Neal Cox) that the devices being used did not meet current NRC requirements and that he would have to call the equipment vendor to make arrangements to receive an alarm ratemeter, he continued to perform radiography without an alarm ratemeter on four occasions before the violation was discovered during the NRC inspection.

In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy) 10 CFR Part 2, Appendix C, the failure to wear alarm ratemeters during radiography operations is normally categorized as a Severity Level III violation. However, because N.V. Enterprises was aware of the requirement and did not cease operations, this violation has been categorized as willful and at Severity Level II. The NRC notes that N.V. Enterprises states that its personnel were wearing, and are continuing to wear, devices that emit a constant audible chirp in a radiation field, the frequency of which is dependent on the intensity of the radiation field. However, these devices do not satisfy the requirements of 10 CFR 34.33(a).

The NRC also recognizes that N.V. Enterprises took immediate actions to come into compliance with this requirement following the inspection. You agreed to suspend radiographic operations following the inspection and did not resume radiographic operations until you obtained alarm ratemeters. During the enforcement conference, you described additional corrective actions that you took immediately following the inspection, including: 1) a complete review of your operating procedures to ensure they reflected current requirements; 2) revisions to your operating procedures to reflect alarm ratemeter requirements; 3) a complete review of all personnel monitoring equipment to ensure proper calibration and performance; and 4) a complete review of applicable NRC regulations to ensure that you were in compliance with all other NRC requirements. An NRC inspection in February 1993 confirmed that N.V. Enterprises has been complying with the alarm ratemeter requirement and other NRC requirements.

To emphasize the importance of taking immediate action upon discovering a violation to restore compliance with NRC requirements, and the importance of maintaining an awareness of all NRC requirements, particularly those that are designed to ensure the safety of radiography personnel and the public, I have been authorized 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 violation described above and in the Notice.

The base value of a civil penalty for a Severity Level II violation is $8,000. The civil penalty adjustment factors in the Enforcement Policy were considered and resulted in a $4,000 net reduction. In making this decision, the NRC determined: 1) that a 50-percent decrease was warranted for your corrective actions; 2) that a 100-percent decrease was warranted based on your good past performance; and 3) that a 100-percent increase was warranted because the

violation occurred on multiple occasions between January 10 and October 22, 1991. The remaining adjustment factors were considered but did not result in any further adjustments to the penalty.

As an owner of the business and a radiographer, Mr. Cox continues to be involved in decisions that have the potential to affect the safety of employees and the public. Therefore, in light of the willful violation and in order to determine whether additional regulatory action is needed, N.V. Enterprises is hereby required, pursuant to sections 161c, 161o, 182, and 186 of the Atomic Energy Act of 1954, as amended, and the Commission's regulations in 10 CFR 2.204 and 10 CFR 30.32(b), to provide in writing, under oath or affirmation within 30 days of the date of this letter, a statement of why the NRC should have confidence that he will take prompt action to comply when he learns of new requirements in the future.

N.V. Enterprises 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

James L. Milhoan
Regional Administrator

Enclosure:
Notice of Violation and Proposed Imposition
of Civil Penalty

cc: Howard Hutchings, Manager
Environmental Health Program
Cheyenne, Wyoming

MAY 7 1993

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

N.V. Enterprises
Casper, Wyoming

Docket 030-30082
License 49-26888-01
EA 93-033

During an NRC inspection conducted on October 22, 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 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 34.33(a) requires, in part, that the licensee not permit any individual to act as a ragiographer or a radiographer's assistant unless at all times during radiographic operations, the individual wears a direct reading pocket dosimeter, an alarm ratemeter, and either a film badge or a thermoluminescent dosimeter (TLD).
>
> Contrary to the above, on numerous occasions between January 10, 1991, and October 22, 1991, a licensee radiographer did not wear an alarm ratemeter while conducting radiographic operations.
>
> This is a Severity Level II violation (Supplement VI).
> Civil Penalty - $4,000

Pursuant to the provisions of 10 CFR 2.201, N.V. Enterprises (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 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 7th day of May 1993

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

SEP 30 1993

Docket No. 030-30082
License No. 49-26888-01
EA 93-033

N.V. Enterprises
ATTN: Neal A. Cox
President
Post Office Box 2129
Evanston, Wyoming 82601

SUBJECT: CONFIRMATORY ORDER

This is in reference to the Notice of Violation and Proposed Imposition of Civil Penalty (Notice) issued by the NRC on May 7, 1993, your Answer to the Notice dated June 1, 1993, and your July 27, 1993 request for termination of License No. 49-26888-01 with the accompanying NRC Form 314.

You have requested termination of your license and transferred all licensed materials. You have also indicated your consent to an agreement under which you would not own, manage, or serve as Radiation Safety Officer (RSO) of any entity engaged in NRC licensed activities for three years if the NRC would withdraw the civil penalty. Based on your commitment, we have prepared the attached Confirmatory Order. Please review and sign both copies, under oath or affirmation, and return them within 30 days of the date of this letter, to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555. After they have been signed, a copy will be returned to you. If you decide to enter into this Confirmatory Order, the NRC will not impose the civil penalty and the matter will be considered settled without payment of the proposed civil penalty. In addition Amendment No. 2 will be issued, which will formally terminate your license. However, should you elect not to enter into this agreement or should you violate any of the terms of Section IV of the Order, then the civil penalty of $4000 will be imposed.

If you have any questions concerning this matter, please call Geoffrey Cant of this Office, at (301) 504-3283.

Sincerely,

Joseph R. Gray, Deputy Director
Office of Enforcement

cc: James L. Milhoan, RIV
State of Wyoming

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

NOV 0 9 1993

Docket No. 030-30082
License No. 49-26888-01
EA 93-033

N.V. Enterprises
ATTN: Neal A. Cox
President
Post Office Box 2129
Evanston, Wyoming 82601

SUBJECT: CONFIRMATORY ORDER

This refers to the Confirmatory Order that we forwarded to you on September 30, 1993 and which you executed and returned to us. It also refers to your request for termination of your license.

The Confirmatory Order has been signed by James Lieberman, Director, Office of Enforcement. A fully executed copy is enclosed. The civil penalty in the amount of $4,000 proposed on May 7, 1993 is withdrawn. The other provisions of this Confirmatory Order, including the provisions concerning your functioning in NRC licensed activities, are now in effect.

Also enclosed is Amendment No. 2, which terminates your license, No. 49-26888-01.

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,

Joseph R. Gray, Deputy Director
Office of Enforcement

Enclosures: As stated

cc: State of Wyoming

UNITED STATES
NUCLEAR REGULATORY COMMISSION

In the Matter of	)	
N.V. ENTERPRISES	)	Docket No. 030-30082 License No: 49-26888-01
Casper, Wyoming	)	EA 93-033

CONFIRMATORY ORDER

I

N.V. Enterprises (NV) formerly held NRC Byproduct Material License No. 49-26888-01 (License), issued on July 19, 1988 by the Nuclear Regulatory Commission. The License authorized the possession and use of sealed sources in industrial radiography. The License expired on July 31, 1993. An application for renewal of the License was not filed.

II

An inspection by the Nuclear Regulatory Commission (NRC) was conducted on October 22, 1991, at the Licensee's facility in Casper, Wyoming. This inspection and a subsequent investigation identified one violation of NRC requirements, a failure to wear alarm ratemeters during the performance of industrial radiography. The investigation determined this violation to have been willful on the part of the owner and president of NV, Mr. Neal A. Cox. On May 7, 1993, the NRC issued an Enforcement Action (EA 93-033) against NV consisting of a Notice of Violation and Proposed Imposition of Civil Penalty - $4,000 (Notice). On June 1, 1993, the Licensee filed an Answer and a Reply to the Notice and requested that the NRC permit NV to terminate its license in lieu of paying the civil penalty. In telephone conversations on June 14, 1993 and September 21, 1993, Neal A. Cox advised the NRC, Region IV office that he would not own, manage, or act as Radiation Safety Officer (RSO) of any entity

engaged in NRC licensed activities for a period of three years if the NRC would withdraw the civil penalty. On July 27, 1993, the Licensee submitted a Certificate of Disposition of Materials and a request for termination of its License. Based on the information submitted by NV and NRC confirmation of receipt of the devices containing the licensed radioactive material by the transferee, the NRC is satisfied that NV has transferred all of its licensed materials.

III

The Notice proposed a $4,000 civil penalty and the Licensee filed an Answer and a Reply to the Notice. In telephone conversations on June 14, 1993 and September 21, 1993, with Charles Cain of the NRC, Region IV, Neal A. Cox agreed that he would not own, manage, or act as RSO of any entity engaged in NRC licensed activities for three years and would terminate his license, if the NRC would withdraw the civil penalty. As the parties desire to resolve all matters pending between them, Neal A. Cox agrees, for a period of three years from the date that he signs this Confirmatory Order, that he will not own, manage, or act as Radiation Safety Officer, of any entity engaged in licensed activities within the jurisdiction of the NRC for that same period of time.

IV

Accordingly, pursuant to sections 81, 161b, 161i, 186, and 234 of the Atomic Energy Act of 1954, as amended, and the Commission's regulations in 10 CFR

2.202, 2.205, and 10 CFR Parts 30, 34, and 150, IT IS HEREBY ORDERED, STIPULATED AND AGREED between the NRC and Neal A. Cox as follows:

1. The NRC withdraws the civil penalty of $4,000 as proposed in the Notice dated May 7, 1993 (EA 93-033).

2. For a period of three years from the date Neal A. Cox signs this Confirmatory Order, Neal A. Cox, will not own, manage, or act as Radiation Safety Officer of any entity engaged in licensed activities within NRC jurisdiction, including an Agreement State licensee working under reciprocity, for that same period of time.

3. This Confirmatory Order constitutes settlement without payment of a civil penalty proposed in the Notice dated May 7, 1993 (EA 93-033). However, if Neal A. Cox violates paragraph 2 of this Section, then the civil penalty of $4,000 will be reinstated by an Order Imposing Civil Penalty and the civil penalty of $4,000 will be due in full within 30 days of the date of that Order Imposing Civil Penalty.

4. Neal A. Cox, NV, and their successors and assigns waive the right to contest this Order in any manner, including requesting a hearing on this Order or the Order Imposing Civil Penalty, should one be issued as provided in paragraph 3 of this Section.

5. NRC License No. 49-26888-01 is terminated by attached Amendment No. 2.

FOR THE NUCLEAR REGULATORY COMMISSION

Dated: 11-5-93 BY: James Lieberman

FOR N. V. ENTERPRISES

Dated: 11-2-93 BY: Neal A Cox
Neal A. Cox

Notary:

ACKNOWLEDGEMENT

State of Wyoming)
) ss.
County of Uinta)

The foregoing instrument was acknowledged before me by Neal A Cox this 2nd day of Nov, 1993.

Witness my hand and official seal.

(Signed) Ann Collins
Uinta Co. Clerk

My term expires: 1-2-95

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION II
101 MARIETTA STREET, N.W., SUITE 2900
ATLANTA, GEORGIA 30323-0199

SEP 29 1993

Docket No. 030-19126
License No. 45-19703-01
EA 93-219

Schnabel Engineering Associates, Inc.
ATTN: Mr. Ray E. Martin
President
One West Cary Street
Richmond, Virginia 23220-5609

Gentlemen:

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY - $375 (NRC INSPECTION REPORT NO. 45-19703-01/93-02)

This refers to the Nuclear Regulatory Commission (NRC) inspection conducted by Mr. J. Henson on August 16 and August 25, 1993, at your facility in Richmond, Virginia. The inspection included a review of the facts and circumstances related to an incident that occurred on July 11, 1993, involving a moisture density gauge that was left unattended and subsequently damaged by heavy equipment at a construction site. The report documenting this inspection was sent to you by letter dated September 1, 1993. During the inspection, violations of NRC requirements were identified. An enforcement conference was conducted in the NRC Region II office in Atlanta, Georgia on September 20, 1993, with Mr. Gilbert Seese, Radiation Protection Officer, 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 September 23, 1993.

The violation in Part I of the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice) involved the failure to maintain constant surveillance and immediate control of a Troxler Model 3401B moisture/density gauge in an unrestricted area.

The root cause of this violation was the failure of the technician to maintain constant surveillance and immediate control of the gauge. Another important contributing cause was management's failure to assure that the technician, a qualified temporary employee, was properly retrained and informed of information that re-emphasized surveillance and control requirements. The NRC considers this to have been a significant event, since the gauge was damaged while unattended. The safety significance associated with this particular violation is the potential unnecessary radiation exposures that could have occurred had the sealed sources been severely damaged in the accident and radioactive material released. 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 staff recognizes that corrective action was taken by the technician who immediately recognized the significance of the event and secured the site, cleared all personnel from the area and notified the Radiation Protection Officer. In addition, although this was not an event that was required to be reported to the NRC, the Radiation Protection Officer reported the event to the NRC both by telephone and in writing. His initiative enabled the NRC to follow up the event in a timely manner.

In order to emphasize the importance of maintaining constant surveillance and control of licensed material and ensuring that operational activities are conducted safely and in accordance with requirements, I have been authorized to issue the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice) in the amount of $375 for the Severity Level III violation in Part I of the Notice. The base value of a civil penalty for this Severity Level III violation is $500. The civil penalty adjustment factors in the Enforcement Policy were considered.

Mitigation of 25 percent was applied for the factor of identification because although the violation in Part I of the Notice was self-disclosing, consideration was given to the initiative taken to determine root cause and notify the NRC. Mitigation of 50 percent was warranted for corrective action. Your immediate corrective action included refresher training for all gauge users, a review of regulatory guidelines related to gauge use and transportation, and a discussion of the event. Additional actions included increased field audits of gauge users by the Radiation Protection Officer and management personnel, development of a stringent internal enforcement program and review of training procedures to ensure the adequacy of those procedures. Escalation of 50 percent was applied for the factor of licensee performance based on the results of two previous inspections conducted by the NRC. In a February 1993 inspection, there were no violations identified, but an inspection in January 1991 identified multiple violations, several of which were repeat violations. 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 decreased by 25 percent.

The violation cited in Part II of the Notice was categorized at Severity Level IV and involved the failure to properly complete required shipping papers when the damaged gauge was sent to the gauge manufacturer. This violation is of some concern because of the damaged condition of the gauge and the potential radiological hazards associated with shipping radioactive material. Properly completed shipping papers are intended to provide important information to emergency response personnel in the event of an accident during shipping.

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 Virginia

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

Schnabel Engineering Associates, Inc.
Richmond, Virginia

Docket No. 030-19126
License No. 45-19703-01
EA 93-219

During an NRC inspection conducted on August 16 and August 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, 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 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 11, 1993, licensed material consisting of approximately 8 millicuries of cesium-137 and 40 millicuries of americium-241 contained in a moisture/density gauge located at a temporary job site in Richmond, Virginia, 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).
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 172.203(c) requires, that the letters "RQ" be entered on the shipping paper either before or after the basic description required for each hazardous substance. Pursuant to 49 CFR 172.101, radioactive material is classified as hazardous material. 49 CFR 172.203(d) requires, in part, that the description for a shipment of radioactive material include: (1) the name of each radionuclide, (2) the physical and chemical form of the material, (3) the activity contained in each package of the shipment in terms of curies, millicuries, or microcuries,

(4) the category of label applied to each package (e.g., RADIOACTIVE WHITE-I), and 5) the transport index assigned to each package in the shipment bearing RADIOACTIVE YELLOW-II OR -III labels.

Contrary to the above, on July 13, 1993, the licensee delivered a package of licensed material to a common carrier for transport and did not include the letters "RQ", the name of each radionuclide in the package, and the activity contained in the package in the shipping papers provided to the carrier.

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

Pursuant to the provisions of 10 CFR 2.201, Schnabel Engineering Associates, 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 27th day of September 1993

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

JUL 28 1993

Docket No. 030-12319
License No. 35-17178-01
EA 93-172

Tulsa Gamma Ray, Inc.
ATTN: James C. Moss, President
1127 South Lewis Avenue
Tulsa, Oklahoma 74104

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY - $5,000 (NRC INSPECTION REPORT NO. 030-12319/93-01)

This refers to the inspection conducted on June 17, 1993, in Tulsa, Oklahoma. This inspection focused on an April 7, 1993, incident involving the loss of a radiography camera from a Tulsa Gamma Ray, Inc. vehicle. The inspection findings were described in a report issued on June 25, 1993. On July 19, 1993, apparent violations identified during this inspection were discussed with you at an enforcement conference conducted in the NRC's Region IV office in Arlington, Texas. A list of conference attendees is enclosed. The conference was open to public observation in accordance with the terms of a pilot program begun by the NRC in July 1992.

The violations in the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice) include: 1) Tulsa Gamma Ray's failure to properly block and brace licensed radioactive material during transport; and 2) Tulsa Gamma Ray's failure to maintain immediate control of licensed radioactive material. The failure to comply with these requirements resulted in the loss of a radiography camera containing a 34-curie iridium-192 sealed source. The camera was recovered by a member of the public and was returned to Tulsa Gamma Ray within an hour of the incident.

As discussed during the enforcement conference, NRC regulations require licensees to establish and maintain positive control of material to prevent incidents of this type, which can create, and have created, a substantial hazard to unsuspecting members of the public. Thus, violations that result in the loss of radioactive material are a significant regulatory concern to the NRC. Tulsa Gamma Ray is fortunate that the material involved in this incident was promptly recovered and did not result in a substantial hazard.

The NRC notes that Tulsa Gamma Ray was cited on May 4, 1993, for a failure to maintain direct surveillance of a radiography camera in September 1992. Although the circumstances in that case were different, in that the camera was at a job site and was not lost, the same fundamental regulatory principle was involved. Tulsa Gamma Ray's corrective action in each case has been to counsel the responsible individual and discuss the incident with other radiography personnel. While these actions may prove to be sufficient, the NRC encourages Tulsa Gamma Ray to reexamine its corrective actions for both incidents to assure that employees understand the importance of these

requirements and to assure itself that existing procedures are adequate to minimize the potential for, and prevent a recurrence of, such incidents.

In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy) 10 CFR Part 2, Appendix C, the violations related to the April 7 incident are classified in the aggregate as a Severity Level III problem. To emphasize the importance of maintaining control of radioactive material and the importance of effecting lasting corrective actions to prevent incidents of this type, I have been authorized to issue the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice) in the amount of $5,000 for this Severity Level III problem. The base value of a civil penalty for a Severity Level III problem is $5,000. The civil penalty adjustment factors in the Enforcement Policy were considered, but resulted in no adjustment as none 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. 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. Enforcement conference attendance list

cc w/Enclosures: State of Oklahoma

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

Tulsa Gamma Ray, Inc.
Tulsa, Oklahoma

Docket: 030-12319
License: 35-17178-01
EA 93-172

During an NRC inspection conducted on June 17, 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 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 April 7, 1993, licensed material consisting of 34 curies of iridium-192 in a radiography exposure device was not secured against unauthorized removal and was not under constant surveillance and immediate control of the licensee while in an unrestricted area. Specifically, a radiography exposure device fell from a licensee vehicle onto a public highway, an unrestricted area, and was recovered by a member of the public.

B. 10 CFR 71.5(a) requires that each 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 170-189.

49 CFR 177.842 requires, in part, that radioactive material packages be so blocked and braced that they cannot change position during conditions normally incident to transportation.

Contrary to the above, on April 7, 1993, the licensee's representatives transported an Amersham Model 660 B exposure device, containing an iridium-192 sealed source, outside the confines of its facility and the exposure device was not blocked and braced such that it could not change position during conditions normally incident to transportation. Specifically, the exposure device was not sufficiently blocked and braced within the vehicle's darkroom where it is routinely placed for transport and the package fell out of the vehicle onto a public highway.

These violations represent a Severity Level III problem (Supplement IV). Civil Penalty - $5,000.

Pursuant to the provisions of 10 CFR 2.201, Tulsa Gamma Ray, 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 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 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 28th day of July 1993

Enclosure 2

ENFORCEMENT CONFERENCE ATTENDANCE

LICENSEE/FACILITY: Tulsa Gamma Ray, Inc., Tulsa, Oklahoma
TIME/DATE: 9 a.m., July 19, 1993
MEETING LOCATION: NRC Region IV, Arlington, Texas
EA NUMBER: 93-172

Tulsa Gamma Ray, Inc.

James C. Moss, President, Tulsa Gamma Ray, Inc.

Nuclear Regulatory Commission

James L. Milhoan, Regional Administrator, Region IV (RIV)
William L. Brown, Regional Counsel, RIV
L.J. Callan, Director, Division of Radiation Safety and Safeguards, RIV
Charles L. Cain, Chief, Nuclear Materials Inspection Section, RIV
Linda Kasner, Senior Radiation Specialist, NMIS, RIV
Robert Brown, Senior Radiation Specialist, NMIS, RIV
Mark Shaffer, Radiation Specialist, NMIS, RIV
Heather Astwood, Intern, RIV
Gary Sanborn, Enforcement Officer, RIV
Geoffrey Cant, Enforcement Specialist, Office of Enforcement

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

NOV 24 1993

Docket No. 030-12319
License No. 35-17178-01
EA 93-172

Tulsa Gamma Ray, Inc.
ATTN: James C. Moss, President
1127 South Lewis Avenue
Tulsa, Oklahoma 74104

SUBJECT: ORDER IMPOSING CIVIL MONETARY PENALTY - $5,000

This refers to your letter dated September 7, 1993, in response to the Notice of Violation and Proposed Imposition of Civil Penalty (Notice) sent to you by our letter dated July 28, 1993. Our letter and Notice described violations of NRC requirements related to the transportation and security of a radiography camera. The violations were related to an April 7, 1993 incident involving a radiographic camera falling from a Tulsa Gamma Ray, Inc. (TGR) vehicle onto a public highway and being recovered by a member of the public. To emphasize the importance of maintaining control of radioactive material and the importance of effecting lasting corrective actions to prevent incidents of this type, a civil penalty of $5,000 was proposed for the violations.

In your September 7, 1993 response, you admitted the violations but requested that the NRC reconsider the penalty based on the reasons you stated in your letter. A summary of the reasons for your request for reconsideration and the NRC's evaluation of your reasons are contained in the Appendix to the enclosed Order.

After consideration of your request for mitigation of the penalty, we have concluded for the reasons given in the Appendix to the enclosed Order Imposing Civil Monetary Penalty that the full amount of the penalty should be imposed by Order. Accordingly, we hereby serve the enclosed Order on Tulsa Gamma Ray, Inc., imposing a civil monetary penalty in the amount of $5,000. The NRC will review the effectiveness of your corrective actions during future inspections.

You requested that the $2,700 inspection fee you have already paid be applied to the civil penalty amount. Although the assessment of an inspection fee has no bearing on a civil penalty amount, the NRC has determined that the inspection fee should not have been assessed in this case. You will receive a refund for the full $2,700 fee from the NRC's License Fee Branch.

CERTIFIED MAIL
RETURN RECEIPT 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,

Hugh L. Thompson, Jr.
Deputy Executive Director for
Nuclear Materials Safety, Safeguards
and Operations Support

Enclosure As Stated:
Order Imposing Civil Monetary Penalty
w/Appendix
cc w/enclosure: State of Oklahoma

UNITED STATES
NUCLEAR REGULATORY COMMISSION

In the Matter of	)	
	)	
Tulsa Gamma Ray, Inc.	)	Docket 030-12319
Tulsa, Oklahoma	)	License 35-17178-01
	)	EA 93-172

ORDER IMPOSING CIVIL MONETARY PENALTY

I

Tulsa Gamma Ray, Inc. (Licensee or TGR) is the holder of NRC Materials License No. 35-17178-01 issued by the Nuclear Regulatory Commission (NRC or Commission). The license authorizes the Licensee to possess and use sealed radioactive sources to perform industrial radiography in accordance with the conditions of the license.

II

An inspection of the Licensee's activities was conducted June 17, 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 July 28, 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 penalty proposed for the violations.

The Licensee responded to the Notice in a letter dated September 7, 1993. In its response, the Licensee admitted the violations which resulted in the proposed civil penalty, 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 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 the civil penalty in the amount of $5,000 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.

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

Hugh L. Thompson, Jr.
Deputy Executive Director for
Nuclear Materials Safety, Safeguards
and Operations Support

Dated at Rockville, Maryland
this 24th day of November 1993

APPENDIX

EVALUATION AND CONCLUSIONS

On July 28, 1993, a Notice of Violation and Proposed Imposition of Civil Penalty (Notice) was issued for violations identified during an NRC inspection. Tulsa Gamma Ray, Inc. responded to the Notice on September 7, 1993. The Licensee admitted the violations that resulted in the proposed civil penalty, but requested mitigation. The NRC's evaluation and conclusions regarding the Licensee's request follow:

Restatement of Violations

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 April 7, 1993, licensed material consisting of 34 curies of iridium-192 in a radiography exposure device was not secured against unauthorized removal and was not under constant surveillance and immediate control of the licensee while in an unrestricted area. Specifically, a radiography exposure device fell from a licensee vehicle onto a public highway, an unrestricted area, and was recovered by a member of the public.

B. 10 CFR 71.5(a) requires that each 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 170-189.

49 CFR 177.842 requires, in part, that radioactive material packages be so blocked and braced that they cannot change position during conditions normally incident to transportation.

Contrary to the above, on April 7, 1993, the licensee's representatives transported an Amersham Model 660 B exposure device, containing an iridium-192 sealed source, outside the confines of its facility and the exposure device was not blocked and braced such that it could not change position during conditions normally incident to transportation. Specifically, the exposure device was not sufficiently

blocked and braced within the vehicle's darkroom where it is routinely placed for transport and the package fell out of the vehicle onto a public highway.

These violations represent a Severity Level III problem (Supplement IV).
Civil Penalty - $5,000.

Summary of Licensee's Request for Mitigation

In its September 7, 1993, letter, the Licensee admitted the violations but requested mitigation of the penalty, citing the following reasons:

1. The NRC did not completely consider the Licensee's comments at the enforcement conference regarding corrective action and past inspection history.

2. The NRC requirement to maintain constant surveillance during a radiographic operation is almost impossible to comply with at all times and a $5,000 penalty is unrealistic.

3. To assess a $5,000 civil penalty for failing to block and brace a radiographic camera is excessive because the violation was caused by human error that cannot be completely eliminated by training or corrective action, and no hazard to the public, no release of radiation, and no damage from radiation occurred.

4. It is not fair to assess a $5,000 penalty on TGR when the NRC makes no effort to enforce DOT requirements on common carriers to block and brace a Type B shipping container.

5. If the NRC still considers a $5,000 penalty appropriate, the $2,700 inspection fee already paid by TGR should be applied to the $5,000 penalty.

NRC Evaluation of Licensee's Request for Mitigation

The NRC's evaluation of the Licensee's arguments follows:

1. The Licensee's corrective action consisted of counseling and fining the radiographer responsible for the incident, and discussing the incident with other TGR radiography personnel. TGR took no apparent action to assess the adequacy of its existing procedures to prevent a recurrence of this type of incident. For example, when asked at the enforcement conference whether TGR had considered revising its existing procedures to require drivers to perform a final check of the vehicle to assure that everything was in order, the Licensee said no. The Licensee's general

reaction to this incident was that "accidents" of this nature will happen and, therefore, corrective actions would be of limited utility. While the actions taken by the Licensee may be adequate in the short term, when this incident is fresh, we do not consider the Licensee's actions worthy of mitigation of the penalty because we are not convinced the Licensee has taken sufficient steps to prevent a recurrence in the long term.

With regard to past inspection history, we do not dispute the basic contention that TGR has transported radiographic devices for years without a mishap of this type. However, one of the violations in this case, a failure to comply with 10 CFR 20.207(a), is identical to a violation involved in a recent enforcement action involving this Licensee (EA 92-261). Although the citation in case number EA 92-261 was not issued until May 1993, subsequent to the April 7, 1993, incident, the violation occurred in September 1992 and had been the subject of an enforcement conference with the Licensee on January 26, 1993. While we do not consider the violations associated with the April 7, 1993 incident an indication of poor or declining performance, the combination of the September 1992 and April 1993 incidents causes us to question the adequacy of the Licensee's actions to emphasize the importance of maintaining control of radicactive material. We do not consider the Licensee's past performance to be either good or poor, and thus it is not a basis for mitigating the civil penalty.

2. The Licensee's statements regarding surveillance during radiographic operations may be relevant to violations of 10 CFR 20.207(a) that occur while a camera is being used to perform radiography provided that the violations do not result in the loss of a radioactive source or unnecessary radiation exposure to members of the general public. For example, in the case cited above, EA 92-162, the violation was classified at Severity Level IV based on the radiographer not exercising sufficient controls for a relatively brief period of time. However, this case does not involve a failure to maintain surveillance during radiographic operations, but in transporting licensed materials, and the NRC does not accept the argument that it is not always possible to comply with 10 CFR 20.207(a). When a failure to maintain surveillance results in the loss of radioactive material or unnecessary radiation exposure to a member of the general public, we believe such violations are appropriately classified at Severity Level III and that civil penalties should be assessed, if appropriate, after applying the civil penalty adjustment factors. The action taken by the NRC in this case is consistent with the Enforcement Policy and past practice.

3. A failure to block and brace that does not result in the loss of a radioactive source or in unnecessary radiation exposure to a member of the general public may be classified at a severity level lower than Severity Level III, and a civil penalty not considered. In this case, however, the failure to block and brace the radiography camera contributed to its falling from the Licensee's vehicle onto a public highway and being recovered by a member of the general public. The violations constitute a significant failure to control licensed material which posed a realistic potential for significant exposures to members of the public. Such violations are appropriately classified at Severity Level III in accordance with the Enforcement Policy. The action taken by the NRC in this case is consistent with the Enforcement Policy and past practice.

4. While the NRC does not regulate common carriers, the NRC does require its licensees to comply with United States Department of Transportation (DOT) regulations in order to ensure adequate control of licensed material. DOT regulations require blocking and bracing for certain materials in order to ensure that material is properly secured to prevent its loss during transport. Failure to block and brace constitutes a violation of 10 CFR 71.5(a). The overlap in NRC and DOT authorities does not affect the validity of this citation, which is consistent with NRC requirements. The NRC routinely cites licensees for violations of DOT regulations concerning transportation of radioactive material.

5. The payment of the inspection fee is a separate issue and has no bearing on the size of a civil penalty assessed for violations of NRC requirements. However, in this case, it appears that the inspection fee was assessed in error and will be refunded to the Licensee.

NRC Conclusion

The licensee has not provided any information that would give the NRC a basis for considering a reduction in the size of the proposed civil penalty. Consequently, the proposed civil penalty in the amount of $5,000 should be imposed by order.

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

MAY 20 1993

Docket No. 030-32240
License No. 11-27085-01
EA 93-082

Twin Falls Clinic and Hospital
ATTN: Brent Bodily, Administrator
666 Shoshone Street East
Twin Falls, Idaho 83301

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY - $5,000 (NRC INSPECTION REPORT NO. 30-32240/93-01)

This refers to the inspection conducted on March 17-18, 1993, at the Twin Falls Clinic and Hospital (TFC&H), Twin Falls, Idaho. A report describing the results of this inspection was issued on April 30, 1993. On May 7, 1993, you and other TFC&H representatives participated in a telephonic enforcement conference with the NRC to discuss the hospital's failure to develop and implement a Quality Management Program as required by 10 CFR 35.32. The NRC became aware of this violation prior to the inspection and issued a Confirmatory Action Letter on March 15, 1993, confirming TFC&H's commitment to comply immediately with the provisions of 10 CFR 35.32(a)(1). A list of the participants in the enforcement conference is enclosed (Enclosure 1).

As discussed during the enforcement conference, 10 CFR Part 35 was revised effective January 27, 1992. The revised rule required NRC medical licensees to establish and maintain a written Quality Management Program (QMP) to provide high confidence that byproduct material or radiation from byproduct material would be administered as directed by the authorized user. The QMP must include written policies and procedures and requires the use of a written directive prior to the administration to patients of iodine-131 in quantities greater than 30 microcuries.

NRC's inspection found that TFC&H had administered doses ranging from 6.4 to 23.8 millicuries of iodine-131 as sodium iodide to 14 patients between November 17, 1992 and March 15, 1993, and had not established and maintained a written QMP. In addition, the inspection found that the hospital had no equivalent procedures in place to otherwise achieve the intent of a QMP, i.e., to provide high confidence that byproduct material would be administered as directed by an authorized user.

During discussions with licensee personnel, the NRC inspector was informed that none of the TFC&H's responsible nuclear medicine personnel were aware of the QMP requirement. However, NRC's inspection determined that the nuclear medicine department's files contained NRC correspondence which informed TFC&H of the revision of 10 CFR Part 35 and the effective date of the rule. The

fact that no one in the department was aware of the QMP requirement does not relieve the hospital of its responsibility as an NRC license holder to be in compliance with existing requirements and to have mechanisms in place to become aware of and respond to changes in NRC requirements.

During the May 7, 1993 enforcement conference, TFC&H argued that the physician's written instructions on the patient's chart effectively met the NRC requirement to use written directives prior to administering iodine-131 therapy doses. During a follow-up telephone conference call on May 10, 1993, you and other members of TFC&H staff participated in a discussion regarding information which had been provided to the NRC subsequent to the enforcement conference. However, as acknowledged by the TFC&H participants in the May 10 conference call: 1) there were no procedures requiring that the information contained in the patient's chart be reviewed by the nuclear medicine technologist prior to administering iodine-131; and 2) the communications between the authorized user and the technologist were strictly oral. Therefore, what TFC&H had in place prior to its development of a QMP did not meet the objective of the regulation, i.e., to provide high confidence that byproduct material will be administered as directed by an authorized user.

The NRC considers your failure to implement a QMP a significant regulatory concern. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy) 10 CFR Part 2, Appendix C (Federal Register, Vol. 57, No. 32, February 18, 1992), this violation has been categorized at Severity Level III.

The NRC acknowledges that TFC&H took action to restore compliance following the discovery of this violation. TFC&H committed on March 11, 1993, to immediately comply with the provisions of 10 CFR 35.32(a)(1) and to submit a QMP within 30 days of that date. As indicated above, these commitments were described in a Confirmatory Action Letter issued by the NRC to TFC&H on March 15, 1993. TFC&H submitted a QMP to the NRC on March 29, 1993, which provides for, among other things, the use of written directives. In addition, you stated during the enforcement conference that a written prescription from the authorized user is provided to the radiology department where the nuclear medicine procedure will be performed. Finally, you stated that the hospital's Radiation Safety Committee will review documentation from NRC to ensure that TFC&H remains in compliance with changing requirements.

To emphasize the importance of implementing a QMP and the importance of maintaining an awareness of current requirements, I have been authorized to issue the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice) in the amount of $5,000 for the Severity Level III violation described above and in the Notice.

The base value of a civil penalty for a Severity Level III violation is $2,500. The civil penalty adjustment factors in the Enforcement Policy were considered and resulted in a $2,500 increase. In making this adjustment, the NRC: 1) increased the penalty by 50 percent of the base value because this

violation was discovered by the NRC; 2) decreased the penalty by 50 percent of the base value because TFC&H took immediate corrective action and action to prevent a recurrence of the violation; and 3) increased the penalty by 100 percent of the base value because TFC&H had received specific prior notice of this requirement and had failed to act on it. The other adjustment factors in Section VI.B.2 of 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 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.

Sincerely,

James L. Milhoan

James L. Milhoan
Regional Administrator

Enclosures:
1) List of enforcement conference attendees
2) Notice of Violation and Proposed Imposition of Civil Penalty

cc w/Enclosures:
State of Idaho

Enclosure 1

ENFORCEMENT CONFERENCE PARTICIPANTS

May 7, 1993, Enforcement Conference*

NRC Region IV representatives

L. Joseph Callan, Director, Division of Radiation Safety and Safeguards
William Fisher, Chief, Nuclear Materials Licensing Section, DRSS
Robert Brown, Radiation Specialist, NMLS, DRSS
William Brown, Regional Counsel
Russell Wise, Enforcement Specialist
Heather Astwood, Intern

Twin Falls Clinic & Hospital representatives

Brent Bodily, Administrator
Carole Ricks, M.D., Radiation Safety Officer
Billie Bartholomew, Staff Radiologic Technologist

*Conference conducted telephonically

Enclosure 2

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

Twin Falls Clinic & Hospital
Twin Falls, Idaho

Docket No. 030-32240
License No. 11-27085-01
EA 93-082

During an NRC inspection conducted on March 17-18, 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 35.32(a), which became effective January 27, 1992, 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 for, among other things, any administration of quantities greater than 30 microcuries of I-131.
>
> Contrary to the above, between November 17, 1992, and March 15, 1993, the licensee administered I-131 to 14 patients in quantities greater than 30 microcuries and did not establish and maintain a written quality management program to provide high confidence that byproduct material or radiation from byproduct material would be administered as directed by the authorized user.
>
> This is a Severity Level III violation (Supplement VI).
> Civil Penalty - $5,000

Pursuant to the provisions of 10 CFR 2.201, Twin Falls Clinic and 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 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 20th day of May 1993

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

AUG 06 1993

Docket No. 030-32240
License No. 11-27085-01
EA 93-082

Twin Falls Clinic & Hospital
ATTN: Mr. Brent Bodily
Administrator
666 Shoshone Street East
Twin Falls, Idaho 83301

SUBJECT: ORDER IMPOSING CIVIL MONETARY PENALTY - $5,000

This refers to your letter dated May 21, 1993, in response to the Notice of Violation and Proposed Imposition of Civil Penalty (Notice) sent to you by our letter dated May 20, 1993. Our letter and Notice described a violation of 10 CFR 35.32(a) regarding the requirement to establish and maintain a Quality Management Program (QMP).

To emphasize the importance of implementing a QMP and the importance of maintaining an awareness of current requirements, a civil penalty of $5,000 was proposed.

In your response, you admitted the violation but requested that the NRC reconsider the penalty based on the reasons you described in your letter. A summary of the reasons for your request for mitigation and the NRC's evaluation of them is contained in the enclosed Order.

After consideration of your request for mitigation of the penalty, we have concluded, for the reasons given in the Appendix to the enclosed Order Imposing Civil Monetary Penalty, that the full amount of the penalty should be imposed by Order. Accordingly, we hereby serve the enclosed Order on Twin Falls Clinic & Hospital, imposing a civil monetary penalty in the amount of $5,000. 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

Enclosure: As Stated

cc w/enclosure:
State of Idaho

UNITED STATES
NUCLEAR REGULATORY COMMISSION

In the Matter of	)	
	)	Docket No. 030-32240
TWIN FALLS CLINIC & HOSPITAL	)	License No. 11-27085-01
Twin Falls, Idaho	)	EA 93-082

ORDER IMPOSING CIVIL MONETARY PENALTY

I

Twin Falls Clinic & Hospital (Licensee) is the holder of NRC License No. 11-27085-01 issued by the Nuclear Regulatory Commission (NRC or Commission) on September 30, 1992. The license authorizes the Licensee to use various radioisotopes in accordance with the conditions specified therein. The license is due to expire on October 31, 1996.

II

An inspection of the Licensee's activities was conducted during March 17-18, 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 May 20, 1993. The Notice states the nature of the violation, the provisions of the NRC's requirements that the Licensee had violated, and the amount of the civil penalty proposed for the violation.

The Licensee responded to the Notice dated May 21, 1993. In its response, the Licensee admitted the violation which resulted in the proposed civil penalty, 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 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 $5,000 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 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 violation 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 6th day of August 1993

APPENDIX

EVALUATION AND CONCLUSION

On May 20, 1993, a Notice of Violation and Proposed Imposition of Civil Penalty (Notice) was issued for a violation identified during an NRC inspection. Twin Falls Clinic & Hospital responded to the Notice on May 21, 1993. The Licensee admitted the violation that resulted in the proposed civil penalty, but requested mitigation. The NRC's evaluation and conclusion regarding the Licensee's request are as follows:

Restatement of Violation

> 10 CFR 35.32(a), which became effective January 27, 1992, 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 for, among other things, any administration of quantities greater than 30 microcuries of I-131.
>
> Contrary to the above, between November 17, 1992, and March 15, 1993, the licensee administered I-131 to 14 patients in quantities greater than 30 microcuries and did not establish and maintain a written quality management program to provide high confidence that byproduct material or radiation from byproduct material would be administered as directed by the authorized user.
>
> This is a Severity Level III violation (Supplement VI).
> Civil Penalty - $5,000

Summary of Licensee's Request for Mitigation

In its May 21, 1993, letter, the Licensee admitted the above violation but requested mitigation of the penalty, citing the following reasons:

1. During a "licensing inspection" of the facility on January 14, 1992, less than two weeks before the QMP was to be submitted, the inspector endorsed the activities of Twin Falls Clinic & Hospital (TFC&H). No mention of 10 CFR 35.32(a) was made by the inspector, thus giving TFC&H a false impression of compliance with all NRC regulations.

2. TFC&H took immediate action to establish a written QMP upon discovery of the violation, and now requires the Radiation Safety Committee to review documentation from NRC to ensure that the Nuclear Medicine Department remains in compliance with changing requirements.

3. NRC Inspection Report 030-32240/93-01 identifies this violation as a level IV which would carry no associated penalty.

NRC Evaluation of Licensee's Request for Mitigation

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

1. The NRC has no record of any NRC inspection of TFC&H around the January 14, 1992 timeframe, and NRC cannot confirm TFC&H's assertion that NRC inspected TFC&H on January 14, 1992. The Licensee may be confused because the NRC issued a byproduct material license to TFC&H on January 14, 1992. In any event, TFC&H is responsible for ensuring that it is familiar with and complies with all NRC requirements applicable to their licensed activities, including the requirement to establish and maintain a written QMP.

2. The Enforcement Policy provides for up to 50 percent mitigation for prompt and extensive corrective action. Licensees are expected and required to take corrective actions for violations. The NRC gave TFC&H credit for its corrective actions in the May 20, 1993 Notice. As the letter transmitting the Notice indicated on Page 2 and 3, the penalty was decreased by 50 percent of the base value ". . . because TFC&H took immediate corrective action and action to prevent a recurrence of the violation."

3. The NRC has reviewed Inspection Report 030-32240/93-01 and is unable to find any reference to this violation of 10 CFR 35.32(a) being classified at Severity Level IV. Four additional violations were found during the inspection and were cited at Severity Level IV in a Notice of Violation issued with the inspection report. However, they were unrelated to the violation of 10 CFR 35.32(a) that was the subject of the enforcement conference and the basis for the civil penalty. The NRC has classified the violation at Severity Level III in accordance with the Enforcement Policy, Supplement VI, C.6. In this case, the example given for a Severity Level III violation is a substantial failure to implement the QMP as required by 10 CFR 35.32. TFC&H had no written QMP or procedures established to meet the objectives and requirements of 10 CFR 35.32.

NRC Conclusion

The NRC has concluded that the licensee has not provided any information that would give the NRC a basis for considering a reduction in the size of the proposed civil penalty. Consequently, the proposed civil penalty in the amount of $5,000 should be imposed.

UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

BEFORE THE ATOMIC SAFETY AND LICENSING BOARD

In the Matter of	)	
TWIN FALLS CLINIC & HOSPITAL	)	Docket No. 030-32240-CivP
(Byproduct Material License No. 11-27085-01)	)	EA 93-082

JOINT MOTION FOR ORDER APPROVING AND INCORPORATING STIPULATION FOR SETTLEMENT OF PROCEEDING AND SETTLING AND TERMINATING THE PROCEEDING

The NRC Staff and Twin Falls Clinic & Hospital, Twin Falls, Idaho (Twin Falls) hereby jointly move the Atomic Safety and Licensing Board for an order approving and incorporating the accompanying Stipulation for Settlement of Proceeding, executed by both parties, and settling and terminating this proceeding, pursuant to 10 C.F.R. § 2.203.

BACKGROUND

On August 6, 1993, the Staff issued an Order Imposing Civil Monetary Penalty (Civil Penalty Order) in the amount of $5,000 to Twin Falls. The Civil Penalty Order, which followed the issuance of a Notice of Violation and Proposed Imposition of Civil Penalty dated May 20, 1993 (Notice of Violation), was based on Twin Falls' failure to establish and implement a Quality Management Program as required by 10 C.F.R. § 35.32. The base penalty for this failure, as outlined in Appendix C to Part 2--General Statement of

Policy and Procedure for NRC Enforcement Actions, 10 C.F.R. Part 2, App. C, is $2,500. This base penalty was escalated 100%, bringing the penalty imposed to a total of $5,000, because the Staff concluded that Twin Falls had received specific prior notice of the requirement imposed by 10 C.F.R. § 35.32 and had failed to act on such notice. *See* 10 C.F.R. Part 2, App. C, Section VI.B.2.(d).

Twin Falls admitted in its response to the Notice of Violation that it had in fact failed to comply with the Quality Management Program regulation, due to "human error." However, Twin Falls took issue with the amount of the penalty imposed, and requested a hearing.

DISCUSSION

An inspection of Twin Falls was conducted in March 1993 concerning whether Twin Falls had implemented a Quality Management Program, which was required by regulation to be in place by January 1992. Following the inspection, which confirmed that Twin Falls had not implemented a Quality Management Program, the Staff issued the Notice of Violation to Twin Falls accompanied by a letter that stated in part that "NRC's inspection determined that the nuclear medicine department's files contained NRC correspondence which informed [Twin Falls] of the revision of 10 CFR Part 35 and the effective date of the rule." The letter continued to inform Twin Falls that the base penalty for failure to establish and implement a Quality Management Program was being

escalated because Twin Falls had received information concerning the Quality Management Program requirement, but had failed to act upon it.

Upon further investigation, the Staff has determined that while several notices and informational mailings regarding the Quality Management Program requirement were sent to Twin Falls from as early as July 1991 through 1992, the inspection of Twin Falls in March 1993 in fact did not reveal that Twin Falls had received that correspondence. In view of the Staff's determination, the statement in the letter transmitting the Notice of Violation that "NRC's inspection determined that [Twin Falls'] files contained NRC correspondence" was not accurate.

Given that the Notice of Violation was issued based on an erroneous understanding of the evidence gathered by the inspection, the Staff will reduce the penalty to the base amount. Twin Falls, acknowledging that it had in fact violated 10 C.F.R. § 35.32, is willing to pay the base penalty of $2,500; thus, the parties are willing to compromise and settle this matter by Twin Falls paying a total civil monetary penalty of $2,500. The attached Stipulation reflects this compromise.

The Staff believes that approval of the Stipulation and termination of this proceeding are in the public interest. Twin Falls has acknowledged the importance of implementing a Quality Management Program and has represented that it has taken steps to ensure that it will be in compliance with all current NRC regulatory requirements. It is the Staff's view that settlement of this matter does not foreclose the escalation of civil penalties by the Staff in other appropriate cases based on prior notice.

CONCLUSION

In consideration of the foregoing, the parties jointly move the Atomic Safety and Licensing Board for an order approving and incorporating the accompanying Stipulation for Settlement of Proceeding and settling and terminating this matter. A proposed order is attached in this regard.

Respectfully submitted,

Steven R. Hom
Counsel for NRC Staff

(See attached counterpart signature page)

Brent Bodily
Representative for Twin Falls
Clinic & Hospital

Dated at Rockville, Maryland
this 22nd day of November, 1993

CONCLUSION

In consideration of the foregoing, the parties jointly move the Atomic Safety and Licensing Board for an order approving and incorporating the accompanying Stipulation for Settlement of Proceeding and settling and terminating this matter. A proposed order is attached in this regard.

Respectfully submitted,

Steven R. Hom
Counsel for NRC Staff

Brent Bodily
Representative for Twin Falls
Clinic & Hospital

Dated at Rockville, Maryland
this day of November, 1993

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

SEP 30 1993

Docket 030-00503
License 42-00220-08
EA 93-217

Department of Veterans Affairs
Veterans Administration Medical Center (VAMC)
ATTN: Alan G. Harper, Medical Center Director
4500 South Lancaster Road
Dallas, Texas 75216

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY - $3,750 (NRC INSPECTION REPORT NO. 030-00503/93-01)

This refers to the inspection conducted on July 14, July 29-30, August 2-3, and August 6, 1993, at the Veterans Administration Medical Center (VAMC), Dallas, Texas. A report describing the results of this inspection, which focused on the VAMC's licensed radiation teletherapy program, was issued on September 3, 1993. On September 22, 1993, you and other VAMC representatives participated in an enforcement conference with the NRC in the NRC's Arlington, Texas office to discuss the VAMC'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).

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 NRC's inspection found that the VAMC had developed a QMP relative to its Cobalt-60 radiation teletherapy program, but that facility personnel had not strictly adhered to its requirements on numerous occasions between February 1992 when the QMP was implemented and May 1992 when the VAMC discontinued use of its Cobalt-60 teletherapy unit.

The NRC considers the VAMC's failure to follow the requirements of its QMP significant because: 1) the deviations from the requirements created the potential for misadministrations to occur; 2) in one case, a patient did receive significantly more radiation to the legs than was intended, although this is not believed to have had any impact on the patient; and 3) the NRC would have expected the VAMC to focus more attention on meeting these requirements in light of the enforcement action taken against the VAMC in October 1991 (EA 91-117). In that the VAMC is about to reactivate its Cobalt-60 teletherapy program, the NRC stresses the need for effective corrective actions for the violations discovered during this inspection.

The violations in Section I of the enclosed Notice of Violation and Proposed Imposition of Civil Penalty include various failures of the VAMC to implement a QMP that met the objectives of the NRC's rule. For some of these failures, there were multiple examples, indicating a programmatic weakness in the

implementation of the QMP. In addition, the VAMC did not ensure that radiation therapists were trained in the specific provisions of the facility's QMP. Thus, the VAMC's implementation of its QMP failed to meet the primary objective of the NRC regulation -- to provide high confidence that radiation from byproduct material would be administered as directed by an authorized user. 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 has classified the violations in the aggregate as a Severity Level III problem.

Although the NRC noted improvements during its recent inspections of the VAMC's teletherapy and broad-scope nuclear medicine programs, the results of this inspection do not indicate that the personnel responsible for ensuring compliance with all regulatory requirements of your teletherapy program were performing up to either your or the NRC's expectations. Thus, the NRC considers this aspect of your corrective actions most important. At the enforcement conference, the VAMC described the corrective actions that it had implemented or was planning to correct the violations and resolve the NRC's concerns. These included the development of a revised and improved QMP, the establishment of an administrative office for radiation therapy, significant personnel changes and additions, plans to conduct training of all personnel involved in implementing the program prior to the reactivation of the Cobalt-60 teletherapy unit, and the development of a system of reports to ensure that the QMP is being implemented in accordance with NRC regulations.

To emphasize the importance of ensuring compliance with this important regulatory requirement, particularly with respect to the VAMC's plans to reactivate its teletherapy program this fall, I have been authorized 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 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 and resulted in a $1,250 increase. While the NRC considered the VAMC's corrective actions worthy of mitigation, this was offset by escalation based on these violations having been identified by the NRC through its inspections, and on the NRC's view that these violations were an indicator of continued poor performance with respect to the management of the teletherapy program. The other adjustment factors were considered but 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 several violations that were discussed briefly at the enforcement conference but which were unrelated to the NRC's primary concern about the VAMC's QMP. These violations have been classified at Severity Level IV and have not been 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) Enforcement conference participants

cc w/Enclosures:

State of Texas Radiation Control Program Director

Milton Gross, M.D., Director
Nuclear Medicine Service (111E)
Department of Veterans Affairs
810 Vermont Avenue NW
Washington, D.C. 20420

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

Department of Veterans Affairs
Veterans Administration Medical Center
Dallas, Texas

Docket 030-00503
License 42-00220-08
EA 93-217

During an NRC inspection conducted on July 14, July 29-30, August 2-3, and August 6, 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 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 35.25(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, from February 18 to May 29, 1992, the licensee permitted the use of a cobalt-60 teletherapy unit by four radiation therapists, individuals working under the supervision of two authorized users, and had not instructed the radiation therapists in the licensee's written quality management program.

B. 10 CFR 35.32(a) requires, in part, that the 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.

Pursuant to 10 CFR 35.32(a)(1), the QMP must include written policies and procedures to meet the objective that, prior to administration, a written directive is prepared for any teletherapy radiation dose.

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 a radiopharmaceutical or radiation and containing certain information including for teletherapy the total dose, dose per fraction, treatment site, and overall treatment period.

Contrary to the above:

(1) in May 1992 the licensee's staff administered three doses of 180 centigray (cGy) each to a patient, using a cobalt-60 teletherapy unit, and no written directive was prepared prior to or following the treatment administration;

(2) for teletherapy treatments initiated between February 18 and April 20, 1992, the licensee's authorized users completed 16

written directives and revisions to written directives which were not signed by the authorized user(s);

(3) for teletherapy treatments initiated between February 18 and April 6, 1992, the licensee's authorized users completed 7 written directives and revisions to written directives which were not dated by the authorized user(s);

(4) for teletherapy treatments initiated between February 18 and May 29, 1992, the licensee's authorized users completed 44 written directives which did not specify the overall treatment period; and

(5) for teletherapy treatments initiated between February 18 and May 4, 1992, the licensee's authorized users completed 7 written directives and revisions to written directives which did not specify the treatment site.

C. 10 CFR 35.32(a) requires, in part, that the licensee establish and maintain a written QMP to provide high confidence that byproduct material or radiation from byproduct material will be administered as directed by the authorized user.

1. Pursuant to 10 CFR 35.32(a)(4), the QMP must include written policies and procedures to meet the specific objective that each administration is in accordance with a written directive.

The licensee's QMP, dated February 18, 1992, includes written policies and procedures to meet the objective that each administration of radiation was in accordance with a written directive as described below.

(a) The section titled "Dosimetry Calculations" requires, in part, that for manual dosimetry calculations, all calculations will be done by the simulation technologist and double-checked by the dosimetrist prior to treatment and that by the third day of treatment, either the physicist, chief technologist, or a staff technologist will perform a third check.

Contrary to the above, the license failed to maintain its QMP in that it failed to comply with the written policy described above. Specifically, for patient treatments completed during February 18 through May 29, 1992, double checks of dosimetry calculations were not always performed prior to treatment administration and in two cases, dosimetry calculations were never double-checked or reviewed a third time prior to the completion of treatment.

(b) The section titled "Verification of Written Directive" requires, in part, that the physicist/dosimetrist will check

both the written directive and the actual treatment to make sure they match during weekly chart evaluations.

Contrary to the above, the licensee failed to maintain its QMP in that it failed to comply with the written policy described above. Specifically, for three patient treatments completed during February through May 1992, the written directive and actual treatment were not checked through weekly chart evaluations during each week of treatment.

(c) The section titled "Quality Control Port Films" requires, in part, that all treatment volumes will be ported the first day treatment is delivered unless the physician specifies "no ports," and that port films will be taken on a weekly basis after the initial treatment to assure continuing treatment of the volume specified, or as specified by the physician.

Contrary to the above, the licensee failed to maintain its QMP in that it failed to comply with the written policy described above. Specifically, for approximately 30 patient treatments completed during February 18 through May 29, 1992, port films were not taken the first day of treatment or weekly throughout treatment and no other instructions were specified by the physician.

(d) The section titled "Treatment Verification" requires, in part, that when a patient is to complete treatment due to completion of the normal course of treatment, the patient is too ill to finish treatment, the patient is deceased, or another physician requests that the patient's treatment be discontinued, the information should be noted on the treatment sheet (a portion of the treatment chart) by drawing a red line and marking "STOP" under that specific treatment area and that if this is an early completion, the chart should be directed to the radiation oncologist so he/she is notified of the situation.

Contrary to the above, the licensee failed to maintain its QMP in that it failed to comply with the written policy described above. Specifically, several patient treatments initiated between February 18 and May 29, 1992, were discontinued prematurely and the information describing the completion, or discontinuation, of treatment was not noted on the corresponding treatment sheet, nor was a red line or "STOP" marked on the treatment record.

2. Pursuant to 10 CFR 35.32(a)(4) the QMP must include written policies and procedures to meet the specific objective that each administration is in accordance with a written directive.

Contrary to the above, in one case involving a treatment which was started on February 11, 1992, radiation was not administered in accordance with the authorized user's written directive in that for the final week of treatment, the written directive prescribed a weekly dose of 300 cGy for the anterior and posterior legs in 3 treatment fractions of 100 cGy each, and the licensee administered approximately 626 cGy to the anterior and posterior legs in three treatment fractions during the final week of treatment.

These violations represent a Severity Level III problem (Supplement VI). Civil Penalty - $3,750

II. Violations Not Assessed a Civil Penalty

A. 10 CFR 35.14 requires, in part, that a licensee notify the NRC by letter within 30 days when an authorized user or teletherapy physicist permanently discontinues performance of duties under the license.

Contrary to the above, on June 30, 1992, one of the licensee's authorized users permanently discontinued performance of duties under the license; two of the licensee's three teletherapy physicists had permanently discontinued performance of duties under the license in October 1991, and the third teletherapy physicist permanently discontinued performance of duties under the license on July 31, 1992; and as of August 6, 1993, a period in excess of 30 days, the licensee had not notified the NRC.

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

B. 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 radiation safety program.

Contrary to the above, from January 1991 until June 1992, the licensee's Radiation Safety Committee did not review, with the assistance of the Radiation Safety Officer, the licensee's radiation safety program.

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

C. 10 CFR 35.59(b) 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 4,000 curies of cobalt-60 for leakage between June 3, 1991, and May 29, 1992, a period in excess of 6 months, and no other interval was approved by the Commission or an Agreement State. The licensee had measured wipe samples taken from areas surrounding the source housing on January 28, 1992, but failed to evaluate the samples

for cobalt-60 contamination and had instead attempted to measure uranium contamination from the depleted uranium shielding using a gamma counting system.

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

D. 10 CFR 35.634(f) requires that a licensee retain a record of each monthly spot-check required by 10 CFR 35.634(a) and (d) for 3 years.

Contrary to the above, as of August 6, 1993, the licensee failed to retain records for monthly spot-checks performed in April and May 1992.

This is a repeat violation.

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

E. 10 CFR 35.51(d) requires, in part, that a licensee retain a record of each survey instrument calibration for 3 years.

Contrary to the above, as of August 6, 1993, the licensee did not retain a record of survey instrument calibrations performed since August 1991 on its Victoreen Model 507A survey instrument and two Victoreen Model 470A survey instruments, a retention period of less than 3 years.

This is a Severity Level V violation (Supplement VI).

Pursuant to the provisions of 10 CFR 2.201, the Department of Veterans Affairs, Veterans Administration Medical Center, Dallas, Texas, (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 30th day of September 1993

Enclosure 2

ENFORCEMENT CONFERENCE ATTENDANCE

LICENSEE: Department of Veterans Affairs, VAMC, Dallas, Texas

TIME/DATE: 1 p.m. CDT, September 22, 1993

MEETING LOCATION: NRC Region 4, Arlington, Texas

EA NUMBER: 93-217

VAMC representatives

Alan Harper, Director
Bill Cox, Assistant Director
Lynn Stockebrand, Administrator, Radiation Oncology
Wallace T. Ford, Assistant Safety Officer (Interim)
Maria Blum, Chief-elect, Nuclear Medicine
Shelly West, Chief Technologist
Greg McDaniel, Ph.D., Teletherapy Physicist
Birchmans John, Radiation Oncologist

NRC Region 4 representatives

John M. Montgomery, Deputy 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
Gilbert Guerra, Radiation Specialist, NMIS, DRSS
Jackie Burks, Health Physicist, NMLS, DRSS
Gary F. Sanborn, Regional Enforcement Officer

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

November 30, 1993

Docket No. 030-02146
License No. 21-13125-01
EA 93-263

Bronson Methodist Hospital
ATTN: Patrick Ludwig
President and CEO
252 East Lovell Street
Kalamazoo, MI 49007

Dear Mr. Ludwig:

SUBJECT: NOTICE OF VIOLATION
NRC INSPECTION REPORT NO. 030-02146/93001

This refers to the routine safety inspection conducted on March 25, 1993, at Bronson Methodist Hospital in Kalamazoo, Michigan, during which significant violations of NRC requirements were identified. The report documenting the inspection was mailed to you on July 22, 1993. You were offered an opportunity to further discuss the issues related to the violations at an enforcement conference but declined the invitation based upon your belief that all pertinent facts were known and had been discussed.

The inspection found, in part, that portions of your Quality Management Program (QMP), implemented in January 1992, were deficient. Specifically, the inspection determined that the QMP did not specify that the authorized user must sign written directives; that the QMP did not assure that changes to written directives were documented and signed by the authorized users; and that the QMP did not include procedures to conduct and evaluate representative samples of patient administrations. The NRC considered these to be significant failures.

As a result of these failures, on at least three separate occasions 150 millicuries of I-131 were administered to patients without written directives being signed by the authorized user; on at least one occasion a written directive was verbally changed and not formally documented; and a representative sample of patient administrations was not reviewed.

The NRC recognizes that the safety significance of these violations was minimal because in all of the cases the authorized

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

user personally administered the doses and no misadministrations occurred. We also are aware that as a matter of practice the authorized user prescribes and administers all radiopharmaceutical doses. Furthermore, although the written QMP was incomplete, the NRC observed that you had implemented many of the program requirements.

The root causes of the violations appeared to be a misunderstanding by the authorized user and the RSO as to the requirements of the QMP regulations. They noted for example that it was a common medical practice for physicians' nurses to obtain instructions from physicians and sign documents for them using the physicians' names and their own initials. They believed this was an acceptable practice for the QMP as well. Nevertheless, the staff recognizes that you took immediate corrective actions when the violations were identified and the authorized user stated that he will personally sign all written directives. You also promptly revised your QMP and resubmitted it to the NRC.

Regardless of the absence of any misadministrations, the QMP did not meet the objectives of the NRC requirements. 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. However, I have been authorized not to propose a civil penalty in this case for the following reasons: The base civil penalty was escalated 50% because it was identified by the NRC. It was also mitigated 50% because of your good corrective actions which included immediately changing your procedures to require the authorized user to sign all written directives and, as noted above, promptly resubmitting your revised QMP to the NRC. Furthermore, the civil penalty was mitigated 100% because of your good past performance. You have not had any misadministrations; the authorized user personally administers all therapeutic radiopharmaceuticals; and during the past five years you have had only five relatively minor violations. The other factors were considered and no other escalation or mitigation was considered appropriate. Therefore, on balance, the base civil penalty was 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.

Sincerely,

Edward H Jhaumm/for

John B. Martin
Regional Administrator

Enclosure:
Notice of Violation

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

Bronson Methodist Hospital
Kalamazoo, MI

Docket No. 030-02146
License No. 21-13125-01
EA 93-263

During an NRC inspection conducted on March 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, the violations are listed below:

A. 10 CFR 35.32(a)(1) requires, in part, that the licensee establish and maintain a quality management program which 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 of either sodium iodide I-125 or I-131.

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 a radiopharmaceutical or radiation and containing certain information including for any administration of quantities greater than 30 microcuries of either sodium iodide I-125 or I-131, the dosage.

Contrary to the above, as of March 25, 1993, the licensee's quality management program did not include a written procedure to meet the objective that a written directive be prepared prior to administering greater than 30 microcuries of either sodium iodide I-125 or I-131. Specifically, on December 18, 1992, December 29, 1992, and February 24, 1993, doses of 150 millicuries of I-131 were administered and the written directives were not signed by the authorized user. (01013)

B. 10 CFR 35.32(a)(1) requires, in part, that the licensee establish and maintain a written quality management program which must include written policies and procedures to meet the objective that, prior to administration, a written directive is prepared such that each administration is in accordance with the written directive. Footnote 1 states that a written revision to an existing written dirctive may be made for any diagnostic or therapeutic procedure provided that the revision is dated and signed by an authorized user prior to the administration of the radiopharmaceutical dosage.

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 a radiopharmaceutical or radiation and containing certain information including for any administration of quantities greater than 30 microcuries of either sodium iodide I-125 or I-131, the dosage.

Contrary to the above, as of March 25, 1993, the licensee failed to establish a quality management program that assured that a written revision to an existing written directive be made, dated or signed by an authorized user prior to the administration of a radiopharmaceutical dosage. Specifically, the licensee's policies and procedures did not include procedures for making written revisions to written directives. As a result, on March 18, 1993, a dated and signed written directive prescribed 12.0 millicuries of I-131. The authorized user verbally revised the dose to 10.69 millicuries which was administered by the authorized user on March 20, 1993, and the written directive was not revised, dated and signed by the authorized user. (01023)

C. 10 CFR 35.32(b) requires, in part, that the license develop procedures for and conduct a review to verify compliance with all aspects of the quality management program at intervals no greater than 12 months.

Contrary to the above, as of March 25, 1993, the licensee had not developed procedures for conducting a review to verify compliance with the licensee's quality management program. Specifically, the licensee failed to develop procedures for and to evaluate a representative sample of brachytherapy patient administrations. (01033)

This is a Severity Level III problem (Supplement VI).

Pursuant to the provisions of 10 CFR 2.201, Bronson Methodist 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 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 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 30th day of November, 1993

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION II
101 MARIETTA STREET, N.W., SUITE 2900
ATLANTA, GEORGIA 30323-0199

NOV 18 1993

Docket No. 030-29462
License No. 45-23645-01NA
EA 93-194

Department of the Navy
ATTN: RADM J. Walker, USN
Chairman
Navy Radiation Safety Committee
Chief of Naval Operations (N45)
Washington, D.C. 20350-2000

Gentlemen:

SUBJECT: NOTICE OF VIOLATION

This letter refers to an incident that you initially identified in June 1990 involving the falsification of personnel dosimetry records at the Naval Station Branch Clinic, San Diego, California. When you first reported this incident to us during the December 20, 1990 meeting of the Navy Radiation Safety Committee (NRSC), you advised us that a formal investigation was underway. In addition, the Navy had conducted reviews and investigations between April 1990 and November 1990 and determined that no overexposures had occurred. Subsequently, in light of the independence and expected scope of your investigation, we decided to allow you to complete it prior to determining any NRC action in this matter. We received a copy of the final investigation as contained in the Manual of the Judge Advocate General (JAGMAN) report in this case on May 10, 1993.

After reviewing the thoroughness of your investigation, NRC has determined not to conduct its own investigation. Based on the Navy's investigation, we have concluded that certain of your activities were in violation of NRC requirements, as specified in the enclosed Notice of Violation (Notice). This violation is of significant regulatory concern because the safe conduct of licensed activities depends on the character and integrity as well as the ability of the involved individuals. Consequently, the violation in the enclosed Notice has been categorized as Severity Level III.

In addition to the violation, the Navy investigation identified numerous weaknesses in your radiation safety program. There was an apparent lack of management oversight dedicated to this critical component of the Naval Hospital San Diego's and Navy radiation safety program. This lack of oversight was documented in the JAGMAN investigation report and in RADM Walker's letter to the NRC dated October 16, 1992, and was evidenced by: 1) the lack of time the Radiation Health Program Representative and his immediate supervisor had to carry out their duties; 2) the failure of the Naval Hospital's command to establish clear oversight responsibility for the

dosimetry program; and 3) the failure of audits to identify these problems (the Navy Dosimetry Center did not identify unreturned dosimeters in a timely manner).

We recognize that the U.S. Navy identified the violation, conducted a thorough investigation of the matter, although it could have been more timely, and implemented extensive corrective actions. The corrective actions included, among other things: (1) disciplining the responsible Radiation Health Program Representative and removing him from radiation safety activities; (2) replacing the Radiation Health Program Coordinator responsible for supervising local radiation health programs; (3) clarifying and strengthening the oversight and audit of the branch radiation health program by, in part, establishing direct full time responsibilities at each level; (4) establishing a dosimetry tracking system; (5) auditing the Navy Dosimetry Center; (6) directing all navy hospitals in the United States to review their branch radiation health programs, correct identified deficiencies and provide a status report to the Navy Bureau of Medicine; and (7) adding dosimetry program reviews of hospital radiological health programs to the audits conducted by the BUMED Inspector General.

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, in view of your positive actions in this case which included identification, investigation, and corrective actions taken as described above, I have been authorized after consultation with the Commission not to propose a civil penalty in this case. No further information is needed with regard to your corrective actions and no additional responses are required.

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. We will continue to review the effectiveness of your corrective actions during future NRC inspections.

Should you have any questions concerning this letter, please contact Mr. John Pelchat at (404) 331-5083.

Sincerely,

Stewart D. Ebneter
Regional Administrator

Enclosure:
Notice of Violation

cc w/encl:
Commonwealth of Virginia

NOV 18 1993

NOTICE OF VIOLATION

Department of the Navy
Washington, D.C.

Docket No. 030-29462
License No. 45-23645-01NA
EA 93-134

During an NRC review of the circumstances of a record falsification at the Naval Station Branch Clinic, San Diego, California, and a review of the U.S. Navy's Manual of the Judge Advocate General investigation report, 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 30.9(a) requires, in part, that information required by the Commission's regulations to be maintained by a licensee shall be complete and accurate in all material respects.

10 CFR 20.401(a) requires, in part, that each licensee maintain records showing the radiation exposures of all individuals for whom personnel monitoring is required under Section 20.202 of the regulations in this part.

Contrary to the above, between at least May 16, 1990 and September 24, 1990, accurate records were not maintained by the Department of the Navy in accordance with 10 CFR 20.401 for radiography personnel involved in licensed activities at the Shore Intermediate Maintenance Activity, San Diego, California. Specifically, these records were falsified by a Radiation Health Program Representative at the Naval Station Branch Clinic San Diego to indicate radiation dosimetry had been returned to the Navy Dosimetry Center for processing, when in fact, it had not.

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

Dated at Atlanta, Georgia
This 15th day of November 1993

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

October 16, 1993

Docket No. 030-02646
License No. 34-00398-08
EA 93-229

St. Luke's Medical Center
ATTN: Mr. Jeffrey Jeney
Vice President, Ancillary
Services
11311 Shaker Blvd.
Cleveland, OH 44104

Dear Mr. Jeney:

SUBJECT: NOTICE OF VIOLATION
(NRC INSPECTION REPORTS NO. 030-02646/93001;
030-17512/93001)

This refers to the inspection conducted on August 26 and 27, 1993, at Cleveland, Ohio, to review the circumstances surrounding the transportation of 250 millicuries of cesium-137 without the proper shipping requirements being met. The report documenting this inspection was sent to you by letter dated September 20, 1993. A significant violation of NRC requirements was identified during the inspection, and on September 28, 1993, we conducted a telephone enforcement conference to discuss the event. Attending the conference were you, Mr. Roy Caniano, Chief of the Nuclear Material Safety Branch, and other members of our respective staffs.

Briefly, on August 7, 1993, you delivered for transport by a common carrier 250 millicuries of cesium-137. This was packaged erroneously by your staff as limited quantity whereas it should have been packaged as type A quantity which would have required special handling and labeling. Because of the mistake, the proper specification packaging, shipping paper and certification, marking, and labeling as required by 49 CFR 173.421 were omitted.

Proper shipping papers and labeling 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. The events described above involve significant noncompliance with shipping paper and labeling requirements. Therefore, the violation has been classified as a Severity Level III violation.

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

The root cause of the violation appears to have been a misunderstanding between members of your staff and representatives of the U. S. Department of Transportation (DOT). You stated at the enforcement conference that you had called DOT and requested information on packaging requirements, and that you were informed that packaging the material as limited quantity was satisfactory as long as the dose rate anywhere on the package was less than 0.5 mrem per hour, which it was. We called DOT after the conference and confirmed that you had conferred with representatives of that agency. However, we were not able to verify what you were told; the representative acknowledges the call but could not recall the specifics of the conversation. Whether or not DOT offered a verbal interpretation of the requirement, licensees have the ultimate responsibility to comply with the regulations. Although we can empathize with your position, we can not condone it.

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 although we escalated the base civil penalty 50% because we identified the violation, we also mitigated it 50% for your corrective actions. These included a commitment not to ship any more radioactive material except by a licensed broker. We also mitigated the base civil penalty 100% for your past performance; in the last two routine inspections (in 1989 and 1991) you had only three severity level IV violations. Also, you have not had any violations involving the transportation of radioactive materials. We considered the other factors and no other escalation or mitigation was considered appropriate.

During the inspection, we also identified another violation for your failure to conduct weekly radiation surveys in areas where radiopharmaceuticals, or radiopharmaceutical waste is stored. This is classified as a Severity Level IV violation.

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. No. 96-511.

Sincerely,

John B. Martin
Regional Administrator

Enclosure:
Notice of Violation

NOTICE OF VIOLATION

St. Luke's Medical Center
Cleveland, Ohio

Docket No. 030-02646
License No. 34-00398-08
EA 93-229

During an NRC inspection conducted from August 26-27, 1993, violations 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 violations are listed below:

I. 10 CFR 71.5(a) requires in part that licensees who deliver licensed material to a carrier for transport, shall comply with the applicable requirements of the regulations appropriate to the mode of transport of the Department of Transportation (DOT) in 49 CFR 170-189.

49 CFR 173.421 states that radioactive materials whose activity per package does not exceed the limits specified in 49 CFR 173.423 are excepted from the specification packaging, shipping paper and certification, marking, and labeling requirements of the regulations provided certain conditions specified therein are met.

49 CFR 173.423, Table 7, lists materials package limits for radioactive materials and lists the limit for special form solids as 0.001(A1). 49 CFR 173.435 defines the A1 value for cesium-137 as 30 curies; therefore, the limited quantity for cesium-137 for exception to these transport regulations is 30 millicuries.

Contrary to the above, on April 7, 1993, the licensee delivered to a carrier for transport approximately 250 millicuries of cesium-137 (a non-exempt quantity) as special form without the required packaging, shipping paper and certification, marking, and labeling.

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

II. 10 CFR 35.70(b) requires that each licensee survey with a radiation detection survey instrument at least once each week all areas where radiopharmaceuticals or radiopharmaceutical waste is stored.

Contrary to the above, since April 1989 the licensee did not survey with a radiation detection survey instrument Room T-40, an area where radiopharmaceutical waste is stored.

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

Pursuant to the provisions of 10 CFR 2.201, St. Luke'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, 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 16th day of October 1993

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

October 27, 1993

Docket No. 030-31234
License No. 34-23416-01
EA 93-246

Summit Testing and Inspection Company
ATTN: John Malivuk, P.E.
Radiation Safety Officer
P. O. Box 2231
Akron, Ohio 44309

Dear Mr. Malivuk:

SUBJECT: NOTICE OF VIOLATION
(NRC INSPECTION REPORT NO. 030-31234/93001)

This refers to the special safety inspection conducted September 15 through 22, 1993, to review the circumstances surrounding an incident that occurred July 8, 1993, in which a soil moisture/density gauge, containing licensed material, was damaged. The report documenting the inspection was mailed to you by letter, dated October 6, 1993. Violations of NRC requirements were identified during the inspection, and on October 12, 1993, an enforcement conference was held by telephone.

On July 8, 1993, you informed us via telephone, that earlier in the day a Troxler Model 3411B soil moisture/density gauge containing licensed materials (sealed sources of nominally 8.4 millicuries of cesium-137 and 40 millicuries of americium-241) was damaged at a construction project in Copley, Ohio. The inspection disclosed that the authorized user had left the gauge unattended, walking approximately 150 feet from the device in order to inspect a concrete placement. A bulldozer, operating in the area of the gauge, ran over and damaged the gauge. As a result, the source rod was broken and the Cs-137 source capsule was dislodged. Subsequently, you recovered the gauge and its sources without incident. No contamination was identified on the bulldozer or in the area of the incident. Leak tests of the gauge and the sealed sources were also negative.

Subsequent to the event and during an internal review of your program, you identified a second violation of NRC requirements, in that, all required periodic sealed source leak tests had not been completed. Following identification of the issue, you performed the required leak tests with negative results.

The violations identified during the inspection are fully described in the enclosed Notice of Violation (Notice). The

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

first violation was considered significant because the technician failed to secure or maintain constant surveillance of the gauge while at a temporary job site. The violation demonstrated a significant failure to control licensed material and was 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 second violation represented a repeat of a previous violation and was categorized at Severity Level IV.

The root causes of the violations and your subsequent corrective actions were discussed during the October 12, 1993, telephone enforcement conference. The major factors contributing to the first violation were attributed to human error and the technician's failure to understand and implement all aspects of the radiation safety program. The second violation appeared to result primarily from your ineffective corrective actions to a previous similar violation. Specifically, your previous program for ensuring the timely completion of sealed source leak tests was not well documented nor discussed with all gauge users.

The NRC recognizes that your corrective actions consisted of, but were not limited to, remedial training of all the licensee users on their responsibilities while using gauges, development and distribution of an employee disciplinary policy specifically addressing the consequences of leaving a gauge unattended, and implementation of a new system to track and document the completion of the required periodic leak testing of sealed sources.

In accordance with the Enforcement Policy a civil penalty is considered for 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 proposed. Full mitigation of the civil penalty was appropriate because of your prompt and comprehensive corrective actions (as described above) and your good past performance. The other escalation and mitigation factors were considered and no adjustment was deemed necessary.

The second violation, involving your failure to ensure that routine leak tests were performed for sealed sources, was determined to be a repeat violation. The violation did not meet the NRC's policy for the use of enforcement discretion because it should have been prevented by your corrective actions for the previous violation. Future similar violations could result in

escalated enforcement action, including the issuance of 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 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

See Attached Distribution

NOTICE OF VIOLATION

Summit Testing and Inspection Company
Akron, Ohio

Docket No. 030-31234
License No. 34-23416-01
EA 93-246

During an NRC inspection conducted from September 15 through 22, 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 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 8, 1993, licensed material consisting of 8.4 millicuries (nominal) of cesium-137 and 40 millicuries (nominal) of americium-241 as sealed sources contained in a Troxler moisture/density gauge located at a construction site in Copley, Ohio, an unrestricted area, was not under constant surveillance and immediate control of the licensee. Specifically, at approximately 2:30 p.m., an authorized user left the gauge unattended and the gauge was run over and damaged by a construction vehicle. (01013)

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

B. Condition 12.A.(1) of License No. 34-23416-01 requires, in part, that sealed sources containing byproduct material be tested for leakage and/or contamination at intervals not to exceed six months.

Contrary to the above, two moisture/density gauges, containing 8.4 millicuries (nominal) of cesium-137 and 40 millicuries (nominal) of americium-241 as sealed sources, were not tested for leakage and/or contamination at intervals not to exceed six months. Specifically, sealed sources contained in Gauge Serial No. 17399 were not tested from June 24, 1992 to August 10, 1993, and sealed sources in Gauge Serial No. 19352 were not tested from September 9, 1992 to August 10, 1993, intervals exceeding six months. (01014)

This is a repeat violation.
This is a Severity Level IV violation (Supplement VI).

Pursuant to the provisions of 10 CFR 2.201, Summit Testing and Inspection 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 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 27th day of October 1993

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

DEC 07 1993

Docket No. 030-19066
License No. 06-19661-01MD
EA No. 93-286

Mr. Frank M. Comer, Program Director
Syncor Corporation
628 Hebron Avenue, Building D
Glastonbury, Connecticut 06033

Dear Mr. Comer:

SUBJECT: NOTICE OF VIOLATION
(NRC Inspection Report No. 030-19066/93-001)

This letter refers to the NRC inspection conducted on November 2, 1993, at your facility in Glastonbury, Connecticut, of activities authorized by NRC License No. 06-19661-01MD. The inspection report was sent to you on November 19, 1993. During the inspection, three apparent violations of NRC requirements were identified. On November 24, 1993, an enforcement conference was conducted with you and members of your staff by telephone, to discuss the apparent violations, their causes and your corrective actions. A copy of the Enforcement Conference Report is enclosed.

The most significant violation identified during the inspection involved an instance during which proper security and control over licensed radioactive material was not maintained. As a result, the material was improperly disposed of in the trash. On July 27, 1993, the State of Connecticut's Department of Environmental Protection contacted the NRC and you about a radiation detector alarming at a waste incinerator facility, with the waste attributed to your facility. You immediately recovered the waste and determined that it was contaminated with iodine-131 with an exposure rate of about 17 milli-Roentgen per hour at contact with the bag. Your investigation determined that the bag containing the radioactive waste was inadvertently discarded when a janitor, who was not appropriately instructed on restricted area cleaning, removed the waste held for decay-in-storage in the iodine compounding room.

You stated at the enforcement conference that your analysis indicated approximately 10 microcuries of iodine-131 would result in a 17 milli-Roentgen per hour contact dose, which was a revision from your prior estimate of 10 millicuries. Although no radioactive incident involving exposure or contamination of the public occurred, the NRC is nevertheless concerned that the release of the radioactive material in the public domain created such a potential. Therefore, this violation has been categorized at Severity Level III.

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

You indicated that after the event the appropriate janitorial staff were instructed in restricted area procedures to assure that the radioactive trash stored in properly marked containers was not removed. Arrangements were made to allow only these janitorial staff to access the facility restricted areas. The pharmacy staff was also trained to allow only the inserviced janitorial staff to have access to the restricted areas. Additionally, all radioactive trash, held for decay, is being marked with a distinctive radioactive symbol to distinguish this trash from ordinary trash.

Notwithstanding these actions, to emphasize the need to maintain adequate control over licensed material at all times, and to assure that your corrective actions are long lasting, I have been authorized to issue the enclosed Notice of Violation (Notice) for the Severity Level III violation. 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, because of your prompt and comprehensive corrective actions and your prior good performance, no civil penalty is being assessed.

The other violations identified in the inspection included your failure to hold radioactive trash less than ten half-lives prior to disposal as required by the license, and transfer of NRC licensed material to an authorized client at an unauthorized location of use. These violations are also included in the Notice and are classified at Severity Level IV. The first violation is of particular concern to the NRC because of its repetitive nature. At the enforcement conference you discussed the root causes and your corrective actions for preventing recurrence of this violation, which included issuing a corporate directive to alert the involved personnel, generating a training document, and providing the specific training to your staff, and additional changes in your waste management program including separation and holding of waste for twelve half-lives. As to the second violation, you indicated that you: (1) are currently verifying all the addresses of your client licensees to ensure the address contained in your system is the same as the one on the license, (2) have provided training to the drivers performing radiopharmaceutical delivery to ensure they deliver to the client's authorized use location, and (3) are providing training to increase the awareness of pharmacy personnel regarding the need to verify the delivery address.

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'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,

Thomas T. Martin
Regional Administrator

Enclosures:
1. Notice of Violation
2. Enforcement Conference Report

ENCLOSURE 1

APPENDIX A

NOTICE OF VIOLATION

Syncor Corporation
Glastonbury, Connecticut

Docket No. 030-19066
License No. 06-19661-01MD
EA No. 93-286

During an NRC inspection conducted on November 2, 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 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 27, 1993, licensed material consisting of iodine-131 located in the iodine compounding 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).

IFS Code 01013

B. Condition 19 of License No. 06-19661-01MD permits the 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 holds such byproduct material for decay a minimum of ten half-lives.

Contrary to the above, on September 30, 1993, the licensee disposed of iodine-131 waste in ordinary trash without first holding this material for decay a minimum of ten half-lives.

This is a repetitive Severity Level IV violation (Supplement VI).

IFS Code 02014

C. 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 November and December, 1992, the licensee transferred technetium-99m, byproduct material, to Cameo Diagnostic Centre Inc., a person who was not authorized to receive such byproduct material under the terms of a specific license issued by the Commission or Agreement State. Specifically, in November and December, 1992, the licensee transferred byproduct material to Cameo Diagnostic Centre Inc., at 155 Maple Street, Springfield, Massachusetts, an unauthorized location of use, since the Cameo Diagnostic Centre, Inc. license only authorized use at the time at 110 Maple Street, Springfield, Massachusetts.

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

IFS Code 03014

Pursuant to the provisions of 10 CFR 2.201, Syncor Corporation 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 7th day of December 1993

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

OCT 07 1993

Docket No. 030-14311
License No. 29-00968-02
EA No. 93-225

Mr. Paul Matteucci, Plant Manager
Wheaton Glass Company
Third and G Streets
Millville, New Jersey 08332

Dear Mr. Matteucci:

SUBJECT: NOTICE OF VIOLATION (NRC Inspection Report No. 030-14311/93-001)

This letter refers to the reactive NRC safety inspection conducted on August 24 and September 3, 1993, at your facility in Millville, New Jersey, of activities authorized by the NRC License No. 29-00968-02. The inspection was conducted to review the circumstances associated with a radiological incident involving the partial loss of shielding of a 5 curie cesium-137 source within a Kay-Ray gauging device at your facility. During the inspection, the NRC also reviewed two violations related to the event that were identified by your staff and reported to the NRC. The inspection report was provided to you on September 17, 1993. On September 28, 1993, an enforcement conference was conducted with you and members of your staff to discuss the event, the related violations, their causes and your corrective actions. A report on this enforcement conference is enclosed (Enclosure 2).

The loss of shielding for the source occurred on August 21, 1993, when the source housing of the gauge melted while mounted on the external surface of a glass furnace. The gauge was used as a process control device to measure glass levels within the furnace. The lead shielding apparently melted when a power outage occurred at the facility, and you utilized natural gas in a "high-fire" condition to ensure that the glass would not solidify in the furnace during the outage. Replaceable bricks had been removed from the furnace a few days earlier to test a non-nuclear level device. However, instead of replacing the bricks when the testing was completed, a piece of fiberboard was placed in the opening, and that fiberboard failed during the "high-fire" condition, thereby leading to excessive temperatures outside the furnace and resultant melting of the lead shielding.

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

The Chief Engineer, standing approximately ten feet from the gauge noticed that some lead had accumulated on a mounting bracket adjacent to the gauge. Although he informed the Plant Engineer, Electrical Engineer, and the Furnace Engineer on that date, a decision was made that no action needed to be taken, and the Radiation Safety Officer (RSO) was not notified until two days later after the Chief Engineer noted that there appeared to be more lead on the mounting bracket and adjacent areas, including the floor, than had been originally noticed on August 21, 1993.

The NRC is very concerned that notwithstanding the damage that existed to the lead shielding of the source on August 21, 1993, your emergency procedures were not followed for approximately two days. These procedures required you to immediately rope off the area around the source housing, remove all unauthorized personnel from the area, and notify the electrical shop supervisor who in turn would contact the RSO. Failure to promptly notify the RSO resulted in the continued existence of radiation levels in excess of the regulatory limit in the vicinity of the particular furnace. If an individual had been continuously present in that unrestricted area, the individual could have received a dose in excess of two millirem in any one hour or 100 millirem in any seven consecutive days. More specifically, the exposure rate near the damaged gauge was approximately 200 mR/hr at four feet from the gauge, resulting in unnecessary radiation exposure to several individuals who passed through that area during those two days.

While the maximum exposure received by any individual was approximately 200 millirem, and this did not exceed any regulatory limit for personnel exposure, the failure to initiate promptly the emergency procedures, and the existence of excessive radiation levels in an unrestricted area, constitute violations of NRC requirements that created a substantial potential for an exposure in excess of the regulatory limit to several individuals at the facility. Given the levels that existed, the two violations are categorized 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 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) immediate action to rope off the area and eliminate the existing radiological threat; (2) prompt and appropriate removal of the damaged gauge by a contractor; (3) training of individuals regarding the event, including the importance of recognizing any potential problems with the devices; and (4) issuance of a memorandum to your staff which stated that daily inspections of nuclear gauges are now required, and immediate notification to appropriate personnel is also required if any lead leakage is noted. While the immediate actions were prompt and extensive, some of these actions could have been initiated in a more timely manner, such as your proposed training of personnel, as well as the issuance of the memorandum sent to the staff, which was not done until approximately thirty days after the event.

OCT 07 1993

Normally, a civil penalty is issued for such violations 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; (2) changes to the facility appropriately consider the potential radiological impacts from the changes; and (3) emergency procedures are promptly initiated and followed whenever a radiological incident occurs at the facility. 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 event and the violations, your corrective actions, and your prior good enforcement history. Nonetheless, the NRC emphasizes that any similar violations in the future could result in escalated enforcement action, including the issuance of 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. In your response, you should also verify that the proposed training of personnel, included training on your emergency response procedures, had been completed. 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,

William T. Martin for

Thomas T. Martin
Regional Administrator

Enclosures:
1. Notice of Violation
2. Enforcement Conference Summary Report

ENCLOSURE 1

NOTICE OF VIOLATION

Wheaton Glass Company
Millville, New Jersey 08332

Docket No. 030-14311
License No. 29-00968-02
EA 93-225

During an NRC inspection conducted on August 24 and September 3, 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 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 which, if an individual were continuously present in the area, could result in his receiving a dose in excess of two millirems in any one hour or 100 millirems in any seven consecutive days.

Contrary to the above, between August 21 to 23, 1993, the licensee allowed the existence of radiation levels in the vicinity of the "P" furnace of the licensee's facility, an unrestricted area, such that if an individual were continuously present in the area, he could have received a dose in excess of two millirems in any one hour or 100 millirems in any seven consecutive days. Specifically, exposure rates near a damaged Kay-Ray gauge containing a 5 curie cesium-137 source were approximately 200 mR/hr at four feet from the gauge.

IFS Violation Code 01013

B. Condition 17 of License No. 29-00968-02 requires that licensed material be possessed and used in accordance with statements, representations and procedures contained in an application dated August 5, 1988.

Item No. 9 of the August 5, 1988 application requires that the licensee's emergency procedure be followed in the event of an emergency involving the gauge. Step 1 of the emergency procedure states that this procedure will apply whenever there is major damage to the Kay-Ray source housing or its lead shielding. Step 2 requires immediately roping off the area around the source housing, and removing all unauthorized personnel from that area. Step 3 requires notifying the electrical shop supervisor, who will contact the Radiation Safety Officer (RSO) and distribute the survey meter(s) and personnel dosimeters to the qualified individuals responding to the problem.

Contrary to the above, on August 21, 1993, the licensee did not follow their emergency procedures in an emergency when major damage to the Kay-Ray lead shielding was identified by the licensee. Specifically, when an accumulation of lead was noticed outside the gauge source housing located on the "P" furnace, the area was not immediately roped off; all unauthorized personnel were not removed from the area; and the RSO was not notified.

IFS Violation Code 01023

These violations are classified in the aggregate at Severity Level III (Supplements IV and VI).

Pursuant to the provisions of 10 CFR 2.201, Wheaton Glass 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 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 Act, 42 U.S.C. 2232, this response shall be submitted under oath or affirmation.

Dated at King of Prussia, Pennsylvania
this 7th day of October 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

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

OCT 27 1993

IA 93-002

Mr. George D. Shepherd
(HOME ADDRESS DELETED
UNDER 10 CFR 2.790)

Dear Mr. Shepherd:

SUBJECT: ORDER PROHIBITING INVOLVEMENT IN CERTAIN NRC-LICENSED ACTIVITIES (EFFECTIVE IMMEDIATELY)

The enclosed Order is being issued because of your violations of 10 CFR §§ 30.10, 34.33(a), 34.42, and 34.43(b) of the Commission's regulations as described in the Order. Based on an investigation conducted by the NRC's Office of Investigations, the NRC staff has determined that you deliberately failed to wear an alarm ratemeter, failed to post boundaries, and failed to perform radiation surveys of the exposure device and guide tube, during the performance of radiographic operations on July 1, 1992, in violation of NRC requirements. Also, you encouraged a new assistant radiographer to discontinue using his alarm ratemeter. In addition to the Order, I have enclosed a copy of the synopsis of the investigation.

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 with your address deleted 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: All Agreement States
Western Stress, Inc.
SECY

UNITED STATES
NUCLEAR REGULATORY COMMISSION

In the Matter of) IA 93-002

George D. Shepherd)
)

ORDER PROHIBITING INVOLVEMENT IN CERTAIN
NRC-LICENSED ACTIVITIES
(EFFECTIVE IMMEDIATELY)

I

George D. Shepherd has been employed as a radiographer in the field of industrial radiography since 1980. On approximately June 15, 1992, Mr. Shepherd was hired by Western Stress, Inc. (WSI or Licensee). WSI holds Materials License No. 42-26900-01 issued by the Nuclear Regulatory Commission (NRC or Commission) pursuant to 10 CFR Parts 30 and 34. The license authorizes the conduct of industrial radiography activities in accordance with the conditions specified therein.

II

On July 1, 1992, NRC conducted a field inspection of WSI at the Hess Oil Refinery in St. Croix, U.S. Virgin Islands. During this inspection, Mr. Shepherd, who was the lead radiographer, and an assistant radiographer were observed performing radiographic operations without alarm ratemeters as required by 10 CFR 34.33(a). The violation was observed by the inspector as he entered the immediate vicinity of the work area. When Mr. Shepherd and the assistant radiographer observed the inspector, the assistant radiographer went to the work vehicle to get the

alarm ratemeters. The inspector also observed that the radiographers had not posted the restricted area during radiographic operations, as required by 10 CFR 34.42, nor had Mr. Shepherd performed a survey of the exposure device and source guide tube following each radiographic exposure, as required by 10 CFR 34.43(b). As a result of this inspection, a Notice of Violation and Proposed Imposition of a Civil Penalty was issued to WSI on July 30, 1992.

Between July 29, 1992 and April 30, 1993, an investigation was conducted by the NRC Office of Investigations (OI) to determine whether the conduct of Mr. Shepherd and the assistant radiographer was willful. Based on that investigation the NRC staff concludes that Mr. Shepherd deliberately and repeatedly violated the NRC requirement to wear an alarm ratemeter during radiographic operations and according to the testimony of the assistant radiographer, encouraged the assistant radiographer to discontinue using his alarm ratemeter. In addition, based on the investigation, the NRC staff concludes that on July 1, 1992, Mr. Shepherd deliberately violated the NRC posting and surveying requirements. Specifically, he was aware of the regulatory requirements to rope off and conspicuously post the area in which radiographic operations were being performed and to perform a radiation survey of the entire circumference of the exposure device and the source guide tube after each radiographic

exposure, and yet failed to meet the regulatory requirements of 10 CFR 34.43 and 10 CFR 34.42.

III

Based on the above, Mr. Shepherd engaged in deliberate misconduct which caused the licensee to be in violation of 10 CFR 34.33(a), 34.43, 34.42, and 30.10. The NRC must be able to rely on the Licensee and its employees to comply with NRC requirements, including the requirements to wear alarming ratemeters, to rope off and post the area of radiographic operations, and to perform post-exposure surveys. Compliance with NRC requirements as to posting and roping of radiation areas is necessary to protect members of the public, including licensee employees, from potential danger. Performance of a survey of the radiographic device after each exposure is an important safety requirement to prevent overexposures. Mr. Shepherd's deliberate actions in causing the Licensee to violate these requirements have raised serious doubts as to whether he can be relied on to comply with NRC requirements. Mr. Shepherd's deliberate misconduct cannot and will not be tolerated.

Consequently, I lack the requisite reasonable assurance that licensed activities can be conducted in compliance with the Commission's requirements and that the health and safety of the public will be protected if Mr. Shepherd were permitted at this

time to perform radiographic operations in any area where the NRC maintains jurisdiction. Therefore, the public health, safety and interest require that Mr. Shepherd be prohibited from performing or supervising licensed activities for either an NRC licensee or an Agreement State licensee (operating in areas of NRC jurisdiction in accordance with 10 CFR 150.20) for a period of two years from the date of this order. In addition, for a period of two years commencing after the two-year prohibition, Mr. Shepherd should be required to notify the NRC of his employment by any person (including any entity) engaged in licensed activities under an NRC or Agreement State license (where the work is performed in areas under NRC jurisdiction), so that appropriate inspections can be performed. During that same two-year period, Mr. Shepherd should also be required to provide a copy of this Order to any person employing him and who holds an NRC license or an Agreement State license and performs licensed activities in NRC jurisdiction. 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 effective immediately.

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, 10 CFR 30.10, and 10 CFR 150.20, IT IS HEREBY ORDERED, EFFECTIVE IMMEDIATELY, THAT:

1. George D. Shepherd is prohibited for two years from the date of this Order from performing, supervising, or engaging in any way in licensed activities under an NRC license, or an Agreement State license when activities under that license are conducted in areas of NRC jurisdiction pursuant to 10 CFR 150.20.

2. For a period of two years commencing after the expiration of the two-year period of prohibition, George D. Shepherd shall notify the Regional Administrator, NRC Region II, 101 Marietta Street, NW, Suite 2900, Atlanta, Georgia 30323, at least five days prior to the performance of licensed activities, of his being employed to perform or supervise such licensed activities. Licensed activities include those performed for an NRC licensee or an Agreement State licensee doing work in areas of NRC jurisdiction. The notice shall include the name, address, and telephone number of the NRC or Agreement State licensee and the location where the licensed activities will be performed. In addition, for that same period of two years commencing after completion of the two-year period of prohibition, Mr. Shepherd shall provide a copy of this Order to his employer prior to performing licensed activities in areas of NRC jurisdiction

for any employer holding either an NRC license or an Agreement State license.

The Regional Administrator, NRC Region II, may, in writing, relax or rescind any of the above conditions upon demonstration by Mr. Shepherd of good cause.

V

In accordance with 10 CFR 2.202, George D. Shepherd 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 30 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 George D. Shepherd or any 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 II, 101

Marietta Street, N. W., Suite 2900, Atlanta, Georgia 30323, and to George D. Shepherd if the answer or hearing request is by a person other than George D. Shepherd. If a person other than George D. Shepherd 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 George D. Shepherd 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), George D. Shepherd, 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 processing. 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 27th day of October 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.4

2. TITLE AND SUBTITLE

Enforcement Actions: Significant Actions Resolved
Quarterly Progress Report
October - December 1993

3. DATE REPORT PUBLISHED

MONTH	YEAR
March	1994

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, D.C. 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 (October - December 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 Evaluation

13. AVAILABILITY STATEMENT

Unlimited

14. SECURITY CLASSIFICATION

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