NUREG–0940
Vol. 11, No. 2

Enforcement Actions: Significant Actions Resolved

Quarterly Progress Report
April–June 1992

U.S. Nuclear Regulatory Commission

Office of Enforcement

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Available from

Superintendent of Documents
U.S. Government Printing Office
Post Office Box 37082
Washington, D.C. 20013-7082

A year's subscription consists of 4 issues for
this publication.

Single copies of this publication
are available from National Technical
Information Service, Springfield, VA 22161

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Manuscript Completed: August 1992
Date Published: August 1992

Office of Enforcement
U.S. Nuclear Regulatory Commission
Washington, DC 20555

ABSTRACT

This compilation summarizes significant enforcement actions that have been resolved during one quarterly period (April - June 1992) and includes copies of letters, Notices, and Orders sent by the Nuclear Regulatory Commission to licensees with respect to these enforcement actions. It is anticipated that the information in this publication will be widely disseminated to managers and employees engaged in activities licensed by the NRC, so that actions can be taken to improve safety by avoiding future violations similar to those described in this publication.

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ENFORCEMENT ACTIONS: SIGNIFICANT ACTIONS RESOLVED

April - June 1992

INTRODUCTION

This issue of NUREG 0940 is being published to inform NRC licensees about significant enforcement actions and their resolution for the second quarter of 1992. 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.

With this issue an additional part is being included in NUREG-0940. In promulgating the regulations concerning deliberate misconduct by unlicensed persons (56 FR 40664, August 15, 1991), the Commission directed that a list of all persons who are currently the subject of an order prohibiting their employment in licensed activities be made available with copies of the Orders. Part III of this volume contains that information. It will be included for each person as long as the order remains effective. The Commission believes this information may be useful to licensees in making employment decisions.

A brief summary of each significant enforcement action that has been resolved in the second quarter of 1992 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 an action taken against an individual.

I. REACTOR LICENSEES

A. Civil Penalties and Orders

Carolina Power and Light Company, Raleigh, North Carolina (Brunswick Steam Electric Plant) Supplement I, EA 92-024

A Notice of Violation and Proposed Imposition of Civil Penalty in the amount of $100,000 was issued March 24, 1992 to emphasize the importance of ensuring that proceduralized work controls are adequate. The action was based on inadequate work control related to the emergency diesel generators. The procedure used to degrease the EDG in preparation for painting was inadequate in that it specified use of a degreasing agent which left a residue that set up and prevented operation of the fuel racks. Though the fuel racks were required to be lubricated after cleaning, no signoff step was provided. Consequently, after being notified that the EDG was ready to be lubricated, maintenance personnel decided to postpone it until after the upcoming weekend. Two days later, the EDG received a valid start signal and failed. The base civil penalty was escalated by 100% for the Licensee's poor past performance. The licensee responded and paid the civil penalty on April 23, 1992.

Consumers Power Company, Jackson, Michigan (Palisades Nuclear Generating Plant) Supplement I, EA 92-074

A Notice of Violation and Proposed Imposition of Civil Penalty in the amount of $75,000 was issued June 2, 1992 to emphasize the need for implementing adequate management controls to ensure that independent evaluations are promptly reviewed to assess their impact on equipment operability. The action was based on a violation involving the licensee's failure to establish measures to promptly identify and correct significant EQ nonconformances following receipt of a contractor's report reviewing EQ equipment. The civil penalty was escalated by 50% for poor past performance in the EQ area. The licensee paid the civil penalty on June 12, 1992.

Florida Power Corporation, Crystal River, Florida (Crystal River, Unit 3) Supplement I, EA 92-002

A Notice of Violation and Proposed Imposition of Civil Penalty in the amount of $50,000 was issued April 9,

1992 to emphasize that the NRC considers serious the lack of adequate command, control and communications on the part of the control room staff that permitted the bypassing of the Engineered Safety Actuation System (ESFAS). The action was based on the inadequate performance of the licensed members of the control room staff which led to bypassing the ESFAS, thereby rendering the high pressure injection system unavailable during the existence of a valid demand signal. The licensee responded and paid the civil penalty on May 8, 1992.

Iowa Electric Light, Cedar Rapids, Iowa
(Duane Arnold Energy Center) Supplement IV, EA 92-056

A Notice of Violation and Proposed Imposition of Civil Penalty in the amount of $12,500 was issued May 1, 1992 to emphasize the need for stringent radiation protection controls to prevent a substantial potential for an exposure in excess of 10 CFR Part 20 limits. The action was based on health physics violations during an ISI inspection of the recirculation system riser that had a significant potential for overexposure to two contract workers. The violations involved the failure to conduct an adequate survey of the work site and the failure to provide adequate training for the contract workers regarding operation of electronic dosimeters and the response to the alarms. The civil penalty was mitigated 25% for licensee identification of the root causes of the self-identifying event and an additional 50% for the licensee's prompt and comprehensive corrective action. The licensee responded and paid the civil penalty on May 26, 1992.

David M. Manning, New York Power Authority, White Plains, New York (Fitzpatrick Nuclear Facility) EA 91-054

An Order Suspending License (Effective Immediately) and Order to Show Cause Why License Should Not be Revoked was issued May 2, 1991. The action was based on (1) the operator's attempt to conceal his use of cocaine by substituting a bogus urine sample on October 9, 1990 when selected for a random drug test in accordance with fitness for duty requirements; (2) the operator not informing the NRC of a drug habit when that information was required by NRC Form 396 which the operator submitted to the NRC on April 14, 1986; and (3) the operator's failure to provide a second urine sample on October 9, 1990 as required because he knew that the sample would be "dirty" with cocaine. In addition, the operator failed to conform to the prohibition against

drug use in the Commission requirements demonstrated an intentional disregard for the important obligations of a licensed operator. The operator replied on June 6, 1991 and requested a hearing on the order against his license. The Order was modified on May 9, 1991 to allow the operator to resume Part 50 activities provided New York Power Authority implement the drug testing program specified by Order (See EA 91-053). In addition the operator was permitted to seek reinstatement of his Part 55 duties following the successful completion of the specified 3-year drug rehabilitation program. The Board issued a decision January 21, 1992 and it became final March 20, 1992.

New York Power Authority, White Plains, New York
(Fitzpatrick Nuclear Facility) EA 91-053

An Order Modifying License (Effective Immediately) was issued May 2, 1991. The Order was issued to suspend the Part 55 License of an operator and remove that individual from Part 50 licensed duties. The licensee responded May 31, 1991 requesting a hearing and a modification of the Order. An Order Modifying the Order was issued August 9, 1992 allowing the operator to resume Part 50 activities provided the licensee implemented the specified drug testing program. A Motion for Approval of Settlement Agreement was signed October 7, 1991. The Board issued a decision January 21, 1992 and it became final March 20, 1992.

Northern States Power Company, Minneapolis, Minnesota
(Prairie Island Nuclear Generating Plant, Unit 2)
Supplement I, EA 92-067

A Notice of Violation and Proposed Imposition of Civil Penalty in the amount of $12,500 was issued May 21, 1992 to emphasize the need for adequate procedures for reduced inventory operations. The action was based on an inadequate operation procedure which resulted in an unplanned loss of shutdown cooling with the unit in cold shutdown (Mode 5), loops not filled. The base civil penalty was mitigated for the licensee's determination of the root cause of the self-disclosing event, the licensee's comprehensive actions, and for good past performance, and was escalated for the prior notice provided to the licensee in the form of various generic documents on loss of shutdown cooling events. The licensee responded and paid the civil penalty on June 15, 1992.

B. Severity Level III Violation, No Civil Penalty

Commonwealth Edison Company, Downers Grove, Illinois (Byron Nuclear Station) Supplement VII, EA 92-019

A Notice of Violation was issued April 22, 1992 based on an incident of discrimination by a licensee contractor. This involved a quality control inspector employed by the contractor who was fired after contacting the NRC and appearing at a DOL hearing for another employee of the contractor. A civil penalty was not proposed because (1) the time that had passed since this violation occurred, (2) the plant was under construction at the time of the violation and has since been completed and operating for several years without further violations of this type, (3) no similar violations have occurred at other CECo NRC-licensed facilities, and (4) the apparent isolated nature of the violation.

Tennessee Valley Authority, Chattanooga, Tennessee (Sequoyah Nuclear Plant, Unit 2) Supplement I, EA 92-065

A Notice of Violation was issued May 19, 1992 based on a violation involving the discovery of the Unit 2 ice condenser in a degraded condition. During the performance of inspections while the unit was in Mode 5 for the Cycle 5 refueling outage, ice condenser inspections revealed that 27 of the 48 ice condenser doors required excessive force to open. Water intrusion, freezing, and expansion within the floor assembly caused the lower-ice-condenser concrete floor pad to be raised up to three inches which caused the metal flashing at the base of the doors to interfere with the door's operation. A civil penalty was not proposed because the licensee's staff identified the violation and because of the licensee's prompt and extensive corrective actions that included shutting down the operating unit, initiating rapid followup activity to correct the violation, installing an on-line monitoring system, and modifying maintenance practices.

II. MATERIALS LICENSEES

A. Civil Penalties and Orders

Allied Inspection Services, Inc., St. Clair, Michigan Supplement VI, EA 91-135

A Notice of Violation and Proposed Imposition of Civil Penalty in the amount of $5,000 was issued October 25, 1991 to emphasize the importance of wearing alarm

ratemeters during radiographic operations, and the importance of being cognizant of current NRC requirements. The action was based on a violation regarding licensee radiography personnel's failure to wear alarm ratemeters during radiographic operations on approximately 162 separate occasions, two of which occurred after the licensee became aware of the requirement. The licensee responded October 28, 1991 requesting consideration of its financial condition. A promissory note was signed by the licensee on April 20, 1992 and the first payment was made May 1, 1992.

Alonso and Carus Iron Works, Inc., Catano, Puerto Rico
Supplement VI, EA 92-012

A Notice of Violation and Proposed Imposition of Civil Penalty in the amount of $2,500 was issued April 22, 1992 to emphasize the importance of conducting safe radiographic operations and to ensure compliance with regulatory requirements and license conditions. The action was based on a violation involving the failure of a licensee radiographer to conduct radiation surveys following three successive radiographic exposures. After an investigation it was determined that the violation was not willful because the radiographer was under extreme emotional distress at the time. The base civil penalty was mitigated for prompt and extensive corrective action. The licensee responded and paid the civil penalty on May 14, 1992.

ATEC Associates, Inc., Indianapolis, Indiana
Supplements IV and VI, EA 92-051

A Notice of Violation and Proposed Imposition of Civil Penalties in the amount of $2,375 was issued April 30, 1992 to emphasize the importance of complying with license and regulatory requirements and ensuring effective management oversight of licensed activities. The action was based on numerous violations that was grouped into two problems involving the failure to control access to licensed material and regulatory breakdown in the control of licensed activities. The base civil penalty for the first group of violations was increased 150% because NRC identified the violations and there were multiple occurrences and the base civil penalty for the second group of violations was increased 125% because NRC identified the violations, the corrective action at the time of the enforcement conference was not comprehensive, and the licensee had prior opportunity to identify the problems. The licensee responded and paid the civil penalties May 21, 1992.

Certified Testing Laboratories, Inc., Bordentown, New Jersey
Supplement VII, EA 89-079

A Notice of Violation and Proposed Imposition of Civil Penalty in the amount of $8,000 and Order to Show Cause Why License Should Not Be Modified was issued March 9, 1990 to emphasize the importance of the licensee's responsibilities for ensuring that (1) licensed activities are conducted safely and in accordance with the conditions of the license, (2) accurate records of these activities are maintained, and (3) all information communicated to the NRC (either orally or in writing) is both complete and accurate. The action was based on the VP/RSO falsifying reports of audits that were never performed and willfully providing false information to the NRC in April 1988. The Order required the licensee to show cause why the license should not have been modified to remove the VP/RSO from all licensed activities. The licensee responded March 27, 1990 denying part of the violations and requesting mitigation. After consideration by the staff, an Order Imposing Civil Monetary Penalty was issued August 29, 1990. A Settlement was agreed to concerning the provisions of the Order to Show Cause. A hearing was requested as to the civil penalty. The Atomic Safety and Licensing Board modified the civil penalty and assessed $5,000. The licensee paid the civil penalty in the amount of $5,000 on April 7, 1992.

Chemetron Corporation, Pittsburgh, Pennsylvania
Supplement IV, EA 91-060

A Notice of Violation and Proposed Imposition of Civil Penalty in the amount of $7,500 was issued August 14, 1991 to emphasize the need for strict control of licensed material. The action was based on the failure to maintain control of licensed material on a contamination site in Ohio. The licensee responded September 30, 1991 requesting a reduction in the severity level of the violation and mitigation of the civil penalty. After considering the licensee's response, an Order Imposing Civil Monetary Penalty was issued January 13, 1992. The licensee paid the civil penalty April 1, 1992.

Department of Veterans Affairs, Houston, Texas
Supplements IV and VI, EAs 91-096 and 91-157

A Notice of Violation and Proposed Imposition of Civil Penalty in the amount of $25,000 and Confirmatory Order were issued November 15, 1991 to emphasize the importance of taking necessary steps to maintain a

radiation safety program that ensures strict compliance with all radiation safety requirements and is commensurate with NRC's expectations of a broad-scope medical licensee. The action was based on numerous violations of radiation safety requirements and the failure of the licensee to implement corrective actions for previous violations to preclude recurrence. The licensee responded December 11, 1991 contesting several violations and requesting mitigation. After considering the licensee's response, an Order Imposing Civil Monetary Penalty was issued March 4, 1992. The licensee paid the civil penalty on April 3, 1992.

General Electric Company, Wilmington, North Carolina
Supplement VI, EA 91-185

A Notice of Violation and Proposed Imposition of Civil Penalty in the amount of $20,000 was issued March 13, 1992 to emphasize the importance of ensuring that criticality control measures are maintained at the highest degree of effectiveness. The action was based on a number of violations related to inadequate procedures or the operations staff's failure to follow procedures that collectively resulted in ineffective process and mass limit controls. Because these violations created the potential for an inadvertent criticality, they were aggregated into a Severity Level II problem. The licensee responded and paid the civil penalty on April 9, 1992.

Georgetown University Medical Center, Washington, DC
Supplements IV and VI, EA 92-016

A Notice of Violation and Proposed Imposition of Civil Penalty in the amount of $3,750 was issued April 16, 1992 to emphasize (1) the importance of appropriate management attention to, and oversight of, the radiation safety program to ensure activities are conducted safely and in accordance with the requirements; (2) the seriousness with which the NRC views willful actions that cause or contribute to violations of NRC requirements; and (3) the importance of ensuring proper security of licensed material at the facility in the future. The action was based on violations that collectively indicate a breakdown in the control of the licensee's radiation safety and compliance program. An investigation concluded that the root cause of one violation, involving the failure of the Radiation Safety Committee to perform an annual audit of the entire radiation safety program, was a willful decision on the part of the former Radiation Safety Officer not to initiate the audit. Another violation involving the failure to secure licensed material recurred repeatedly,

even after the responsible technologists were retrained. The base civil penalty was escalated because NRC identified the violations and because the licensee's past enforcement history included other violations involving the lack of control of licensed material. However, mitigation was allowed because the licensee's corrective action was prompt and comprehensive. The licensee responded and paid the civil penalty on April 30, 1992.

Hospital de Damas, Ponce, Puerto Rico
Supplement VI, EA 92-038

A Notice of Violation and Proposed Imposition of Civil Penalty in the amount of $3,750 was issued March 27, 1992 to emphasize the importance of maintaining an effective radiation safety program and ensuring compliance with regulatory requirements and license conditions. The action was based on violations involving training, radiation surveys, leak testing of sources, and instrument calibration. The base civil penalty was escalated because the NRC identified the violations and because of the licensee's past performance. The licensee responded and paid the civil penalty on April 23, 1992.

Ketchikan General Hospital, Ketchikan, Alaska
Supplement VI, EA 91-146

A Notice of Violation and Proposed Imposition of Civil Penalty in the amount of $2,500 was issued January 13, 1992 to emphasize the need for effective management and Committee oversight of the licensee's radiation safety program. The action was based on violations involving the failure to (1) conduct annual reviews of the radiation safety program, (2) conduct dose calibrator linearity tests, (3) conduct a dose calibrator geometry test upon installation, (4) perform survey meter calibrations, (5) label syringes or syringe shields, (6) conduct quarterly inventories of sealed sources (repeat violation) (7) check the exhaust port of the xenon system, (8) record the dose calibrator model and serial number of daily constancy and quarterly linearity records, (9) include the Radiation Safety Officer's signature on records for dose calibrator accuracy tests, leak tests and physical inventories, (10) include trigger levels and survey meter identification on records for daily surveys and weekly wipe tests, and (11) record surveys of previously contaminated waste destined for non-radioactive disposal. The licensee responded in letters dated February 5 and 26, 1992. The licensee requested mitigation on the basis that the licensee is a small, rural, isolated facility with

limited financial resources. After considering the licensee's response, the staff issued an Order Imposing Civil Penalty in the amount of $1,000 on May 4, 1992. The licensee paid the civil penalty on May 8, 1992.

Mayaquez Medical Center, Mayaquez, Puerto Rico
Supplement IV, EA 92-039

An Order Modifying Licenses and a Notice of Violation were issued April 22, 1992. The action was based on violations that include significant and continuing problems in the areas of management controls, program organization, personnel radiation protection, facilities and equipment, control of accountability of licensed materials, and patient protection during treatment. An Order Modifying Licenses was issued rather than a civil penalty because of the licensee's inability to pay. The Order requires, in part, that the licensee obtain independent consulting services, submit a written Performance Improvement Plan, and submit monthly reports until the Performance Improvement Plan is completed.

Sequoyah Fuels Corporation, Gore, Oklahoma
EA 91-067

An Order Modifying License (Effective Immediately) and Demand for Information was issued October 3, 1991. The action involves a number of significant safety violations and regulatory problems with regard to the August 1990 solvent extraction tank excavation. The Order was based on NRC's conclusions that certain licensee managers failed to follow NRC requirements and the conditions of the NRC license, that a certain employee made false statements and withheld information from the NRC, and that the licensee's Health and Safety and Environmental Programs are in need of substantial improvement to assure the health and safety of the general public, the licensee's employees, contractor personnel who work at the site, and protection of the environment.

Sequoyah Fuels Corporation, Gore, Oklahoma
EA 91-196

A Confirmatory Order Modifying License (Effective Immediately) was issued January 13, 1992. The Order was issued to confirm the commitments made by the Licensee in a December 18, 1991 letter to notify the NRC should the Licensee desire to utilize certain individuals for the performance or supervision of licensed activities.

Sequoyah Fuels Corporation, Gore, Oklahoma
EA 92-045

An Order Modifying License (Effective Immediately) and Demand for Information was issued March 13, 1992. The action imposed as license conditions new reporting requirements intended to give the NRC added assurance that issues of potential safety and regulatory significance are promptly brought to NRC's attention. The Demand for Information seeks the Licensee's basis for having confidence that its Vice President for Regulatory Affairs will communicate fully with the NRC on issues concerning potential conditions that may impact on public health and safety.

Sequoyah Fuels Corporation, Gore, Oklahoma
EA 92-059

A Confirmatory Order Modifying License (Effective Immediately) was issued April 3, 1992. The action modifies Section IV.C of the March 13, 1992 Order which required the reporting of any failure that leads to one of three specified contamination events. The new revision requires the reporting of any occurrence that would lead to one of those events, regardless of the cause. Subsection 2 was modified to require the reporting of any contamination event in restricted areas that requires activities in that area to be suspended for more than 8 hours pending decontamination, as opposed to 24 hours.

Sibley Memorial Hospital, Washington, D.C.
Supplement VI, EA 92-080

A Notice of Violation and Proposed Imposition of Civil Penalty in the amount of $2,500 was issued June 2, 1992 to emphasize the importance of adequate attention to, and oversight of the radiation program, so as to ensure that (1) licensed activities are conducted safely and in accordance with requirements, and (2) violations, when they exist, are promptly identified and corrected. The violations involved problems in conducting required training, maintaining records, and performing surveys, bioassays, physical inventories, and calibration of the dose calibrator. Escalation was offset by mitigation for prompt and effective corrective action because NRC identified the violations. The licensee responded and paid the civil penalty on June 18, 1992.

St. Joseph's Hospital and Medical Center, Paterson, New Jersey, EA 92-013

A Confirmatory Order Modifying License (Effective Immediately) was issued February 10, 1992. The action

confirms certain actions concerning the role of the responsible individual and implementing additional procedural requirements which were agreed to by the licensee as a result of the Notice of Violation and Proposed Imposition of Civil Penalties issued December 3, 1991. The Notice of Violation was issued for violations associated with unauthorized moving of a high dose rate afterloader and failure to provide complete and accurate information to the NRC. The Order confirms these actions as part of the license for a period of three years.

Taylor Hospital, Ridley Park, Pennsylvania
Supplements IV and VI, EA 92-064

A Notice of Violation and Proposed Imposition of Civil Penalty in the amount of $1,250 was issued May 1, 1992 to emphasize the importance of management, the radiation safety committee, and the radiation safety officer maintaining proper control of radioactive material at the facility. The action was based on the improper disposal of a device containing a 14 millicurie americium-241 source, as well as two other violations, involving the failure to perform inventories and leak tests of the source. The base civil penalty was mitigated for the licensee's prior performance. The licensee responded and paid the civil penalty on May 22, 1992

University of Cincinnati, Cincinnati, Ohio
Supplement VII, EA 91-071

A Notice of Violation and Proposed Imposition of Civil Penalty in the amount of $2,000 and a Demand for Information was issued May 1, 1992 to emphasize the need for total candor of licensee representatives in their dealings with the NRC. The action was based on the licensee providing incomplete and inaccurate information to an NRC inspector concerning leak test and inventory cards for sealed sources. The base civil penalty was mitigated due to the licensee's identification and reporting of the violation and immediate corrective action. Full mitigation was not warranted due to the willful nature of the violation and the fact that it involved a Deputy RSO. The licensee responded and paid the civil penalty on May 20, 1992.

Western Atlas International, Houston, Texas
Supplement V, EA 91-121

A Notice of Violation and Proposed Imposition of Civil Penalty in the amount of $10,000 was issued December 20, 1992 to emphasize the significance of violations that

put the general public at risk, and to assure that the licensee's corrective actions are lasting. The action was based on the licensee's failure to install the safety pin on a transportation package closure mechanism and to adequately block and brace the package, resulting in the loss of the package and an exposure to a member of the public. The violation was categorized as a Severity Level I and the civil penalty was based on "industrial users of material" category. Mitigation of the base civil penalty for good past performance was offset because the licensee had prior Notice regarding the defect in the closure mechanism. The licensee responded January 24, 1992 requesting mitigation of the civil penalty. After considering the licensee's response, an Order Imposing Civil Monetary Penalty was issued June 5, 1992. The licensee paid the civil penalty on June 11, 1992.

B. Severity Level III Violation, No Civil Penalty

Bothwell Regional Health Center, Sedalia, Missouri
Supplement VI, EA 92-070

A Notice of Violation was issued May 6, 1992 based on violation including the failure to (1) perform an adequate weekly chart check to detect arithmetic errors, and (2) review the dose calculations within three working days after administering the first teletherapy fractional dose when the prescribed dose is to be administered in more than three fractions. A civil penalty was not proposed because the licensee identified the violation and the excellent past regulatory performance of the licensee.

Harper Hospital Division, Detroit, Michigan
Supplement VI, EA 92-069

A Notice of Violation was issued April 22, 1992 based on a cobalt-60 teletherapy misadministration. The violations involved the failure of the radiation therapists to follow the procedures of the licensee's quality management program, and to notify the NRC of the misadministration within one calendar day of discovery. A civil penalty was not issued because the licensee identified the violation, the licensee's corrective actions were immediate and comprehensive, and the licensee's past performance was good.

Yale-New Haven Hospital, New Haven, Connecticut
Supplements IV and VI, EA 92-052

A Notice of Violation was issued April 15, 1992 based on violations involving a radiation exposure in the amount

of approximately 40 rem to the tip of the left finger of an individual. Two other violations of NRC requirements that contributed to the overexposure were several examples of the failure to follow procedures and the inadequate survey by the individual of the radiological conditions and hazards that led to the overexposure. A civil penalty was not issued based on the licensee's enforcement history and because the licensee identified and reported the matter and took prompt and extensive corrective action.

III. INDIVIDUAL ACTIONS

Patrick F. C. Chun, M.D. IA 91-001

A Termination of NRC License and Order Prohibiting Certain Involvement in NRC-Licensed Activities for One Year was issued November 12, 1991. The action was issued because the licensee provided false information to the NRC, including the claim that: (1) the licensee was self-employed when he was actually an employee of the Tulsa Heart Center (THC), (2) the licensee owned the equipment when he actually was using THC's equipment, and (3) the licensee was the employer when in fact THC was. The Licensee requested a hearing on November 18, 1991. On November 27, 1991, an Order Modifying Order was issued. An Order Approving Settlement Agreement and Terminating Proceeding was issued May 26, 1992. The Licensee agreed that for a one-year period he would not apply for or hold an NRC license, not be named on an NRC license in any capacity, and would not perform any activities as an authorized user either under a broad scope license or as a visiting authorized user.

I.A. REACTOR LICENSEES, CIVIL PENALTIES AND ORDERS

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION II
101 MARIETTA STREET, N.W., SUITE 2900
ATLANTA, GEORGIA 30323

MAR 24 1992

Docket Nos. 50-325 and 50-324
License Nos. DPR-71 and DPR-62
EA 92-024

Carolina Power and Light Company
ATTN: Mr. Lynn W. Eury
Executive Vice President
Power Supply
Post Office Box 1551
Raleigh, North Carolina 27602

Gentlemen:

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY - $100,000
(NRC INSPECTION REPORT NOS. 50-325/92-01 AND 50-324/92-01)

This refers to the Nuclear Regulatory Commission (NRC) inspection conducted by Mr. R. Prevatte on January 4-31 and February 3, 1992, at the Brunswick Steam Electric Plant. The inspection included a review of the facts and circumstances related to the use of an inadequate maintenance procedure during cleaning activities on emergency diesel generator (EDG) No. 2 which consequently resulted in the failure of the EDG to start on demand on January 6, 1992, while Unit 1 was at 20 percent power and Unit 2 was at 100 percent power. The report documenting this inspection was sent to you by letter dated February 13, 1992. As a result of this inspection, a violation of NRC requirements was identified. An enforcement conference was held on March 3, 1992, in the NRC Region II office to discuss the violation, its cause, and your corrective actions to preclude recurrence. A summary of the conference was sent to you by letter dated March 4, 1992.

The violation in the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice) involved an inadequate maintenance procedure which was used by plant services maintenance personnel to clean EDG No. 2 in preparation for painting. The procedure was inadequate in that it had not been properly evaluated to determine whether the materials and processes used to clean EDG No. 2 would impact the operability of the diesel generator or would otherwise constitute an unreviewed safety question. On January 3, 1992, with EDG No. 2 in operable status, plant services personnel, using a degreasing solvent with water, proceeded to spray the left side of EDG No. 2. Though the procedure required that the fuel control racks be lubricated after cleaning, the procedure did not contain a signoff step, and following receipt of notification that the cleaning was complete, maintenance personnel decided that the lubrication of the fuel control racks could be done on the morning of January 6, 1992. As a result, the cleaning solvent dried leaving a residue which formed a crystalline adhesive bond that effectively disabled the fuel control racks by mechanical binding. On January 6, 1992, with reactor power at 20 percent, an overspeed test was performed on the unit 2 Main Turbine Generator. As the turbine was tripped, reverse power and diesel auto start alarms were received; however, EDG No. 2

failed to start. Subsequent investigation revealed that EDG No. 2 fuel control racks were not moving and when a mechanic pushed the manual control lever on the fuel control racks to move them, the EDG started.

In this case, there was no loss of offsite power and EDG Nos. 1, 3, and 4 did start, as designed, on receipt of the diesel auto start signal. Other safety issues become evident when consideration is given to the effect of spraying diesel generator electrical systems with solvent, particularly when the personnel involved in such activity may not have the requisite knowledge or procedural guidance regarding the constraints on such activity. This event is seen as a continuation of significant problems related to work control that have yet to be adequately resolved.

The significance of this violation, and the basis of NRC's concern, is not focused on the diesel generator, but centers on the apparent inability of Carolina Power and Light Company management to properly and consistently control work on components and systems at the Brunswick Steam Electric Plant that are important to safety. On August 30, 1990, escalated enforcement action (EA 90-130) was issued with a proposed civil penalty of $62,500 to emphasize the importance of proper work control and job planning associated with activities related to the installation of a traversing incore probe on July 5, 1990. On November 30, 1990, a Severity Level III violation (EA 90-154) was issued for the failure to follow procedures and the subsequent inaccurate completion of procedural requirements associated with a maintenance surveillance test. On March 26, 1991, EA 91-023 was issued with a proposed civil penalty of $50,000 for violations involving the failure to follow procedures related to a calibration test of a process computer point on the feedwater control system. On May 31, 1991, EA 91-045 was issued with a proposed civil penalty of $87,500 for violations involving the failure to follow procedures. On January 3, 1992, EA 91-158 was issued with a proposed civil penalty of $125,000 for violations involving inadequate corrective action related to work control and independent verification inadequacies.

Therefore, in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy) 10 CFR Part 2, Appendix C (1991), this violation raises a significant regulatory concern and has been categorized at Severity Level III. To emphasize the importance of ensuring that proceduralized work controls are adequate, 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 $100,000 for the Severity Level III violation. The base value of a civil penalty for a Severity Level III violation is $50,000.

The escalation and mitigation factors in the Enforcement Policy were considered. The self-disclosing nature of the event did not warrant escalation or mitigation for identification and reporting. As to corrective action to prevent recurrence, immediate corrective action was taken to correct the diesel generator operability problem. However, your long-term corrective action to address overall work control problems is essentially similar to your past corrective action that has not been proven particularly effective. In addition, it appears to the NRC staff that you have mischaracterized the root cause of the problem as failure to

require a post-maintenance test as opposed to failure to adequately evaluate whether the ...d activity would constitute an unreviewed safety question and take action... ...ppropriate. Therefore, your corrective actions do not warrant mitigation. Escalation of 100 percent was warranted for past performance which reflects a history of the continuing problem related to work control. 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 100 percent.

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

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

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

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:
S. H. Smith, Jr.
President & CEO
Carolina Power and Light Co.
P. O. Box 1551
Raleigh, NC 27602

R. A. Watson
Sr. Vice President
Carolina Power and Light Co.
P. O. Box 1551
Raleigh, NC 27602

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

Carolina Power and Light Company
Brunswick Steam Electric Plant
Units 1 and 2

Docket Nos. 50-369 and 50-324
License Nos. DPR-71 and DPR-62
EA 92-024

During an NRC inspection conducted on January 4-31, and February 3, 1992, a violation of NRC requirements was identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C (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:

> Technical Specification 6.8.1.a requires that written procedures shall be established and implemented as recommended in Appendix "A" of NRC Regulatory Guide 1.33, November 1972. Section 1.1 of Appendix "A" requires that procedures for maintenance which can affect the performance of safety-related equipment be properly preplanned and performed with written procedures or instructions appropriate to the circumstances.
>
> Contrary to the above, on January 3, 1992, the licensee performed a maintenance work activity on Emergency Diesel Generator (EDG) No. 2, a safety-related component, using a procedure that was not appropriate to the circumstances. Specifically, the procedure, Repainting Diesel Generators, dated May 16, 1991 and updated January 2, 1992, did not receive an adequate review to evaluate the impact of the planned work on the operability of EDG No. 2. The maintenance work activity performed under this procedure resulted in the failure of EDG No. 2 to start upon receipt of a valid start signal on January 6, 1992.

This is a Severity Level III violation (Supplement 1).
Civil Penalty - $100,000

Pursuant to the provisions of 10 CFR 2.201, Carolina Power and Light 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 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 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. 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 II, and a copy to the NRC Resident Inspector at the facility that is the subject of this Notice.

Dated at Atlanta, Georgia
this 24th day of March 1992

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

June 2, 1992

Docket No. 50-255
License No. DPR-20
EA 92-074

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

Dear Mr. Hoffman:

SUBJECT: PALISADES NUCLEAR GENERATING PLANT
NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY - $75,000
(NRC INSPECTION REPORT NO. 50-255/92011(DRS))

This refers to the special safety inspection conducted during the period of February 12-14, February 25-27, March 24-27, and April 16, 1992, at the Palisades Nuclear Generating Plant. The inspection included a review of the circumstances surrounding the main steam isolation valves being inoperable in the event of a high energy line break, and your disposition of a contractor's review of the environmental qualification (EQ) equipment list. The report documenting this inspection was sent to you by letter dated April 27, 1992. During this inspection a violation of NRC requirements was identified.

Your plan for enhancing the environmental qualification of electrical equipment was sent to the NRC by letter dated April 30, 1992, and an enforcement conference was held on May 1, 1992, to discuss the violation, its causes, and your corrective actions. The report summarizing the conference was sent to you by letter dated May 6, 1992.

In response to previous EQ program problems, you commissioned a contractor to perform an independent review of the EQ equipment list. The contractor's report, which identified a number of deficiencies in the EQ equipment list as well as in the plant's equipment data base, was received by your staff in December 1990. Your initial screening review of the report, performed shortly after it was received, did not identify any immediate concerns

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with compliance with 10 CFR 50.49. Based on other priorities a more detailed review of the report was deferred. In March 1991, the plant was returned to service following a six month outage. The detailed review of the contractor's report began in November 1991. As a result of the review, you determined on February 5, 1992, that the main steam isolation valves could be rendered inoperable by a steam line break outside of containment. Since the plant was operating at 100 percent power, a 72 hour temporary waiver of compliance was requested. However, on February 6, 1992, you determined that the deficiency could not be corrected in 72 hours and promptly shut down the plant. At least six other significant EQ deficiencies were identified as a result of the detailed review and were reported to the NRC.

We believe that your initiation of a special independent review of the EQ program in light of past problems in this area was a very positive action. The contractor's report was briefly reviewed upon its receipt to assess the significance of the items raised and to determine what, if any, immediate corrective actions were necessary. However, this review was not sufficiently comprehensive nor given sufficient management attention to assure that items having potential impact on operability were promptly addressed. Notwithstanding indications in the report that certain equipment in harsh environments was not environmentally qualified, it was nearly a year before a detailed review of the report was undertaken.

The root cause of this problem appears to be either a lack of detailed knowledge about EQ requirements on the part of the reviewer or excessive workloads associated with the steam generator replacement project which caused the initial review to be superficial. An independent contractor review, such as the one performed, requires a thorough initial review by personnel having sufficient time and expertise to assure that immediate operability issues, if they exist, are identified and corrected. Additionally, we are concerned that there was no formal tracking of the contractor's report to ensure both management's awareness of the report and a timely completion of the detailed review.

One violation is described in the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice) involving failure to establish measures to promptly identify and correct

significant EQ nonconformances. This violation is a significant regulatory concern because it resulted in safety-related equipment, nonsafety-related equipment which affects safety-related equipment, and accident monitoring instruments not being environmentally qualified for an extended period of time. Most notably, the violation resulted in the main steam isolation valve circuitry not being able to perform its intended safety function under certain conditions. Therefore, in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy) 10 CFR Part 2, Appendix C (1991), this violation has been categorized at Severity Level III.

We acknowledge your corrective actions to enhance the Palisades EQ program, including your decision to shut down the plant and initiate modifications to relocate or replace non-EQ equipment. However, even at the Enforcement Conference, you did not appear to recognize the need for independent evaluations, such as the special contractor review performed in this case, to be reviewed by personnel having sufficient expertise and time to assure operability issues, where they exist, are identified and promptly resolved. The EQ issues addressed in the contractor report are complicated from technical and regulatory viewpoints. Notwithstanding, the process followed in this case to establish the significance of the contractor report findings and the course of licensee action was not acceptable.

To emphasize the need for implementing adequate management controls to ensure that independent evaluations are promptly reviewed to assess their impact on equipment operability, 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 violation described in the Notice. The base value of a civil penalty for a Severity Level III violation is $50,000.

The civil penalty adjustment factors in the Enforcement Policy were considered. We considered escalating the base civil penalty for identification and reporting because the NRC identified your failure to take immediate corrective actions when you first reviewed the contractor's report. However, you also identified that there was an EQ violation and promptly notified the NRC. Therefore, no adjustment was made for this factor. The base civil penalty was not mitigated for your corrective actions in that those actions were not sufficiently comprehensive, as discussed above. Likewise, escalation was not considered to be warranted for this factor since you ultimately corrected the EQ

deficiencies. The base civil penalty was escalated by 50 percent for past performance because of your prior EQ violations. We considered escalating the base civil penalty for duration, considering the lengthy period of time during which the specific EQ deficiencies existed and the year during which corrective actions were not initiated following their identification by your contractor. However, considering the proactive action on your part to initiate the contractor review which led to the eventual correction of the EQ problems, we have determined that additional escalation for duration is not appropriate. The other factors in the Enforcement Policy were considered and no further adjustment to the base civil penalty was considered appropriate. Therefore, based on the above, the base civil penalty has been increased by 50 percent.

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

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

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

Sincerely,

A. Bert Davis

A. Bert Davis
Regional Administrator

Enclosure:
Notice of Violation and Proposed
Imposition of Civil Penalty

See Distribution Next Page

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

Consumers Power Company
Palisades Nuclear Generating Plant

Docket No. 50-255
License No. DPR-20
EA 92-074

During an NRC inspection conducted from February 12-14, February 25-27, March 24-27, and April 16, 1992, a violation of NRC requirements was identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C (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:

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

10 CFR 50.49(e) and (f) require, in part, that each item of electrical equipment important to safety must be qualified for the most severe design basis accident (harsh) environment during or following which the equipment is required to remain functional by appropriate testing, analysis, or a combination thereof.

Contrary to the above, from December 1990 until November 1991, the licensee failed to establish measures to promptly identify and correct significant environmental qualification nonconformances identified in a contractor report dated December 28, 1990, and which were conditions adverse to quality. Specifically, until it initiated its detailed review of the contractor report in November 1991, the licensee failed to promptly identify and correct the following conditions adverse to quality and affecting electrical equipment important to safety:

1. On January 20, 1992, the licensee identified that the residual heat removal heat exchanger temperature element TE-0351B was not qualified for a harsh environment (Licensee Event Report No. 255/92-006).

2. On February 5, 1992, the licensee identified that the main steam isolation valve actuator solenoid valves SV-0506, SV-0508, SV-0513, and SV-0524 were not qualified for a harsh environment (Licensee Event Report No. 255/92-007).

3. On February 14, 1992, the licensee identified that the main steam line radiation elements RE-2323 and RE-2324 were not qualified for a harsh environment (Licensee Event Report No. 255/92-012).

4. On February 17, 1992, the licensee identified that the plant stack flow transmitter FT-1818 was not qualified for a harsh environment (Licensee Event Report No. 255/92-013).

5. On February 25, 1992, the licensee identified that solenoid valves SV-0823A, SV-0823B, SV-0826A, and SV-0826B, and position switches POS-0823 and POS-0826 used for control and indication of the control valves for the service water outlet flow from the component cooling water heat exchangers were not qualified for a harsh environment. Additionally, they were not electrically isolated from environmentally qualified instruments in the same electrical scheme (Licensee Event Report No. 255/92-016).

6. On March 5, 1992, the licensee identified that the containment electrical penetration connectors for the solenoid valves which supply control air to the safety injection tanks pressure and fill control valves were not qualified for a harsh environment (Licensee Event Report No. 255/92-018).

7. On March 9, 1992, the licensee identified that 39 position switch circuits were not qualified for a harsh environment, in that they contained unqualified wire nuts to make electrical connections (Licensee Event Report No. 255/92-019).

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

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

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

In requesting mitigation of the proposed penalty, the factors addressed in Section V.B of 10 CFR Part 2, Appendix C (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 Gereral, 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 Palisades Nuclear Generating Plant.

FOR THE NUCLEAR REGULATORY COMMISSION

A. Bert Davis
Regional Administrator

Dated at Glen Ellyn, Illinois
this 2nd day of June 1992

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION II
101 MARIETTA STREET, N.W., SUITE 2900
ATLANTA, GEORGIA 30323

APR 0 9 1992

Docket No. 50-302
License No. DPR-72
EA 92-002

Florida Power Corporation
Mr. P. M. Beard, Jr.
Senior Vice President, Nuclear Operations
ATTN: Manager, Nuclear Operations Licensing
Post Office Box 219 - NA-21
Crystal River, Florida 32629

Gentlemen:

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY $50,000
(NRC INSPECTION REPORT NO. 50-302/91-25)

This refers to the Nuclear Regulatory Commission (NRC) inspection conducted on December 8 - 23, 1991, at the Crystal River Unit 3 facility. The inspection included a review of the facts and circumstances related to the reactor trip and safety injection event that occurred on December 8, 1991, and the subsequent failure to make timely notification to the NRC and State of Florida authorities of that event. The report documenting this inspection was sent to you by letter dated January 6, 1992. An enforcement conference was held on January 13, 1992, in the NRC Region II office to discuss the violations, their cause, and your corrective actions. A summary of the enforcement conference was sent to you by letter dated January 27, 1992.

On December 8, 1991, while increasing reactor power from 10 percent in preparation for phasing the unit to the grid, the operators transferred the auxiliary steam supply to the main steam system. In anticipation of a decrease in reactor coolant system (RCS) temperature from the increased steam flow, control rods were withdrawn twice to increase power and maintain RCS temperature. As power and RCS pressure increased, the pressurizer spray valve RCV-14 opened, but failed to close. However, the main control board valve position indicator showed that RCV-14 was closed. With RCS pressure decreasing due to continued pressurizer spray, the operators made two more power increases to approximately 15 percent of full power without an understanding of the cause of the depressurization.

RCS pressure reached the reactor trip setpoint of 1800 psig approximately 15 minutes after RCS depressurization began and the reactor automatically tripped at 3:09 a.m. RCS pressure decreased to 1650 psig at which time the "ES A and B Not Bypassed" alarms annunciated. The purpose of these alarms is to notify the operators that the automatic actuation of the Engineered Safety Feature Actuation System (ESFAS) for high pressure injection (HPI) may be bypassed to prevent an inadvertent actuation of HPI during a controlled plant

shutdown and cooldown. Approximately one minute after the alarms annunciated, both ESFAS trains of the automatic actuation of HPI on RCS Pressure Low were inappropriately bypassed. Within approximately six minutes, sufficient actuation logic bistables tripped, as indicated by main control panel alarms, to actuate the ESFAS HPI had it not been bypassed. Twelve seconds later, the operators took the "A" train of HPI actuation out of bypass and it immediately actuated. Four seconds after that, the "B" train was taken out of bypass and it also immediately actuated.

The NRC is particularly concerned about the performance of the control room staff during this event. A critical nonroutine plant evolution was conducted on the midnight shift by a crew that had not trained together. The initial response of the crew to the RCS pressure transient was inadequate in that it did not focus on the symptom (decreasing RCS pressure), but rather the expected results of a power increase. Additionally, inadequate command, control, and communication by that crew resulted in bypassing a critical safety feature while the reactor was in the midst of a transient and before the cause was known and the SRO did not countermand that action in a timely manner. Further, the emergency operating procedures were exited by the operators before they completed all applicable steps. The control room staff also failed to follow procedures that resulted in late notification of the event to the NRC and the State of Florida.

In addition to the control room staff's performance, NRC is also concerned that an erroneous spray valve position indication, caused by inadequate maintenance, and deficiencies in the adequacy of alarm response procedures and implementation of the abnormal operating procedures unnecessarily challenged the ability of the operators to respond to the transient in an acceptable manner.

Violation I in the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice) involves failure to comply with Technical Specification (TS) 3.3.2.1 when both ESFAS instrument channels for HPI actuation were bypassed, thereby rendering the automatic safety system unavailable during the existence of a valid signal. This violation is a serious concern to the NRC because it involves non-conservative actions by NRC licensed plant operations staff.

In accordance with the guidance contained in Supplement I of the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy), 10 CFR Part 2, Appendix C (1991), this violation could be categorized at a severity level higher than Severity Level III. However, given the safety significance of this case, specifically, that manual actuation for HPI was available and that adequate subcooling margin was always maintained, this violation has been categorized at Severity Level III.

The Enforcement Policy states that civil penalties are considered for Severity Level III violations. The escalation and mitigation factors set forth in the Enforcement Policy are normally considered in making adjustments to the base civil penalty. These factors would normally result in complete mitigation of the civil penalty based on your comprehensive corrective actions and your good past performance. However, the NRC considers the lack of adequate command, control, and communications on the part of your control room staff that permitted the bypassing of the ESFAS to be especially serious. Therefore, 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, and the Commission, 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 violation.

Violation II.A in the Notice involves a failure to follow procedures that resulted when operations personnel improperly implemented Abnormal Procedure AP-380, Engineered Safeguards Actuation. A followup action step in that procedure isolates possible causes of RCS pressure decrease. Had the procedure been properly implemented during the event and all applicable actions taken, the pressurizer spray block valve would have been isolated significantly earlier in the transient. The implications of this violation are of particular concern especially in view of three previous nuclear plant examination reports (50-302/OL-89-02, /OL-90-02, and /OL-91-301) which emphasized the apparent generic weakness in the use of procedures by operators. The NRC also notes that the operators failed to refer to the annunciator response procedure that was directly applicable to the decreasing reactor coolant system pressure. Moreover, the NRC is concerned that this procedure would have been of minimal help because it was oriented toward control circuit failures. We understand that you have programs currently underway to improve both emergency operating procedures and annunciator response procedures.

Violation II.B involves the failure of the Emergency Coordinator to promptly initiate an assessment and classification of the December 8, 1991, event as an Unusual Event. The event was not recognized as a condition requiring classification as an Unusual Event until after plant conditions had stabilized. The delay in classifying the proper emergency action level of the event caused required reporting to be untimely to both the NRC and State of Florida authorities. The NRC is concerned because the Shift Supervisor, who was the Emergency Coordinator, relied on his knowledge of the requirements for timely notification rather than checking the procedures.

Violation II.C in the Notice involves the failure to notify the NRC of a valid high pressure injection within one hour as required by 10 CFR 50.72.

Violation II.D in the Notice involves the failure to correct conditions adverse to quality. Repetitive failures of pressurizer spray valve RCV-14 position indication that occurred in June 1990 and July 1991 were not effectively corrected. The missing valve stem anti-rotation key and retaining bolt should have been identified earlier through your maintenance activities in response to previous problems. This condition initiated the transient on December 8, 1991 and contributed to the operators being misled during the transient.

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, including those recommended in your report of January 10, 1992, entitled "Generic Implications of Reactor Trip Events in December 1991." That report addressed a number of recommended corrective actions that included (1) the revision of procedures and operating practices, as necessary, to assure predictable and consistent operation of

systems and plant evolutions, and (2) providing remedial training to the shift on duty during the transient. As these recommendations transcend the corrective actions for the violations described in the Notice, your response should also address any plans to (1) assure that plant management's policies for procedure usage and adherence are established, discussed with, and understood by plant personnel, and (2) provide training to all operating shifts concerning appropriate operator actions and conservative operating practices expected for such transients. 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,

James L. Milhoan for
Stewart D. Ebneter
Regional Administrator

Enclosure:
Notice of Violation and
Proposed Imposition of Civil Penalty

cc w/encl:
Gary L. Boldt
Vice President, Nuclear Production
Florida Power Corporation
P. O. Box 219-SA-2C
Crystal River, FL 32629

P. F. McKee, Director
Nuclear Plant Operations
Florida Power Corporation
P. O. Box 219-NA-2C
Crystal River, FL 32629

R. C. Widell, Director
Nuclear Operations Site Support
Florida Power Corporation
P. O. Box 219-NA-2I
Crystal River, FL 32629

cc w/encl con't: (see next page)

cc w/encl con't:
A. H. Stephens
General Counsel
Florida Power Corporation
MAC - A5D
P. O. Box 14042
St. Petersburg, FL 33733

Attorney General
Department of Legal Affairs
The Capitol
Tallahassee, FL 32304

Jacob Daniel Nash
Office of Radiation Control
Department of Health and
Rehabilitative Services
1317 Winewood Boulevard
Tallahassee, FL 32399-0700

Administrator
Department of Environmental
Regulation
Power Plant Siting Section
State of Florida
2600 Blair Stone Road
Tallahassee, FL 32301

Robert G. Nave, Director
Emergency Management
Department of Community Affairs
2740 Centerview Drive
Tallahassee,FL 32399-2100

Chairman
Board of County Commissioners
Citrus County
110 N. Apopka Avenue
Inverness, FL 36250

Robert B. Borsum
B&W Nuclear Technologies
1700 Rockville Pike, Suite 525
Rockville, MD 20852-1631

State of Florida

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

Florida Power Corporation
Crystal River Nuclear Plant
Unit 3

Docket No. 50-302
License No. DPR-72
EA 92-002

During an NRC inspection conducted on December 8 - 23, 1991, 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 (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 violations and associated civil penalty are set forth below:

I. Violation Assessed a Civil Penalty

A. Technical Specification (TS) section 3.3.2.1 requires that the Engineered Safety Feature Actuation System (ESFAS) instrumentation channels shall be OPERABLE as stated in Table 3.3-3. TS Table 3.3-3 states that two out of three channels of the "Reactor Coolant System Pressure Low" ESFAS instrumentation for High Pressure Injection must be available in Modes 1, 2, or 3.

Contrary to the above, on December 8, 1991, at 3:13 a.m., the "Reactor Coolant System Pressure Low" ESFAS instrumentation for High Pressure Injection was not OPERABLE or available while the reactor was in Mode 3. Specifically, at 3:13 a.m., a licensed operator bypassed all three channels of both trains for over six minutes during a Reactor Coolant System (RCS) pressure transient. The bypass of these channels disabled automatic High Pressure Injection, Diverse Containment Isolation, Emergency Feedwater Initiation and Control, and start of the Emergency Diesel Generators. As a result, the system failed to automatically actuate when called upon by a valid low RCS pressure condition.

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

II. Violations Not Assessed a Civil Penalty

A. TS 6.8.1 requires that written procedures shall be established, implemented, and maintained as recommended in Appendix "A" of Regulatory Guide 1.33, November 1972. Appendix "A" recommends procedures for correcting abnormal or alarm conditions. Abnormal Procedure AP-380, "Engineered Safeguards Actuation," states in follow-up action 3.14 to "Close RCV-13."

Contrary to the above, on December 8, 1991, procedures for correcting abnormal conditions were not implemented in that RCV-13 (the pressurizer spray block valve) was not closed in accordance with Abnormal

Procedure AP-380. As a result, the RCS pressure transient was not terminated until 35 minutes after the Engineered Safeguards Actuation occurred.

This is a Severity Level IV Violation (Supplement I)

B. 10 CFR 50.54(q) requires that a licensee follow and maintain in effect emergency plans which meet the prescribed standards. The licensee's Radiological Emergency Response Plan (RERP) was developed using the guidance of NUREG-0654/FEMA-REP-1, "Criteria for Preparation and Evaluation of Radiological Emergency Response Plans and Preparedness Support of Nuclear Power Plants." RERP Section 8.2 states "Emergency Action Levels are used to assure that the initial classification of emergencies can be accomplished rapidly, based on specific instrument readings, alarms, and observations...." RERP Section 13.1 states "For each emergency classification...the Emergency Coordinator shall assure that those assessment activities required to identify fully the nature of the emergency are completed quickly...." RERP Table 8.1 indicates that an "Unusual Event" was the appropriate Emergency Action Level classification for a valid actuation of ECCS and required prompt notification of offsite authorities.

Contrary to the above, on December 8, 1991, the RERP reporting requirements applicable for notification of offsite authorities were not properly implemented. A valid actuation of the High Pressure Injection portion of ECCS occurred, with discharge into the RCS, which was not rapidly classified as an Unusual Event nor promptly reported to offsite authorities. High Pressure Injection actuated at 3:19 a.m., and an Unusual Event was declared at 4:55 a.m., 96 minutes after the High Pressure Injection. Authorities for the State of Florida were notified of the Unusual Event at 5:15 a.m., almost two hours after the High Pressure Injection.

This is a Severity Level IV Violation (Supplement VIII).

C. 10 CFR 50.72 (b)(1)(iv), requires that the licensee shall notify the NRC as soon as practical and in all cases within one hour of the occurrence of any event that results in or should have resulted in Emergency Core Cooling System (ECCS) discharge into the RCS as the result of a valid signal.

Contrary to the above, on December 8, 1991, the licensee did not notify the NRC within one hour of an event that resulted in ECCS discharge into the RCS. A valid actuation of the High Pressure Injection portion of ECCS occurred, with discharge into the RCS, at 3:19 a.m. The NRC was notified at 5:32 a.m., two hours and thirteen minutes after the High Pressure Injection.

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

D. 10 CFR Part 50, Appendix B, Criterion XVI, requires measures be established to assure that conditions adverse to quality, such as failures, malfunctions, deficiencies, and deviations are promptly identified and corrected.

Contrary to the above, conditions adverse to quality were not promptly identified and corrected. Repetitive malfunctions of the pressurizer spray valve (RCV-14) position indication that occurred in June 1990, and July 1991, were not effectively corrected. As a result, on December 8, 1991, the RCV-14 valve malfunctioned resulting in a reactor coolant system pressure transient and erroneous indication of the valve position as closed when the valve was stuck open.

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

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

Within the same time as provided for the response required above under 10 CFR 2.201, the Licensee may pay the civil penalty by letter addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, with a check, draft, money order, or electronic transfer payable to the Treasurer of the United States in the amount of the civil penalty proposed above, or the cumulative amount of the civil penalties if more than one civil penalty is proposed, or may protest imposition of the civil penalty in whole or in part, by a written answer addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission. Should the Licensee fail to answer within the time specified, an order imposing the civil penalty will be issued. Should the Licensee elect to file an answer in accordance with 10 CFR 2.205 protesting the civil penalty, in whole or in part, such answer should be clearly marked as an "Answer to a Notice of Violation" and may: (1) deny the 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 response noted above (Reply to Notice of Violation, letter with payment of civil penalty, and Answer to a Notice of Violation) should be addressed to: Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555 with a copy to the Regional Administrator, U.S. Nuclear Regulatory Commission, Region II and a copy to the NRC Resident Inspector at the facility that is the subject of this Notice.

Dated at Atlanta, Georgia
this 9th day of April 1992

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

May 1, 1992

Docket No. 50-331
License No. DPR-49
EA 92-056

Iowa Electric Light
and Power Company
ATTN: Mr. Lee Liu
Chairman of the Board
and Chief Executive Officer
IE Towers
Post Office Box 351
Cedar Rapids, Iowa 52406

Dear Mr. Liu:

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY - $12,500
(NRC INSPECTION REPORT NO. 50-331/92007)

This refers to the special safety inspection conducted March 17 through March 27, 1992, to review the circumstances surrounding a higher than expected radiation exposure event which occurred at the Duane Arnold Energy Center on March 15, 1992. The report documenting this inspection was mailed to you by letter dated April 3, 1992. Significant violations of NRC requirements were identified during the inspection, and on April 9, 1992, an enforcement conference was held in the Region III office. Attending the enforcement conference were Mr. R. W. McGaughy, Vice President - Production; Dr. Carl J. Paperiello, Deputy Regional Administrator, NRC Region III; and other members of our respective staffs. A copy of the enforcement conference report was mailed to you on April 15, 1992.

The incident occurred on March 15, 1992, and involved two contract workers who were performing inservice inspection (ISI) work on the 'A' riser of the reactor recirculation system. Radiation survey data indicated that radiation levels in the work area were expected to be about 800 millirems per hour (mrem/hr). However, radiation surveys conducted after the incident indicate the radiation levels were actually as high as 15 Rem/hr in the work area. At the enforcement conference, you indicated that a subsequent review of plant records for similar reactor conditions found that similar high radiation fields (15 - 20 Rem/hr) were encountered.

Both workers were issued electronic dosimeters set to alarm at an accumulated dose of 250 mrem or a dose rate of 2000 mrem/hr. The workers were briefed on the radiological work conditions, but were not given a demonstration of the alarm signals provided by the electronic dosimeter. The electronic dosimeter dose rate alarm activated as soon as one worker entered the area. The worker informed his supervisor of the alarm, but both stated they were unaware of your

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

policy to exit a work area upon activation of a high dose rate alarm and both thought that no action was required until the intermittent tone became constant. Therefore, both the worker and the supervisor decided the work activity should continue. The worker remained at the work site for 5 to 10 minutes and exited to obtain another piece of equipment. The worker then reentered the area for another 5 to 10 minutes to complete the set-up of equipment. The worker indicated that his dose rate alarm activated the entire time that he was in the area, but he did not hear the alarm for the accumulated dose. Upon exiting the work area, the worker read the electronic dosimeter and found that it read 1,310 mrem. A second worker had remained in a lower dose rate area until the first worker exited the work area. The second worker entered the area and his dose rate alarm activated. After exiting the work area at the direction of a radiation protection technician, the second worker found his electronic dosimeter read 200 mrem. It is possible that the work area dose rate could have been higher and that the workers could have remained in the work area for a longer period of time, both of which would have led to higher doses to the workers.

The violations, which are described in the enclosed Notice of Violation, pertain to: (1) the failure to perform an adequate survey of the radiation levels in the specific work area, and (2) the failure to instruct workers in the purposes and functions of the protective devices employed and the appropriate response to warnings made in the event of any unusual occurrence, and the failure to keep workers informed of radiation levels. Although the unplanned radiation exposure received by the individuals was not in excess of regulatory limits, the absence of adequate surveys and instructions created a substantial potential for a radiation exposure in excess of regulatory limits. Therefore, 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 (1992).

The root causes of the violations and the subsequent corrective actions were discussed during the April 9, 1992, enforcement conference. The major factors contributing to the violations appeared to be inadequate instructions to workers regarding the operation of electronic dosimeters and inadequate pre-job evaluations of the work site dose rate. The NRC recognizes that immediate corrective actions were taken when the violations were identified.

This substantial potential for a radiation exposure in excess of regulatory limits is of significant concern to the NRC because two independent circumstances, an inadequate evaluation of the radiological conditions and the inadequate instruction on the use of electronic dosimetry, contributed to the incident. Had the radiation protection technicians been given better information on the nature and exact location of the planned inservice inspection (ISI) work so that a survey of the specific work area could be performed, or had the radiation protection technicians accompanied the workers to the job site to determine the radiation levels in the specific work area, or had better instructions concerning

the use of electronic dosimeters been given, the incident might have been avoided. The incident might also have been avoided if survey data obtained during previous outages had been effectively utilized to evaluate the radiological hazards present while performing the ISI work on the riser with the reactor vessel water level lowered. To emphasize the need for stringent radiation protection controls to prevent a substantial potential for an exposure in excess of 10 CFR Part 20 limits, whether or not such exposure occurs, 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 $12,500 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 and the amount of the civil penalty was mitigated by 75 percent. Considering that the matter was not reportable, the civil penalty was reduced 25 percent because of your initiative in identifying the root cause of the self-disclosing event. The civil penalty was mitigated an additional 50 percent because of your prompt and extensive corrective actions, which included an immediate cessation of all work activities in the drywell and a plant wide work stand-down on the following day so that the circumstances surrounding the event could be discussed with all plant workers. The remaining factors in the enforcement policy were also 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, 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,

Carl J. Paperiello for

A. Bert Davis
Regional Administrator

Enclosure: Notice of Violation and Proposed
Imposition of Civil Penalty

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

Iowa Electric Light and Power Company
Duane Arnold Energy Center

Docket No. 50-331
License No. DPR-49
EA 92-056

During an NRC inspection conducted March 17 through 27, 1992, violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C (1992), the Nuclear Regulatory Commission proposes to impose a civil penalty pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (A 42 U.S.C. 2282, and 10 CFR 2.205. The particular violations and associate 1 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 10 CFR Part 20 and which are reasonable under the circumstances to evaluate the extent of radioactive hazards that may be present. As defined in 10 CFR 20.201(a), "survey" means an evaluation of the radiation hazards incident to the production, use, release, disposal, or presence of radioactive materials or other sources of radiation under a specific set of conditions.

Contrary to the above, on March 15, 1992, the licensee did not make an adequate survey to assure compliance with that part of 10 CFR 20.101 that limits the radiation exposure to the whole body. Specifically, dose rates in the area of the recirculation system 'A' riser were not determined by survey of the specific work location.

B. 10 CFR 19.12 requires, in part, that all individuals working in or frequenting any portion of a restricted area be kept informed of radiation in the frequented portions of the restricted area, be instructed in the purposes and functions of the protective devices employed, and be instructed in the appropriate response to warnings made in the event of any unusual occurrence that may involve exposure to radiation.

Contrary to the above, on March 15, 1992, two workers involved with the inservice inspection of the recirculation system 'A' riser in the drywell, a high radiation area, were not adequately instructed in the operation of their digital dosimeters [illegible] that the alarm signals were not demonstrated or otherwise appropriately described; were not adequately instructed in the appropriate response to the digital dosimeter alarms; and were not adequately informed of the actual radiation levels in their work area.

This is a Severity Level III problem (Supplement IV).
Cumulative Civil Penalty - $12,500 (assessed equally between the two violations).

Pursuant to the provisions of 10 CFR 2.201, Iowa Electric and 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 of 10 CFR Part 2, Appendix C (1992), should be addressed. Any written answer in accordance with 10 CFR 2.205 should be set forth separately from the statement or explanation in reply pursuant to 10 CFR 2.201, but may incorporate parts of the 10 CFR 2.201 reply by specific reference (e.g., citing page and paragraph numbers) to avoid repetition. The attention of the Licensee is directed to the other provisions of 10 CFR 2.205, regarding the procedure for imposing a civil penalty.

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

FOR THE NUCLEAR REGULATORY COMMISSION

Carl J. Paperiello for

A. Bert Davis
Regional Administrator

Dated at Glen Ellyn, Illinois
this 1st day of May 1992

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

MAY 02 1991

Docket No. 55-8615
License No. SOP-10561-1
EA 91-054

Mr. David M. Manning
HOME ADDRESS DELETED
UNDER 10 CFR 2.790

Dear Mr. Manning:

SUBJECT: ORDER SUSPENDING LICENSE (EFFECTIVE IMMEDIATELY) AND ORDER TO SHOW CAUSE WHY LICENSE SHOULD NOT BE REVOKED

The enclosed Order is being issued to you as a result of certain NRC concerns regarding actions by you as a Senior Reactor Operator at the Fitzpatrick Nuclear Power Plant. The Order suspends your Part 55 license and provides you an opportunity to show cause why your license should not be revoked. The Order also provides you with an opportunity for a hearing on these matters.

In addition, an Order is also being issued on this date to New York Power Authority modifying that license to prohibit your involvement in activities subject to the Part 50 license. A copy of that Order is also enclosed. You may also request a hearing on that Order.

Although you participated in the licensee's Employee Assistance Program, these Orders are being issued because of your lack of trustworthiness as demonstrated by: (1) your attempt to conceal use of cocaine by substituting a bogus urine sample on October 9, 1990 when selected for a random drug test in accordance with fitness for duty requirements; (2) your not informing the NRC of a drug habit when that information was required by an NRC Form 396, which you completed on April 14, 1986 and submitted to the NRC; and (3) your failure to provide a second urine sample on October 9, 1990 as required by 10 CFR Part 26 because you knew that the sample would be "dirty" with cocaine. In addition, your failure to conform to the prohibition against drug use in the Commission requirements, which have the purpose of protecting the public health and safety, demonstrates an intentional disregard for the important obligations of a licensed operator.

Questions concerning these Orders may be addressed to James Lieberman, Director, Office of Enforcement. He can be reached at 301-492-0741.

In accordance with Section 2.790 of the NRC's "Rules of Practice," Part 2, Title 10, Code of Federal Regulations, a copy of this letter and the enclosures will be placed in the NRC's Public Document Room.

Sincerely,

James H. Sniezek

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

Mr. David M. Manning

Enclosures:
1. Order
2. Letter to New York Power Authority (NYPA) with attached Order

cc w/encls:
Public Document Room

UNITED STATES
NUCLEAR REGULATORY COMMISSION

In the Matter of	)	
	)	Docket No. 55-8615
David M. Manning	)	License No. SOP-10561-1
Senior Reactor Operator	)	EA 91-054

ORDER SUSPENDING LICENSE (EFFECTIVE IMMEDIATELY) AND ORDER TO SHOW CAUSE WHY LICENSE SHOULD NOT BE REVOKED

I

David M. Manning (Licensee) is the holder of Senior Reactor Operator License No. SOP-10561-1 (License) issued by the Nuclear Regulatory Commission (NRC or Commission) pursuant to 10 CFR Part 55 on September 9, 1988. The license authorizes the Licensee to manipulate, and supervise the manipulation of, the controls of the nuclear power reactor at the New York Power Authority's (Facility Licensee) Fitzpatrick Nuclear Power Plant in Scriba, New York.

II

On October 9, 1990, the Licensee, while on duty at the Fitzpatrick facility, was requested by the Facility Licensee to provide a urine sample to the nurse at the plant after being randomly selected as part of the routine fitness for duty chemical testing program required of the Facility Licensee by the NRC pursuant to 10 CFR 26.24. After receiving a sample from the Licensee, the nurse checked the temperature of the sample and found that the temperature was below specifications in 10 CFR Part 26, Appendix A, Section 2.4(g)(14), for accepting the sample. As a result, the Licensee was requested to provide another urine sample to the Facility Licensee pursuant to the same section of the Appendix. The Licensee refused to provide another sample. As a result,

the Facility Licensee, in accordance with 10 CFR 26.27(c), removed the Licensee from licensed operator duties for cause, placed the Licensee on 14 days leave, and referred the Licensee to an Employee Assistance Program. Although the Licensee has completed the inpatient portion of that program, the Licensee is still in an outpatient status, is subject to monthly random testing, and has not been returned to the duties authorized by his Part 55 license. However, the Licensee now has unescorted access and is involved in licensed activities subject to the Part 50 license at the Fitzpatrick facility.

III

On April 24, 1991, the Licensee was interviewed by an investigator from the NRC Office of Investigations concerning the circumstances surrounding the reasons why the temperature of his initial sample was below the specifications, as well as his refusal to provide a second urine sample to the Facility Licensee on October 9, 1990. During that interview, the Licensee indicated that when he received notice from the Facility Licensee that he was selected to provide a urine sample for the random drug test on October 9, 1990, he retrieved a bogus urine sample from his locker which he had previously stored there, a practice that he had started in August 1990 for this contingency, and went to the men's room on the way to the test and heated the sample to what he thought would be body temperature. The Licensee stated that he put the sample in his pants and went to the test facility where he provided that sample to the nurse. The Licensee admitted that, although he was informed by the nurse,

shortly thereafter, that another sample was required because the temperature was below the specifications required by the testing program, he refused to provide another sample. The Licensee noted that because of his refusal to provide another sample as required by the fitness for duty program regulations, he was informed by his department supervisor, as well as the Resident Manager for the Fitzpatrick facility, that he would be placed on 14 days leave, and would be referred to the Employee Assistance Program for evaluation.

During the interview with the NRC investigator, the Licensee indicated that he did not want to provide the requested sample to the nurse when selected for testing on October 9, 1990 (a Tuesday) because he knew it was "dirty" from cocaine. The Licensee stated that he had used about 1 gram of cocaine on the Sunday before the test. The Licensee also noted that he had been using cocaine since 1977 and had also used "speed" during that time. The Licensee further indicated that on weekends he used cocaine in amounts from 1 to 3 grams.

The Licensee also admitted to the NRC investigator that he had previously been referred to the Employee Assistance Program as a result of a test that indicated cocaine use on an annual physical screening in August 1988. However, the Licensee stated that he had not used cocaine or any other controlled substance since October 1990, that he was now drug free, and that he had attended a thirty-day inpatient substance abuse clinic.

IV

The responsibilities associated with a senior reactor operator license issued pursuant to 10 CFR Part 55 are significant with respect to the protection of the public health and safety. The character of the individual, which includes the individual's exercise of sound judgment, is a consideration in issuing an operator license. See Section 182a of the Atomic Energy Act of 1954, as amended. In determining whether or not an individual seeking a license to be a reactor operator has the necessary character, including sound judgement, the Commission may take into account a history of illegal drug use by the applicant. Prior to May 26, 1987 each applicant for a reactor operator license was required to certify that the applicant had no drug or narcotic habit on the Certificate of Medical History, NRC Form 396. Since that time, the NRC has required an evaluation of the applicant prepared by a licensed medical practitioner as part of a license application. See 10 CFR 55.23(a). This evaluation is presented on a Certificate of Medical Examination, NRC Form 396. See 10 CFR 55.23. Among the factors to be considered by the certifying physician are factors such as use of illegal drugs or abuse of alcohol. See Form 396; also ANSI/ANS 3.4-1983, Section 5.2.2.

In accordance with 10 CFR Part 26, the Facility Licensee established a program to provide reasonable assurance that nuclear power plant personnel are not under the influence of any substance, legal or illegal, which affects their ability to safely and competently perform their duties, including measures for early detection of persons who are not fit to perform licensed activities.

V

The Licensee's actions described in sections II and III above raise significant concerns regarding the Licensee's integrity and trustworthiness. Specifically, these concerns are: (1) the Licensee intentionally engaged in a premeditated scheme to avoid detection of his drug use and to violate the fitness for duty program required by the NRC by storing a "clean" sample in his locker (which he admitted to have begun doing about three months prior to the test), and substituting that sample for the real sample that was required when he was selected for a random test; (2) notwithstanding his admitted use of cocaine between 1977 and October 1990, the Licensee, in a Certificate of Medical History (Form 396) signed by him on April 14, 1986, answered "No" to Question 24, "Have you ever had or do you now have any of the following?...Drug, narcotic habit or excessive drinking" (The Licensee did note on the Form 396 that he was convicted of "Driving While Ability Impaired" in Oneida City Court, Oneida, New York in April 1982.); and (3) the Licensee refused to provide another sample to the Facility Licensee for testing when the temperature of the initial sample was below specifications because he knew that his sample would be "dirty" with cocaine even though the Facility License is required by Part 26 to obtain a second sample, and the Licensee is required by Part 55 to abide by all of the requirements of the Facility License. In addition, the Licensee's failure to conform to the prohibition against drug use in New York Power Authority's program and the Commission's requirements, which have the purpose of protecting the public health and safety, demonstrates an intentional disregard for the important obligations of a licensed operator. The above actions demonstrate a lack of trustworthiness by the Licensee and an inability or unwillingness to

comply with the Commission's requirements. Therefore, the NRC does not have the necessary reasonable assurance that the Licensee will carry out his duties to operate the Fitzpatrick facility safely in a trustworthy manner and observe all applicable requirements including obligations relating to the fitness for duty requirements of the Facility License.

VI

Based on the above, if at the time the License was issued, the NRC had known of the Licensee's inability or unwillingness to refrain from the use of illegal drugs, and if the NRC had known of the Licensee's willingness to attempt to circumvent compliance with the Commission's regulations, the License would not have been issued. Section 186 of the Atomic Energy Act of 1954, as amended, and 10 CFR 55.61(b) provide that a license may be revoked for any reason for which a license would not be issued upon an original application.

Consequently, in view of the above and lacking the requisite reasonable assurance that the Licensee will abide by Commission requirements, I have determined that the public health and safety requires that the License be suspended. Pursuant to 10 CFR 2.204, I find that the public health and safety requires that this Order must be effective immediately.

VII

Accordingly, pursuant to Sections 107, 161b, 161i, 182, and 186 of the Atomic Energy Act of 1954, as amended, and the Commission's regulations in 10 CFR 2.202, 2.204, and 10 CFR Part 55, IT IS HEREBY ORDERED, EFFECTIVE IMMEDIATELY, THAT LICENSE NO. SOP-10561-1 IS HEREBY SUSPENDED PENDING FURTHER ORDER.

The Regional Administrator, NRC Region I, may relax or terminate this condition for good cause shown.

VIII

Further, pursuant to sections 107, 161b, 161c, 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 Part 55, IT IS HEREBY ORDERED THAT the Licensee shall show cause why License No. SOP-10561-1 should not be revoked and why it should not have been suspended.

IX

Pursuant to 10 CFR 2.202(b), the Licensee shall show cause, as required by Section VIII above, by filing a written answer under oath or affirmation within 20 days after the date of issuance of this Order, setting forth the matters of fact and law on which the Licensee relies. Any other person adversely affected

by this Order may submit an answer to this Order within 20 days of the date of this Order. The Licensee may answer this Order, as provided in 10 CFR 2.202(d), by consenting to the entry of an Order suspending or revoking its license. Any answer to this Order shall be submitted to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555. Copies also shall be sent to the Assistant General Counsel for Hearings and Enforcement at the same address, and to the Regional Administrator, NRC Region I, 475 Allendale Road, King of Prussia, Pennsylvania 19406.

X

The Licensee or any other person adversely affected by this Order may request a hearing on this Order within 20 days of its issuance. Any request for a hearing shall be submitted to the Secretary, U.S. Nuclear Regulatory Commission, ATTN: Chief, Docketing and Service Section, Washington, D.C. 20555, and shall include a copy of the answer to the Order. Copies of the hearing request also shall be sent to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, to the Assistant General Counsel for Hearings and Enforcement at the same address, to the Regional Administrator, NRC Region I, 475 Allendale Road, King of Prussia, Pennsylvania 19406, and to the Licensee if the hearing request is by a person other than the Licensee. If a person other than the Licensee requests a hearing, that person shall set forth with particularity the manner in which his interest is adversely affected by this Order and shall address the criteria set forth in 10 CFR 2.714(d).

If a hearing is requested by the Licensee 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.

XI

In the absence of any request for hearing, the provision specified in Section VII 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. If an answer to this Order is submitted as provided in section IX but a hearing is not requested, the Order may be relaxed or rescinded as provided in section VII. However, unless the Order is relaxed or rescinded, the Order provision of section VII is final.

In addition, in the absence of any request for a hearing and in the absence of adequate cause being shown as provided in sections VIII and IX, an Order will be issued making the provisions specified in Section VIII effective and final without further proceedings.

FOR THE NUCLEAR REGULATORY COMMISSION

James H. Sniezek

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

Dated at Rockville, Maryland
this 2nd day of May 1991

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

AUG 09 1991

Docket No. 55-8615
License No. SOP-10561-1
EA 91-054

Mr. David M. Manning
HOME ADDRESS DELETED
UNDER 10 CFR 2.790

Dear Mr. Manning:

SUBJECT: MODIFICATION OF ORDER ISSUED BY NRC MAY 2, 1991

This refers to your June 6, 1991 response to the Order Suspending License (Effective Immediately) and Order to Show Cause Why License Should Not Be Revoked issued by the NRC on May 2, 1991. The subject Order was issued as a result of NRC concerns regarding actions by you as a Senior Reactor Operator at the FitzPatrick Nuclear Power Plant.

The NRC staff has carefully reviewed your response and has determined that the information provided warrants a modification of the original Order. Therefore, the Order has been modified to allow eventual consideration for resumption of Part 55 duties at FitzPatrick and to set conditions that must be satisfied before such consideration. Also enclosed is a copy of an Order that modifies our May 2, 1991 Order to the New York Power Authority.

Questions concerning these Orders may be addressed to Marian Zobler, counsel for the Staff. She can be reached at 301-492-1572.

In accordance with Section 2.790 of the NRC's "Rules of Practice," Part 2, Title 10, Code of Federal Regulations, a copy of this letter and the enclosure will be placed in the NRC's Public Document Room.

Sincerely,

James H. Sniezek

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

Enclosures: As Stated

cc w/encls:
Public Document Room (PDR)
Local Public Document Room (LPDR)
NRC Resident Inspector
D. Geoffrey Gosch, Esq.

UNITED STATES
NUCLEAR REGULATORY COMMISSION

In the Matter of

David M. Manning
Senior Reactor Operator

Docket No. 55-8615
License No. SOP-10561-1
EA 91-054

MODIFICATION OF ORDER SUSPENDING LICENSE
(EFFECTIVE IMMEDIATELY)

I

David M. Manning (Licensee) is the holder of Senior Reactor Operator License No. SOP-10561-1 (License) issued by the Nuclear Regulatory Commission (NRC or Commission) pursuant to 10 C.F.R. Part 55 on September 2, 1988. The License authorizes the Licensee to manipulate, and supervise the manipulation of, the controls of the nuclear power reactor at the New York Power Authority's (Facility Licensee) FitzPatrick Nuclear Power Plant in Scriba, New York.

II

On May 2, 1991, an Order Suspending License (Effective Immediately) and Order to Show Cause Why License Should Not Be Revoked was issued to the Licensee. The Licensee responded to this Order on June 6, 1991, by requesting relief from the conditions of this Order or a hearing at which he and witnesses on his behalf may be heard.

In his response, the Licensee admitted some of the factual allegations of sections I, II, III, and V of this Order but denied any inference or subjective conclusion that he is not reliable, trustworthy, a person of integrity or is not a person that the Commission and his employer, the Facility Licensee, can reasonably be assured will exercise sound judgment in the safe and efficient operation of the FitzPatrick facility. The Licensee further denied that he willfully or materially misrepresented his drug habit on NRC Form 396.

The Licensee further asserted that denial is one of the symptoms of cocaine use, which is manifested in attempts to avoid drug tests or other disclosure of that use.

In support of these assertions, the Licensee described his participation in various rehabilitation programs. The Licensee further stated that he has committed himself to compliance with and obedience to the Fitness for Duty requirements of the Commission and the Facility Licensee, has been drug tested eight times since his return to work and all test results have been negative, and continues to be subject to frequent random testing.

III

The Staff has carefully reviewed the Licensee's response, including financial and medical records attached thereto, and the arguments made in it, and has consulted a medical expert in the field of drug rehabilitation. The Staff agrees that denial, including attempts to conceal use of illegal drugs, may be a symptom of the drug use itself, and therefore, the drug user may attempt to conceal the drug use.

However, the Staff does not agree, based on expert medical advice, that the Licensee's progress to date indicates that he is rehabilitated or that the symptoms that may be associated with drug use, including denial, are completely eradicated. Rehabilitation requires long-term abstinence accompanied by counseling and participation in support groups, among other measures. Since the Licensee's efforts to date, however successful, represent only detoxification and short-term abstinence, the Staff is not prepared to conclude that he is rehabilitated and to permit his resumption of licensed duties. The Staff has concluded, based on the reasons given in the initial Order and Licensee's answer, that the License should remain suspended. However, based on expert medical advice, the License will not be revoked and the suspension will be for a period of time that will allow adequate assurance that the Licensee is rehabilitated. This time period must include testing, counseling, and other measures to ensure that the Licensee has abstained from drug use and to provide a high degree of assurance that he will not resume drug use in the future.

IV

Therefore, pursuant to sections 107, 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 55, IT IS HEREBY ORDERED, EFFECTIVE IMMEDIATELY, THAT THE ORDER OF MAY 2, 1991, IS HEREBY MODIFIED TO REQUIRE THAT:

A. The License No. SOP-10561-1 is suspended for a minimum of three years from the date of this Order.

B. License No. SOP-10561-1 may be reinstated and/or renewed provided Licensee provides the Staff with evidence that he has completed the following three year drug rehabilitation program. The three year drug rehabilitation program shall commence upon written notification by Licensee to the Regional Administrator, NRC Region I, of Licensee's intent to comply with the program and approval by the Staff of the parties to conduct the drug tests required by C(1) below, if the Facility Licensee does not conduct the tests, and the party described in C(5) below. After completion of the program, Licensee may apply for such license reinstatement or renewal. In addition, Licensee must also comply with all the requirements of 10 C.F.R. Part 55, including submission of a favorable medical certification.

C. The three year drug rehabilitation program must include:

(1) Drug testing conducted by the Facility Licensee or a third party mutually acceptable to the Licensee and the NRC Staff that includes:

(a) random observed drug tests at least once a week for the first year of the program;

(b) random observed drug tests at least twice a month for the second year of the program;

(c) random observed drug tests at least once a month for the third year of the program; and

(d) for the entire three years of the program, observed drug testing on the first day back from any unexcused or unanticipated absence of 24 hours or more, or after any scheduled absence of more than three calendar days;

(2) participation in self-help groups or other group counseling meetings, such as those conducted by Alcoholics Anonymous and Narcotics Anonymous, at least three times a week for the three years of the program;

(3) neurological and neuro-psychological testing by qualified clinicians mutually acceptable to the Licensee and the Staff within six months prior to applying for renewal or reinstatement of his license under 10 C.F.R. Part 55;

(4) meeting with NRC senior management and an NRC medical consultant prior to return to 10 C.F.R. Part 55 licensed duties; and

(5) participation, for the purposes of monitoring his progress, in an initial interview and in follow-up sessions at least twice a month for the first year of this program and at least once a month for the next two years with a qualified professional drug counselor who is mutually acceptable to the Licensee and the Staff.

D. Licensee must inform NRC Region I Regional Administrator immediately of any positive drug test and maintain records of each negative drug test and each

attendance at self-help meetings and counseling sessions as referenced in C(2) and C(5) above. Licensee must provide the Region I Regional Administrator with these records on a semiannual basis. Any deviations from the requirements of C(2) and C(5) above shall be explained and justified in the records provided to the Regional Administrator.

E. The portion of the May 2, 1991 Order requiring Mr. Manning to show cause why license should not be revoked, 56 Fed. Reg. 22020 (May 13, 1991), is hereby rescinded.

Upon application by Licensee, the Regional Administrator, NRC Region I, may relax or terminate these conditions for good cause shown.

V

In his answer to the May 2, 1991 Order Suspending License (Effective Immediately) and Order to Show Cause Why License Should Not Be Revoked, the Licensee requested a hearing. In response, an Atomic Safety and Licensing Board was established and a

proceeding is underway. Thus, in accordance with 10 C.F.R. §§ 2.717(b) and 2.718, any further answers by the parties shall be as directed by the presiding Licensing Board.

FOR THE NUCLEAR REGULATORY COMMISSION

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

Dated at Rockville, Maryland
this 9th day of August 1991

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

MAY 02 1991

Docket No. 50-333
License No. DPR-59
EA 91-053

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

Dear Mr. Beedle:

SUBJECT: ORDER MODIFYING LICENSE (EFFECTIVE IMMEDIATELY)

The enclosed Order Modifying License (Effective Immediately) is being issued to you as a result of certain NRC concerns regarding the actions of Mr. David Manning, an employee licensed as a Senior Reactor Operator at your Fitzpatrick Nuclear Facility. The Order modifies your license to prohibit Mr. Manning from being involved in activities subject to your Part 50 license. Both you and Mr. Manning have an opportunity for a hearing on this Order.

In addition, an Order is being issued on this date to Mr. Manning suspending his Part 55 license. A copy of that Order is also enclosed.

Although Mr. Manning participated in your Employee Assistance Program, these Orders are being issued because of his lack of trustworthiness as demonstrated by: (1) his attempt to conceal his use of cocaine by substituting a bogus urine sample on October 9, 1990 when selected for a random drug test in accordance with fitness for duty requirements; (2) his not informing the NRC of a drug habit when that information was required by an NRC Form 396, completed by him on April 14, 1986 and submitted to the NRC; and (3) his failure to provide a second urine sample on October 9, 1990 as required by 10 CFR Part 26 because he knew that the sample would be "dirty" with cocaine. In addition, Mr. Manning's failure to conform to the prohibition against drug use in the Commission requirements, which have the purpose of protecting the public health and safety, demonstrates an intentional disregard for the important obligations of a licensed operator.

Questions concerning these Orders may be addressed to James Lieberman, Director, Office of Enforcement. He can be reached at 301-492-0741.

In accordance with Section 2.790 of the NRC's "Rules of Practice," Part 2, Title 10, Code of Federal Regulations, a copy of this letter and the enclosures will be placed in the NRC's Public Document Room.

Sincerely,

James H. Sniezek

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

Enclosures: As Stated

cc w/encls:
J. Brons, President and Chief Operations Officer
S. Zulla, Vice President, Nuclear Engineering
W. Josiger, Vice President, Nuclear Operations & Maintenance
J. Gray, Director, Nuclear Licensing, BWR
A. Klausmann, Senior Vice President, Appraisal & Compliance Services
G. Tasick, Quality Assurance Superintendent
G. Wilverding, Manager, Nuclear Safety Evaluation
G. Goldstein, Assistant General Counsel
Department of Public Service, State of New York
State of New York, Department of Law
Public Document Room (PDR)
Local Public Document Room (LPDR)
Nuclear Safety Information Center (NSIC)
NRC Resident Inspector
State of New York, SLO Designee

UNITED STATES
NUCLEAR REGULATORY COMMISSION

In the Matter of	)	
	)	Docket No. 50-333
New York Power Authority	)	License No. DPR-59
Fitzpatrick	)	EA 91-053

ORDER MODIFYING LICENSE (EFFECTIVE IMMEDIATELY)

I

New York Power Authority (Licensee) is the holder of Facility Operating License No. DPR-59, issued by the Nuclear Regulatory Commission (NRC or Commission) pursuant to 10 CFR Part 50. The License authorizes the operation of the Fitzpatrick facility in Scriba, New York, in accordance with the conditions specified therein.

II

On October 9, 1990, David M. Manning (Mr. Manning), a licensed Senior Reactor Operator licensed under 10 CFR Part 55 at the Fitzpatrick facility, while on duty at the facility, was requested by the Licensee to provide a urine sample to the nurse at the plant after being randomly selected as part of the routine fitness for duty chemical testing program required of the Licensee by the NRC pursuant to 10 CFR 26.24. After receiving a sample from Mr. Manning, the nurse checked the temperature of the sample and found that the temperature was not within the range specified in 10 CFR Part 26, Appendix A, Section 2.4(g)(14), for accepting the sample. As a result, Mr. Manning was requested to provide another urine sample pursuant to the same section of Appendix A. Mr. Manning

refused to provide another sample. As a result, the Licensee, in accordance with 10 CFR 26.27(c), removed Mr. Manning from licensed operator duties for cause, placed Mr. Manning on 14 days leave, and referred Mr. Manning to an Employee Assistance Program. Although Mr. Manning has completed the inpatient portion of that program, Mr. Manning is still in an outpatient status, is subject to monthly random testing, and has not been returned to the duties authorized by his Part 55 license. However, Mr. Manning now has unescorted access and is involved in activities subject to the 10 CFR Part 50 license at the Fitzpatrick facility.

III

On April 24, 1991, Mr. Manning was interviewed by an investigator from the NRC Office of Investigations concerning the circumstances surrounding the reasons why his initial sample was outside the acceptable temperature range, as well as his refusal to provide a second urine sample to the Licensee on October 9, 1990. During that interview, Mr. Manning indicated that when he received notice from the Licensee that he was selected to provide a urine sample for the random drug test on October 9, 1990, he retrieved a bogus urine sample from his locker which he had previously stored there and went to the men's room on the way to the test and heated the sample to what he thought would be body temperature. Mr. Manning stated that he put the sample in his pants and went to the test facility where he provided that sample to the nurse. Mr. Manning admitted that, although he was informed by the nurse, shortly thereafter, that another sample was required because the temperature was below the specifications

required by the testing program, he refused to provide another sample. Mr. Manning noted that because of his refusal to provide another sample as required by the fitness for duty program regulations, he was informed by his department supervisor, as well as the Resident Manager for the Fitzpatrick facility, that he would be placed on 14 days leave, and would be referred to the Employee Assistance Program for evaluation.

During the interview with the NRC investigator, Mr. Manning indicated that he did not want to provide the requested sample to the nurse when selected for testing on October 9, 1990 (a Tuesday) because he knew it was "dirty" from cocaine. Mr. Manning stated that he had used about 1 gram of cocaine on the Sunday before the test. Mr. Manning also noted that he had been using cocaine since 1977 and had also used "speed" during that time. Mr. Manning further indicated that on weekends he used cocaine in amounts from 1 to 3 grams.

Mr. Manning also admitted to the NRC investigator that he had previously been referred to the Employee Assistance Program as a result of a test that indicated cocaine use during an annual physical screening in August 1988. However, Mr. Manning claimed that he had not used cocaine or any other controlled substance since October 1990, that he was now drug free, and that he had attended a thirty-day inpatient substance abuse clinic.

IV

In accordance with 10 CFR Part 26, the Licensee established a program to provide reasonable assurance that nuclear power plant personnel are not under

the influence of any substance, legal or illegal, which affects their ability to safely and competently perform their duties, including measures for early detection of persons who are not fit to perform licensed activities.

Mr. Manning's actions described above raise significant concerns regarding his integrity and trustworthiness. Specifically, these concerns are: (1) Mr. Manning intentionally engaged in a premeditated scheme to avoid detection of his drug use and to violate the fitness for duty program required by the NRC by storing a "clean" sample in his locker (which he admitted to have begun doing about three months prior to the test), and substituting that sample for the real sample that was required when he was selected for a random test; (2) notwithstanding his admitted use of cocaine between 1977 and October 1990, Mr. Manning, in a Certificate of Medical History (Form 396) signed by him on April 14, 1986, answered "No" to Question 24, "Have you ever had or do you now have any of the following?...Drug, narcotic habit or excessive drinking" (Mr. Manning did note on the Form 396 that he was convicted of "Driving While Ability Impaired" in Oneida City Court, Oneida, New York in April 1982.); and (3) Mr. Manning refused to provide another sample to the Licensee for testing when the temperature of the initial sample was below the specifications because he knew that his sample would be "dirty" with cocaine, even though the Licensee is required by Part 26 to obtain a second sample, and Mr. Manning is required by Part 55 and his Senior Reactor Operator's license to abide by all of the requirements of the Facility License. In addition, Mr. Manning's failure to conform to the prohibition against drug use in the Commission requirement , which have the purpose of protecting the public health and safety, demonstrates an intentional disregard for the important obligations of a licensed operator. The above actions

demonstrate a lack of trustworthiness by Mr. Manning and an inability or unwillingness to comply with the Commission's requirements. Therefore, the NRC does not have the necessary reasonable assurance that Mr. Manning will carry out Part 50 activities safely, in a trustworthy manner, and observe all applicable requirements including obligations relating to the Licensee's fitness for duty requirements.

V

Mr. Manning's actions described above are unacceptable and, accordingly, I have issued a separate Order suspending his 10 CFR Part 50 license. Furthermore, as a result of his actions, I lack the requisite reasonable assurance that, with Mr. Manning involved in any activities licensed under 10 CFR Part 50, the Licensee's current operations can be conducted such that the health and safety of the public, including the Licensee's employees, will be protected. Therefore, the public health and safety require that License No. DPR-59 be modified to prohibit Mr. David M. Manning from involvement in licensed activities under this license. Furthermore, pursuant to 10 CFR 2.204, I find that the public health and safety require that this Order must be effective immediately.

VI

Accordingly, pursuant to Sections 103, 161b, 161c, 161i, and 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 Part 50, IT IS HEREBY ORDERED, EFFECTIVE IMMEDIATELY, THAT:

License No. DPR-59 is modified by adding the following condition:

> Mr. David M. Manning shall not participate in any licensed activity under License No. DPR-59 without prior written approval of the Regional Administrator, Region I. If such approval is sought, the Licensee shall provide a statement as to its basis for concluding that Mr. Manning will properly carry out licensed activities in light of his past conduct and lack of trustworthiness as described in this Order.

The Regional Administrator, NRC Region I, may relax or terminate this condition for good cause shown.

VII

The Licensee, Mr. Manning, or any other person adversely affected by this Order may submit an answer to this Order or request a hearing on this Order within 20 days of the date of this Order. The answer may set forth the matters of fact and law on which the Licensee, Mr. Manning, or other person adversely affected relies and the reasons as to why the Order should not have been issued. Any answer filed within 20 days of the date of this Order may also request a hearing. Any answer or request for hearing shall be submitted to the Secretary, U.S. Nuclear Regulatory Commission,

ATTN: Chief, Docketing and Service Section, Washington, D.C. 20555. Copies shall also be sent to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, to the Assistant General Counsel for Hearings and Enforcement at the same address, to the Regional Administrator, NRC Region I, 475 Allendale Road, King of Prussia, Pennsylvania 19406, and to the Licensee if the answer or hearing request is by a person other than the Licensee. If a person other than the Licensee or Mr. Manning requests a hearing, that person shall set forth with particularity the manner in which the person's interest is adversely affected by the Order and should address the criteria set forth in 10 CFR 2.714(d).

If a hearing is requested by the Licensee, Mr. Manning, 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.

In the absence of any request for a hearing, the provisions specified in Section VI above shall be final 20 days from the date of this Order without further order or proceedings. AN ANSWER OR REQUEST FOR A HEARING SHALL NOT STAY THE IMMEDIATE EFFECTIVENESS OF THIS ORDER.

If an answer to this Order is submitted as provided above but a hearing is not requested, the Order may be relaxed or rescinded as provided in section

VI. However, unless the Order is relaxed or rescinded, the Order is final as provided above.

FOR THE NUCLEAR REGULATORY COMMISSION

James H. Sniezek

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

Dated at Rockville, Maryland
this 2nd day of May 1991

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

AUG 09 1991

Docket No. 50-333
License No. DPR-59
EA 91-053

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

Dear Mr. Beedle:

SUBJECT: MODIFICATION OF ORDER ISSUED BY NRC MAY 2, 1991

This letter is in response to your May 31, 1991 response to the Order Modifying License (Effective Immediately) issued by the NRC on May 2, 1991 and the letter you faxed to me on August 8, 1991, supplementing your original response. In the August letter you outlined the follow-up drug testing frequency that has been applied to Mr. Manning in the past, and the testing program you intend to apply to Mr. Manning in the future.

As I told you during our telephone conversation on August 6, 1991, after careful review of your May 31, 1991 response, and after further medical consultation, the Staff has finalized the conceptual approach outlined in our July 16, 1991 response. On that same day, a copy of what the Staff would consider as an acceptable follow-up program was faxed to you. Your response was the letter dated August 8, 1991. After full consideration of your August 8, 1991 response, I have decided, for the protection of the public health and safety, to issue the enclosed modified order which incorporates the terms of the follow-up drug testing program contained in the fax to you on August 6, 1991.

In addition, an Order is being issued on this date to Mr. Manning modifying the order issued to him on May 2, 1991. A copy of that Order is also enclosed.

In accordance with Section 2.790 of the NRC's "Rules of Practice," Part 2, Title 10, Code of Federal Regulations, a copy of this letter and the enclosures will be placed in the NRC's Public Document Room.

Sincerely,

James H. Sniezek

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

Enclosures: As stated

UNITED STATES
NUCLEAR REGULATORY COMMISSION

In the Matter of

New York Power Authority
FitzPatrick

Docket No. 50-333
License No. DPR-59
EA 91-053

MODIFICATION OF ORDER MODIFYING LICENSE
(EFFECTIVE IMMEDIATELY)

I

New York Power Authority (Licensee) is the holder of Facility Operating License No. DPR-59, issued by the Nuclear Regulatory Commission (NRC or Commission) pursuant to 10 C.F.R. Part 50. The License authorizes the operation of the FitzPatrick facility in Scriba, New York, in accordance with the conditions specified therein.

II

On May 2, 1991, an Order Modifying License (Effective Immediately) was issued to the Licensee to prohibit participation by a licensed Senior Reactor Operator, David M. Manning, in Part 50 licensed activities without the prior written approval of the NRC Regional Administrator, Region I.

The Licensee responded to this Order on May 31, 1991, by requesting that the NRC reconsider the matter and rescind this Order. To support this request, the Licensee asserted that the decision as to who is fit to work at the FitzPatrick plant is properly the management

responsibility of the Licensee and that the facts and law do not support issuance of this Order.

Stating that the rehabilitation of the employee is one of the objectives of 10 C.F.R. Part 26, the Licensee asserted that reinstatement to duties is part of rehabilitation and that this Order had usurped the Licensee's authority in that decision. The Licensee further stated that decisions concerning reliability and trustworthiness have traditionally been the responsibility of management and that the NRC has recognized a licensee's competence to make these determinations. Therefore, the Licensee argued that there is no basis for the NRC to overturn the Licensee's decision to reinstate Mr. Manning's grant of unescorted access.

The Licensee argued that Mr. Manning's untrustworthiness was symptomatic of the substance abuse problem for which he underwent treatment and concluded that "in the absence of a substance abuse problem . . . there is no reason to assume that Mr. Manning would attempt to cheat in a random drug test, misrepresent a drug habit on a Certificate of Medical History, or otherwise attempt to deceive the NRC or fail to comply with NRC requirements", adding, "[t]he Authority [Licensee] believes that the successful rehabilitation of Mr. Manning . . . eradicated the substance abuse problem, including the deceit that accompanied it."

In conclusion, the Licensee stated that this Order defeats the entire purpose of an otherwise successful rehabilitation, stating that there was "ample basis to conclude that Mr. Manning was rehabilitated."

III

The Staff has carefully reviewed the Licensee's response and the arguments made in it and consulted a medical expert in the field of drug rehabilitation. The Staff agrees that denial, including attempts to conceal use of illegal drugs, may be a symptom of the drug use itself, and that reinstatement to productive work is an important step in the process of rehabilitation.

However, the Staff does not agree, based on expert medical advice, that Mr. Manning's progress to date indicates that he is rehabilitated or that the symptoms that may be associated with drug use, including denial, have been completely eradicated. Rehabilitation requires long-term abstinence accompanied by counseling and participation in support groups, among other measures. Since Mr. Manning's efforts to date, however successful, represent only detoxification and short-term abstinence, the Staff is not prepared to conclude that he is rehabilitated and to permit his return to Part 50 licensed duties. The Staff has determined, for the reasons set forth in the initial Order and in Licensee's answer, that Mr. Manning may perform Part 50 licensed activities only if he can provide continuing assurance that he has not returned to using drugs.

IV

Therefore, pursuant to Sections 103, 161b, 161i, 161o, 182, and 186 of the Atomic Energy Act or 1954, as amended, and the Commission's regulations in 10 C.F.R. 2.204 and 10 C.F.R. Part 50, THE ORDER OF MAY 2, 1991 IS HEREBY MODIFIED TO REQUIRE THAT:

1) The provisions of the Order Modifying License (Effective Immediately) issued on May 2, 1991, 56 Fed. Reg. 22022 (May 15, 1991), directing that David M. Manning be removed from 10 C.F.R. Part 50 licensed activities, are modified to allow Mr. Manning to be returned to Part 50 activities provided Licensee complies with the following provisions:

   a) for three years from the date of Mr. Manning's return to Part 50 licensed activities, the Licensee will conduct random drug tests of David M. Manning and observe the collection of urine samples provided by Mr. Manning in accordance with Section 2.4(f) of Appendix A, 10 C.F.R. Part 26 and its established procedures. The period between each drug test must not exceed 90 days, with a new 90-day period beginning the day after a test is conducted;

   b) for three years from the date of Mr. Manning's return to Part 50 licensed activities, the Licensee will conduct observed drug tests of Mr. Manning on the first day back from any unexcused or

unanticipated absence of 24 hours or more, or after any scheduled absence of more than three calendar days;

c) Licensee must notify the NRC Region I Regional Administrator of any positive result within 24 hours.

The Regional Administrator, NRC Region I, may relax or terminate these conditions for good cause shown.

V

In its answer to the May 2, 1991 Order Modifying License (Effective Immediately), the Licensee requested a hearing. In response, an Atomic Safety and Licensing Board was established and a proceeding is underway. Thus, in accordance with 10 C.F.R. §§ 2.717(b) and 2.718, any further answers by the parties shall be as directed by the presiding Licensing Board.

FOR THE NUCLEAR REGULATORY COMMISSION

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

Dated at Rockville, Maryland
this 9th day of August 1991

October 7, 1991

UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

BEFORE THE ATOMIC SAFETY AND LICENSING BOARD

In the Matter of	)	Docket No. 050-333-OM
	)	ASLBP No. 91-645-02-OM
NEW YORK POWER AUTHORITY	)	Facility Operating
	)	License No. DPR-59
(James A. FitzPatrick	)	E.A. 91-053
Nuclear Power Plant)	)	

SETTLEMENT AGREEMENT

On May 2, 1991, the NRC staff (Staff) issued an "Order Modifying License (Effective Immediately)" to the New York Power Authority (NYPA) with respect to the James A. FitzPatrick Nuclear Power Plant. 56 Fed. Reg. 22022 (May 13, 1991). The Order Modifying License modified NYPA's facility license No. DPR-59 to prohibit Mr. David M. Manning, a licensed senior reactor operator, from involvement in licensed activities under this license. On May 31, 1991, NYPA filed its answer to the Order Modifying License. In its answer, NYPA requested reconsideration of or a hearing on the Order Modifying License. In Response to NYPA's answer, the Staff issued "Modification of Order Modifying License (Effective Immediately)" on August 9, 1991. 56 Fed. Reg. 41378, August 20, 1991. After discussions between the Staff and NYPA, both the Staff and NYPA agree that it is in the public interest to terminate this proceeding without further litigation and agree to the following terms and conditions.

1. NYPA withdraws its request for a hearing dated May 31, 1991.

2. The Staff withdraws both Orders issued to NYPA, dated May 2 and August 9, 1991.

3. NYPA agrees that it will not deviate from the follow-up drug testing program it established for David M. Manning, in accordance with 10 C.F.R. Part 26, without first obtaining the concurrence of NRC Region 1 Regional Administrator. Such drug testing program is as follows:

   a. for three years from the date of David M. Manning's return to Part 50 licensed activities,[1] NYPA will conduct random drug tests of Mr. Manning and observe the collection of urine samples provided by Mr. Manning in accordance with Section 2.4(f) of Appendix A, 10 C.F.R. Part 26 and its established procedures. The period between each drug test will not exceed 90 days, with a new 90-day period beginning the day after a test has been conducted.

   b. for three years from the date of Mr. Manning's return to Part 50 licensed activities, NYPA will conduct observed drug tests of Mr. Manning, as described in item a above, on:

      1) the first day back from any unexcused or unanticipated absence of 24 hours or more; or

      2) after any scheduled absence of more than three calendar days.

---

[1] Mr. Manning returned to Part 50 duties on August 28, 1991. Letter to the Board from D. Jeffrey Gosch, dated August 30, 1991.

c. NYPA will notify the NRC Region I Regional Administrator of any positive result within 24 hours.

4. The Staff and the Licensee shall jointly move the Atomic Safety and Licensing Board for an Order approving this Settlement Agreement and terminating this proceeding. This agreement shall become effective upon Approval by the Licensing Board.

FOR THE NUCLEAR REGULATORY COMMISSION

Marian L. Zobler
Counsel for NRC Staff

FOR THE NEW YORK POWER AUTHORITY

Gerald C. Goldstein
Counsel for the New York Power Authority

Arthy J. Levine
Counsel for the New York Power Authority

Dated October 7, 1991

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

May 21, 1992

Docket No. 50-306
License No. DPR-60
EA 92-067

Northern States Power Company
ATTN: Mr. L. R. Eliason
Vice President, Nuclear
Generation
414 Nicollet Mall
Minneapolis, Minnesota 55401

Dear Mr. Eliason:

SUBJECT: PRAIRIE ISLAND NUCLEAR GENERATING PLANT - UNIT 2
NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY - $12,500
(NRC INSPECTION REPORT NO. 50-306/92006(DRP))

This refers to the special safety inspection conducted during the period of February 20 through March 30, 1992, at the Prairie Island Nuclear Generating Plant, Unit 2. The inspection included a review of the circumstances surrounding the interruption of shutdown cooling during reduced inventory operations on February 20, 1992.

The report documenting this inspection was sent to you by letter dated April 10, 1992. During this inspection a violation of NRC requirements was identified. An Augmented Inspection Team (AIT) conducted the initial NRC review of this event and its findings are documented in Inspection Report No. 50-306/92005 sent to you by letter dated March 17, 1992. An enforcement conference was held on April 21, 1992, to discuss the violation, its cause, and your corrective actions. The report summarizing the conference was sent to you by letter dated April 30, 1992. The event was reported via the Emergency Notification System on February 20, 1992, and a Licensee Event Report was submitted to the NRC by letter dated March 23, 1992

On February 20, 1992, Prairie Island Unit 2 was in cold shutdown for a scheduled refueling and maintenance outage. Reactor Coolant System (RCS) temperature was being maintained at

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RETURN RECEIPT REQUESTED

approximately 135 degrees Fahrenheit as indicated on the core exit thermocouples. Water was being drained from the RCS to establish conditions for removing steam generator manways and installing steam generator nozzle dams in preparation for eddy current testing. RCS water level was allowed to decrease below the level necessary for continued operation of the inservice residual heat removal (RHR) pump, making it necessary to shut off the pump and interrupt operation of the RHR system. Makeup water to the RCS was added in accordance with procedures, and the standby RHR pump was placed in service for shutdown cooling. Although one core exit thermocouple reached 221.5 degrees Fahrenheit, the maximum calculated average RCS temperature remained below 171 degrees Fahrenheit, which represented an approximate increase of 36 degrees Fahrenheit as the result of the 22 minute event.

The NRC recognizes that the actual impact of the event on plant nuclear safety was minimal. However, while the sudden increase in temperature did not have significant consequences, the conditions which allowed this event to occur are cause for significant regulatory concern. Specifically, interruptions of shutdown cooling have been of particular concern to the NRC staff over the past few years because it has been recognized that such situations provide the potential for adverse impact on the safety of the nuclear reactor when plant systems, that might normally be available to mitigate such situations, are not required to be operable. The root causes for the event were fully discussed in the AIT report and during the enforcement conference.

One violation with three examples is described in the enclosed Notice of Violation (Notice). The violation involves an inadequate procedure for RCS reduced inventory operation. The root cause of the violation was plant management's over-reliance on engineering experience in the control room to provide detailed guidance to the operators for RCS reduced inventory operations rather than providing an adequate procedure. This violation represents a significant regulatory concern because, as discussed above, any unexpected loss of shutdown cooling can lead to situations in which nuclear safety can be compromised. Better training, planning, and command and control could have prevented this event. It was also of concern that the operators continued the drain down in spite of indications that should have caused questioning of whether the instruments were properly monitoring the situation. Therefore, in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy) 10 CFR Part 2, Appendix C (1992), this violation has been categorized at Severity Level III.

The staff recognizes that immediate corrective action was taken when the violation was identified. We also understand that you will develop a new procedure to support reduced inventory operations while keeping the RCS intact, validate this new procedure on a simulator prior to its use, and review the adequacy of all other critical evolution procedures. In addition, at the enforcement conference you discussed a number of other actions that were being considered including hardware changes designed to preclude a repetition of this event.

To emphasize the need for adequate procedures for reduced inventory operations, 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 $12,500 for the Severity Level III violation described in the Notice. The base value of a civil penalty for a Severity Level III violation is $50,000.

The civil penalty adjustment factors in the Enforcement Policy were considered. The base civil penalty was mitigated by 25 percent for identification. Although the event was self-disclosing, you demonstrated initiative in identifying the root cause of the violation. The base civil penalty was mitigated by 50 percent for the corrective actions, discussed above, that you have initiated or plan to implement. Additionally, the base civil penalty was mitigated by 100 percent for your good past performance. However, the base civil penalty was escalated by 100 percent due to the fact that you had prior opportunities to identify the inadequate procedure. NRC and industry notices have been extensive regarding the loss of shutdown cooling. For example, Generic Letter 88-17 was issued, in part, in response to the April 1987 Diablo Canyon loss of decay heat removal event, to emphasize the safety significance that the NRC places on partial loss of shutdown cooling events and loss of control of reactor vessel level during mid-loop operation. The NRC also sent copies of that Generic Letter to every individual licensed operator to reemphasize that point. In addition, Northern States Power was aware of the October 1991 Vogtle loss of decay heat removal event. While you did provide some additional training in response to the notice that was received, that notice should have caused you to more fully evaluate and enhance your procedures and training. The other factors in the enforcement policy were considered, and no further adjustment to

the base civil penalty was considered appropriate. Therefore, based on the above, the base civil penalty has been decreased by 75 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,

A. Bert Davis

A. Bert Davis
Regional Administrator

Enclosure: Notice of Violation and Proposed
Imposition of Civil Penalty

SEE DISTRIBUTION NEXT PAGE

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

Northern States Power Company
Prairie Island Nuclear
Generating Plant - Unit 2

Docket No. 50-306
License No. DPR-60
EA 92-067

During an NRC inspection conducted from February 20 through March 30, 1992, a violation of NRC requirements was identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C (1992), the Nuclear Regulatory Commission proposes to impose a civil penalty pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (Act), 42 U.S.C. 2282, and 10 CFR 2.205. The particular violation and associated civil penalty are set forth below:

10 CFR 50, Appendix B, Criterion V states, in part, that activities affecting quality shall be prescribed by documented instructions, procedures, or drawings of a type appropriate to the circumstances.

Contrary to the above, on February 6, 1992, the licensee issued procedure D2, "RCS Reduced Inventory Operation," Revision 21, for draining the Reactor Coolant System (RCS), which was not of a type appropriate to the circumstances of its use in that:

1. The procedure did not specify an indicated Tygon tube reading of RCS level at which the operator was required to verify that the wide range Emergency Response Computer System (ERCS) RCS level indication was functioning.

2. The procedure did not provide adequate direction for controlling RCS pressure, a frequency for recording RCS level or RCS pressure readings, or a precaution indicating RCS pressure higher than about three psig would prevent the ERCS RCS level indicators from functioning.

3. The procedure did not specify any frequency for calculating holdup tank volume for comparison with the change in volume based on the change in RCS level indication and did not clearly specify a level-to-volume ratio to be used to calculate holdup tank volume.

This is a Severity Level III violation (Supplement I).
Civil Penalty - $12,500

Pursuant to the provisions of 10 CFR 2.201, the Northern States 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 of 10 CFR Part 2, Appendix C (1992),

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

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

FOR THE NUCLEAR REGULATORY COMMISSION

A. Bert Davis
Regional Administrator

Dated at Glen Ellyn, Illinois
this 21st day of May 199.

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

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

April 22, 1992

Dockets No. 50-454 and 50-455
Licenses No. NPF-37 and NPF-66
Construction Permit CPPR-131
EA 92-019

Commonwealth Edison Company
ATTN: Mr. Cordell Reed
Senior Vice President
Opus West III
1400 Opus Place
Downers Grove, Illinois 60515

Dear Mr. Reed:

SUBJECT: NOTICE OF VIOLATION
(U.S. Department of Labor Case No. 87-ERA-4)

This refers to the results of an investigation and hearing conducted by the U. S. Department of Labor (DOL) into a complaint filed on October 3, 1986, by a quality control inspector formerly employed by the Hatfield Electric Company at the Byron Nuclear Station. In his complaint (DOL Case No. 87-ERA-4), the former quality control inspector alleged that Hatfield Electric Company improperly terminated his employment on September 12, 1986, following his contacts with the NRC in May and June 1986, and his August 19, 1986, appearance at a DOL hearing involving another former employee of Hatfield Electric. An October 31, 1986, decision by the DOL Area Director instructed the Hatfield Electric Company to reinstate the former quality control inspector. That decision was appealed by Hatfield Electric Company and was upheld by a DOL Administrative Law Judge on August 13, 1987. Subsequently, on January 22, 1992, the DOL Deputy Secretary affirmed the Administrative Law Judge's recommended decision.

After reviewing that decision, the NRC finds that a violation of the Commission's regulations has occurred. An enforcement conference is not being held in this case because additional information is not necessary. The NRC review of the technical electrical components by the Hatfield Electric Company at the

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Byron Nuclear Station was documented in NRC Inspection Report Nos. 50-454/86031; 50-455/86017, which was mailed to you on December 5, 1986.

The violation described in the enclosed Notice of Violation concerns an incident of discrimination in violation of 10 CFR 50.7, "Employee Protection." Specifically, under 10 CFR 50.7, discrimination by a Commission licensee, or its contractor, against an employee for engaging in certain protected activities is prohibited. The activities which are protected include 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 action against his or her employer for the administration or enforcement of these requirements, or testifying in any Commission proceeding.

This has been categorized as a Severity Level III violation because discrimination by first-line supervisors against employees for raising safety concerns or participating in formal proceedings is a significant regulatory concern, whether the actions were taken by the licensee or its contractor.

Such discriminatory acts could create a chilling effect which could lead to individuals not raising safety issues. Such an environment cannot be tolerated if licensees are to fulfill their responsibility to protect the public health and safety. It is imperative that managers and supervisors of the licensee and its contractors avoid actions that discriminate against individuals for cooperating in proceedings under the Atomic Energy Act or the Energy Reorganization Act or for raising safety concerns. The actions of the licensee and its contractors must also promote an environment conducive to the reporting of safety issues. Therefore, to emphasize the importance of maintaining an environment in which employees are free to provide information or safety concerns without fear of retaliation, I am issuing the enclosed Notice of Violation in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy) 10 CFR Part 2, Appendix C (1986).

Normally, a civil penalty is considered for a Severity Level III violation. However, after consultation with the Commission, I

have decided that a civil penalty will not be proposed in this case. In reaching this decision the staff considered: (1) the time that has passed since this violation occurred; (2) that the plant was under construction at the time of the violation and has since been completed and operating for several years without further violations of this type; (3) that no similar violations have occurred at other CECo NRC-licensed facilities since the occurrence of this September 12, 1986, violation; and (4) the apparent isolated nature of the violation.

The NRC acknowledges that your July 29, 1986, letter described corrective actions in response to a similar, previous enforcement action (EA 86-87). The corrective actions for this earlier violation included: (1) meeting with senior management of all site contractors to discuss their obligations under 10 CFR 50.7; (2) developing an "early warning" system to determine if a discharge involving worker protection is lawful; and (3) pre-planning reductions-in-force to determine whether a discharge is improperly motivated.

While normally a written response to a Notice of Violation is required, we are not requiring a response to the specific violation for the above reasons. However, we note that the individuals involved in the September 12, 1986, discriminatory act are employed in the quality assurance organization of the William Pope Company, another contractor at the Byron Nuclear Station. Therefore, we are requesting that you provide written assurance that the individuals responsible for the September 12, 1986, discriminatory act now appreciate the need for open communications when an employee raises a safety concern.

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, Pub. L. No. 96-511.

Sincerely,

Carl J Paperiello for

A. Bert Davis
Regional Administrator

Enclosure: Notice of Violation

cc w/enclosure:
DCD/DCB (RIDS)
M. Wallace, Vice President
PWR Operations
T. Kovach, Nuclear Licensing Manager
T. Schuster, Nuclear Licensing
Administrator
R. Pleniewicz, Station Manager
D. Brindle, Regulatory Assurance
Supervisor
Resident Inspectors: Byron, Braidwood,
Zion
Richard Hubbard
J. W. McCaffrey, Chief
Public Utilities Division
Diane Chavez, DAARE/SAFE
Licensing Project Manager, NRR
Robert Newmann, Office of Public
Counsel, State of Illinois Center
Robert M. Thompson, Administrator
Wisconsin Division of Emergency
Government

NOTICE OF VIOLATION

Commonwealth Edison Company
Byron Nuclear Station

Dockets No. 50-454 and 50-455
Licenses No. NPF-37 and NPF-66
Construction Permit CPPR-131
EA 92-019

Based on the results of an investigation and hearing conducted by the U. S. Department of Labor (DOL Case 87-ERA-4) and the resulting Order of the Deputy Secretary of Labor, dated January 29, 1992, the NRC determined that a violation of its regulations occurred. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C (1986), the violation is 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 or other actions relating to the compensation, terms, conditions, and privileges of employment.
>
> Contrary to the above, an employee of Hatfield Electric Company, a subcontractor of the Commonwealth Edison Company, who was a quality control inspector at the Byron Nuclear Power Station, was discharged on September 12, 1986, by Hatfield Electric Company, for engaging in protected activities. These protected activities were: (1) reporting to the NRC on May 9, 1986, the Hatfield Electric Company's inadequate installation and inspection of electrical components at the Byron Nuclear Power Station, and (2) participating as a witness on August 19, 1986, in a hearing conducted by the U. S. Department of Labor under Section 210 of the Energy Reorganization Act of 1974, as amended (Labor Department Case No. 86-ERA-33).

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

A reply is not required because the licensee's letter of July 29, 1986, described the corrective actions to prevent recurrence and

similar violations have not occurred at either the Byron Nuclear Station or the other NRC licensed facilities operated by the Commonwealth Edison Company since this violation occurred on September 12, 1986.

FOR THE NUCLEAR REGULATORY COMMISSION

Carl J Paperiello for

A. Bert Davis
Regional Administrator

Dated at Glen Ellyn, Illinois
the 22 day of April 1992

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

MAY 19 1992

Docket Nos. 50-327 and 50-328
License Nos. DPR-77 and DPR-79
EA 92-065

Tennessee Valley Authority
ATTN: Dr. Mark O. Medford
Vice President
Nuclear Assurance, Licensing
and Fuels
3B Lookout Place
1101 Market Street
Chattanooga, Tennessee 37402-2801

Gentlemen:

SUBJECT: NOTICE OF VIOLATION
(NRC INSPECTION REPORT NOS. 50-327/92-06 AND 50-328/92-06)

This refers to the Nuclear Regulatory Commission (NRC) inspection conducted by Mr. W. Holland on March 1 - April 7, 1992, at the Sequoyah Nuclear Plant. The inspection included a review of the facts and circumstances related to a failure to comply with Technical Specification requirements for the operability of ice condenser inlet doors on Units 1 and 2 for an unknown period of time during operation in Modes 1, 2, 3, and 4, which you identified and reported on March 17, 1992. On March 23, 1992, a Confirmation of Action Letter was sent to you confirming that several actions related to the ice condenser problems be completed prior to the restart of Unit 1. The report documenting this inspection was sent to you by letter dated April 9, 1992. As a result of this inspection, a violation of NRC requirements was identified. An enforcement conference was held on May 1, 1992, in the NRC Region II office to discuss the violation, its cause, and your corrective actions to preclude recurrence. A summary of the enforcement conference was sent to you by letter dated May 1, 1992.

The violation in the enclosed Notice of Violation (Notice) involved the discovery of the Unit 2 ice condenser in a degraded condition. During the performance of routine inspections while the unit was in Mode 5 for the Cycle 5 refueling outage, ice condenser inspections revealed that 27 of the 48 ice condenser doors required excessive force to open. Approximately 15 of the doors were severely restrained in that force above the maximum torque required by Technical Specifications 4.6.5.3.1.b.1 and 4.6.5.3.1.b.3 would have been required to open the doors. Water intrusion, freezing, and expansion within the floor assembly caused the lower-ice-condenser concrete floor pad to be raised up to three inches which caused the metal flashing at the base of the doors to interfere with the door's operation. A similar problem was found in Unit 1. This condition was caused by a combination of the failure to install sealant material in some of the wear slab joints during initial installation that allowed water intrusion to the floor assembly and the maintenance defrosting and cleaning activities that allowed water to accumulate on the floor.

This violation is of concern to the NRC because it represents the gradual degradation of a safety system. This degradation may have occurred through at least two cycles and could have been detected through more detailed licensee inspection activities or better scheduling of surveillance activities. Therefore, this violation has been categorized at Severity Level III.

In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy) 10 CFR Part 2, Appendix C (57 FR 5791, February 18, 1992), a civil penalty is considered for a Severity Level III violation. However, after consultation with the Director, Office of Enforcement, and the Deputy Executive Director for Nuclear Reactor Regulation, Regional Operations and Research, I have decided that a civil penalty will not be proposed in this case because your staff identified the violation and because of your prompt and extensive corrective actions that included shutting down the operating unit, initiating rapid followup activity to correct the violation, installing an on-line monitoring system, and modifying maintenance practices.

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,

James L. Milhoan for

Stewart D. Ebneter
Regional Administrator

Enclosure:
Notice of Violation

cc w/encl:
Mr. J. B. Waters, Director
Tennessee Valley Authority
ET 12A
400 West Summit Hill Drive
Knoxville, Tennessee 37902

NOTICE OF VIOLATION

Tennessee Valley Authority
Sequoyah Nuclear Plant
Units 1 and 2

Docket Nos. 50-327 and 50-328
License Nos. DPR-77, DPR-79
EA 92-065

During an NRC inspection conducted on March 1 - April 7, 1992, a violation of NRC requirements was identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C (57 FR 5791, February 18, 1992), the violation is listed below:

> Technical Specification 3.6.5.3 requires, in part, that the ice condenser inlet doors be operable when in MODES 1, 2, 3, and 4.
>
> Contrary to the above, on March 17 and 18, 1992 numerous ice condenser doors on both units were discovered to require force in excess of the torque values required for operability as specified in Technical Specifications 4.6.5.3.1.b.1 and 3. This condition resulted in the ice condenser system being in a degraded condition and could have existed for an extended period of time with both units operating in Mode 1.

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

Pursuant to the provisions of 10 CFR 2.201, Tennessee Valley Authority (Licensee) is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555, with a copy to the Regional Administrator, Region II, and a copy to the NRC Resident Inspector at the Sequoyah 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 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 Atlanta, Georgia
this 19th day of May 1992

II.A. MATERIALS LICENSEES, CIVIL PENALTIES AND ORDERS

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

October 25, 1991

Docket No. 030-15055
License No. 21-18428-01
EA 91-135

Allied Inspection Services, Inc.
ATTN: Mr. T. Donald Grashaw
4704 Ketchum Road
P. O. Box 268
St. Clair, MI 48079

Dear Mr. Grashaw:

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY - $5,000
(NRC INSPECTION REPORT NO. 030-15055/91001(DRSS))

This refers to the inspection conducted on September 26, 1991, at your St. Clair, Michigan facility. The report documenting this inspection was sent to you by letter dated October 11, 1991. During this inspection, violations of NRC requirements were identified. An Enforcement Conference was held on October 16, 1991, at the NRC Region III Office to discuss the violations, their causes, and your corrective actions.

During the inspection, it was determined that you and your staff had performed radiographic operations on approximately 162 occasions from January 10, 1991, through September 23, 1991, as listed in your utilization log, without wearing personnel monitoring alarm ratemeters. The requirement for alarm ratemeters became effective on January 10, 1991, after being published as a final rule in the Federal Register on January 10, 1990. Additionally, the March/June 1990 edition of the NRC Office of Nuclear Materials Safety and Safeguards Newsletter discussed the new rule. You stated that you did not receive these publications in the mail. However, in early September 1991 you received an NRC Information Notice (IN 91-49) which alerted you to the alarm ratemeter requirement. You promptly ordered ratemeters on September 12, 1991; however, radiographic operations were performed on two subsequent occasions prior to receiving the ratemeters on September 24, 1991.

We are concerned with your failure to be cognizant of current NRC requirements which resulted in multiple violations over an eight month period. Once you were alerted to the alarm ratemeter requirement by the NRC Information Notice, you made an effort to come into compliance. However, you continued to perform radiographic operations without alarm ratemeters. In the future, when violations of NRC requirements are identified, we expect you to correct the violation before proceeding, rather than continue to violate NRC requirements. If it is not reasonable for you to correct the violation, you should promptly contact the NRC Regional Office for further guidance.

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

NRC requires strict compliance with all regulations designed to ensure that radiographic operations do not result in unnecessary or potentially harmful radiation exposures to radiography personnel or the general public. The alarm ratemeters required by 10 CFR 34.33 are intended to give an early and audible warning of unexpected high radiation levels allowing radiography personnel to take prompt corrective actions. Therefore, in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy) 10 CFR Part 2, Appendix C (1991), this violation has been categorized at Severity Level III.

At the Enforcement Conference you presented your longer term corrective actions which included reviewing NRC correspondence more thoroughly upon receipt, date stamping all NRC correspondence when received, periodically reviewing NRC correspondence for missing documents, and implementing a system for tracking required tasks. NRC staff suggested several other prudent corrective actions, including revising the quarterly audit checklist to include the wearing of alarm ratemeters as an audit line item, and reviewing all previously issued NRC correspondence to ensure that other requirements have not been missed.

To emphasize the importance of wearing alarm ratemeters during radiographic operations, and the importance of being cognizant of current NRC 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.

The base value of a civil penalty for a Severity Level III violation is $5,000. The civil penalty adjustment factors in the Enforcement Policy were considered and on balance no adjustment to the base civil penalty has been deemed appropriate. Mitigation of the base civil penalty for the identification and reporting factor was not warranted in that you continued to perform radiographic operations without the ratemeters on two occasions after you became aware of the requirement. No mitigation of the base civil penalty was warranted for the corrective action factor in that your longer term corrective actions, as discussed above, were not sufficiently comprehensive. Full 100 percent mitigation of the base civil penalty was warranted for your good past performance. However, 100 percent escalation of the base civil penalty was warranted for the prior notice and multiple occurrence factors. You allowed radiographic operations to be performed on approximately 162 separate occasions without alarm ratemeters after the effective date of the requirement, two of which were after you became aware of the requirement. The other adjustment factors in the Policy were considered and no further adjustment to the base civil penalty was considered appropriate.

Four additional violations not assessed a civil penalty were identified as described in 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. 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, Pub. L. No. 96-511.

Sincerely,

A. Bert Davis

A. Bert Davis
Regional Administrator

Enclosure: Notice of Violation
and Proposed Imposition of Civil
Penalty

cc w/enclosure:
DCD/DCB (RIDS)
J. Lieberman, Director,
Office of Enforcement
State of Michigan

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

Allied Inspection Services, Inc.
St. Clair, Michigan

Docket No. 030-15055
License No. 21-18428-01
EA 91-135

During an NRC inspection conducted on September 26, 1991, 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 (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 violations and associated civil penalty are set forth below:

I. Violation Assessed a Civil Penalty

10 CFR 34.33(a) requires, in part, that the 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 approximately 162 occasions from January 10, 1991, through September 23, 1991, the attending licensee radiographer(s) and radiographer's assistant did not wear an alarm ratemeter while conducting radiographic operations at field sites.

This is a Severity Level III violation (Supplement VI).
Civil Penalty - $5,000.

II. Violations Not Assessed a Civil Penalty

A. 10 CFR 34.33(c) requires that pocket dosimeters be checked at intervals not to exceed one year for correct response to radiation.

Contrary to the above, from November 6, 1989, to September 26, 1991, an interval exceeding one year, pocket dosimeters were not checked for correct response to radiation.

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

B. 10 CFR 71.5(a) requires that licensees who transport licensed material outside the confines of their plants or deliver licensed material to a carrier for transport comply with the applicable requirements of the regulations appropriate to the mode of transport of the Department of Transportation (DOT) in 49 CFR Part 170-189.

1. 49 CFR 172.203(d)(1)(iii) requires that the description for a shipment of radioactive material include the activity contained in each package of the shipment in terms of curies, millicuries or microcuries.

   Contrary to the above, from January 31, 1991 to September 26, 1991, the licensee routinely transported iridium-192 source No. 1718 without updating the activity included on the description for shipment to account for the source's 74 day half-life. Specifically, on September 26, 1991, the description for shipment for iridium-192 source No. 1718 stated the activity as 80 curies when the actual activity was approximately 9.7 curies.

2. 49 CFR 172.604(a) requires, in part, that a person who offers a hazardous material for transportation provide on a shipping paper a 24-hour emergency response telephone number for use in the event of an emergency involving the hazardous material. Pursuant to 49 CFR 172.101, radioactive material is classified as a hazardous material.

   Contrary to the above, from January 31, 1991 to September 26, 1991, the licensee failed to include on its shipping papers a 24-hour emergency response telephone number, during routine transport of its iridium-192 source No. 1718, a hazardous material.

3. 49 CFR 177.817(e)(2) requires that the driver and carrier store the shipping paper as follows:

   (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 inside of the door on the driver's side of the vehicle; or (b) on the driver's seat in the vehicle.

   Contrary to the above, as of September 26, 1991, the licensee routinely transported licensed material consisting of iridium-192 and cobalt-60 sealed radiography sources and, when the driver was not at the vehicle's controls, the shipping paper was stored by attaching it to the inside rear window of the vehicle or by posting it inside the trailer located behind the vehicle.

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

Pursuant to the provisions of 10 CFR 2.201, Allied Inspection Services, 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 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 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 of10 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 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.

FOR THE NUCLEAR REGULATORY COMMISSION

A Bert Davis

A. Bert Davis
Regional Administrator

Dated at Glen Ellyn, Illinois
this 22nd day of October 1991

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION II
101 MARIETTA STREET, N.W., SUITE 2900
ATLANTA, GEORGIA 30323

APR 2 2 1992

Docket No. 030-20541
License No. 52-21350-01
EA 92-012

Alonso and Carus Iron Works, Inc.
ATTN: Mr. Laureano Carus, President
Post Office Box 566
Catano, Puerto Rico 00632

Gentlemen:

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY - $2,500 (NRC INSPECTION REPORT NO. 52-21350-01/91-01 AND NRC OFFICE OF INVESTIGATIONS REPORT NO. 2-91-014)

This refers to the Nuclear Regulatory Commission (NRC) inspection conducted by Mr. L. Franklin on October 7, 9, 10 and 17, 1991, at your facility in Catano, Puerto Rico, and at a field radiography site at the San Juan Airport, San Juan, Puerto Rico. This also refers to an investigation conducted by Mr. R. Burch of the NRC Office of Investigations (OI), Region II Field Office, which was completed on March 27, 1992.

The inspection included a review of the activities conducted under your license with respect to radiation safety and compliance with NRC regulations and the conditions of your license. As a result of the inspection findings, a Confirmation of Action Letter was sent to you by letter dated October 25, 1991, to confirm actions you were to take to ensure that your radiographers perform surveys during radiographic operations in accordance with NRC regulations. The report documenting this inspection was sent to you by letter dated November 25, 1991. As a result of this inspection, violations of NRC requirements were identified.

The investigation referred to above included a review of the apparent intentional failure by one of your radiographers, who was also the assistant Radiation Safety Officer, to perform surveys during field radiographic operations at the San Juan Airport on October 11, 1991, pursuant to the requirements of 10 CFR 34.43. The investigation concluded there were mitigating circumstances that contributed to the radiographer's failure to comply with the survey requirements. The mitigating circumstances, in part, involved the radiographer experiencing extreme emotional stress related to a close family member being terminally ill which may have impaired his ability to properly perform radiographic operations. The synopsis of the OI investigation report was sent to you by letter dated April 9, 1992.

An enforcement conference was conducted by telephone on April 15, 1992, with Ms. G. Bonilla, your management representative, Mr. W. Rivera, Radiation Safety Officer, and Mr. J. Ruiz-Carlo, a Radiographer, to discuss the violations, their cause, and your corrective actions to preclude recurrence. As indicated

during the enforcement conference, the NRC had not taken final enforcement action until this time, pending completion of the investigation. During the enforcement conference, the licensee's representatives indicated their understanding of this action and agreed with the violations. A list of the attendees at the enforcement conference is enclosed.

The violation described in Part I of the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice) involved the failure to perform required radiation surveys during radiographic operations at the San Juan Airport on October 11, 1991. In this particular event, a radiographer was observed by an NRC Inspector to have performed three successive radiographic exposures without performing a survey that included the guide tube to determine that the sealed source had been returned to its shielded position after each exposure. Inherent in radiographic operations is the potential for significant radiation hazards and the NRC relies on radiographers to perform required actions such as surveys to minimize these hazards to both themselves and the general public.

When the NRC issues a license to use radioactive material, it is expected that the licensee, and particularly licensee radiographers, will fully meet their regulatory responsibilities to ensure that the use of licensed materials does not endanger the public health and safety. Although we recognize that personal stress may have contributed to the radiographer's inability to conduct licensed activities in accordance with NRC requirements, it is nevertheless incumbent on the licensee to ensure that personnel engaged in licensed activities can safely perform radiographic operations. Licensees must ensure that radiographers understand that if they are unable to perform licensed radiography duties in a safe manner because of illness or other technical problems such as the inability to perform surveys because of a difficult set-up, they must inform their supervision.

Therefore, in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy) 10 CFR Part 2, Appendix C (1991), the violation in Part I of the Notice has been categorized at Severity Level III because required radiation surveys were not conducted following three successive radiographic exposures.

To emphasize the importance of conducting safe radiographic operations and to ensure compliance with regulatory requirements and license conditions, I have been authorized to issue the enclosed Notice of Violation and Proposed Imposition of Civil Penalty in the amount of $2,500 for the Severity Level III violation set forth in Part I of the Notice. The base value of a civil penalty for a Severity Level III violation is $5,000.

After careful review of all the circumstances involved in this case, we have decided to mitigate the civil penalty by 50 percent. Considerations included the fact that NRC identified the violation involving the failure to survey, the discussions about surveys that the NRC inspector had with the radiographer on the day prior to the event, your subsequent corrective actions, and your good past performance.

The violation described in Part II of the enclosed Notice involved the failure to post the high radiation area in which radiography was being performed on October 11, 1991. Although the violation was categorized at Severity Level IV, it is a concern because of the safety implications associated with high radiation areas and providing adequate warning to the public that radiographic operations are underway.

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.

By letter dated December 13, 1991, you were issued an Order (EA 91-171) modifying your license to restrict your utilization of the radiographer involved in the radiographic activity at the San Juan Airport on October 11, 1991. The radiographer subsequently responded to the Order by letter dated December 30, 1991, wherein he explained his actions of October 11, 1991, and requested a hearing on the Order. As a result of that information, the NRC staff conducted additional follow up review between January 24-30, 1992, during which the radiographer advised that after reconsidering his comments in the December 30th letter, he agreed that his actions on October 11, 1991, did not meet regulatory requirements. On February 20, 1992, a settlement agreement was reached wherein certain actions were to be effectuated to meet the terms of the settlement agreement. On March 24, 1992, the NRC Atomic Safety and Licensing Board approved the settlement agreement and terminated further proceedings. We do not plan any further action relative to the Order other than ensuring that the terms and conditions of the Settlement Agreement are fulfilled.

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

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

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

Sincerely,

Stewart D. Ebneter

Stewart D. Ebneter
Regional Administrator

Enclosures:
1. Notice of Violation and Proposed
   Imposition of Civil Penalty
2. List of Enforcement Conference Attendees

cc w/encls:
Commonwealth of Puerto Rico

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

Alonso and Carus Iron Works, Inc.
Catano, Puerto Rico

Docket No. 030-20541
License No. 52-21350-01
EA 92-012

During an NRC inspection conducted on October 7, 9, 10 and 17, 1991, 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 (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 violations and associated civil penalty are set forth below:

I. Violation Assessed a Civil Penalty

10 CFR 34.43 (b) requires, in part, the licensee to ensure that a survey with a calibrated and operable radiation survey instrument is made after each radiographic exposure to determine that the sealed source has been returned to its shielded position.

Contrary to the above, on October 11, 1991, a licensee radiographer did not perform a survey after three radiographic exposures to determine that the sealed source had been returned to its shielded position after each exposure.

This is a Severity Level III violation (Supplement VI).
Civil Penalty - $2,500

II. Violation Not Assessed a Civil Penalty

10 CFR 34.42 requires, notwithstanding any provisions in 10 CFR 20.204 (c), that areas in which radiography is being performed be conspicuously posted as required by 10 CFR 20.203 (b) and (c)(1).

10 CFR 20.203 (c)(1) requires that each high radiation area shall be conspicuously posted with a sign or signs bearing the radiation caution symbol and the words "CAUTION HIGH RADIATION AREA."

Contrary to the above, on October 11, 1991, during radiography performed at San Juan International Airport, San Juan, Puerto Rico, the licensee did not post the high radiation area in which industrial radiography was being performed.

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

Pursuant to the provisions of 10 CFR 2.201, Alonso and Carus Iron Works, 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 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 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 22nd day of April 1992

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

April 30, 1992

Docket No. 030-13245
License No. 13-17732-01
EA 92-051

ATEC Associates, Inc.
ATTN: James Sherer
Assistant Vice President
5150 East 65th Street
Indianapolis, IN 46220-4871

Dear Mr. Sherer:

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTIES - $2,375
(NRC INSPECTION REPORT NO. 030-13245/92001(DRSS))

This refers to the routine safety inspection conducted on February 25 through March 19, 1992 of activities authorized by NRC License No. 13-17732-01 at your facility in Indianapolis, Indiana, and at one of your temporary job sites. During the inspection, a substantial number of violations of NRC requirements were identified. The report documenting this inspection was sent to you by letter, dated March 27, 1992. On April 7, 1992, an enforcement conference was conducted with you and Mr. Tim Keller, your Radiation Protection Officer, to discuss the apparent violations, their causes and your corrective actions. A copy of the enforcement conference report was sent to you on April 21, 1992.

During the enforcement conference, we discussed the apparent whole body dose of 2.14 rems to one of your workers during the fourth calendar quarter of 1990. We expressed concern that this appeared to be an apparent violation of 10 CFR 20.101(a), failure to maintain a radiation worker's quarterly radiation exposure below 1.25 rems. Your RSO informed us that subsequent to the 1992 inspection, he conducted a more thorough investigation of the circumstances surrounding the exposure and concluded that the worker did not receive the dose. We have, therefore, not cited you for the apparent overexposure, but have, instead, cited you for failing to conduct an adequate evaluation pursuant to 10 CFR 20.201(b) at the time of the inspection. Accordingly, we have not cited you for failure to make a written report to the NRC regarding the apparent overexposure.

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

During the enforcement conference, we also discussed an apparent violation of 10 CFR 20.405(a)(i)(iv) involving your failure to report in writing to the NRC, within 30 days, an incident at a temporary job site which resulted in damage to a moisture/density gauge. The report was required because the damage to the gauge was in excess of $2000. You stated that the incident occurred on June 20, 1991 instead of June 6 and that the written report was only four days late. After further consideration of this matter, and in view of the fact that the NRC no longer requires licensees to make a written report based on damage to property in excess of a specified dollar amount, we have not included this item in the Notice.

The remaining violations that were identified during the inspection are described in the enclosed Notice of Violation and Proposed Imposition of Civil Penalties (Notice). These violations are divided into two areas of concern: (1) violations associated with a failure to control access to licensed material and (2) violations associated with a regulatory breakdown in the management control of licensed activities.

The violations involving failure to control access to licensed material include: (1) failure to secure a moisture/density gauge from unauthorized removal; (2) failure to lock the source in a moisture/density gauge to prevent accidental exposure while the gauge was not being used; and (3) failure to maintain immediate control of a moisture/density gauge while it was not in storage at a temporary job site. The latter violation resulted in the gauge being run over and damaged by construction equipment. These violations are of concern to the NRC because they could have resulted in unnecessary radiation exposure to members of the public. Therefore, in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy) 10 CFR Part 2, Appendix C (1992), violations involving failure to control access to licensed material have been classified in the aggregate as a Severity Level III problem.

The violations involving a regulatory breakdown in the management control of licensed activities include: (1) use and storage of moisture/density gauges at unauthorized locations; (2) use of the gauges by persons who had not completed the training required by your NRC license; (3) failure to adequately evaluate an exposure that appeared to exceed regulatory requirements; (4) failure to

leak test sealed sources and conduct sealed source inventories at the required frequency; (5) failure to maintain radiation exposure records and post copies of regulatory documents and notices as required; and (6) failure to comply with several transportation requirements including blocking and bracing of a gauge during transport and adequately documenting and maintaining a shipping paper in the appropriate location. These violations demonstrate a significant lack of management attention to, and control of, activities authorized by your NRC license. Therefore, in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy) 10 CFR Part 2, Appendix C (1992), violations associated with a regulatory breakdown in the management control of licensed activities have been classified in the aggregate as a Severity Level III problem.

The root causes of the violations and the subsequent corrective actions were discussed during the April 7, 1992, enforcement conference. The NRC recognizes that some corrective actions have been initiated and appear acceptable. However, they tend to focus on the individual violations and not on the root cause of the violations, namely, the laxity by which you approached the supervision and overall management of radiation safety practices and compliance with regulatory requirements. Incumbent upon any NRC licensee is the responsibility to protect public health and safety, including the health and safety of the employees, by assuring that all requirements of the NRC license are met and any potential violation of NRC requirements is identified and expeditiously corrected.

To emphasize the importance of complying with license and regulatory requirements and ensuring effective management oversight of licensed activities, I am issuing the enclosed Notice of Violation and Proposed Imposition of Civil Penalties (Notice) in the cumulative amount of $2,375 for the two Severity Level III problems identified above.

The base value of a civil penalty for each Severity Level III violation is $500. The civil penalty adjustment factors in the Enforcement Policy were considered and the amount of the civil penalty for violations involving failure to control access to licensed material was increased by 150 percent. The civil penalty was initially increased by 50 percent because all of the

violations were identified by the NRC, when they should have been identified by licensee management. The civil penalty was increased by an additional 100 percent because there were multiple occurrences of the access control problems. In three instances, there was a failure to control access to licensed material contained in the moisture/density gauges. The remaining factors in the enforcement policy were considered and no further adjustment is considered appropriate. Therefore, based on the above, the civil penalty for violations associated with failure to control access to licensed material is $1,250.

The amount of the civil penalty for violations involving a regulatory breakdown in the management control of licensed activities was increased by 125 percent. This civil penalty was initially increased by 50 percent because, again, all of the violations were identified by the NRC, when they should have been identified by licensee management. Escalation of the civil penalty by an additional 25 percent is warranted because the corrective actions that you have taken and those that you are considering do not sufficiently address the root cause of the violations - inadequate attention to, and control over, the radiation safety and compliance program. During the enforcement conference, for example, it was apparent that your Radiation Safety Officer had not yet reviewed all the commitments made in various licensing submittals to the NRC, a situation that NRC finds unacceptable. The civil penalty was increased by an additional 50 percent because you had prior notice of the potential for violations associated with the transportation of licensed material as a result of specific precautionary and instructional information that was provided to you by the NRC. In this instance you were sent Information Notice No. 90-35, "Transportation of Type A Quantities of Non-Fissile Radioactive Materials." Each of the regulatory requirements for the six transportation violations identified during the inspection is addressed in the Information Notice. Licensees are expected to take prompt action to assure compliance with the regulatory requirements that are discussed in such notices. The remaining factors in the enforcement policy were also considered and no further adjustment to the base civil penalty is considered appropriate. Therefore based on the above, the civil penalty associated with a regulatory breakdown in the management control of your licensed activities is $1,125.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. In addition to your specific response to the violations, please also address the actions you have implemented or plan to take to ensure timely and lasting improvement in your radiation safety program. You should address the management and oversight of the program and any improvements needed in the procedures and practices to achieve and maintain compliance with NRC requirements and license conditions, including internal or external audits to assess the effectiveness of your program.

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

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

Sincerely,

A Bert Davis

A. Bert Davis
Regional Administrator

Enclosure:
Notice of Violation and Proposed
Imposition of Civil Penalties

cc/enclosure:
DCD/DCB (RIDS)

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTIES

ATEC Associates, Inc.
Indianapolis, IN 46120

Docket No. 030-13245
License No. 13-17732-01
EA 92-051

During an NRC inspection conducted from February 25 through March 19, 1992, violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C (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 Failure To Control Access To Licensed Material

A. 10 CFR 20.207(a) requires that licensed materials stored in an unrestricted area be secured from unauthorized removal from the place of storage.

Contrary to the above, on February 26, 1992, a moisture/density gauge containing licensed materials was stored in the back of an open bed pickup truck in an unrestricted area, during the lunch hour and was not secured from unauthorized removal from the place of storage.

B. 10 CFR 20.207(b) requires that licensed materials in an unrestricted area and not in storage be tended under the constant surveillance and immediate control of the licensee.

Contrary to the above, on June 20, 1991, a Campbell Pacific Nuclear moisture/density gauge containing licensed materials was placed in an unrestricted area at a temporary job site and was neither in storage nor under the immediate control of the licensee.

C. Condition 17 of License No. 13-17732-01 requires that licensed material be possessed and used in accordance with the statements, representations and procedures contained in an application dated November 27, 1987, and other referenced documents.

The application dated November 27, 1987, contains a description of the licensee's Radiation Protection Program. Item No. 3.1 of the Radiation Protection Program specifies that locks be maintained on radioactive equipment to prevent accidental exposure of a sealed source when not under the direct supervision of approved personnel.

Contrary to the above, on February 26, 1992, a lock was not in place on a moisture/density gauge, radioactive equipment, to prevent accidental exposure of the sealed source and the gauge was not under the direct supervision of approved personnel.

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

Cumulative Civil Penalty - $1,250 (assessed equally among the three violations)

II. Violations Associated With a Regulatory Breakdown in the Management Control of Licensed Activities

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 assure compliance with that part of 10 CFR 20.101 that limits the radiation exposure to the whole

body of an individual in a restricted area to one and one-quarter rems per calendar quarter. Specifically, as of February 26, 1992, the licensee failed to conduct an adequate evaluation of the radiation hazards that may have existed during the fourth quarter of 1990 to determine the validity of an apparent whole body dose of 2.14 rems to an individual as indicated by the individual's film badge.

B. 10 CFR 20.401(a) requires that each licensee maintain records showing radiation exposures on Form NRC-5, in accordance with the instructions contained in that form, or on clear and legible records containing all the information required by Form NRC-5.

Contrary to the above, as of February 26, 1992, licensee did not maintain exposure records containing the required information. Specifically, the licensee's exposure records did not include social security numbers or birthdates for 11 individuals for whom radiation monitoring is required.

C. 10 CFR 19.11(a) and (b) require, in part, that the licensee post current copies of Part 19, Part 20, the license, license conditions, documents incorporated into the license, license amendments and operating procedures; or that the licensee post a notice describing these documents and where they may be examined.

Contrary to the above, as of February 26, 1992, none of the required documents or notices were posted.

D. Condition 10 of License No. 13-17732-01 requires that licensed material be used at the licensee's facilities located at 5150 East 65th Street, Indianapolis, Indiana and 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.

Contrary to the above, from early 1991 to February 26, 1992, licensed material was used at a facility located in Terre Haute, Indiana, and from January 1992 to February 26, 1992, licensed material was used at a facility located in Evansville, Indiana. Neither facility is an authorized place of use or a temporary job site.

E. Condition 11.A of License No. 13-17732-01 requires that licensed material be used by, or under the supervision and in the physical presence of, individuals who have satisfactorily completed the device manufacturer's training program for gauge users and have been designated by the licensee's Radiation Protection Officer. The licensee shall maintain records of the individuals who have been designated as authorized users.

Contrary to the above, as of February 26, 1992, licensed material was used by at least 10 individuals who had not completed the device manufacturer's training program for gauge users, who were not under the supervision and in the physical presence of individuals who had satisfactorily completed the device manufacturer's training program for gauge users, and who had not been designated by the licensee's Radiation Protection Officer.

F. Condition 12.A(1) of License No. 13-17732-01 requires that sealed sources be tested for leakage and/or contamination at intervals not to exceed 6 months, unless exempted by Condition 12.A(2).

Contrary to the above, several sealed sources, containing millicurie quantities of cesium-137 and americium-241 and not exempted by Condition 12.A(2), were not tested for leakage or contamination at the required frequency. Specifically, sealed sources in Serial No. MD-0059540 moisture/density gauge were not leak tested between October 29, 1990 and January 1992; sealed sources in Serial No. MD-9119195 moisture/density gauge were not leak tested between

March 25, 1991 and January 1992; and sealed sources in Serial No. MD-0049516 were not leak tested between October 23, 1990 and January 1992.

This is a repeat violation.

G. Condition 15 of License No. 13-17732-01 requires that the licensee conduct a physical inventory every 6 months to account for all gauges received and possessed under the license. The records of the inventories shall be maintained for two years from the date of the inventory for inspection by the Commission, and shall include the quantities and kinds of byproduct material, manufacturer's name and model numbers, location of gauge and the date of the inventory.

Contrary to the above, as of February 26, 1992 the licensee's records indicated that the last physical inventory of gauges received and possessed under the license was conducted on April 3, 1991.

H. 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 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.

1. 49 CFR 177.842(d) requires that packages of radioactive material be so blocked and braced that they cannot change position during conditions normally incident to transportation.

Contrary to the above, on February 26, 1992, a moisture/density gauge containing radioactive material was transported by a representative of the licensee outside the confines of its plant and the gauge was not blocked or braced so that it could not change position during conditions normally incident to transportation. Specifically, the gauge was allowed to slide freely, approximately two feet in each direction

in the pickup truck because of (1) the length of the chain which secured the gauge storage case to the truck bed and (2) the lack of an additional block or brace.

2. 49 CFR 177.817(e) requires a driver of a motor vehicle containing hazardous material to ensure that the shipping paper is readily available to, and recognizable by, authorities in the event of accident or inspection. Specifically, the driver shall store the shipping paper as follows: (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 inside of the door on the driver's side of the vehicle; or (B) on the driver's seat in the vehicle. Pursuant to 49 CFR 172.101, radioactive material is classified as a hazardous material.

   Contrary to the above, on February 26, 1992, the driver of a motor vehicle containing radioactive material in a moisture/density gauge did not have the shipping paper readily available as required. Specifically, the driver, who was employed by the licensee, stored the shipping paper inside the case containing the moisture/density gauge when he was not at the vehicle's controls. The driver stated further that the shipping paper is typically stored in the gauge case, even when he is at the vehicle's controls.

3. 49 CFR 172.203(d)(1)(iii) requires, in part, that the description on the shipping paper for a shipment of radioactive material include the activity of the package in terms of curies, millicuries, or microcuries.

Contrary to the above, on February 26, 1992, the shipping papers for shipments of radioactive material, gauges possessed by the licensee, indicated 0.00 curies of cesium-137, although the gauges contained a nominal 8 millicuries of cesium-137. Pursuant to 49 CFR 172.101, radioactive material is classified as a hazardous material.

4. 49 CFR 172.201(d) requires that each shipping paper which accompanies a hazardous material contain an emergency response telephone number.

   Contrary to the above, on February 26, 1992, the shipping paper accompanying a moisture/density gauge containing radioactive material did not contain an emergency response telephone number.

5. 49 CFR 172.203(c)(2) requires that for shipment of a reportable quantity of radioactive material, the letters "RQ" be entered on the shipping paper either before or after the basic description required for each hazardous substance.

   Contrary to the above, on February 26, 1992, the shipping paper accompanying a reportable quantity of radioactive material in a moisture/density gauge did not contain the letters "RQ."

6. 49 CFR 172.324(b) requires that packages containing reportable quantities of radioactive material be marked with the letters "RQ" on the package in association with the proper shipping name.

   Contrary to the above, on February 26, 1992, two cases containing moisture/density gauges, reportable quantities of radioactive material, were not marked with the letters "RQ" as required.

These violations are categorized in the aggregate as a Severity Level III problem (Supplements IV, V, and VI).

Cumulative Civil Penalty - $1,125 (assessed equally among the 13 violations).

Pursuant to the provisions of 10 CFR 2.201, ATEC Associates, Inc. (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 is achieved. If an adequate reply is not received within the time specified in this Notice, an order or a demand for information may be issued as to why the license should not be modified, suspended, or revoked or why such other actions as may be proper should not be taken. Consideration may be given to extending the response time for good cause shown. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, this response shall be submitted under oath or affirmation.

Within the same time as provided for the response required under 10 CFR 2.201, the Licensee may pay the civil 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 of 10 CFR Part 2, Appendix C (1992), should be addressed. Any written answer in accordance with 10 CFR 2.205 should be set forth separately from the statement or explanation in reply pursuant to 10 CFR 2.201, but may incorporate parts of the 10 CFR 2.201 reply by specific reference (e.g., citing page and paragraph numbers) to avoid repetition. The attention of the Licensee is directed to the other provisions of 10 CFR 2.205, regarding the procedure for imposing a civil 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.

FOR THE NUCLEAR REGULATORY COMMISSION

A Bert Davis

A. Bert Davis
Regional Administrator

Dated at Glen Ellyn, Illinois
this 30th day of April 1992

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

MAR 0 9 1990

Docket No. 030-12145
License No. 29-14150-01
EA 89-79

Certified Testing Laboratories, Inc.
ATTN: Joseph F. Citardi
President
155 U.S. Route 130
Bordentown, New Jersey 08505

Gentl_ _n:

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY - $8,000
AND ORDER TO SHOW CAUSE WHY LICENSE SHOULD NOT BE MODIFIED
(NRC Inspection Report No. 88-001 and Investigation Report 1-88-008)

This letter refers to the NRC safety inspection conducted on April 22, 1988, at Bordentown, New Jersey of activities authorized by NRC License No. 29-14150-01. This letter also refers to the subsequent inve tigation conducted by the NRC Office of Investigations (OI). The report of the inspection, as well the synopsis of the OI investigation, were forw ded to you on November 28, 1989. During the inspection and investigation, violations of NRC requirements were identified. On December 12, 1989, an enforcement conference was held with you and a member of your staff during which these violations, their causes, and your corrective actions were discussed.

The violations are described in the enclosed Notice of Violation and Proposed Imposition of Civil Penalty. The violations include: (1) the falsification of two field audit inspection reports dated July 20, 1987, and July 21, 1987, by the Vice President/Radiation Safety Officer (VP/RSO) in that records were created, when in fact, the VP/RSO admitted to an OI investigator that the audits were not performed on those dates; and (2) the VP/RSO willfully providing information that was not accurate in all material respects in that during a telephone call with three NRC representatives in April 1988 the VP/RSO stated that he personally performed the audit on July 21, 1987, when in fact, no such audit was performed.

During the transcribed enforcement conference on December 12, 1989, the VP/RSO asserted (in contradiction to his statements to the OI in February 1989) that he had performed the audits of the two radiographers at the required three month interval. The VP/RSO asserted that the particular audit reports were lost, and that since his subsequent documentation of the audits was not contemporaneous with their performance he stated that he may have entered the wrong dates for when the audits were performed when he finally prepared the audit reports. Subsequently, on December 19, 1989, legal counsel for the licensee submitted to Region I (1) a source utilization log and radiography report purporting to establish that one of the radiographers had performed radiography on July 20, 1987, which the licensee asserts is corroboration for the performance of the audit on July 20, 1987 by the VP/RSO, and (2) information that the other radiographer performed radiography on July 14 and 27,

1987, and suggests that the audit may have been conducted on either of those dates instead of July 21, 1989.

Notwithstanding the VP/RSO's contention at the enforcement conference, and the supplemental information provided after the conference, the NRC has concluded that (1) the VP/RSO willfully falsified two field audit inspection reports dated July 20, 1987 and July 21, 1987, and thereby caused the licensee to be in violation of a condition of its license and (2) the VP/RSO willfully provided inaccurate information to the NRC on April 25, 1988. This conclusion is based on the admissions by the VP/RSO to OI during the February 1989 interview that he made up the field audit reports, as well as the documentary evidence establishing that the field audit reports were duplicated by "whiting out" information and placing a date on the report that could not have been correct.

A license to use radioactive material is a privilege that confers upon the licensee, its officials and employees, the special trust and confidence of the public. When the NRC issues a license, it is expected and required that the licensee, as well as its employees and contractors, be completely candid and honest in all of their dealings with the NRC. This includes ensuring the complete and accurate recording and maintenance of records of performance of activities required by the license, since the NRC relies on these records to determine compliance with regulatory requirements. Creation of falsified field audit inspection reports by the VP/RSO, indicating that the field audits were performed on the specified dates without actually having performed the audits, and then willfully providing information that was not accurate in all material respects to the NRC during a telephone conversation, in an apparent attempt to authenticate one of the audits, violates that trust. Further, these actions by the VP/RSO call into question your ability to properly perform licensed activities while the responsible individual is still involved in those activities.

Accordingly, I have determined that, in the interest of public health and safety, the enclosed Order to Show Cause Why License Should Not Be Modified should be issued. The order requires, in part, that you show cause why the VP/RSO, in light of his involvement in wrongdoing, should not be removed from any involvement in the performance and supervision of all licensed activities. Should Mr. Joseph Cuozzo be removed from the position of RSO and any other position involving the performance or supervision of licensed activities including supervision of any RSO, you must suspend all licensed activities until such time that a qualified individual is approved to serve as RSO by the NRC in an amendment of your license.

In addition to the Order, to emphasize the importance of your responsibilities for ensuring that (1) licensed activities are conducted safely and in accordance with the conditions of your license; (2) accurate records of these activities are maintained; and (3) all information communicated to the NRC (either orally or in writing) is both complete and accurate, I am issuing the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice) in the amount of $8,000 for the violations set forth in Section I of the enclosed Notice.

The violations set forth in Section I of the Notice have been classified in the aggregate as a Severity Level II problem in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C, (Enforcement Policy) (1988), that was in effect at the time of the violation, because they involved falsification of records and willfully

prc ding information that was not accurate in all material respects to the NRC by a licensee official responsible for the Radiation Safety Program, namely, the VP/RSO. The base civil penalty amount for a Severity Level II violation is $8,000. The escalation and mitigation factors in the enforcement policy were considered and no adjustment to the base civil penalty amount was considered appropriate.

Two other violations of NRC requirements were identified during the inspection and are set forth in Section II of the enclosed Notice. These violations have been classified at Severity Level IV.

You are required to respond to the enclosed Notice and Order and, in preparing your response, you should follow the instructions specified therein. In your response, you should document the specific actions taken and any additional actions you plan to prevent recurrence. In addition, your response to this letter should describe the changes that have been made and actions that have been or will be implemented to ensure that (1) licensed activities are conducted in accordance with the license, and (2) records of licensed activities, as well as information submitted to the NRC, are complete and accurate. This response should also provide your basis for concluding that each person involved in licensed activities understands his or her responsibility and is committed to assure that NRC requirements will be followed and records or information submitted to the NRC be complete and accurate. After reviewing your response to this Notice, including your proposed corrective actions, and the results of future inspections, the NRC will determine whether further enforcement action is necessary to ensure compliance with NRC regulatory requirements.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," Part 2 Title 10, Code of Federal Regulations, a copy of this letter and the enclosures will be placed in the NRC's Public Document Room.

The responses directed by this letter and the enclosures are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, Pub. L. 96-511.

Sincerely,

Hugh L. Thompson, Jr.
Deputy Executive Director for
Nuclear Materials Safety, Safeguards
and Operations Support

Enclosures:
1. Notice of Violation and Proposed Imposition of Civil Penalty
2. Order Modifying License and Order to Show Cause

cc w/encls:
Public Document Room (PDR)
Nuclear Safety Information Center (NSIC)
State of New Jersey
Mr. Joseph Cuozzo

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

Certified Testing Laboratories, Inc.
Borcentown, New Jersey

Docket No. 030-12145
License No. 29-14150-01
EA 89-79

During an NRC inspection conducted on April 22, 1988, at the licensee's facility in Bordentown, New Jersey, and a subsequent investigation by the NRC Office of Investigations, 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 (1988), 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 the associated civil penalty are set forth below:

I. VIOLATIONS ASSESSED A CIVIL PENALTY

A. Condition 16 of License No. 29-14150-01 requires, in part, that licensed material be possessed and used in accordance with statements, representations and procedures contained in a letter dated January 7, 1985. Item No. 5 of this letter requires the Radiation Safety Officer or his designated representative to perform unannounced field audit inspections of each radiographer at intervals not to exceed three months.

Contrary to the above,

1. field audit inspection reports, dated July 20, 1987 and July 21, 1987, documenting quarterly field audits of two radiographers, were created by the Vice President/Radiation Safety Officer (VP/RSO); however, field audits of the indicated radiographers were not performed on the recorded dates, as admitted by the VP/RSO in an interview with an NRC investigator on February 8, 1989.

2. between July 1987 and January 6, 1988, no field audits for one specific radiographer were performed.

B. 10 CFR 30.9(a) requires, in part that information provided to the Commission by a licensee be complete and accurate in all material respects.

Contrary to the above, information provided by the VP/RSO during a telephone conversation with three NRC representatives on April 25, 1988, was inaccurate in that the Vice President/Radiation Safety Officer (VP/RSO), in response to questions regarding the field audit inspection report dated July 21, 1987 stated that he personally performed the field audit inspection. This statement by the VP/RSO was not accurate in all material respects in that the VP/RSO subsequently admitted to an NRC investigator on February 8, 1989 that he had not audited the radiographer on July 21, 1987, but had "made up" the audit report to give the appearance of compliance with the quarterly audit requirement. The statement was material because it had the potential to affect an ongoing NRC review of the matter.

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

Civil Penalty - $8,000 (assessed equally between the two violations)

II. VIOLATIONS NOT ASSESSED A CIVIL PENALTY

A. 10 CFR Part 20.105(b) requires that, except as authorized by the Commission pursuant to 10 CFR 20.105(a), radiation levels in unrestricted areas be limited so that an individual, who was continuously present in the area, could not receive a dose in excess of 2 millirems in any hour, or 100 millirems in any seven consecutive days.

Contrary to the above, on April 22, 1988, radiation levels in the laboratory portion (an unrestricted area) of the licensee's facility at Bordentown, New Jersey, were such that an individual who was continuously present in the area could have received a dose in excess of 2 millirems in any hour, or 100 millirems in any seven consecutive days. Specifically, radiation levels of 4 millirems per hour existed 18 inches from the outside surface of a storage bin located in the laboratory area.

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

B. 10 CFR Part 34.24 requires, in part, that each radiation survey instrument used to conduct physical radiation surveys shall be calibrated at intervals not to exceed three months.

Contrary to the above, between January 25 and February 2, 1988, physical radiation surveys were conducted with a survey instrument which had not been calibrated at three month intervals. Specifically, these surveys were performed with a radiation survey instrument which was last calibrated on October 19, 1987, an interval of more than three months prior to the date of use.

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

Pursuant to the provision of 10 CFR 2.201, Certified Testing Laboratories, Inc. is hereby required to submit a written statement or explanation to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, within 30 days of the date of the Notice. The 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, (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 Atomic Energy 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 to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, with a check, draft, or money order 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 "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, 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 (1989), 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 Atomic Energy Act, 42 U.S.C. 2282c.

The responses to the Director, Office of Enforcement, noted above (Reply to a 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, DC 20055 with a copy to the Regional Administrator, U.S. Nuclear Regulatory Commission, Region I, 475 Allendale Road, King of Prussia, Pennsylvania 19406.

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 9th day of March 1990

UNITED STATES
NUCLEAR REGULATORY COMMISSION

In the Matter of	)	
	)	Docket No. 030-12145
CERTIFIED TESTING LABORATORY, INC.	)	License No. 29-14150-01
Bordentown, New Jersey	)	EA 89-079

ORDER TO SHOW CAUSE WHY LICENSE SHOULD NOT BE MODIFIED

I

Certified Testing Laboratory, Bordentown, New Jersey (Licensee) is the holder of Byproduct Material License No. 29-14150-01 (license) issued by the Nuclear Regulatory Commission (NRC or Commission) pursuant to 10 CFR Parts 30 and 34. The license authorizes the use of byproduct material for the conduct of industrial radiography and related activities. The license originally issued on January 10, 1973, was last renewed on February 5, 1987, and is due to expire on April 30, 1990.

II

On April 22, 1988, an NRC inspection was conducted at the Licensee's facilities in Bordentown, New Jersey. In addition to the inspection activities that identified the violations noted at that time, the NRC inspectors also reviewed the Licensee's field audit reports of radiographer's activities. The inspectors noted that there was a radiographer's field inspection audit report issued for July 21, 1987, which was signed by Mr. Joseph Cuozzo, the Licensee's Vice President and Radiation Safety Officer (VP/RSO) for the Bordentown facility; however, there was no corresponding source utilization log showing that the radiographic device had been logged out on July 21, 1987, nor was there a corresponding radiation survey report documenting that radiography had been performed. Further, the Licensee's payroll records indicated that the radiographer who was alleged to have been audited on July 21, 1987, was on vacation during this time period.

On April 25, 1988, during a telephone conversation with three NRC representatives, the VP/RSO orally informed them that he personally audited the radiographer in question on July 21, 1987. Although the VP/RSO was asked to locate and mail to the NRC a copy of the utilization record for that date to verify that the radiographic device was in use, such source utilization log was never sent.

Subsequently, during an interview by the NRC Office of Investigations (OI) on February 8, 1989, Mr. Joseph Cuozzo admitted that the July 21, 1987, radiography field inspection audit report, as well as a second audit report dated July 20, 1987, were fraudulent in that he had not audited either individual although his signature at the bottom of each document so indicated. Mr. Cuozzo stated that he was very busy during the time period and no radiography or field audits were performed on those days. Mr. Cuozzo also stated that he "made up" both documents to give the appearance that he was conforming with the three month audit requirement, after reviewing the field survey files and discovering that neither radiographer had been audited within three months of his previous audit, as required. Mr. Cuozzo stated he accomplished the falsification when he "whited out" the radiographer's name and audit date from a previous, valid audit, made a copy of the document, and then inserted the names of the radiographers allegedly audited on each of the audit reports. Mr. Cuozzo said he then inserted the date of performance of the audits as July 20, 1987 and July 21, 1987, respectively. The original "whited out" field survey report was provided to the NRC during the investigation. In addition, Mr. Cuozzo provided a signed letter dated February 8, 1989, stating that the forms were made up and audits were never actually performed on July 20, 1987 and July 21, 1987. These facts establish a violation of a license condition requiring a quarterly field audit of each

radiographer. Furthermore, the information provided by Mr. Cuozzo during the April 25, 1988, telephone call with the NRC was also false, and constitutes a willful failure to provide information to the NRC that is complete and accurate in all material respects.

Dur ng a subsequent transcribed enforcement conference by the NRC with the Licensee on December 12, 1989, at the Licensee's facility, Mr. Cuozzo (in contradiction to his previous statements to the OI investigator) indicated that he had actually performed the audits of the two radiographers within the three month interval as required by the license. However, Mr. Cuozzo indicated that the particular audit reports were lost, and because his subsequent documentation of the audits was [illegible] ntemporaneous with their performance, he may have entered the wrong dates [illegible] dit [illegible]re performed.

Notwithstanding Mr. Cuozzo s assertion at the enforcement conference, his statements and admissions .o the NRC investigator on February 8, 1989, the documentary evidence indicating that information on the original audit report was "whited out," and the absence of any utilization log for July 21, 1987, establish that, at a minimum, the field audit report for July 21, 1987 was fraudulent, and that the VP/RSO's oral statement to the NRC representatives on April 25, 1988 was false.

III

The NRC in its investigation and inspection process must be able to obtain complete and accurate information from the Licensee in order to carry out the NRC's statutory mission. False statements to Commission officials cannot and

will not be tolerated. The actions of Mr. Cuozzo raise questions concerning whether the Licensee will comply with Commission requirements while Mr. Cuozzo is the Radiation Safety Officer at the Bordentown facility. In addition, these actions, as well as the conflicting information provided by Mr. Cuozzo during the inspection, investigation, and enforcement conference, raise substantial questions whether Mr. Cuozzo would comply with Commission requirements in the performance or supervision of any licensed activities.

Therefore, in view of the potential for serious adverse effects to the health and safety of the public that could arise from inadequately managed and supervised activities under a radiography license, and in light of Mr. Cuozzo's past actions, I am ordering that the Licensee show cause why Mr. Cuozzo should not be removed from the position of Radiation Safety Officer (RSO) of the Bordentown facility and from all involvement in the performance or supervision of NRC licensed activities.

IV

Accordingly, pursuant to Sections 81, 161b, 161c, 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 34, IT IS HEREBY ORDERED THAT:

Certified Testing Laboratory, Inc., shall show cause why License No. 29-14150-01 should not be modified to add the following condition:

Mr. Joseph Cuozzo shall not serve as Radiation Safety Officer or in any other position involving the performance or supervision of any licensed activities for Certified Testing Laboratories, Inc., including the supervision of any Radiation Safety Officer.

V

The licensee shall show cause, as required by Section IV above, by filing a written answer under oath or affirmation within thirty days after the date of issuance of this Order, setting forth the matters of fact and law on which the Licensee relies to demonstrate that the prohibition of Mr. Joseph Cuozzo from performance of licensed activities is not warranted. Mr. Joseph Cuozzo may also file a written answer within thirty days after the issuance of this Order, setting forth the matters of fact and law relied upon to demonstrate that modification of License No. 29-14150-01 is not warranted. The Licensee may answer this Order, as provided in 10 CFR 2.202(d), by consenting to the entry of an order in substantially the form proposed in this Order.

VI

The Licensee, Mr. Cuozzo, or any other person adversely affected by this Order may request a hearing within thirty days of the date of its issuance. Any answer to this Order or request for hearing shall be submitted to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555. Copies shall also 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 I, 475 Allendale Road, King of Prussia, Pennsylvania 19406. If a person other than the Licensee or Mr. Cuozzo requests a hearing, that person shall set forth with particularity the manner in which his interest is adversely affected by this Order and shall address the criteria set forth in 10 CFR 2.714(d). Upon the Licensee's consent to the condition set forth in Section IV of this Order, or upon failure of the Licensee and Mr. Cuozzo to file an answer within the specified time, and in the absence of any request for a hearing, the license is modified to include the condition specified in Section IV above without further Order or proceedings.

If a hearing is requested by the Licensee 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 a hearing shall be whether 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 9th day of March 1990

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

AUG 2 9 1990

Docket No. 030-12145
License No. 29-14150-01
EA 89-79

Certified Testing Laboratories, Inc.
ATTN: Joseph F. Citardi
President
155 US Route 130
Bordentown, New Jersey 08505

Gentlemen:

Subject: ORDER IMPOSING A CIVIL MONETARY PENALTY - $8,000

This letter refers to your letter dated March 27, 1990, in response to the Notice of Violation and Proposed Imposition of Civil Penalty (Notice) sent to you with the NRC letter dated March 9, 1989. The NRC letter and Notice described violations which were identified during an NRC inspection conducted in 1988 and a subsequent investigation by the NRC Office of Investigations (OI). The violations included falsification of records and a false statement to the NRC by the Vice President/Radiation Safety Officer (VP/RSO). To emphasize the importance of ensuring that licensed activities are conducted safely and in accordance with the conditions of your license, accurate records are maintained, and information communicated to the NRC is complete and accurate, a civil penalty in the amount of $8,000 was proposed for the two violations set forth in Section I of the Notice. Those violations were classified in the aggregate at Severity Level II.

In your response to the Notice, you (1) admit Part I.A.2 of Violation I.A, but do not admit Part I.A.1 of that violation nor Violation I.B; (2) claim that the violations in Section I are more appropriately classified at Severity Level V, and (3) request mitigation of the civil penalty, for several stated reasons. After careful consideration of your response, we have concluded, for the reasons given in the Appendix attached to the enclosed Order Imposing a Civil Monetary Penalty, that the violations did occur as stated in the Notice, and that the violations in Section I were appropriately classified in the aggregate at Severity Level II. Further, we find that you have not provided an adequate basis for any mitigation of the associated penalty. Accordingly, we hereby serve the enclosed Order on Certified Testing Laboratories imposing a civil monetary penalty in the amount of $8,000.

In your response, you also requested a hearing concerning the proposed penalty. However, your request was premature since the penalty has not, until this date, been imposed by Order. As noted in the enclosed Order, you may either pay the imposed penalty or request a hearing. In the absence of a Hearing Request by the licensee, the VP/RSO is not entitled to a hearing.

In accordance with Section 2.790 of the NRC's "Rules of Practice," Part 2, Title 10, Code of Federal Regulations, a copy of this letter and the enclosures will be placed in the NRC's Public Document Room. In your March 27, 1990 letter, you requested a copy of the OI report of an interview with the VP/RSO in February 1989. As your attorney was orally advised by NRC staff counsel on or about June 19, 1990, this document can be made available for release to you with the understanding that if it is released, a copy will also be placed in the NRC's Public Document Room.

Sincerely,

Hugh L. Thompson, Jr.
Deputy Executive Director
for Nuclear Materials Safety, Safeguards,
and Operations Support

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

cc w/encls:
Public Document Room (PDR)
Nuclear Safety Information Center (NSIC)
State of New Jersey

UNITED STATES
NUCLEAR REGULATORY COMMISSION

In the Matter of	
CERTIFIED TESTING LABORATORIES, INC. Bordentown, New Jersey	Docket No. 030-12145 License No. 29-14150-01 EA 89-79

ORDER IMPOSING A CIVIL MONETARY PENALTY

I

Certified Testing Laboratories, Inc., Bordentown, New Jersey (the "licensee") is the holder of License No. 030-12145 (the "license") issued by the Nuclear Regulatory Commission (the "Commission" or "NRC") pursuant to 10 CFR Parts 30 and 34. The license authorizes the use of by-product material for the conduct of industrial radiography and related activities. The license was originally issued on January 10, 1973, was last renewed on February 5, 1987, and was due to expire on April 30, 1990. However, the licensee requested renewal of the license in an application dated March 20, 1990. On April 10, 1990, NRC Region I issued a letter notifying the licensee that the license remains in effect under a timely renewal application pursuant to 10 CFR 30.37(b), pending Commission action on the renewal application.

II

The NRC concucted a safety inspection of the licensee's activities at the licensee's facility on April 22, 1988. Subsequently, the NRC Office of Investigations performed an investigation. Based on the inspection and investigation, the NRC found 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 was served upon the licensee by letter dated March 9, 1990. The Notice stated the nature of the

violations, the provisions of the NRC's requirements that the licensee had violated, the severity level of the violations, and the amount of the civil penalty proposed for the violations. The licensee responded to the Notice by letter dated March 27, 1990. In its response, the licensee admits Violation I.A.2, does not admit Violations I.A.1 and I.B. requests a lower severity level classification, and requests mitigation of the penalty.

III

After consideration of the licensee's response and the statement of facts, explanation, and arguments contained therein, the NRC staff has determined, as set forth in the Appendix to this Order, that (1) the violations occurred as stated in the Notice, (2) the violations in Section I of the Notice were appropriately classified in the aggregate at Severity Level II, (3) and the $8,000 penalty proposed for the violations set forth in the Notice of Violation and Proposed Imposition of Civil Penalty 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 $8,000 within thirty days of the date of this Order, by check, draft, or money order, payable

to the Treasurer of the United States and mailed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555.

The licensee may request a hearing within thirty days of the date of this order. A request for a hearing shall 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, Document Control Desk, Washington, D.C. 20555. A copy of the hearing request should also 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 thirty days 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 the hearing shall be:

(a) whether the licensee committed Violations I.A.1 and I.B, as set forth in the Notice of Violation referred to in Section II above, and

(b) whether, on the basis of those violations and Violation I.A.2 set forth in the Notice of Violation that the licensee admitted, this Order should be sustained.

FOR THE NUCLEAR REGULATORY COMMISSION

Hugh L. Thompson, Jr.,
Deputy Executive Director
for Nuclear Materials Safety, Safeguards,
and Operations Support

Dated at Rockville, Maryland
this 29th day of August 1990

APPENDIX

EVALUATION AND CONCLUSION

On March 9, 1990, a Notice of Violation and Proposed Imposition of Civil Penalty was issued to Certified Testing Laboratories, Inc., Bordentown, New Jersey, for violations identified during an NRC inspection and subsequent investigation by the NRC Office of Investigations. The licensee responded to the Notice on March 27, 1990. In its response, the licensee (1) does not admit certain parts of the two violations for which a penalty was proposed; (2) claims that the Severity Level for the violations assessed a civil penalty is more appropriately a Severity Level V rather than a Level II as cited; and (3) requests mitigation of the civil penalty for a number of stated reasons, including its corrective actions, past performance, and ability to pay. The NRC evaluation and conclusion concerning the licensee's response are as follows:

1. Restatement of Violations Assessed a Civil Penalty

I. VIOLATIONS ASSESSED A CIVIL PENALTY

A. Condition 16 of License No. 29-14150-01 requires, in part, that licensed material be possessed and used in accordance with statements, representations and procedures contained in a letter dated January 7, 1985. Item No. 5 of this letter requires the Radiation Safety Officer or his designated representative to perform unannounced field audit inspections of each radiographer at intervals not to exceed three months.

Contrary to the above,

1. field audit inspection reports, dated July 20, 1987 and July 21, 1987, documenting quarterly field audits of two radiographers, were created by the Vice President/Radiation Safety Officer (VP/RSO); however, field audits of the indicated radiographers were not performed on the recorded dates, as admitted by the VP/RSO in an interview with an NRC investigator on February 8, 1989.

2. between July 1987 and January 6, 1988, no field audits for one specific radiographer were performed.

B. 10 CFR 30.9(a) requires, in part, that information provided to the Commission by a licensee be complete and accurate in all material respects.

Contrary to the above, information provided by the VP/RSO during a telephone conversation with three NRC representatives on April 25, 1988, was inaccurate in that the Vice President/Radiation Safety Officer (VP/RSO), in response to questions regarding the field audit inspection report dated July 21, 1987, stated that he personally performed the field audit inspection. This statement by the VP/RSO was not accurate in all material respects in that the VP/RSO subsequently admitted to an NRC investigator on February 8, 1989 that he had not audited the

radiographer on July 21, 1987, but had "made up" the audit report to give the appearance of compliance with the quarterly audit requirement. The statement was material because it had the potential to affect an ongoing NRC review of the matter.

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

Civil Penalty - $8,000 (assessed equally between the two violations)

2. Summary of Licensee Response

The licensee admits, in part, one of the two violations in Section I of the Notice for which the civil penalty was proposed. Specifically, the licensee admits Part I.A.2 of Violation I.A., noting that the failure to perform the audits between July 1987 and January 1988 was caused by the VP/RSO's inattention to the requirements of his position, as well as the low level of activity during the period. However, the licensee does not admit Part I.A.1 of the violation, claiming that the audits more likely than not were done and simply documented after the fact (although in one case, a wrong date was selected.) While the licensee does not specifically admit or deny Violation I.B. concerning the accuracy of statements made to three NRC representatives by the VP/RSO on April 25, 1988, the answer appears to deny the violation by noting the lack of information to suggest a motive for the VP/RSO to "attempt to mislead the NRC about whether he had performed the audits."

The licensee states that, if any audits were done in July 1987, the associated audit reports were prepared a significant number of months after these audits. The licensee further states that the failure to prepare audit reports at the same time as the audit, or immediately afterwards, was a violation of company policy. The licensee indicates that submittal of these reports to the NRC without a clear label (such as "Conformed Copy; Initial Reports Probably Lost; Audit Performed July, 1987; Report Prepared April, 1988") made these reports incomplete and created a false impression of accuracy.

In support of its contention that it is far more likely than not that the audits were done but documented afterwards, the licensee states that records reflect that the radiography that the VP/RSO asserts he audited was performed at the Bordentown offices of Certified during the entire day on each of three days in July (specifically, on July 20, 1987 by one radiographer, and on July 14 and 27, 1989 by another radiographer); the work area is one closed door and less than 75 feet from the VP/RSO's office; and the VP/RSO's practice is to frequently visit the work area during the day. Thus, he had ample opportunity to observe the radiographer's work. Furthermore, the licensee states that there is no information which would suggest any motive for the VP/RSO to either prepare willfully false reports or to attempt to mislead the NRC about whether he had performed the audits, since the VP/RSO had at all times conceded that he had not performed any audits between August 1987 and January 1988. If the VP/RSO

simply asserted that he could not recall whether he had performed the July audits (given that the reports were not in his files at the time of the inspection), the missed audits for July would hardly have been more serious than the missed audits over the following six months. The licensee notes that the VP/RSO did not attempt to "make up" audit reports for the period between August 1987 and January 1988.

The licensee requests that if the NRC continues to maintain its conclusion that the July 1987 audit reports were willfully falsified by the VP/RSO, then the licensee requests a copy of the OI report of interview with the RSO on February 8, 1989, since the finding of willfulness was based primarily on that report of interview. (As noted in the cover letter, the OI report can be made available subject to certain conditions.)

The licensee also maintains that under the standards contained in the Enforcement Policy, Supplement VII, the severity level of the violations in Section I is more appropriately a Severity Level V rather than a Severity Level II, and therefore the penalty should be at most $500, based on a Severity Level V classification. In support of this contention, the licensee claims that if the audits had been performed in July, as it believes, but the reports were either never prepared or lost, then the late reports with an incorrect date for the one audit seem to be "incomplete or inaccurate information which [was] provided to the Commission and the incompleteness or inaccuracy is of minor significance."

The licensee also contends that, based upon application of the escalation/mitigation factors set forth in the policy, the civil penalty should be either cancelled or mitigated. Specifically, the licensee claims that, in light of the extensive oversight now being provided by the corporate radiation safety director, a decrease in the penalty by approximately 50% is appropriate under the Corrective Action factor. In addition, the licensee maintains that the prior good performance of the VP/RSO should cause a reduction of the penalty, perhaps by as much as 100%.

The licensee also requests that the NRC give consideration to their ability to pay the civil penalty. The licensee claims that "gross revenues (SALES) from all licensed activities at the Bordentown location were only about $48,000 in 1987 (and $37,000 last year). After direct labor and other costs, net revenues were probably less than $8,000 for both years combined." The licensee also notes its intent to charge the VP/RSO for any penalty ultimately imposed by the NRC, claiming that such penalty would be the direct result of his carelessness, and the VP/RSO still faces the possibility of discharge if the evidence discloses willfulness on his part. The licensee claims that it seriously doubts that the mistakes by the VP/RSO meet the "more than mere negligence" standard required for such a serious penalty. The licensee also notes that the VP/RSO's errors have already caused him a $2,500 fee personally and the threat of a federal prosecution for a number of months. In light of the sanctions he has already suffered, the licensee maintains that a letter or reprimand to the individual would constitute an adequate sanction.

The licensee also requests a hearing unless the fine is dropped or reduced to $500 or below.

3. NRC Evaluation of Licensee Response

The NRC concludes that the reports were falsified since the VP/RSO (notwithstanding any subsequent contentions) did admit in his interview with the OI investigator in February 1989, that he made up both documents after reviewing files and discovering that no other radiographer had been audited within three months of the previous audit. Further, when enforcement action was apparent, the VP/RSO changed his story as to whether he personally made changes to the audit documents. Moreover, there may have been other instances of falsification of records that were not cited, e.g., on the records of the 1/6/87 and 1/6/88 audits for the same individual, the only difference is the year, with all other factors being the same, including the time of observation, the location, the size of the pipe, and the slant of a typed entry.

With respect to the licensee's contention that the violation should be classified at Severity Level V, the NRC maintains that the violations in Section I are of more than "minor safety significance" because the NRC relies on such records, as well as statements concerning such records, to ensure that the radiographers are being audited so as to verify that they perform their tasks safely and in accordance with requirements. Completion of these records by the VP/RSO without actually performing the audits, and then providing inaccurate information to the NRC, represents, at a minimum, careless disregard for NRC requirements. Therefore, the violations were appropriately classified in the aggregate at Severity Level II.

With respect to the licensee's requests to cancel or mitigate the civil penalty based on its corrective actions, prior enforcement history and its ability to pay, the NRC concludes that (1) the licensee's corrective actions were not sufficiently prompt to provide basis for mitigation of the penalty; (2) the licensee's past enforcement history, consists of eight violations in 1986 and 1987 and, accordingly, provides no basis for mitigation of the penalty; and (3) the licensee provides insufficient basis for concluding that the payment of the proposed penalty would either put the licensee out of business or adversely affect its ability to safely conduct licensed activities, since the licensee did, in fact, acknowledge a profit at its facility.

With respect to the licensee's statement that it intends to charge any penalty imposed by the NRC to the VP/RSO, the NRC notes that such an action is a licensee decision that is not considered by the NRC when determining whether to escalate or mitigate a civil penalty, as the NRC considers the circumstances of the licensee, not individuals within the licensee.

4. NRC CONCLUSION

The licensee has not provided sufficient basis for the NRC to (1) reclassify the Severity Level of the violations in Section I of the Notice, or (2) reduce the associated $8,000 penalty for the violations. Therefore, the NRC concludes that a civil penalty in the amount of $8,000 should be imposed by Order.

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

August 14, 1991

Docket No. 040-08724
License No. SUB-1357
EA 91-060

Chemetron Corporation
ATTN: Michael Lederman
President
c/o Sunbeam-Oster Company, Inc.
Centre City Tower, 21st Floor
650 Smithfield Street
Pittsburgh, Pennsylvania 15222

Dear Mr. Lederman:

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY - $7,500
(NRC INSPECTION REPORT NO. 040-08274/91002)

This refers to the special safety inspection at the Chemetron Corporation, Newburgh Heights, Ohio, facility, conducted March 19 through April 15, 1991. During the inspection, a violation of NRC requirements was identified, and on May 16, 1991, an enforcement conference was held in the Region III office. A copy of the enforcement conference report was mailed to you on May 24, 1991.

The May 24, 1991, letter transmitting the enforcement conference report requested that you provide a plan to perform radiation surveys of all equipment which originated in Building 21 at your Harvard Avenue site and assess whether other contamination was spread to homes and/or possessions of current and former employees. The letter stated our decision on enforcement action would consider your response to this matter. After requesting a delay in the time to respond to that letter, Chemetron provided its response on July 3, 1991. The response was considered to be deficient in that it did not project schedules, milestones, or written reports. Our concerns regarding your response were documented in a letter dated July 24, 1991.

Our May 24, 1991, letter also stated that our decision on enforcement action would take into account the schedule for site characterization and remediation of the Harvard and Bert Avenue sites, including the contamination addressed in the enclosed violation, requested by Mr. Richard L. Bangart, Director, Division of Low-Level Waste Management and Decommissioning, in a letter to you dated May 9, 1991. There have been several exchanges between Chemetron and the NRC staff regarding this matter. Chemetron's response, dated July 16, 1991, was inadequate in that it did not address the characterization and remediation for the Harvard Avenue site outside the Building 21 area.

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

After considering these matters, we have concluded that Chemetron Corporation has not been proactive or aggressive in gaining control over all radioactive material under its responsibility and in developing firm time lines and schedules for remediation of all hazards. Consequently, we have concluded that enforcement discretion for the unauthorized removal and loss of control of licensed material would be inappropriate and that a civil penalty should be proposed.

The violation described in the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice) addresses Chemetron's failure to secure licensed material in the form of depleted uranium from unauthorized removal and failure to maintain the material under constant surveillance and immediate control. The violation is significant due to the length of time that it has existed, the broad area over which the contaminction was spread, and the fact that it may involve equipment, materials and areas that are no longer under the licensee's control. The NRC acknowledges the contamination represents a relatively low hazard to public health and safety. Nonetheless, non-radiation workers were unnecessarily exposed to licensed material possessed by Chemetron Corporation for which Sunbeam-Oster Company is now responsible. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy) 10 CFR Part 2, Appendix C (1991), this violation has been categorized as a Severity Level III.

The root causes of the violation and the subsequent corrective actions were discussed during the Enforcement Conference. The NRC recognizes that corrective action has been initiated and that your organization is corresponding with the NRC to reach acceptable goals for the completion of this corrective action. The major factor contributing to the violations appeared to be the failure of prior management to recognize the extent of the contamination controls necessary.

To emphasize the need for strict control of licensed material, 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 $7,500 for the Severity Level III violation.

The base value of a civil penalty for a Severity Level III violation is $5,000. The civil penalty adjustment factors in the Enforcement Policy were considered and the amount of the base civil penalty was increased 50 percent due to the NRC identifying the violation in a letter to you dated January 28, 1991, and due to the NRC having to identify the extent of the problem and requesting that you extend your surveys to the other buildings at the Harvard Avenue site. An adjustment was not made for corrective action since your actions were not extensive, though adequate. For instance, current and former employees were not contacted to determine if they had removed any property from the facility and radiation surveys of their homes were not performed. The remaining factors in the Enforcement Policy were also 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,

A. Bert Davis

A. Bert Davis
Regional Administrator

Enclosure: Notice of Violation and Proposed
Imposition of Civil Penalty

cc w/enclosure:
Mr. Robert E. Owen, Administrator,
Radiological Health Program, Ohio
Department of Health
Mr. Donald Schregardus, Director, Ohio
Environmental Protection Agency
Village of Newburgh Heights Mayors
Office
DCD/DCB (RIDS)
Ms. Kathryn Jones, Ohio Environmental
Protection Agency, N.E.D.O.
James Benetti, 5AT-26
U.S. Environmental Protection
Agency

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

Chemetron Corporation
Newburgh Heights, Ohio

Docket No. 040-08724
License No. SUB-1357
EA 91-060

During an NRC inspection conducted March 19 through April 15, 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 (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 is set forth below:

10 CFR 20.207(a) requires that licensed materials stored in an unrestricted area be secure from 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 under constant surveillance and the immediate control of the licensee. As defined in 10 CFR 20.3(a)(17), an unrestricted area includes 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 March 19, 1991, licensed material consisting of depleted uranium as contamination was located on equipment and in structures in Building Numbers 1, 3B, 3C, 4, 5B, 6, 9, 10, 11, 14, 16A, 16B, 17, 19, and 20 at 2910 Harvard Avenue, Newburgh Heights, Ohio, which are unrestricted areas, and this material was not in storage, 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 - $7,500

Pursuant to the provisions of 10 CFR 2.201, the Chemetron 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 Penalty (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each alleged violation: (1) admission or denial of the alleged violation, (2) the reasons for the violation if admitted and, if denied, the reasons why, (3) the corrective steps that have been taken and the results

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

Within the same time as provided for the response required under 10 CFR 2.201, the Licensee may pay the civil penalty by letter addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, with a check, draft, money order, or electronic transfer payable to the Treasurer of the United States in the amount of the civil penalty proposed above, or may protest imposition of the civil penalty in whole or in part, by a written answer addressed to the Director, Office of Enforcement, U. S. Nuclear Regulatory Commission. Should the Licensee fail to answer within the time specified, an order imposing the civil penalty will be issued. Should the Licensee elect to file an answer in accordance with 10 CFR 2.205 protesting the civil penalty, in whole or in part, such answer should be clearly marked as an "Answer to a Notice of Violation" and may: (1) deny the 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
Regional Administrator

Dated at Glen Ellyn, Illinois
this 14th day of August 1991

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

JAN 13 1992

Docket No. 040-08724
License No. SUB-1357
EA 91-060

Chemetron Corporation
ATTN: Michael Lederman
President
Sunbeam-Oster Company, Inc.
Centre City Tower, 21st Floor
650 Smithfield Street
Pittsburgh, Pennsylvania 15222

Dear Mr. Lederman:

SUBJECT: ORDER IMPOSING CIVIL MONETARY PENALTY - $7,500

This refers to your letter, dated September 20, 1991, in response to the Notice of Violation and Proposed Imposition of Civil Penalty (Notice) sent to you by our letter dated August 14, 1991. Our letter and Notice described one violation identified by the NRC during a special safety inspection, conducted March 19 through April 15, 1991. The violation concerned the failure to secure licensed material, in this case depleted uranium as contamination, from unauthorized removal. To emphasize the need for strict control of licensed material, a civil penalty of $7,500 was proposed on August 14, 1991.

In your response to the Notice, you did not contest that the violation occurred, but requested that the severity level of the violation be reduced or the amount of the proposed civil penalty be mitigated in its entirety because your actions in the matter were timely, comprehensive and reasonable. Also, you contended that the violation lacked any demonstrated safety significance, and therefore did not warrant imposition of a civil penalty.

After considering your response, we 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 either reducing the severity level of the violation or mitigating the amount of the civil penalty.

Accordingly, we hereby serve the enclosed Order Imposing Civil Monetary Penalty on Chemetron Corporation imposing a civil monetary penalty in the amount of $7,500. We will review the effectiveness of your corrective actions during a subsequent inspection.

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

Sincerely,

Hugh L. Thompson, Jr., Deputy
Executive Director for Nuclear
Materials Safety, Safeguards and
Operations Support

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

cc w/enclosures:
Mr. Robert E. Owen, Administrator
Radiological Health Program
Ohio Department of Health
Mr. Donald Schregardus, Director
Ohio Environmental Protection Agency
Village of Newburgh Heights Mayor's Office
DCD/DCB (RIDS)
Ms. Kathryn Jones
Ohio Environmental
Protection Agency, N.E.D.O.
James Benetti, 5AT-26
U. S. Environmental Protection Agency

UNITED STATES
NUCLEAR REGULATORY COMMISSION

In the Matter of	)	Docket No. 040-08724
Chemetron Corporation	)	License No. SUB-1357
Newburgh Heights, Ohio	)	EA 91-060

ORDER IMPOSING CIVIL MONETARY PENALTY

I

Chemetron Corporation (Licensee) is the holder of Source Material License No. SUB-1357 issued by the Nuclear Regulatory Commission (NRC or Commission) on June 12, 1979. The License authorizes the Licensee to store and possess depleted uranium contamination incident to conducting radiation surveys and decontamination of facilities, equipment and plant areas at 2910 Harvard Avenue, Newburgh Heights, Ohio, in accordance with the conditions specified therein. Previously, on October 8, 1965, the Atomic Energy Commission (predecessor agency of the NRC) issued Source Material License No. SUB-852 which authorized the Licensee to use depleted uranium compounds in the manufacture of a chemical catalyst at 2910 Harvard Avenue, Newburgh Heights, Ohio, in accordance with the conditions specified therein. Source Material License No. SUB-852 was in effect until superseded on June 12, 1979, with the issuance of Source Material License No. SUB-1357.

II

An inspection of the Licensee's activities was conducted from March 19 through April 15, 1991. The results of the inspection indicated that the Licensee had not conducted its activities in

full compliance with NRC requirements. A written Notice of Violation and Proposed Imposition of Civil Penalty (Notice) was served upon the Licensee by letter dated August 14, 1991. The Notice states the nature of the violation, the provision of the NRC's requirements that the Licensee has violated, and the amount of the civil penalty proposed for the violation. The Licensee responded to the Notice by letter dated September 20, 1991. In its response, the Licensee requested that the severity level of the violation be reduced or the amount of the proposed civil penalty be mitigated in its entirety.

III

After consideration of the Licensee's response and the statements of fact, explanation, and arguments 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 $7,500 within 30 days of the date of this Order, by check, draft,

electronic transfer or money order, payable to the Treasurer of the United States and mailed to the Director, Office of Enforcement, U. S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555.

V

The Licensee may request a hearing within 30 days of the date of this Order. A request for a hearing should be clearly marked as a "Request for an Enforcement Hearing" and shall be addressed to the Director, Office of Enforcement, U. S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555. Copies also shall be sent to the Assistant General Counsel for Hearings and Enforcement at the same address and to the Regional Administrator, NRC Region III, 799 Roosevelt Road, Glen Ellyn, Illinois 60137.

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

In the event the Licensee requests a hearing as provided above, the 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 13th day of January 1992

APPENDIX

EVALUATION AND CONCLUSIONS

On August 14, 1991, a Notice of Violation and Proposed Imposition of Civil Penalty (Notice) was issued for the violation identified during an NRC inspection. Chemetron Corporation responded to the Notice on September 20, 1991. In its response, the Licensee did not contest the violation, but requested that the severity level of the violation be reduced or the amount of the proposed civil penalty be mitigated in its entirety. The NRC's evaluation and conclusion regarding the Licensee's requests are as follows:

I. Restatement of Violation

10 CFR 20.207(a) requires that licensed materials stored in an unrestricted area be secure from 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 under constant surveillance and the immediate control of the licensee. As defined in 10 CFR 20.3(a)(17), an unrestricted area includes 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 March 19, 1991, licensed material consisting of depleted uranium as contamination was located on equipment and in structures in Building Numbers 1, 3B, 3C, 4, 5B, 6, 9, 10, 11, 14, 16A, 16B, 17, 19, and 20 at 2910 Harvard Avenue, Newburgh Heights, Ohio, which are unrestricted areas, and this material was not in storage, 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 - $7,500

II. Summary of Licensee's Response Concerning Severity Level

The Licensee did not contest the violation. The Licensee contends that the NRC did not give full consideration to the circumstances surrounding the violation. The Licensee argues that the severity level of the violation should be reduced to Level IV, based on the following: (1) the safety significance of the violation is low; (2) the NRC acknowledged that Chemetron's current management was not responsible for the actual violation; (3) the present Chemetron management team identified the violation to the NRC; and (4) Chemetron's remediation efforts were reasonable.

First, the Licensee refers to the NRC's characterization of the contamination as representing a relatively low hazard to the public health and safety. The Licensee also notes that the contamination is limited to an industrial complex, access to which is carefully controlled and is used by only a relatively few individuals.

Second, the Licensee asserts that the NRC's August 14, 1991, letter transmitting the Notice stated that the major factor contributing to the violations was the failure of prior management to recognize the extent of the contamination controls necessary to the project.

Third, the Licensee contends that as early as August 1990 the Licensee identified the spread of contamination.

Fourth, the Licensee concludes that the violation represented an isolated occurrence rather than a programmatic breakdown in the management controls applied to its control of contamination and that its efforts at remediation have been "responsive and effective."

Fifth, the Licensee contends that the violation was not willful in any fashion.

Sixth, the Licensee argues that the NRC has given undue weight to the Licensee's lack of responsiveness to this matter, which it attributes to prior management. The Licensee further asserts that the NRC Enforcement Manual states that the promptness and extensiveness of corrective actions are normally not considered at all for the purposes of determining severity level and concludes that the NRC should revisit its severity level determination in that regard.

NRC's Evaluation of Licensee's Response Concerning Severity Level

First, with regard to safety significance, the Licensee is correct in stating that the NRC's August 14, 1991, letter transmitting the Notice acknowledged the contamination represents a relatively low hazard to public health and safety. This does not mean that the violation was not of significant regulatory concern. Nor has NRC stated that the level of contamination is not of concern. More than 200 areas of contamination were found in the various buildings with numerous areas in substantial excess of NRC guidelines in Regulatory Guide 1.86 for release for unrestricted use. In fact, the August 14, 1991, letter stated:

> ". . . The violation is significant due to the length of time that it has existed, the broad area over which

> the contamination was spread, and the fact that it may involve equipment, materials and areas that are no longer under the licensee's control. The NRC acknowledges that the contamination represents a relatively low hazard to public health and safety. Nonetheless, non-radiation workers were unnecessarily exposed to licensed material possessed by Chemetron Corporation for which Sunbeam-Oster Company is now responsible. . ."

This statement accurately reflects the situation and categorization of the violation at Severity Level III. Example C.11 of Supplement IV to the NRC enforcement policy provides an example of a Severity Level III violation as the "significant failure to control licensed material." The violation for the failure to control licensed material is significant because of the large area (more than 134,000 square feet in 15 buildings) which had become contaminated and the duration of the violation from the time uncontrolled contamination was first discovered until access to the material was restricted. In this regard, the NRC notes that the Licensee interprets the violation as one of dispersal of the contamination, rather than the failure to maintain control of that material once it was identified. Clearly, both elements are important, but the Licensee failed to establish a restricted area to control access to the contamination. While identifying the areas to which contamination had been previously dispersed is necessary to identify the areas requiring control, the violation stated in the Notice of Violation was of 10 CFR 20.207, and did not involve the actions that caused the dispersal.

The violation described in the Notice concerns the widespread and long-term nature of the contamination and the inadequate controls the Licensee had in place for the purpose of protecting individuals from exposure to radiation and radioactive materials and to prevent the spread of contamination. The NRC's regulatory concern arising from the violation is the Licensee's failure to recognize the significance of controlling access to the contamination, as discussed throughout this Appendix. Accordingly, this was not an isolated occurrence, but resulted from inadequate management controls.

The Licensee's characterization that the contamination is limited to an industrial complex, access to which was carefully controlled and which was utilized by a small number of individuals, does not take into consideration that those individuals are not employees of the Licensee and are therefore members of the general public. These workers,

through no fault of their own, but through the inadequate controls the Licensee had in place for the purpose of protecting individuals from exposure to radiation and radioactive material, have been exposed to the contamination spread by the activities of the Licensee.

Second, with respect to the Licensee's current management responsibility for the violation, the Licensee accurately points out that the NRC stated that the major factor contributing to the violation was the failure of prior management to recognize the extent of the contamination controls necessary to the project. The NRC recognizes that the Licensee's present management team did not become involved with this project until August 1990 and concludes that the present management team did not cause the prior lack of contamination controls. However, regardless of the cause of the violation, current management is responsible for satisfying all Commission requirements.

Third, the Licensee contends that as early as August 1990 the Licensee identified the spread of contamination. The Licensee did inform the NRC that contamination had been spread to Building 20. However, the Licensee did not act promptly to fully discover the extent of the contamination either in Building 20 or elsewhere nor did it act promptly to regain control over that material. These concerns are reflected in the NRC's letter of January 28, 1991, which transmitted Inspection Report No. 040-08724/91001. That letter stated in part:

> ". . . In addition to responding to the violation in the enclosed Notice, we request that you also address the following two concerns that were identified during this inspection:
>
> 1. Low level uranium contamination was discovered in Building 20. We are concerned that the building appears to be contaminated above the NRC's release criteria, is an unrestricted area, and it is currently occupied by non-radiation workers.
>
> 2. Equipment with low level uranium contamination was discovered in Building 14 which is an unrestricted area. It appears that the contaminated equipment originated from the previously demolished Building 21. We are concerned that thorough surveys have not been performed to determine the extent and level of contamination that may exist in Buildings 14 and 20 and in other unrestricted facilities at Harvard Avenue. . ."

While the Licensee may have identified that contamination was spread to Building 20, the NRC had to inquire whether contamination had been spread elsewhere and whether the Licensee had taken any action to comply with 10 CFR 20.207 or restrict access to that contamination.

Fourth, the Licensee contends that it took reasonable remediation steps in light of other decontamination activities. The Licensee's remediation program concerning the disposal of the previously known contamination from Building 21 is irrelevant to the severity level of the violation. Rather, the Licensee failed to recognize the need to control all contamination, which is the basis for classifying the violation at Severity Level III. The Licensee also contended that the violation represented an isolated occurrence rather than a programmatic breakdown in the management controls applied to its control of contamination. As discussed above, the NRC rejects this position. Moreover, the Licensee's assertion that the violation was an isolated occurrence is refuted by the fact that contamination was found in 15 buildings, none of which were previously within the Licensee's restricted radiation area.

Fifth, the NRC acknowledges that the violation was not willful. The NRC did not assert willfulness as a basis for classifying the violation at Severity Level III.

Sixth, the Licensee's lack of responsiveness in this matter is only partially attributable to prior management. The NRC staff is most concerned that the Licensee took only limited actions to identify the extent of contamination after first identifying it in August 1990 until the NRC staff, in its letter of January 28, 1991, prodded the Licensee to take more extensive action, and the Licensee took no action to regain control of that contamination until after the NRC identified that lack of control in the March 1991 inspection.

As for the Licensee's argument that the promptness and extensiveness of corrective actions are normally not considered at all for the purposes of determining severity level, the NRC staff does not fully agree. While corrective action after the identification of a violation is considered under the escalation and mitigation factors, the safety significance of the violation, and the corresponding severity level, depends on the opportunity for exposure to ionizing radiation. In this instance, the Licensee did not take appropriate steps to recognize the need to regain control of source material until after the March 1991

inspection, even though it had a reasonable opportunity to identify that need based on the earlier findings of contamination in buildings 14 and 20. Accordingly, the potential for exposure was increased.

Based on the foregoing, the NRC staff concludes that the violation stated in the Notice is properly classified at Severity Level III.

III. Summary of Licensee's Request for Remission of the Civil Penalty

With respect to the "Identification and Reporting" factor, the Licensee contends that it, and not the NRC, identified the violation. Also, the Licensee contends that the NRC's request that the Licensee extend surveys to other buildings does not appear to be the proper subject of the identification and reporting adjustment factor under the NRC Enforcement Policy. Further, the Licensee argues that whether its response was comprehensive is a separate matter to be considered under the corrective actions adjustment factor, which the staff addressed separately. The Licensee quotes the Enforcement Policy as stating that escalation is considered only "if the NRC identifies the violation provided the licensee should have reasonably discovered the violation before the NRC identified it."

The Licensee also contends that its corrective actions were appropriate and reasonable given the Licensee's established priorities for decontaminating the Harvard Avenue facility and the Bert Avenue landfill.

Specifically, the Licensee quotes the Enforcement Manual as stating "[m]itigation of the base civil penalty may be appropriate if there was essentially no other reasonable action that the licensee should have taken," and asserts that it took all reasonable actions to correct the violation, and therefore deserves mitigation of the civil penalty.

Additionally, the Licensee contends that it is unreasonable to expect Chemetron to be able to anticipate all potential locations of contamination. Finally, the Licensee argues that the NRC abused its discretion by considering extraneous matters, i.e., the site characterization and remediation of the Harvard and Bert Avenue sites beyond the contamination of the buildings cited in the violation.

NRC's Evaluation of Licensee's Request for Remission of the Civil Penalty

As discussed above, the NRC agrees that the Licensee identified the contamination of Building 20. However, it was the NRC's letter of January 28, 1991, which specifically requested the Licensee to determine the extent of the contamination in Buildings 14 and 20 and to determine if contamination had been spread to any other unrestricted area at 2910 Harvard Avenue, Newburgh Heights, Ohio. This NRC questioning of the Licensee led to the discovery of contamination in at least 15 buildings, which the Licensee had not considered. In addition, during its March 1991 inspection, the NRC, and not the Licensee, identified the need to restrict access or otherwise regain control of this contamination. The NRC concludes that the Licensee's identification of contamination in Building 20 in August 1990 should have reasonably led it to identify the other areas of contamination and regain control of that contamination. The NRC staff's primary concern is the Licensee's failure to investigate other potentially contaminated locations which would, and should, have resulted in the Licensee's identification of the contamination in the other buildings. The Licensee presents no reasons why it should not have reasonably identified this additional contamination. The Licensee's failure to identify the full extent of the spread of contamination or the need to regain control of the contamination it did identify are the reasons for increasing the amount of the civil penalty by 50 percent under the civil penalty adjustment factor for identification and reporting.

Regarding the Licensee's contention that its corrective actions were reasonable and appropriate considering its other priorities and that the Licensee could not anticipate all locations to which contamination was spread, the NRC acknowledged in the August 14, 1991, letter transmitting the Notice, ". . . your actions were not extensive, though adequate. For instance, current and former employees were not contacted to determine if they had removed any property from the facility and radiation surveys of their homes were not performed. . ." The Licensee's point that its corrective actions were reasonable and appropriate considering its other priorities is of no relevance as the other priorities to which the Licensee refers are the clean-up of the Harvard and Bert Avenue sites which were known to be contaminated prior to determining that an additional 15 buildings had been contaminated. Further, the fact that the Licensee did not canvass employees to determine what property had been removed from the facility, even after becoming aware that contaminated lumber had been taken from the facility, is indicative of the less than extensive approach the Licensee has taken to ensure that contamination

is controlled and removed from the public domain. Therefore, the NRC concluded that no escalation or mitigation of the amount of the civil penalty is appropriate for the Licensee's corrective actions.

Finally, the Licensee argues that the NRC considered extraneous matters, namely the schedule for site characterization and remediation of the Harvard and Bert Avenue sites, which the Licensee considered impermissible, tainting the decision regarding this enforcement action, and was an abuse of discretion. The Licensee is referring to the following passage in the August 14, 1991, letter transmitting the Notice:

> ". . . we have concluded that Chemetron Corporation has not been proactive or aggressive in gaining control over all radioactive material under its responsibility and in developing firm time lines and schedules for remediation of all hazards. Consequently, we have concluded that enforcement discretion for the unauthorized removal and loss of control of licensed material would be inappropriate and that a civil penalty should be proposed. . ."

This statement was made as a follow-up to the NRC's May 24, 1991, letter which stated that the NRC was withholding a decision concerning the enforcement action pending Chemetron's response on the spread of contamination outside the facility and on the schedule for characterization and remediation of the Harvard and Bert Avenue sites.

Enforcement discretion is addressed in Paragraph V.G of the NRC Enforcement Policy which states, "Because the NRC wants to encourage and support licensee initiative for self-identification and correction of problems, NRC may exercise discretion" [emphasis added]. As relevant here, Paragraph V.G.3 of the NRC Enforcement Policy provides that the NRC may refrain from proposing a civil penalty for a Severity Level III violation, as was the case here, only if: (a) it does not involve the release of radioactive material, (b) it was identified by the licensee and reported, (c) comprehensive corrective action is well underway within a reasonable time following identification, and (d) it was not a violation that reasonably should have been corrected prior to the violation because the Licensee had prior notice of the problem involved. In this case: (a) the violation was identified by the Licensee only at the urging of the NRC, (b) comprehensive corrective action was slow and taken only at the insistence of the NRC, and (c) the Licensee had notice of the problem at least six months before the

violation was identified, and should have corrected it within that time. Accordingly, enforcement discretion was not warranted.

As for the Licensee's contention that the Staff improperly considered the Licensee's failure to submit its characterization reports and remediation plans in a timely fashion in issuing the Notice, the Staff was merely pointing to the Licensee's general pattern of conduct in responding to problems on time as its chief area of concern. This language was intended to improve the Licensee's future responsiveness to potential problems. The Staff's recitation of its concern in no way implies that enforement discretion is warranted, as explained above. The Licensee's contention that the NRC abused its discretion is without basis.

IV. NRC Conclusion

The NRC has concluded, based on the information presented by the Licensee and evaluated by the NRC, that the violation occurred as stated in the Notice and that the Licensee has not provided an adequate basis for either reducing the severity level of the violation or for mitigation of the civil penalty. Consequently, the proposed civil penalty in the amount of $7,500 is justified and appropriate and should be imposed.

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

NOV 15 1991

Docket No. 30-03255
License No. 42-00084-06
EAs 91-096 & 91-157

Department of Veterans Affairs
Veterans Administration Medical Center (VAMC)
ATTN: John Sheehan, Hospital Director
2002 Holcombe Boulevard
Houston, Texas 77211

Gentlemen:

SUBJECT: NOTICE OF VIOLATION, PROPOSED IMPOSITION OF $25,000 CIVIL PENALTY & CONFIRMATORY ORDER (NRC INSPECTION REPORT NO. 30-03255/91-01)

This is in reference to the June 10-12 and June 18-20, 1991, inspection of NRC-licensed activities at the Veterans Administration Medical Center (VAMC), Houston, Texas, and to the discussion of the results of NRC's inspection at an enforcement conference conducted on August 9, 1991, at the VAMC.

NRC's inspection, which was documented in a report issued on July 23, 1991, disclosed 22 violations of radiation safety requirements. The violations involved the VAMC's failure to comply with NRC regulations and license conditions that require the VAMC to: perform radiation and contamination surveys, monitor personnel radiation exposures, conduct inventories of sealed radioactive sources and maintain control of radioactive materials, ensure the proper calibration and use of equipment, ensure that the users and quantities of radioactive material are approved by the Radiation Safety Committee (RSC), and maintain records.

This inspection also revealed that the VAMC's corrective actions for previous violations issued by the NRC were either not implemented or ineffective in precluding recurrence. Six of the 22 violations were repetitive violations involving: the storage of xenon-133 in a location not equipped with a fume hood, the failure in some instances to evaluate radiation exposures or issue radiation monitoring devices to workers, the failure to perform surveys at the required frequencies in certain rooms, the failure to maintain contamination survey records as required, the failure to conduct quarterly inventories of all sealed radioactive sources, and the failure to perform a daily operability check of a survey instrument prior to each day of use.

Collectively, these inspection findings indicate a potentially significant lack of attention to licensed responsibilities. Although none of the violations resulted in any radiation overexposures to hospital staff or release of radioactive contaminants to the environment, these violations created a potential for the safety of VAMC employees, the general public, and, in some cases, patients, to have been compromised. One example of this is the inadvertant incineration of waste containing cerium-141, strontium-85, scandium-46, and chromium-51 radioactive materials. Only the physical characteristics of the radioactive material itself prevented material from being emitted to the environment in the incinerator effluent. The root cause of the incident was attributed to the lack of training of VAMC employees who handle animal carcasses for waste disposal.

These violations can be attributed in some instances to a failing of the radiation safety staff, in some instances to a failing of the users of radioactive material, who themselves have certain responsibilities for meeting requirements, and in other instances to a failing of the radiation safety committee to function as expected. Although the NRC recognizes that you were without a permanent radiation safety officer for some period of time, patient care and licensed activities continued. Thus, it was incumbent on the VAMC to ensure continued compliance with all radiation safety requirements. NRC's concern about these findings is heightened by the fact that NRC assessed the VAMC a $7,500 civil penalty in April 1990 for similar shortcomings in the management of its NRC-licensed activities, and by the fact that the VAMC's radiation safety staff found some of the same violations during its audits and no apparent corrective action was taken.

Inspection findings of this nature in successive inspections reduces NRC's confidence in the VAMC's ability to manage its NRC-licensed activities in a manner consistent with NRC's expectations of a holder of a broad-scope medical license. A broad-scope license provides a significant degree of freedom to a licensee in reviewing and approving both the uses and the users of licensed radioactive material. However, incumbent with that freedom is a heightened degree of responsibility to ensure that all activities that are authorized by the RSC are in fact being carried out in accordance with NRC regulations and the terms of the license.

These recent inspection findings, which are an indication of continued poor management of NRC-licensed activities, are of significant regulatory concern to NRC. Therefore, in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy) 10 CFR Part 2, Appendix C (1991), the violations are classified in the aggregate as a Severity Level III problem.

NRC recognizes that the VAMC has now initiated corrective action for each of the individual violations and has committed to long-term corrective action to resolve the fundamental weaknesses in its radiation safety program. These actions include commitments to (1) increase the size of the radiation safety staff from two to three individuals, (2) increase training for the radiation safety officer (RSO) and assistant RSO, (3) increase audits by the radiation safety staff and RSC, (4) develop an enforcement scheme that can result in the suspension of activities a ./or disciplinary action against individuals including suspension of employees without pay, (5) train new and existing employees who use radioactive material, (6) conduct RSC meetings every two months, and (7) arrange for at least six quarterly audits of NRC-licensed activities by representatives of the Department of Veterans Affairs' National Advisory Committee on Radiation Safety.

To emphasize the importance of taking necessary steps to maintain a radiation safety program that ensures strict compliance with all radiation safety requirements and is commensurate with NRC's expectations of a broad-scope medical licensee, I have been authorized, after consultation with the Director, Office of Enforcement, the Deputy Executive Director for Nuclear Materials Safety, Safeguards and Operations Support, and the Commission, to issue the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice) in the amount of $25,000 for the Severity Level III problem described above.

In determining the size of the civil penalty in this case, NRC deviated, as permitted in its enforcement policy, from the normal base value ($2,500) for medical facilities in Table IA of the Enforcement Policy for a Severity Level III violation. We have done so to impress upon the VAMC the significance that NRC attaches to inspection findings of this nature in successive years. This decision was based in part on the following considerations: 1) NRC's inspection disclosed these violations as opposed to their having been discovered and corrected through the VAMC's own audit processes; 2) the VAMC failed to take effective corrective action for a previous Notice of Violation and Proposed Civil Penalty issued by the NRC in April 1990 and failed to resolve more fundamental shortcomings in the management of NRC-licensed activities; 3) the VAMC failed to act on its own audit findings to correct violations identified by its own radiation safety staff; and (4) six of the 22 violations were repetitive violations from the previous inspection.

In light of the VAMC's past performance, additional action is necessary to give NRC greater confidence that the VAMC will develop the capability to ensure strict compliance with NRC requirements in the conduct of its nuclear medicine and research programs. Therefore, the enclosed Confirmatory Order is being

issued to confirm the VAMC's voluntary commitment to subject its NRC-licensed programs to audits by representatives of the

Department of Veterans Affairs' National Advisory Committee on Radiation Safety.

Questions concerning this Order should be addressed to J. Lieberman, Director, Office of Enforcement, who can be reached at (301) 492-0741.

With regard to the proposed civil penalty, the VAMC is required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing its response. In its response, the VAMC should document the specific actions taken and any additional actions it plans 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,

Hugh L. Thompson
Deputy Executive Director for
Nuclear Materials Safety, Safeguards,
and Operations Support

Enclosures:
1. Notice of Violation and Proposed Imposition of Civil Penalty
2. Confirmatory Order Modifying License

See next page for cc's.

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

Department of Veterans Affairs
VA Medical Center
Houston, Texas

Docket No. 30-03255
License No. 42-00084-06
EA 91-096

During an NRC inspection conducted June 10-12, June 18-20 and June 28, 1991, 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 (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 violations and associated civil penalty are set forth below:

A. License Condition 20 requires, in part, that licensed material be possessed and used in accordance with statements, representations, and procedures contained in the application dated May 22, 1985, and letter dated August 20, 1986.

1. Item 23.D.3(d) of the application dated May 22, 1985, specifies that a bioassay will be performed within 2 weeks of the last possible exposure to (volatile) I-125 or I-131 when operations (in research areas) are being discontinued or when the worker is terminating activities with potential exposure to radioiodine.

   Contrary to the above, the licensee failed to perform a bioassay for an individual within 2 weeks of the individual's last exposure to (volatile) I-125 and I-131, at which time the worker had terminated activities involving the use of radioiodine. Specifically, the individual had last worked with millicurie quantities of liquid radioiodine at the licensee's facility in August 1990, and a bioassay was not performed until March 31, 1991.

2. Item 8 of the letter dated August 20, 1986, specifies, in part, that for bioassays, the radiation safety officer (RSO) will perform the counting and calculations necessary to determine the amount of activity present in the person.

   Contrary to the above, as of June 20, 1991, the RSO had failed to perform the calculations necessary to determine the activity present in individuals for whom bioassays were performed. Specifically, the bioassays performed during the period from January 1990 to June 1991 for individuals working in nuclear medicine

consisted of a thyroid count using a scintillation detection system, but did not include the calculations necessary to determine and evaluate the activity present in the individuals' thyroid glands.

3. Item 21.B.1 of the application dated May 22, 1985, specifies that xenon-133 will be stored in a RADX Corp. "Xenon-Kow II" located in the fume hood in Room 747A of Building 1A.

   Contrary to the above, the licensee did not limit the storage of xenon-133 to the RADX Corp. "Xenon-Kow II" within the designated fume hood in Room 747A of Building 1A, but also stored xenon-133 in Room B-11 of Building 26D on numerous occasions from January 1990 to June 1991.

   This is a repeat violation.

4. Item 7.B(.3) of the application dated May 22, 1985, specifies that the radiation safety committee (RSC) will review the training and experience of users of radioactive material and determine that their qualifications are sufficient to enable them to perform their duties safely and in accordance with Nuclear Regulatory Commission regulations and the conditions of the license.

   Contrary to the above, the RSC had not reviewed a physician user's training and experience prior to the individual's use of gold-198 brachytherapy sources for patient treatments during December 1989 and February 1990.

5. Item 3 of the letter dated August 20, 1986, specifies, in part, that all radioactive material ordered by the V. A. Medical Center is ordered through the RSO who insures that the individual ordering the material is approved for the activity being ordered and that the activity ordered does not exceed the individual's possession limit.

   Contrary to the above, as of June 20, 1991, the RSO had failed to insure that an individual who ordered xenon-133 in curie quantities was approved for the activity ordered and that the activity ordered did not exceed the individual's possession limit. Specifically, the individual ordered and received 3-4 vials of xenon-133 containing 1 curie each per month over several years, although the individual was only approved by the RSC for a maximum possession limit of 400 millicuries.

6. Item 1 of the letter dated August 20, 1986, describes the conditions required for radionuclide use requests and approval by the RSC. Item 1.B. specifies, in part, that the procurement of all radioactive material must be approved by the Radionuclide Use Subcommittee (RUS) of the RSC.

   Contrary to the above, from January 10, 1990 to June 20, 1991, the RUS and RSC failed to approve an individual's procurement of radioactive material. Specifically, the individual had procured microcurie quantities of hydrogen-3, a material that the individual had not been approved to use or procure.

7. Items 22.B.3 and 22.B.4 of the application dated May 22, 1985, specify, in part, that contaminated [animal] carcasses will be placed in labeled plastic bags and stored in labeled radioactive waste drums specifically [designed] for biological waste, and the drums will be turned over to the appropriate commercial firm for disposal.

   Contrary to the above, during the week of May 27, 1991, the licensee failed to place four contaminated animal carcasses, containing approximately 1 millicurie total of cerium-141, strontium-85, scandium-46, and chromium-51, in a waste drum specified for radioactive biologic waste and to transfer the carcasses to a commercial firm for disposal. The carcasses were instead incinerated at the licensee's facility on May 30, 1991.

8. Item 15.H of the application dated May 22, 1985, specifies, in part, that the immediate areas, e.g., hoods, benches, etc., in which radioactive materials are used will be checked at least daily for contamination; that a log record will be maintained of these survey results which are entirely negative; and that any contamination observed will be clearly marked and the RSO notified.

   Contrary to the above, from January 10, 1990 to June 20, 1991, the licensee failed to check at least daily for contamination in all laboratory areas where radioactive material was used, and failed to maintain a record of survey results for laboratory areas which were surveyed daily. Specifically, surveys were not conducted in Rooms 212 and 212A on each day of use, and records were not maintained for surveys conducted in Rooms 116, 118, and 119.

9. Item 15.M of the application dated May 22, 1985,

specifies, in part, that users will perform decontamination procedures when necessary. Item 15.R specifies, in part, that if contamination exceeds a level of 200 disintegrations per minute (dpm) per 100 square centimeters, decontamination will be done.

Contrary to the above, from January 10, 1990 to June 20, 1991, users of radioactive material had failed to routinely perform decontamination procedures when levels of contamination from phosphorus-32 exceeded 200 dpm per 100 square centimeters in Room 207A, a research area.

10. Item 15.R of the application dated May 22, 1985, specifies, in part, that periodic surveys will be conducted monthly in areas where less than 200 microcuries of radioactive material are used and weekly in all other lab areas. Weekly and monthly surveys will consist of a measurement of radiation levels with a survey meter and a series of smear tests to measure contamination levels.

Contrary to the above, from December 1990 to June 1991, the licensee failed to conduct monthly surveys in laboratory areas where less than 200 microcuries of radioactive material were used, and failed to conduct weekly surveys in other laboratory areas where greater than 200 microcuries of radioactive material were used. Specifically, Room 225, where less than 200 microcuries of phosphorus-32 were used, was not surveyed monthly between December 1990 and June 1991. Additionally, Rooms 116, 118, and 119, where quantities in excess of 200 microcuries of phosphorus-32 were used, were not surveyed weekly between January and June 1991.

This is a repeat violation.

B. 10 CFR 20.201(b) requires that each licensee make such surveys as may be necessary to comply with the requirements of Part 20 and 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 20.202(a)(1) requires that each licensee supply appropriate personnel monitoring equipment to, and require the use of such equipment by, each individual who enters a restricted area under such circumstance that he receives, or

is likely to receive, a dose in any calendar quarter in excess of 25 percent of the applicable value specified in 10 CFR 20.101(a).

10 CFR 20.101(a) requires that the licensee limit the whole body and extremity radiation dose of an individual in a restricted area to 1.25 and 18.75 rems per calendar quarter, respectively.

Contrary to the above, as of June 20, 1991, the licensee did not make surveys to assure compliance with that part of 10 CFR 20.101 that limits the radiation exposure to the whole body and extremities, and did not provide personnel monitoring equipment to each individual who entered a restricted area under circumstances such that they were likely to receive a dose in any calendar quarter in excess of 25 percent of the applicable values specified in 10 CFR 20.101(a). Specifically, the licensee failed to evaluate exposures for, or issue monitoring equipment to: (1) two physicians who had physically implanted brachytherapy sources during patient treatments completed in December 1989 and February 1990, and (2) nuclear medicine technology students who physically withdrew and administered radiopharmaceutical doses during 1990. The licensee also failed to evaluate an exposure received by an individual during the fourth quarter of 1990, a period when the individual's monitoring badge was determined to have been overexposed while not in use.

This is a repeat violation.

C. 10 CFR 35.315(a)(8) requires, in part, that a licensee measure the thyroid burden of each individual who helped prepare or administer dosages of iodine-131 in amounts that required the patient to be hospitalized for compliance with 10 CFR 35.75, and that the measurements be performed within 3 days after the administration of the dosage.

Contrary to the above, on September 12 and October 18, 1990, the licensee administered to two patients approximately 100 millicuries each of iodine-131 (in liquid form), dosages which required hospitalization for compliance with 10 CFR 35.75, and the licensee did not measure the thyroid burden of the nuclear medicine technologists and physicians who helped prepare and administer the dosages until September 17 and October 23, 1990, respectively, periods in excess of 3 days.

D. 10 CFR 20.401(c)(1) requires, in part, that records of bioassays made pursuant to 10 CFR 20.108 be preserved until the Commission authorizes disposition. 10 CFR 20.108 states

that where necessary or desirable in order to aid in determining the extent of an individual's exposure to concentrations of radioactive material, the Commission may incorporate appropriate provisions in any license directing the licensee to make available to the individual appropriate bioassay services. Item 23 of the license application dated May 22, 1985 describes the licensee's bioassay procedures.

Contrary to the above, as of June 20, 1991, records of bioassays made pursuant to the conditions of the license for bioassays performed during the third quarter of 1990 were not preserved. Specifically, records regarding routine bioassays for certain individuals in the research staff were not kept, although the NRC had not authorized their disposition.

E. 10 CFR 35.70(a) requires that a licensee survey with a radiation detection survey instrument at the end of each day of use all areas where radiopharmaceuticals are routinely prepared for use or administered.

Contrary to the above, (1) from January 1990 to June 1991, the licensee failed to survey with a radiation detection instrument at the end of each day of use imaging rooms within the nuclear medicine department where radiopharmaceuticals were routinely administered; and (2) from April to June 1991, the licensee failed to survey with a radiation detection instrument at the end of each day of use the nuclear medicine hot lab where radiopharmaceuticals were routinely prepared.

F. 10 CFR 35.70(h) requires, in part, that a licensee retain a record of each survey required by 10 CFR 35.70(e). The record must include, among other items, the removable contamination in each area expressed in disintegrations per minute per 100 square centimeters.

10 CFR 35.70(e) requires that a licensee survey for removable contamination once each week all areas where radiopharmaceuticals are routinely prepared for use, administered, or stored.

Contrary to the above, from April 1991 to June 1991, the licensee did not include in records of removable contamination surveys conducted in areas where radiopharmaceuticals were routinely prepared for use and administered, the removable contamination in each area expressed in disintegrations per minute per 100 square centimeters.

This is a repeat violation.

G. 10 CFR 35.50(c) requires a licensee to perform appropriate checks for constancy and tests for accuracy, linearity, and geometry dependence required by 10 CFR 35.50(b) following adjustments or repair of the dose calibrator.

Contrary to the above, following the repair of the RADX Assayer I dose calibrator in March and April 1991, the licensee did not perform a test for geometry dependence, and such test was appropriate due to the nature of the repair. The licensee had used the dose calibrator to measure patient radiopharmaceutical doses from April to June 1991.

H. 10 CFR 35.51(a)(3) requires that a licensee conspicuously note the apparent exposure rate from a dedicated check source, as determined at the time of calibration, and the date of calibration on any survey instrument used to show compliance with 10 CFR Part 35.

10 CFR 35.51(c) requires, in part, that a licensee check each survey instrument for proper operation with the dedicated check source each day of use.

Contrary to the above, from February to June 20, 1991, the licensee did not conspicuously note on a Ludlum Model 14C survey instrument (Serial No. 81934) used to show compliance with 10 CFR Part 35, the apparent exposure rate from a dedicated check source as determined at the time of calibration, and the date of calibration; and from February to June 20, 1991, the licensee routinely did not check its survey instrument with a dedicated check source on days when the instrument was used. Specifically, the licensee had used the survey instrument for routine surveys in the nuclear medicine department from February to June 1991.

This is a repeat violation.

I. 10 CFR 35.205(e) requires, in part, that a licensee check each month the operation of reusable collection systems for radioactive gases.

Contrary to the above, the licensee used two reusable collection systems for radioactive xenon-133 gas and did not check the operation of the collection systems from January 1990 to June 1991.

J. 10 CFR 35.59(g) requires, in part, that a licensee in possession of a sealed source or brachytherapy source shall conduct a quarterly physical inventory of all such sources in its possession.

Contrary to the above, the licensee did not conduct a

physical inventory of three sealed sources containing cesium-137, iodine-125, and iodine-129 (Serial Nos. 052, 524927, and 222012179A, respectively) from January 10, 1990 to June 20, 1991, a period in excess of a calendar quarter.

This is a repeat violation.

K. 10 CFR 30.51(a) requires that each licensee keep records showing the receipt, transfer, and disposal of byproduct material.

Contrary to the above, as of June 20, 1991, the licensee did not keep records of the disposal of byproduct material. Specifically, no records were kept for the disposal of hydrogen-3 and iodine-125 via the sanitary sewerage system within the nuclear medicine RIA lab.

L. 10 CFR 35.92(b) requires that a licensee retain for 3 years a record of each disposal of byproduct material permitted under 10 CFR 35.92(a), and that the record include the date of the disposal, the date on which the byproduct material was placed in storage, the radionuclides disposed, the survey instrument used, the background dose rate, the dose rate measured at the surface of each waste container, and the name of the individual who performed the disposal.

Contrary to the above, from January 1990 to June 1991, the licensee's records of disposal of byproduct material permitted under 10 CFR 35.92(a) did not include the date on which the byproduct material was placed in storage.

M. 10 CFR 20.403(b) requires, in part, that each licensee shall within 24 hours of discovery of the event, report any event involving licensed material possessed by the licensee that may have caused or threatens to cause (1) a loss of one day or more of the operation of any facilities affected or (2) damage to property in excess of $2,000.

Contrary to the above, the licensee failed to report within 24 hours of discovery an event of May 30, 1991, involving licensed material which resulted in the loss of more than 10 days of operation of an incinerator at the licensee's facility, and damage which required decontamination of the incinerator assessed at $6,000.00. Specifically, the licensee incinerated animal carcasses containing licensed material on May 30, 1991, and the incinerator was not decontaminated and returned to operation until June 13, 1991.

This is a Severity Level III problem (Supplements IV & V). Cumulative Civil Penalty - $25,000 (assessed equally among the 22 violations).

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

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

In requesting mitigation of the proposed penalty, the factors addressed in Section 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 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 1000, Arlington, Texas 76011.

Dated at Rockville, Maryland
this 15th day of November 1991

UNITED STATES
NUCLEAR REGULATORY COMMISSION

In the Matter of	)	Docket No. 30-03255
Department of Veterans Affairs	)	License No. 42-00084-06
Houston, Texas	)	EA 91-157

CONFIRMATORY ORDER MODIFYING LICENSE
(EFFECTIVE IMMEDIATELY)

I

The Department of Veterans Affairs (Licensee) is the holder of NRC License No. 42-00084-06 issued by the Nuclear Regulatory Commission (NRC or Commission) pursuant to 10 CFR Parts 30 & 35. The license authorizes the Licensee to possess and use a variety of radioisotopes in medical research, diagnosis and therapy at the Veterans Administration Medical Center (VAMC) in Houston, Texas. The license was most recently amended in its entirety on February 25, 1991, and was due to expire on August 31, 1991. The Licensee has submitted a timely application for the renewal of the license.

II

As indicated in the Notice of Violation and Proposed Imposition of Civil Penalty ($25,000) issued to the Licensee on this same date, a June 10-12 and June 18-20, 1991 inspection of this Licensee's NRC-licensed activities disclosed 22 violations of NRC radiation safety regulations and license commitments. In April 1990, NRC issued a Notice of Violation and Proposed Imposition of Civil Penalty ($7,500) as a result of similar inspection findings. On May 10, 1990, the licensee paid this civil penalty.

Inspection findings of this nature in successive inspections reduce NRC's confidence in the VAMC's ability to manage its NRC-license activities in a manner consistent with NRC's expectations of a holder of a broad-scope medical license.

At an enforcement conference conducted at the VAMC on August 9, 1991, the Licensee made a number of commitments to take action to resolve what the NRC perceived as fundamental weaknesses in the management of the Licensee's radiation safety program. Among the Licensee's planned corrective actions was a program of quarterly audits of its NRC-licensed programs to be conducted by representatives of the Department of Veterans Affairs (DVA) National Advisory Committee on Radiation Safety.

III

A. By letters dated August 13 and 28, 1991, the Licensee agreed that DVA's National Advisory Committee on Radiation Safety (Advisory Committee) will:

1. Direct audits of the Licensee's NRC-licensed activities;
2. Establish standards for the audit process and submit such standards, and the credentials of the auditors, to NRC Region IV for its approval;
3. Direct six audits at calendar quarterly intervals within 18 months of the date of this Order;
4. Provide written audit reports, including recommended corrective actions for findings identified during the audits, to the Licensee within two weeks of each audit;

5. Provide written audit reports to NRC Region IV within two weeks of each audit; and

6. Evaluate the Licensee's written responses to the audit findings (see paragraph B.1.).

B. By letter dated August 13, 1991, the Licensee agreed that: The Licensee will provide written responses to the Advisory Committee's audit findings, including corrective actions for deficiencies identified during each audit, and measures to prevent recurrence of similar deficiencies.

The NRC staff has reviewed the Licensee's submittal and agrees that conduct of the audits would contribute to providing additional assurance that licensed activities at the VAMC will be carried out in accordance with NRC regulations and license commitments.

I find that the Licensee's commitments as set forth in its letters of August 13 and 28, 1991, are acceptable and necessary and conclude that with these commitments the public health and safety are reasonably assured. In view of the foregoing, I have determined that the public health, safety, and interest require that the Licensee's commitments in its August 13 and 28, 1991, letters be confirmed by this Order. The Licensee has agreed to this action. Pursuant to 10 CFR 2.202, I have also determined

that the public health, safety, and interest require that this Order be immediately effective.

IV

Accordingly, pursuant to sections 81, 161b, 161c, 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, EFFECTIVE IMMEDIATELY, THAT LICENSE NO. 42-00084-06 IS MODIFIED AS FOLLOWS:

A. The Licensee shall have DVA's National Advisory Committee on Radiation Safety (Advisory Committee):

1. Direct audits of the Licensee's NRC-licensed activities;
2. Establish standards for the audit process and submit such standards, and the credentials of the auditors, to NRC Region IV for its approval;
3. Direct six audits at calender quarterly intervals (three months) within 18 months of the date of this Order, the first audit shall be completed within three months of this Order;
4. Provide written audit reports, including recommended corrective actions for findings identified during the audits, to the Licensee within two weeks of the completion of the audit;
5. Provide written audit reports to NRC Region IV within two weeks of each audit; and
6. Evaluate the Licensee's written responses to the audit

findings (see paragraph B.).

B. The Licensee shall provide written responses to the Advisory Committee's audit findings, including corrective actions for deficiencies identified during each audit, and measures to prevent recurrence of similar deficiencies.

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

V

Any person other than the Licensee adversely affected by this Confirmatory Order may request a hearing within 20 days of its issuance. Any request for a hearing shall be submitted to the Secretary, U.S. Nuclear Regulatory Commission, ATTN: Chief, Docketing and Service Section, Washington, D.C. 20555. Copies also shall be sent to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, to the Assistant General Counsel for Hearings and Enforcement at the same address, to the Regional Administrator, NRC Region IV, 611 Ryan Plaza Drive, Suite 1000, Arlington, Texas 76011, and to the Licensee. If such a person requests a hearing, that person shall set forth with particularity the manner in which his interest is adversely affected by this Order and shall address the criteria set forth in 10 CFR 2.714(d).

If a hearing is requested by a person whose interest is adversely affected, the Commission will issue an Order designating the time and place of any hearing. If a hearing is held, the issue to be considered at such hearing shall be whether this Confirmatory Order should be sustained.

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 15th day of November 1991

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

MAR 04 1992

Docket No. 30-03255
License No. 42-00084-06
EA 91-096

Department of Veterans Affairs
Veterans Administration Medical Center (VAMC)
ATTN: John Sheehan, Hospital Director
2002 Holcombe Boulevard
Houston, Texas 77211

Gentlemen:

SUBJECT: ORDER IMPOSING CIVIL MONETARY PENALTY - $25,000

This refers to your letters dated December 11, 1991, in response to the Notice of Violation and Proposed Imposition of Civil Penalty (Notice) sent to you by our letter dated November 15, 1991. Our letter and Notice described 22 violations identified during an NRC inspection on June 10-12 and June 18-20, 1991, at the Veterans Administration Medical Center (VAMC) in Houston, Texas.

To emphasize the importance of taking necessary steps to maintain a radiation safety program that ensures strict compliance with all radiation safety requirements and is commensurate with NRC's expectations of a broad-scope medical licensee, a civil penalty of $25,000 was proposed.

In your responses you contested Violations F, I, and L, and admitted the remaining 19 violations. Citing a number of factors, you requested mitigation of the civil penalty.

After consideration of your responses, we have concluded for the reasons given in the appendix attached to the enclosed Order Imposing Civil Monetary Penalty that Violations F, I, and L occurred as stated in the Notice and that the full amount of the proposed civil penalty should be assessed. Accordingly, we hereby serve the enclosed Order on the VAMC, Houston, Texas, imposing a civil monetary penalty in the amount of $25,000. We will review the effectiveness of your corrective actions during a subsequent inspection.

Pursuant to the provisions of 10 CFR 2.201, your responses to Violations F, I, and L were inadequate and failed to include your corrective steps, results achieved, and date of compliance for each violation. Therefore, you are required to respond to these violations and follow the instructions specified in the Notice sent to you by our letter dated November 15, 1991.

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 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:
State of Texas Bureau of Radiation Control

UNITED STATES
NUCLEAR REGULATORY COMMISSION

In the Matter of	)	
	)	
DEPARTMENT OF VETERANS AFFAIRS	)	Docket No. 30-03255
VETERANS ADMINISTRATION MEDICAL CENTER	)	License No. 42-00084-06
Houston, Texas	)	EA 91-096

ORDER IMPOSING CIVIL MONETARY PENALTY

I

The Department of Veterans Affairs, Veterans Administration Medical Center (VAMC), Houston, Texas (Licensee) is the holder of NRC Materials License No. 42-00084-06 issued by the Nuclear Regulatory Commission (NRC or Commission) on August 27, 1986. The license authorizes the Licensee to possess a variety of radioactive byproduct materials for use in medical research, diagnosis and therapy in accordance with the conditions specified therein.

II

An inspection of the Licensee's activities was conducted on June 10-12 and June 18-20, 1991. 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) and Confirmatory Order Modifying License (Effective Immediately) were served upon the Licensee by letter dated November 15, 1991. The Notice stated the nature of the violations, the provisions of the NRC's requirements that the Licensee had violated, and the amount of the civil penalty proposed for the violations. The Licensee responded to the Notice in two letters dated December 11, 1991. In its response, the Licensee requested mitigation of the proposed penalty based on its contention that: 1) three of the violations (F, I, and L) involved procedures not required at the time of the inspection;

2) the external audits described in the Confirmatory Order and internal audits described in the VAMC response to the Notice are sufficient to attain and maintain compliance with NRC requirements; and 3) the amount of the civil penalty was excessive.

III

After consideration of the Licensee's response and the statements of fact, explanation, and arguments 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 by Order.

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, or money order, or electronic transfer, payable to the Treasurer of the United States and mailed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555.

V

The Licensee may request a hearing within 30 days of the date of this Order. A request for a hearing should be clearly marked as a "Request for an Enforcement Hearing" and shall be addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555. Copies also shall be sent to the Assistant General Counsel for Hearings and Enforcement at the same address and to the Regional Administrator, NRC Region IV, 611 Ryan Plaza Drive, Suite 1000, 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 issues to be considered at such hearing shall be:

(a) whether the Licensee was in violation of the Commission's requirements as set forth in Violations F, I, and L of the Notice referenced in Section II above, and

(b) whether, on the basis of such violations, and the additional violations set forth in the Notice which the Licensee has admitted, this Order should be sustained.

FOR THE NUCLEAR REGULATORY COMMISSION

Hugh L. Thompson Jr.
Deputy Executive Director for
Nuclear Materials Safety, Safeguards
and Operations Support

Dated at Rockville, Maryland
this 4th day of March 1992

APPENDIX

EVALUATIONS AND CONCLUSIONS

On November 15, 1991, a Notice of Violation and Proposed Imposition of Civil Penalty (Notice) and Confirmatory Order were issued for violations identified during an NRC inspection. The licensee responded to the Notice on December 11, 1991. The licensee admitted all the violations with the exception of Violations F, I, and L, argued that the Confirmatory Order was sufficient to attain and maintain compliance, and requested mitigation of the civil penalty. The NRC's evaluation and conclusion regarding the licensee's request are as follows:

Restatement of Violations

A. License Condition 20 requires, in part, that licensed material be possessed and used in accordance with statements, representations, and procedures contained in the application dated May 22, 1985, and letter dated August 20, 1986.

1. Item 23.D.3(d) of the application dated May 22, 1985, specifies that a bioassay will be performed within 2 weeks of the last possible exposure to (volatile) I-125 or I-131 when operations (in research areas) are being discontinued or when the worker is terminating activities with potential exposure to radioiodine.

   Contrary to the above, the licensee failed to perform a bioassay for an individual within 2 weeks of the individual's last exposure to (volatile) I-125 and I-131, at which time the worker had terminated activities involving the use of radioiodine. Specifically, the individual had last worked with millicurie quantities of liquid radioiodine at the licensee's facility in August 1990, and a bioassay was not performed until March 31, 1991.

2. Item 8 of the letter dated August 20, 1986, specifies, in part, that for bioassays, the radiation safety officer (RSO) will perform the counting and calculations necessary to determine the amount of activity present in the person.

   Contrary to the above, as of June 20, 1991, the RSO had failed to perform the calculations necessary to determine the activity present in individuals for whom bioassays were performed. Specifically, the bioassays performed during the period from January 1990 to June 1991 for individuals working in nuclear medicine consisted of a thyroid count using a scintillation detection system, but did not include the calculations necessary to determine and evaluate the activity present in the individuals' thyroid glands.

3. Item 21.B.1 of the application dated May 22, 1985, specifies that xenon-133 will be stored in a RADX Corp. "Xenon-Kow II" located in the fume hood in Room 747A of Building 1A.

Contrary to the above, the licensee did not limit the storage of xenon-133 to the RADX Corp. "Xenon-Kow II" within the designated fume hood in Room 747A of Building 1A, but also stored xenon-133 in Room B-11 of Building 26D on numerous occasions from January 1990 to June 1991.

This is a repeat violation.

4. Item 7.B(.3) of the application dated May 22, 1985, specifies that the radiation safety committee (RSC) will review the training and experience of users of radioactive material and determine that their qualifications are sufficient to enable them to perform their duties safely and in accordance with Nuclear Regulatory Commission regulations and the conditions of the license.

   Contrary to the above, the RSC had not reviewed a physician user's training and experience prior to the individual's use of gold-198 brachytherapy sources for patient treatments during December 1989 and February 1990.

5. Item 3 of the letter dated August 20, 1986, specifies, in part, that all radioactive material ordered by the V. A. Medical Center is ordered through the RSO who insures that the individual ordering the material is approved for the activity being ordered and that the activity ordered does not exceed the individual's possession limit.

   Contrary to the above, as of June 20, 1991, the RSO had failed to insure that an individual who ordered xenon-133 in curie quantities was approved for the activity ordered and that the activity ordered did not exceed the individual's possession limit. Specifically, the individual ordered and received 3-4 vials of xenon-133 containing 1 curie each per month over several years, although the individual was only approved by the RSC for a maximum possession limit of 400 millicuries.

6. Item 1 of the letter dated August 20, 1986, describes the conditions required for radionuclide use requests and approval by the RSC. Item 1.B specifies, in part, that the procurement of all radioactive material must be approved by the Radionuclide Use Subcommittee (RUS) of the RSC.

   Contrary to the above, from January 10, 1990, to June 20, 1991, the RUS and RSC failed to approve an individual's procurement of radioactive material. Specifically, the individual had procured microcurie quantities of hydrogen-3, a material that the individual had not been approved to use or procure.

7. Items 22.B.3 and 22.B.4 of the application dated May 22, 1985, specify, in part, that contaminated [animal] carcasses will be placed in labeled plastic bags and stored in labeled radioactive waste drums specifically [designed] for biological waste, and the drums will be turned over to the appropriate commercial firm for disposal.

Contrary to the above, during the week of May 27, 1991, the licensee failed to place four contaminated animal carcasses, containing approximately 1 millicurie total of cerium-141, strontium-85, scandium-46, and chromium-51, in a waste drum specified for radioactive biologic waste and to transfer the carcasses to a commercial firm for disposal. The carcasses were instead incinerated at the licensee's facility on May 30, 1991.

8. Item 15.H of the application dated May 22, 1985, specifies, in part, that the immediate areas, e.g., hoods, benches, etc., in which radioactive materials are used will be checked at least daily for contamination; that a log record will be maintained of these survey results which are entirely negative; and that any contamination observed will be clearly marked and the RSO notified.

   Contrary to the above, from January 10, 1990, to June 20, 1991, the licensee failed to check at least daily for contamination in all laboratory areas where radioactive material was used, and failed to maintain a record of survey results for laboratory areas which were surveyed daily. Specifically, surveys were not conducted in Rooms 212 and 212A on each day of use, and records were not maintained for surveys conducted in Rooms 116, 118, and 119.

9. Item 15.M of the application dated May 22, 1985, specifies, in part, that users will perform decontamination procedures when necessary. Item 15.R specifies, in part, that if contamination exceeds a level of 200 disintegrations per minute (dpm) per 100 square centimeters, decontamination will be done.

   Contrary to the above, from January 10, 1990 to June 20, 1991, users of radioactive material had failed to routinely perform decontamination procedures when levels of contamination from phosphorus-32 exceeded 200 dpm per 100 square centimeters in Room 207A, a research area.

10. Item 15.R of the application dated May 22, 1985, specifies, in part, that periodic surveys will be conducted monthly in areas where less than 200 microcuries of radioactive material are used and weekly in all other lab areas. Weekly and monthly surveys will consist of a measurement of radiation levels with a survey meter and a series of smear tests to measure contamination levels.

    Contrary to the above, from December 1990 to June 1991, the licensee failed to conduct monthly surveys in laboratory areas where less than 200 microcuries of radioactive material were used, and failed to conduct weekly surveys in other laboratory areas where greater than 200 microcuries of radioactive material were used. Specifically, Room 225, where less than 200 microcuries of phosphorus-32 were used, was not surveyed monthly between December 1990 and June 1991. Additionally, Rooms 116, 118, and 119, where quantities in excess of 200 microcuries of phosphorus-32 were used, were not surveyed weekly between January and June 1991.

    This is a repeat violation.

B. 10 CFR 20.201(b) requires that each licensee make such surveys as may be necessary to comply with the requirements of Part 20 and 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 20.202(a)(1) requires that each licensee supply appropriate personnel monitoring equipment to, and require the use of such equipment by, each individual who enters a restricted area under such circumstances that he receives, or is likely to receive, a dose in any calendar quarter in excess of 25 percent of the applicable value specified in 10 CFR 20.101(a).

10 CFR 20.101(a) requires that the licensee limit the whole body and extremity radiation dose of an individual in a restricted area to 1.25 and 18.75 rems per calendar quarter, respectively.

Contrary to the above, as of June 20, 1991, the licensee did not make surveys to assure compliance with that part of 10 CFR 20.101 that limits the radiation exposure to the whole body and extremities, and did not provide personnel monitoring equipment to each individual who entered a restricted area under circumstances such that they were likely to receive a dose in any calendar quarter in excess of 25 percent of the applicable values specified in 10 CFR 20.101(a). Specifically, the licensee failed to evaluate exposures for, or issue monitoring equipment to: (1) two physicians who had physically implanted brachytherapy sources during patient treatments completed in December 1989 and February 1990, and (2) nuclear medicine technology students who physically withdrew and administered radiopharmaceutical doses during 1990. The licensee also failed to evaluate an exposure received by an individual during the fourth quarter of 1990, a period when the individual's monitoring badge was determined to have been overexposed while not in use.

This is a repeat violation.

C. 10 CFR 35.315(a)(8) requires, in part, that a licensee measure the thyroid burden of each individual who helped prepare or administer dosages of iodine-131 in amounts that required the patient to be hospitalized for compliance with 10 CFR 35.75, and that the measurements be performed within 3 days after the administration of the dosage.

Contrary to the above, on September 12 and October 18, 1990, the licensee administered to two patients approximately 100 millicuries each of iodine-131 (in liquid form), dosages which required hospitalization for compliance with 10 CFR 35.75, and the licensee did not measure the thyroid burden of the nuclear medicine technologists and physicians who helped prepare and administer the dosages until September 17 and October 23, 1990, respectively, periods in excess of 3 days.

D. 10 CFR 20.401(c)(1) requires, in part, that records of bioassays made pursuant to 10 CFR 20.108 be preserved until the Commission authorizes disposition. 10 CFR 20.108 states that where necessary or desirable in order to aid in determining the extent of an individual's exposure to concentrations of radioactive material, the Commission may incorporate appropriate provisions in any license directing the licensee to make available to the individual appropriate bioassay services. Item 23 of the license application dated May 22, 1985, describes the licensee's bioassay procedures.

Contrary to the above, as of June 20, 1991, records of bioassays made pursuant to the conditions of the license for bioassays performed during the third quarter of 1990 were not preserved. Specifically, records regarding routine bioassays for certain individuals in the research staff were not kept, although the NRC had not authorized their disposition.

E. 10 CFR 35.70(a) requires that a licensee survey with a radiation detection survey instrument at the end of each day of use all areas where radiopharmaceuticals are routinely prepared for use or administered.

Contrary to the above, (1) from January 1990 to June 1991, the licensee failed to survey with a radiation detection instrument at the end of each day of use imaging rooms within the nuclear medicine department where radiopharmaceuticals were routinely administered; and (2) from April to June 1991, the licensee failed to survey with a radiation detection instrument at the end of each day of use the nuclear medicine hot lab where radiopharmaceuticals were routinely prepared.

F. 10 CFR 35.70(h) requires, in part, that a licensee retain a record of each survey required by 10 CFR 35.70(e). The record must include, among other items, the removable contamination in each area expressed in disintegrations per minute per 100 square centimeters.

10 CFR 35.70(e) requires that a licensee survey for removable contamination once each week all areas where radiopharmaceuticals are routinely prepared for use, administered, or stored.

Contrary to the above, from April 1991 to June 1991, the licensee did not include in records of removable contamination surveys conducted in areas where radiopharmaceuticals were routinely prepared for use and administered, the removable contamination in each area expressed in disintegrations per minute per 100 square centimeters.

This is a repeat violation.

G. 10 CFR 35.50(c) requires a licensee to perform appropriate checks for constancy and tests for accuracy, linearity, and geometry dependence required by 10 CFR 35.50(b) following adjustments or repair of the dose calibrator.

Contrary to the above, following the repair of the RADX Assayer I dose calibrator in March and April 1991, the licensee did not perform a test

for geometry dependence, and such test was appropriate due to the nature of the repair. The licensee had used the dose calibrator to measure patient radiopharmaceutical doses from April to June 1991.

H. 10 CFR 35.51(a)(3) requires that a licensee conspicuously note the apparent exposure rate from a dedicated check source, as determined at the time of calibration, and the date of calibration on any survey instrument used to show compliance with 10 CFR Part 35.

10 CFR 35.51(c) requires, in part, that a licensee check each survey instrument for proper operation with the dedicated check source each day of use.

Contrary to the above, from February to June 20, 1991, the licensee did not conspicuously note on a Ludlum Model 14C survey instrument (Serial No. 81934) used to show compliance with 10 CFR Part 35, the apparent exposure rate from a dedicated check source as determined at the time of calibration, and the date of calibration; and from February to June 20, 1991, the licensee routinely did not check its survey instrument with a dedicated check source on days when the instrument was used. Specifically, the licensee had used the survey instrument for routine surveys in the nuclear medicine department from February to June 1991.

This is a repeat violation.

I. 10 CFR 35.205(e) requires, in part, that a licensee check each month the operation of reusable collection systems for radioactive gases.

Contrary to the above, the licensee used two reusable collection systems for radioactive xenon-133 gas and did not check the operation of the collection systems from January 1990 to June 1991.

J. 10 CFR 35.59(g) requires, in part, that a licensee in possession of a sealed source or brachytherapy source shall conduct a quarterly physical inventory of all such sources in its possession.

Contrary to the above, the licensee did not conduct a physical inventory of three sealed sources containing cesium-137, iodine-125, and iodine-129 (Serial Nos. 052, 524927, and 222032179A, respectively) from January 10, 1990, to June 20, 1991, a period in excess of a calendar quarter.

This is a repeat violation.

K. 10 CFR 30.51(a) requires that each licensee keep records showing the receipt, transfer, and disposal of byproduct material.

Contrary to the above, as of June 20, 1991, the licensee did not keep records of the disposal of byproduct material. Specifically, no records were kept for the disposal of hydrogen-3 and iodine-125 via the sanitary sewerage system within the nuclear medicine RIA lab.

L. 10 CFR 35.92(b) requires that a licensee retain for 3 years a record of each disposal of byproduct material permitted under 10 CFR 35.92(a), and that the record include the date of the disposal, the date on which the byproduct material was placed in storage, the radionuclides disposed, the survey instrument used, the background dose rate, the dose rate measured at the surface of each waste container, and the name of the individual who performed the disposal.

Contrary to the above, from January 1990 to June 1991, the licensee's records of disposal of byproduct material permitted under 10 CFR 35.92(a) did not include the date on which the byproduct material was placed in storage.

M. 10 CFR 20.403(b) requires, in part, that each licensee shall within 24 hours of discovery of the event, report any event involving licensed material possessed by the licensee that may have caused or threatens to cause (1) a loss of 1 day or more of the operation of any facilities affected or (2) damage to property in excess of $2,000.

Contrary to the above, the licensee failed to report within 24 hours of discovery an event of May 30, 1991, involving licensed material which resulted in the loss of more than 10 days of operation of an incinerator at the licensee's facility, and damage which required decontamination of the incinerator assessed at $6,000.00. Specifically, the licensee incinerated animal carcasses containing licensed material on May 30, 1991, and the incinerator was not decontaminated and returned to operation until June 13, 1991.

Summary of Licensee's Response to Violations F, I, and L

The Licensee contended that three violations -- Violations F, I and L in the Notice -- were invalid. In each case, the Licensee argued that the license that was in effect during the inspection period did not require the Licensee to meet the specific 10 CFR Part 35 requirement that was cited. The license in effect at the time of the inspection was issued on August 27, 1986, prior to the issuance of the subject requirements in 10 CFR Part 35 that became effective on April 1, 1987. The Licensee relies upon their interpretation of an October 16, 1986 Federal Register Notice to argue that the provisions of such a license [issued prior to April 1, 1987] take precedence over the current Part 35 regulations.

Based on the argument that the provisions of its license at the time of the inspection did not require it to maintain records of removable contamination surveys in units of disintegrations per minute per 100 square centimeters ($dpm/100cm^2$), the Licensee denies Violation F.

The Licensee denies Violation I and contends that their license does not require the performance of monthly operability checks of reusable radioactive gas collection systems for the same reasons as stated in Violation F.

Violation L is contested by the Licensee based on the same reasons as were stated in Violations F and I. The Licensee states that their license did not require that records of radioactive waste disposed of by decay-in-storage include the date waste was placed in storage.

NRC Evaluation of Licensee's Response to Violations F, I, and L

Violation F

The Licensee received a violation of 10 CFR 35.70(h) in an earlier Notice of Violation and Proposed Imposition of Civil Penalties issued on April 11, 1990. In the Licensee's response of May 10, 1990, the Licensee acknowledged that the violation had occurred and stated that future removable contamination survey results would be expressed in units of dpm rather than counts per minute. Thus, Violation F is a recurring violation initially identified by the NRC during the previous 1990 inspection.

The staff notes that the Licensee's application dated May 22, 1985, committed the VAMC to comply with the guidance of Appendix I of Regulatory Guide 10.8, Revision 1, October 1980, which did not state explicitly that removable contamination survey results be expressed in units of dpm/100cm^2. However, Appendix I stated that the method for performing such surveys will be sufficient to detect 200 dpm/100cm^2 and stated that areas will be cleaned if the contamination levels exceeded 200 dpm/100cm^2. Thus, the Licensee's practice of recording the results of such surveys in units of cpm/100cm^2 does not ensure compliance with procedures described in Appendix I.

Furthermore, the staff does not agree with the Licensee's reliance on the October 16, 1986 Federal Register notice (Volume 51, No. 200), which published significant revisions to 10 CFR Part 35. The notice said: "The Commission has decided to resolve possible temporary inconsistencies between license conditions and the regulation by providing in the regulation a transition period between the effective date of the rule and the expiration date of each license. During this transition period, if there is an inconsistency between a provision in a license (issued prior to the regulation) and the regulation, the license condition takes precedence over the regulation."

10 CFR 35.999, which addressed the transition period, states: "If the rules in this part conflict with the licensee's radiation safety program as identified in its license ... then the requirements in the license will apply."

In this case, there is no inconsistency or conflict between the provisions in the license and the regulation. Both the provisions in the license and regulation require (one implicitly and the other explicitly) that removable contamination survey results be recorded in units of dpm/100cm^2.

The staff concludes that the citation was valid.

Violation I

The Licensee's application dated May 22, 1985, committed the VAMC to comply with radioactive gas use procedures outlined in Item 21 of the application. These procedures established requirements for radioactive gas use and storage areas,

but did not address the frequency of operability checks of reusable gas collection systems. 10 CFR 35.205(e) requires licensees to check the operation of such systems monthly.

Therefore, the Licensee's procedures were not inconsistent with and did not conflict with 10 CFR 35.25(e). The procedures simply neither addressed the frequency of operability checks nor made any reference to such checks. Since there is no inconsistency or conflict between the license and Part 35, the staff does not agree with the Licensee's assertion that statements contained in the cited October 16, 1986 Federal Register notice exempt the Licensee from this requirement.

The staff concludes that the citation was valid.

Violation L

The Licensee's application dated May 22, 1985, committed the VAMC to comply with the provisions of Appendix J of Regulatory Guide 10.8, Revision 1, October 1980. Appendix J does not address recordkeeping requirements. 10 CFR 35.92(b) requires that records of byproduct material disposal permitted under 10 CFR 35.92(a) include the date on which the byproduct material was placed in storage.

However, nothing in the version of Appendix J referenced in the Licensee's application was inconsistent with or in conflict with the recordkeeping requirements of 10 CFR 35.92 because Appendix J simply did not address recordkeeping. Furthermore, recording the placed-in-storage date of waste that is held for decay before disposal is important in ensuring that the waste has been held for the required minimum time of ten half-lives prior to its disposal. The staff does not agree with the Licensee's assertion that statements contained in the cited October 16, 1986 Federal Register notice would exempt the Licensee from this requirement.

The staff concludes that the citation was valid.

Summary of Licensee's Request for Mitigation

The Licensee's request for mitigation of the proposed penalty was based on: 1) its contention that three of the violations (F, I and L) involved procedures not required at the time of the inspection; 2) its position that the external audits described in the Confirmatory Order and the internal audits described in the VAMC response to the Notice were sufficient to attain and maintain compliance with NRC requirements; and 3) its position that the amount of the civil penalty was excessive.

NRC Evaluation of Licensee's Request for Mitigation

Violations F, I, and L

As discussed above, the staff concludes that Violations F, I, and L were valid citations. Thus, the Licensee's argument for mitigation on this basis is not persuasive.

Confirmatory Order

The Licensee argues that a civil penalty is not necessary to achieve the goal of bringing VAMC procedures into compliance with all applicable NRC regulations. The Licensee contends that the Confirmatory Order, which makes the Licensee's voluntary audit plan a condition of its NRC license, and other actions taken by the Licensee to improve compliance with NRC requirements, will result in improved compliance and will assure that Licensee employees take their responsibilities seriously.

While NRC considers audits and the other actions taken by the Licensee important, the VAMC's actions to assure compliance with NRC requirements are not extraordinary measures given the circumstances that led NRC to take enforcement action. Measures to assure compliance are assumed when NRC grants a license. In this case, NRC found the measures taken by the VAMC lacking in 1990 and again in 1991, despite a penalty of $7,500 having been issued in 1990. As NRC said in the letter transmitting the Notice, "Inspection findings of this nature in successive inspections reduces NRC's confidence in the VAMC's ability to manage its NRC-licensed activities in a manner consistent with NRC's expectations of a holder of a broad-scope medical license."

The purpose of the civil penalty in this case is to emphasize the importance of establishing effective and lasting measures to assure licensee compliance, and to emphasize the responsibility incumbent upon a broad-scope medical licensee to initiate measures to assure compliance with NRC requirements rather than relying upon NRC to discover noncompliance during its infrequent inspections. The VAMC argues that a civil penalty is not necessary to bring about the desired improvements. Prior to the 1990 and 1991 inspections, the VAMC had not properly conducted licensed activities in certain program areas. The VAMC now suggests it will conduct licensed activities in compliance with NRC requirements as it did both at the time of initial licensing and after the issuance of the Notice of Violation and Proposed Imposition of Civil Penalties on April 11, 1990. It is clear that based on past performance, a civil penalty is necessary in this case to emphasize continuous, lasting corrective actions and to deter future noncompliance.

The staff concludes that the issuance of the Confirmatory Order does not warrant reconsideration of the civil penalty.

Civil Penalty Amount Excessive

The Licensee argues that the civil penalty amount is excessive because: 1) the proposed penalty will have the unintended effect of decreasing funds available for patient care; 2) the amount of the penalty is out of proportion to the severity of the violations; 3) the proposed penalty exceeds $25,000 when the costs of the audits are included; and 4) the NRC's deviation from the civil penalty formula prescribed in its Enforcement Policy was unreasonable.

NRC would not expect a $25,000 civil penalty to have a significant financial impact on a facility with an annual operating budget of greater than $160 million. In addition, the VAMC should not fail to recognize the direct connection between patient care and radiation safety. As indicated in the

letter transmitting the Notice, failing to follow radi[illegible] standards can affect the safety of VAMC employees, patients, ar[illegible] public. One of NRC's purposes in issuing the penalty was to empha[illegible] its responsibility to take radiation safety seriously so [illegible] promise personnel and patient safety.

NRC's Enforcement Policy permits it to consider violations collectively and to assign a single severity level to a number of violations, as was done in this case. The fact that the violations would not individually be classified at Severity Level III or above has no bearing on NRC's decision to treat the violations collectively. As was indicated to VAMC representatives at the enforcement conference and in the letter transmitting the Notice, NRC attached greater significance to the collection of violations because they indicated a potentially significant lack of attention to licensed responsibilities. This is the basis for classifying the violations at Severity Level III in the aggregate and assessing a civil penalty.

NRC considers the conduct of the audits a necessary step to ensure that the VAMC in fact maintains its programs in compliance with NRC radiation safety requirements. While the audits will certainly result in additional costs to the VAMC, NRC does not believe that the conduct of the audits negates the need to assess a civil penalty to emphasize the importance that NRC attaches to the situation. As indicated above, NRC believes that civil penalties play an important role in assuring lasting corrective actions and in deterring future noncompliance.

NRC is authorized by law (Section 234 of the Atomic Energy Act of 1954, as amended) to assess civil penalties up to $100,000 per violation per day. As the Licensee notes in its reply, NRC has established, in Section V.B. of its Enforcement Policy, the usual base civil penalty values that reflect the class of licensee and the severity of the violation or violations, and a number of factors that may be considered in making adjustments to the usual base values. As stated in the policy, the civil penalty tables generally take into account the gravity of the violation as a primary consideration and the ability to pay as a secondary consideration, but the deterrent effect of civil penalties is best served when the amount of such penalties takes into account a licensee's ability to pay.

The opening paragraph of the Enforcement Policy states: "The Commission may deviate from this statement of policy as is appropriate under the circumstances of a particular case." Section V.B. of the Enforcement Policy states: "...ineffective licensee programs for problem identification or correction are unacceptable. In cases involving willfulness, flagrant NRC-identified violations, repeated poor performance in an area of concern, or serious breakdown in management controls, NRC intends to apply its full enforcement authority where such action is warranted, including issuing appropriate orders and assessing civil penalties for continuing violations on a per day basis up to the statutory limit of $100,000 per violation per day."

NRC clearly articulated in the letter transmitting the Notice a reasonable basis for deviating from its statement of policy. NRC's reasons included the following: 1) a large number of violations was found in each of two successive

inspections conducted in 1990 and 1991, despite a $7,500 civil penalty being assessed in the 1990 inspection, indicating a failure of the VAMC to resolve fundamental shortcomings in management of licensed activities; 2) NRC inspectors discovered the violations as opposed to their having been detected and corrected by the Licensee; 3) six of the violations were identical to violations cited in 1990, indicating a failure of the VAMC to take specific corrective actions despite commitments to do so; and 4) in some instances the VAMC failed to act to correct violations that had been discovered by its own radiation safety staff.

In addition, in accordance with the statements in Section V.B. of the Enforcement Policy, the staff believes that $25,000 is more likely to have a deterrent effect because, although still a small amount of money relative to the size of the VAMC's annual operating budget, it more appropriately reflects the Licensee's ability to pay than would application of the usual base civil penalty in Tables 1.A and 1.B of the Enforcement Policy.

The staff does not accept the Licensee's argument that the civil penalty proposed in this case was excessive.

NRC Conclusion

The NRC concludes that Violations F, I, and L, denied by the Licensee, occurred as stated. The NRC further concludes that the Licensee has not made a convincing argument for a reduction in the amount of the civil penalty. Consequently, the proposed civil penalty in the amount of $25,000 should be imposed.

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

MAR 13 1992

Docket No. 70-1113
License No. SNM-1097
EA 91-185

General Electric Company
ATTN: Mr. Dallas L. Silverthorne, Manager
Nuclear Fuel and Components
Manufacturing
Post Office Box 780
Wilmington, North Carolina 28402

Gentlemen:

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY - $20,000
(NRC INSPECTION REPORT NO. 70-1113/91-04)

This refers to the Nuclear Regulatory Commission (NRC) inspection conducted by Mr. G. Troup on August 19 - September 13, 1991, at Nuclear Fuel and Components Manufacturing (NF&CM), General Electric Company, Wilmington, NC. The purpose of the inspection was to review the findings of the Incident Investigation Team (IIT) as documented in NUREG-1450, "Potential Criticality Accident at the General Electric Nuclear Fuel and Component Manufacturing Facility, May 29, 1991," (NUREG-1450) issued in August 1991. The IIT was chartered on May 31, 1991, by the NRC's Executive Director for Operations and directed to review the facts and circumstances that led to the inadvertent transfer of approximately 320 pounds of uranium to a waste treatment tank with an unfavorable geometry on May 29, 1991. The charter of the IIT did not include assessing violations of NRC rules and requirements. A Confirmation of Action Letter dated May 31, 1991, documented your commitments to cooperate with the IIT, halt processing of materials in the solvent extraction system, quarantine equipment involved in the incident, and to provide other assistance to the IIT as needed.

The report documenting the August 19 - September 13, 1991 inspection was sent to you by letter dated December 23, 1991. As a result of this inspection to followup on the IIT findings, significant violations of NRC requirements were identified. An enforcement conference was held on February 7, 1992, in the NRC Region II office to discuss the violations, their cause, and your corrective actions to preclude recurrence. A summary of the enforcement conference was sent to you by letter dated February 20, 1992.

On May 28, 1991, routine fuel manufacturing operations at NF&CM facility were in progress with waste treatment operations that consisted of routine transfers from waste accumulation tanks to waste treatment tanks proceeding as normal. In mid-afternoon, Waste Treatment Facility (WTF) operators began pumping the contents of a Waste Accumulation Tank (V-103) to the Nitrate Waste Neutralization

Tank (V-104). On May 29, 1991, through the routine sampling of tank V-104, a 20,000 gallon waste treatment tank with an unfavorable geometry, the WTF staff determined that the tank contained 2333 ppm Uranium (ppm U), a significantly higher amount than normally expected concentrations of uranium. Further investigation by the plant staff identified abnormal concentrations of uranium in the Nitrate Waste Storage Tank (V-103) and Aqueous Waste Quarantine tanks. It was subsequently determined that the source of the uranium was the Solvent Extraction system in the Uranium Recycle Unit (URU) and that the malfunction of a valve in that system resulted in high concentration uranium solutions being released to the Aqueous Waste system and subsequently released to the Secondary Nitrate Waste system.

Violation A described in Part I of the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice) involved the failure to follow procedures involving the process requirements for discharging waste from the Aqueous Waste Quarantine (AWQ) tanks. Specifically, the AWQ tanks were inappropriately sampled while being filled, were not properly isolated, and were not recirculated for the required time of 15 minutes prior to sampling. As a result, the contents of the AWQ tanks were released to tank V-103 and subsequently discharged to tank V-104 without sampling the contents which were subsequently determined to have exceeded the uranium concentration limit of 150 ppm U for discharge.

Violation B in Part I of the Notice involved the failure to have adequate procedures in that 1) there was no procedure for the URU process that defined how the access to the Tune Mode of the process control computer was to be controlled, 2) the procedure for trouble shooting the Solvent Extraction and Aqueous Waste systems did not require the system to be placed in the "problem" step while trouble shooting, nor did it specify any time limits for trouble shooting before the system had to be placed in a temporary shutdown, and 3) there was no procedure which required audits of the configuration control associated with the distributed digital control system for the URU process that assured that unauthorized changes had not been made; consequently, no such audits were performed on the system.

The significance of this event was the potential for a nuclear criticality accident that existed because the safety limits of uranium concentrations in unfavorable geometry tanks had been exceeded and the system of criticality safety controls had deteriorated to the point where process controls and mass limit control were no longer effective. Therefore, in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy) 10 CFR Part 2, Appendix C (1991), the violations in Part I of the Notice are classified in the aggregate as a Severity Level II problem.

The staff recognizes that you have initiated extensive corrective actions to preclude recurrence of this type of event and that those actions are also intended to reinforce your staff's "safety first" attitude with regard to nuclear criticality safety. Significant among these actions was the increase in management oversight of operational activities to include enhancement of technical support by the addition of increased supervisory and technical advisor

resources to each shift. In addition, your corrective actions, such as enhanced training and sensitization of personnel, physical plant changes, procedural changes and verification of key operational controls, should contribute to improved performance.

To emphasize the importance of ensuring that criticality control measures are maintained at the highest degree of effectiveness, I have been authorized, after consultation with the Director, Office of Enforcement, and the Deputy Executive Director for Nuclear Materials Safety, Safeguards, and Operations Support, to issue the enclosed Notice of Violation and Proposed Imposition of Civil Penalty in the amount of $20,000 for the Severity Level II problem. The base value of a civil penalty for a Severity Level II problem is $20,000. The escalation and mitigation factors in the Enforcement Policy were considered.

Neither escalation nor mitigation was warranted for identification and reporting. Although you identified the potential criticality problem and reported it to the NRC, those actions were significantly delayed. Mitigation of 50 percent was warranted for your comprehensive corrective actions as discussed above. Consideration was given to the general trend of improving performance which has been taking place in the recent past as evidenced by the Operational Safety Assessment which was conducted at the facility in March 1991. However, a number of weaknesses were identified during that assessment that preclude full mitigation for this factor. Therefore, mitigation of 50 percent was deemed warranted for this factor.

The NRC Office of Nuclear Material Safety and Safeguards issued NRC Information Notice No. 90-63, "Management Attention to the Establishment and Maintenance of a Nuclear Criticality Safety Program," on October 3, 1990. That Information Notice was provided to alert licensees to an incident that resulted from inadequate management attention to the establishment and maintenance of a nuclear criticality safety program. Attached to that Information Notice was NRC Information Notice No. 89-24, "Nuclear Criticality Safety," which had been previously issued on March 6, 1989. Both of these information notices highlighted the need for continuing vigilance in providing a sound nuclear safety program and should have prompted your staff to review the nuclear safety program at NF&CM. Therefore, escalation of 50 percent was warranted for the factor of prior notice, inasmuch as licensees are expected to take prompt action to assure issues discussed in such notices are properly addressed. Additional escalation of 50 percent was warranted for the fact that, for an extended period of time, inadequate procedures existed and the operations staff had not been complying with established process procedure requirements.

The other adjustment factors in the Policy were considered, and no further adjustment to the base civil penalty is considered appropriate. Therefore, based on the above, a civil penalty of $20,000 is assessed.

The violations described in Part I' of the Notice have been categorized at Severity Level IV. Violation A involved the failure to promptly identify and declare an Alert emergency condition. A potential criticality situation existed from approximately 7:00 a.m. on May 29, 1991 through 6:30 a.m. on

May 30, 1991, which was consistent with the Alert definition in the Radiological Contingency and Emergency Plan (RCEP). Implementation of emergency action is dependent upon an accurate and rapid identification and classification of events that could affect the health and safety of the public. Such a violation would be normally categorized at a higher severity level. However, a lesser severity level was assessed because the facility staff initiated actions consistent with an Alert with the exception that all required notifications were not completed. Violation B involved an inadequate Facility Change Request which permitted the processing of uranium bearing fuel which exceeded the license enrichment limits established and approved for processing in the oxidation sub-area of the facility. This violation is being cited, notwithstanding identification by the facility staff, because NRC requested the document review which resulted in identification of the violations. Violation C involved the failure to provide adequate training to an individual designated an interim Emergency Director.

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

Stewart D. Ebneter
Regional Administrator

Enclosure:
Notice of Violation and Proposed
Imposition of Civil Penalty

cc w/encl:
T. Preston Winslow, Manager
Licensing and Nuclear Materials
Management
General Electric Company
P. O. Box 780, Mail Code J26
Wilmington, NC 28402

State of North Carolina

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

General Electric Company
Nuclear Fuel and Components
Manufacturing
Wilmington, North Carolina

Docket No. 70-1113
License No. SNM-1097
EA 91-185

During an NRC inspection conducted on August 19 - September 13, 1991, 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 (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 violations and associated civil penalty are set forth below:

I. Violations Assessed a Civil Penalty

A. License Condition No. 9 of Special Nuclear Material License No. 1097 (SNM-1097) requires that licensed materials be used in accordance with the statements, representations, and conditions of Part 1 of the license application dated October 23, 1987, and supplements thereto.

Part 1, Chapter 2, Section 2.7 of the license application requires that licensed material processing be conducted in accordance with properly issued procedures or instructions.

Process Requirements and Operator Document (PROD) 103.02, Revision 3, Solvent Extraction and Aqueous Waste Quarantine, Section 3.3.5, required that the Aqueous Waste Quarantine tanks be isolated at 90 percent level ("high set point"), recirculated for 15 minutes before a sample of the contents is collected, and the sample results have a uranium concentration which is acceptable before the Aqueous Waste Quarantine tank can be released to tank V-103. Nuclear Safety Release/Requirements (NSR/R) 02.08.07 required that Aqueous Waste Quarantine tank discharges to tank V-103 must be less than 150 parts per million uranium (ppm U).

Contrary to the above, during May 28-29, 1991, the licensee failed to follow the requirements of PROD 103.02 in that:

1. The Aqueous Waste Quarantine tanks were sampled while filling and were not isolated.

2. The Aqueous Waste Quarantine tanks were not recirculated for the required time, 15 minutes, prior to sampling.

3. Several Aqueous Waste Quarantine tanks were released to tank V-103 and discharged without sampling of the contents, and were subsequently determined to have exceeded the NSR/R limit of 150 ppm U for discharge.

4. Aqueous Waste Quarantine tanks which were measured prior to release actually exceeded the NSR/K limit due to non-representative sampling.

B. License Condition No. 9 of SNM-1097 requires that licensed materials be used in accordance with the statements, representations, and conditions of Part I of the license application dated October 23, 1987, and supplements thereto.

Part I, Chapter 2, Section 2.7 of the license application requires that licensed material processing be conducted in accordance with properly issued procedures or instructions.

Part I, Chapter 2, Section 2.2.1.3 of the license application requires the nuclear safety function to measure the effectiveness of the criticality control program, and that measurement of the effectiveness of the criticality control program is determined through audit programs to assure that nuclear safety criteria are met for the protection of employees, the public and the environment. Part I, Chapter 2, Section 2.8 of the license application requires audits to be performed to assure that plant operations are conducted in accordance with the operating procedures. Part 1, Chapter 2, Section 2.8.1 of the license application requires audits to be performed in accordance with written procedures to determine that actual operations conform to criticality requirements.

Contrary to the above, during the week of May 27, 1991, the licensee failed to have adequate procedures for licensed activities in that:

1. There was no procedure for the Uranium Recycle Unit (URU) process defining how the access to the Tune Mode was to be controlled, specifying limitations on the use of the Tune Mode, or recording of actions taken while in the Tune Mode, including changes to parameters.

2. PROD 103.02, Solvent Extraction and Aqueous Waste Quarantine, which contained instructions for troubleshooting the Solvent Extraction and Aqueous Waste systems was inadequate in that it did not require that the system be placed in the PROBLEM step while troubleshooting, and did not specify any time limit for troubleshooting before the system had to be placed in a temporary shutdown. The PROD also did not provide any criteria for switching from process computer control to manual control.

3. There was no procedure which required audits of configuration control associated with the distributed digital control system for the URU process to assure that unauthorized changes had not been made. As a result, no such audits were performed.

This is a Severity Level II problem (Supplement VI).
Cumulative Civil Penalty - $20,000 (assessed equally between Violations A and B).

II. Violations Not Assessed a Civil Penalty

A. License Condition No. 9 of SNM-1097 requires that licensed materials be used in accordance with the statements, representations, and conditions of Part I of the license application dated October 23, 1987, and supplements thereto.

Part I, Section 8 of the license application requires the licensee to maintain a capability for handling emergencies in accordance with the Radiological Contingency and Emergency Plan (RCEP), submitted to NRC on August 27, 1981, and as revised in its entirety on December 1, 1988, in accordance with regulatory provisions.

Section 3.1 of the RCEP states that criteria are specified for recognizing, characterizing, and declaring each emergency classification or sub-class, as applicable.

Section 3.1.2 of the RCEP defines the Alert classification as an event which involves situations which could lead to identified hazard potentials. The situation has not yet caused damage to the facility nor harm to personnel and does not necessarily require an immediate change in facility operating status. Inherently, this is a situation in which time is available to take precautionary steps and/or mitigate consequences. The RCEP further states that an emergency Alert condition implies a rapid transition to a state of readiness by the facility personnel and possibly by off-site emergency support organizations, the possible cessation of certain routine non-essential functions or activities within the facility and possible precautionary actions that a specific situation may require.

Contrary to the above from approximately 7:00 a.m. on May 29, 1991, through 6:30 a.m. on May 30, 1991, a potential criticality situation existed in the licensee's solvent extraction process (tank V-104) which was consistent with the Alert definition for which the licensee failed to promptly identify and declare as an Alert emergency condition.

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

B. License Condition No. 9 of SNM-1097 requires that licensed materials be used in accordance with the statements, representations, and conditions of Part I of the license application dated October 23, 1987, and supplements thereto.

Part I, Chapter 1, Section 1.8.10 of the license application requires that the maximum enrichment in the Uranium Recycle Operation shall not exceed the minimum U-235 enrichment approved by the nuclear safety function for any Uranium Recycle process. The minimum enrichment approved for any Uranium Recycle process was 4.025 percent U-235.

Contrary to the above, on April 11, 1991, Facility Change Request (FCR) 89.075 was approved for operation by the Manager, Nuclear Safety Engineering, and the Area Manager, to process uranium bearing fuel of up to five percent U-235 in the oxidation subarea of Uranium Recovery and uranium enriched to greater than 4.025 percent U-235 was subsequently processed in that area.

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

C. License Condition 9 of SNM-1097 requires that licensed materials be used in accordance with the statements, representations, and conditions of Part I of the application dated October 23, 1987, and supplements thereto.

Part I, Section 8 of the license application requires the licensee to maintain a capability for handling emergencies in accordance with the RCEP, submitted to NRC on August 27, 1981, and as revised in its entirety on December 1, 1988, in accordance with regulatory provisions.

Section 5.1 of the RCEP states that the Building Manager (i.e., the Area Coordinator during off-hours) shall assume the responsibility for all emergency response actions until such time as the emergency is terminated, or the responsibility is transferred to someone else, or he is relieved by the Emergency Director.

Section 7.2 of the RCEP states that special initial training and periodic retraining programs are provided to plant and support personnel to ensure their readiness for emergencies.

Contrary to the above, the training provided to an individual designated as interim Emergency Director was inadequate in that during the inspection on September 10-13, 1991, the individual interviewed was not fully cognizant of his full responsibility to classify emergency events.

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

Pursuant to the provisions of 10 CFR 2.201, General Electric 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 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. 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, Regior 'I.

Dated at Atlanta, Georgia
this 13th day of March 1992

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

April 16, 1992

Docket Nos. 030-01315; 030-00124
License Nos. 08-01709-04; 08-01709-06
EA 92-016

Georgetown University Medical Center
Attn: John F. Griffith, M.D.
Executive Vice-President and
Director of Medical Center
3800 Reservoir Road
Podium Level
Washington, D. C. 20007

Dear Dr. Griffith:

Subject: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY - $3,750
(NRC Inspection Report No. 91-002 and OI Investigation Report 1-91-007)

This letter refers to the NRC inspection conducted on April 16-18, 1991, as well as a subsequent investigation by the NRC Office of Investigations (OI), at the Georgetown University Medical Center (Georgetown), Washington, D.C., of activities authorized by NRC License Nos. 08-01709-04 and 08-01709-06. The inspection report, as well as the synopsis of the OI investigation, were sent to you on March 6, 1992. During the inspection, seven apparent violations of NRC requirements were identified, one of which was sent to you in a Notice of Violation issued on May 22, 1991. In addition, as a result of the OI investigation, the NRC determined that one of the other six apparent violations was willful. On March 13, 1992, an enforcement conference was conducted with Dr. James Burris, and other members of the Georgetown staff, to discuss the six remaining apparent violations, their causes and your corrective actions. Based on the discussions at the enforcement conference, the NRC has decided not to issue a citation for one of the remaining six apparent violations, for the reasons described in the enforcement conference report which was sent to you under separate cover on March 25, 1992.

The five violations which are being cited in the enclosed Notice, include, but are not limited to: (1) the failure of the Medical Isotopes Committee at Georgetown University Medical Center (Committee on Radiation Control or CRC) to conduct a review of the radiation safety program for 1990; and (2) the failure to maintain security of radioactive materials in the Nuclear Medicine Laboratory at the facility in that the door to the laboratory was routinely left open, and the material was, at times, not under constant surveillance and immediate control of your staff. These two violations are of particular concern to the NRC.

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

With respect to the first violation, the NRC is concerned that the then-Director of the Department of Radiation Control (DDRC) knew that the CRC was required to review the radiation safety program at least annually and knew that he was supposed to prepare an annual audit of the program for the CRC so that the CRC could fulfill this required function; however, he knowingly failed to prepare the annual audit and failed to notify the RSC, of which he was a voting member, that the audit, as well as the required annual review of the radiation safety program by the CRC, were not being performed. Although an audit by a consultant was performed in 1990, it did not constitute the annual review required to be conducted by the CRC.

With respect to the second violation, the NRC is concerned that the failure to maintain proper security of the Nuclear Medicine Laboratory could have resulted in the loss or theft of radioactive material and possible unnecessary exposure to members of the public. The NRC is also concerned that this failure apparently recurred repeatedly, even after employees were retrained.

While the NRC is concerned with the performance of the DDRC, who left the facility in September 1991, the NRC is also concerned that there was a significant increase in the research being performed at the facility prior to the NRC inspection in April 1991, without a corresponding increase in staffing and resources dedicated to ensuring the radiation safety program was being properly implemented. As noted in the synopsis of the OI Report, this appeared to have contributed to the conditions which led to the violations. In view of this finding, it is apparent that management did not provide sufficient attention to, nor oversight of, the radiation safety activities at Georgetown. Therefore, the violations demonstrate a breakdown in the radiation safety program that collectively represent a potentially significant lack of attention toward licensed responsibilities. Accordingly, 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 (57 Fed. Reg. 5791, February 18, 1992).

The NRC recognizes that corrective actions, as described at the enforcement conference, have been taken to ensure that appropriate management attention is provided to the radiation safety program, so as to preclude the recurrence of such violations in the future. These actions included increasing the staffing to three health physicists and three technicians, as well as increasing and renovating the space available to this staff; reorganization of the administration and oversight of the radiation safety program, including the establishment of an Executive Committee that meets once a month on radiation safety matters; retaining a new Radiation Safety Officer at the facility in the summer of 1991; and conducting an audit in 1992 that included a review of the radiation safety activities in 1990. We emphasize the importance of proceeding expeditiously with your plans to provide radiation safety training to the housekeeping and security staff.

Notwithstanding the corrective actions that have been taken or planned, to emphasize (1) the importance of appropriate management attention to, and oversight of, the radiation safety program to ensure activities are conducted safely and in accordance with the requirements; (2) the seriousness with which the NRC views willful actions that cause or contribute to violations of NRC requirements; and (3) the importance of ensuring proper security of licensed material at your facility in the future, I have been authorized to issue the enclosed Notice of Violation and Proposed Imposition of Civil Penalty in the amount of $3,750 for the violations set forth in the enclosed Notice.

The base civil penalty amount for a Severity Level III violation is $2,500. The escalation and mitigation factors set forth in the enforcement policy were considered and the NRC has decided that the civil penalty should be escalated by 50% to $3,750 for the Severity Level III problem because: (1) the violations were identified by the NRC, and therefore, 50% escalation of the base civil penalty amount on this factor is warranted; (2) your corrective actions taken and planned, as described herein, were considered prompt and extensive, and therefore, 50% mitigation of the base civil penalty on this factor is warranted: and (3) your past performance included nine violations during the past two inspections, including a civil penalty issued on July 1990 for violations of NRC requirements involving the lack of control of licensed material, and therefore, 50% escalation of the base civil penalty on this factor is warranted. (The circumstances were not judged to warrant full 100% escalation on this factor.) The other escalation and mitigation factors were considered, and no adjustment on these factors is warranted.

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

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

The responses directed by this letter and the enclosed Notice are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, Pub. L. 96-511.

Sincerely,

Thomas T. Martin
Regional Administrator

Enclosure:
Notice of Violation and
Proposed Imposition of Civil Penalty

cc:
Public Document Room (PDR)
Nuclear Safety Information Center (NSIC)
District of Columbia

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

Georgetown University Medical Center
Washington, D.C.

Docket Nos. 030-01315
030-00124
License Nos: 08-01709-04
08-01709-06
EA 92-016

During an NRC inspection conducted between April 16-18, 1991, and an NRC investigation conducted between May 20, 1991 and January 8, 1992, violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C, 57 Fed. Reg. 5791 (February 18, 1992), the Nuclear Regulatory Commission proposes to impose a civil penalty pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (Act), 42 U.S.C. 2282, and 10 CFR 2.205. The particular violations and associated civil penalty are set forth below:

A. Condition 21 of License No. 08-01709-04 requires that the licensee conduct its program in accordance with the statements, representations, and procedures contained in an application dated October 28, 1985.

Item 7-2 of the license application states that the licensee has the basic routine responsibilities presented in NRC Regulatory Guide 10.8, Revision 1, Appendix B.

Appendix B, Section on Duties, Item 6, of NRC Regulatory Guide 10.8, Revision 1, requires the Medical Isotopes Committee to review the entire radiation safety program at least annually to determine that all activities are being conducted safely and in accordance with NRC regulations and the conditions of the license.

Contrary to the above, as of April 17, 1991, the Medical Isotopes Committee ("Committee on Radiation Control") did not perform an annual review of the entire radiation safety program for 1990 to determine that all activities were being conducted safely and in accordance with NRC regulations and the conditions of the license.

B. 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 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 the purpose of protection of individuals from exposure to radiation and radioactive materials.

Contrary to the above, on April 16, 1991, licensed material located in the Nuclear Medicine laboratory (which was an unrestricted area in that the door was propped open at the time), was not secured against unauthorized removal, and was not under the constant surveillance and immediate control of the licensee.

C. Condition 21 of License No. 08-01709-04 requires that the licensee conduct its program in accordance with the statements, representations, and procedures contained in an application, dated October 28, 1985.

1. Item 19.5.c of the license application requires that the licensee perform thyroid bioassay tests in accordance with the criteria established in NRC Regulatory Guide 8.20, Revision 1.

   NRC Regulatory Guide 8.20, Revision 1, Section C.1.a, Table 1, and Section C.4.a, requires that whenever an individual handles unsealed quantities of radioactive iodine in a fume hood in amounts greater than 10 millicuries during a three month period, a bioassay is to be performed within 72 hours following entry of the individual into the area to use the material. When the work with the radioactive material is on an infrequent basis (less frequently than every two weeks), the bioassay is to be performed within 10 days of the end of the work period during which the radioactive iodine was handled.

   Contrary to the above, as of February 17, 1991, individuals using iodine-125 in quantities greater than 10 millicuries in a three month period in a fume hood, were not given iodine bioassays within the required time periods. Specifically, three individuals handled unsealed iodine-125 in the performance of iodination procedures in January, 1991 using quantities in excess of 10 millicuries; and two of these individuals had not been bioassayed at the time of the inspection in April 1991 (an interval greater than 10 days), and one individual was bioassayed 27 days after handling the iodine-125 to perform the radioiodination.

2. Item 8 of the license application requires that training sessions on radiation safety be held at least yearly for housekeepers and security officers and that a record of these training sessions, including an attendance roster, be maintained.

   Contrary to the above, training sessions in radiation safety were not held for housekeeping and security staff in 1990.

3. Item 23-2.b of the license application requires the Radiation Control Office to inspect, at least quarterly, the Radiation Medicine, Nuclear Medicine, and certain other research laboratories which use greater than 15 millicuries of C-14, H-3, P-32, S-35, Cr-51, Rb-86, or Ca-45, or more than one millicurie of any other nuclide.

   Contrary to the above, as of April 16, 1991, the Radiation Control Office did not perform quarterly inspections of Radiation Medicine, Nuclear Medicine, or certain other research laboratories which use quantities of radionuclides greater than the amounts specified in Item 23-2.

These violations are classified in the aggregate as a Severity Level III problem. (Supplements IV and VI)

Civil Penalty - $3,750 (assessed equally among the five violations)

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

Within the same time as provided for the response required 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 V.B of 10 CFR Part 2, Appendix C, 57 Fed. Reg. 5791 (February 18, 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 pa[illegible]he 10 CFR 2.201 reply by specific reference (e.g., citing page and paragraph numbers) to [illegible]oid repetition. The attention of the Licensee is directed to the other provisions of 10 CFR 2.205, regarding the procedure for imposing a civil penalty.

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

The response noted above (Reply to Notice of Violation, letter with payment of civil penalty, and Answer to a Notice of Violation) should be addressed to: Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555 with a copy to the Regional Administrator, U.S. Nuclear Regulatory Commission, Region I, 475 Allendale Road, King of Prussia, Pennsylvania 19406.

Dated at King of Prussia, Pennsylvania
this 17th day of April 1992

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION II
101 MARIETTA STREET, N.W., SUITE 2900
ATLANTA, GEORGIA 30323

MAR 27 1992

Docket No. 030-03521
License No. 52-10270-01
EA 92-038

Hospital de Damas
ATTN: Mr. Roberto A. Rentas Ramos
Administrator
Ponce By Pass
Ponce, Puerto Rico 00731

Gentlemen:

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY - $3,750 (NRC INSPECTION REPORT NO. 52-10270-01/92-01)

This refers to the Nuclear Regulatory Commission (NRC) inspection conducted by Messrs. H. Bermudez and W. Loo on February 12-13, 1992, at the Hospital de Damas, Ponce, Puerto Rico. The inspection included a review of activities conducted under your NRC license with respect to radiation safety and compliance with NRC regulations and the conditions of your NRC license. The report documenting this inspection was sent to you by letter dated March 5, 1992. As a result of the inspection, violations of NRC requirements were identified. An enforcement conference was held on March 11, 1992, at the Hospital de Damas with you and members of your staff to discuss the violations, their cause, and your corrective actions to preclude recurrence. A summary of the enforcement conference was sent to you by letter dated March 24, 1992.

The 13 violations in Part I of the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice) included the failure: 1) to ensure that radiation safety activities were being performed in accordance with approved procedures, 2) to review the radiation safety program during 1991, 3) to follow procedures relating to monitoring hands for contamination, 4) to perform required surveys, 5) to provide annual refresher training for hospital staff, 6) to properly dispose of radioactive waste, 7) to conduct Radiation Safety Committee meetings at the required intervals, 8) to measure the thyroid burden of the nuclear medicine physician who administered iodine-131 to patients on three occasions, 9) to perform linearity tests as required, 10) to perform constancy checks as required, and 11) to check sealed sources for leakage.

When viewed collectively, these violations span the entire range of the radiation safety program and indicate a significant breakdown in the management and oversight of the program. It appears the breakdown was due, in part, to an overdependence on the consultant and the Chief Nuclear Medicine Technologist who left the facility in 1991, and following the loss of these key individuals, the failure of the Radiation Safety Officer to take adequate steps to assure that licensee personnel had sufficient knowledge of program requirements. In addition, one person was fulfilling the responsibilities associated with the positions of Radiation Safety Officer, Chairman of the Radiation Safety

Committee, and Chief of the Nuclear Medicine Department, a situation that did not provide for an adequate independent overview of the program or ensure that procedures were followed. Furthermore, based on discussions during the enforcement conference, it appears that the radiation safety program has not received adequate attention and oversight by hospital administration which has the ultimate responsibility for ensuring compliance with NRC license conditions. Therefore, in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy) 10 CFR Part 2, Appendix C (1991), the violations in Part I of the Notice are classified in the aggregate as a Severity Level III problem.

The staff recognizes that corrective actions for some of the violations identified during the inspection were implemented before the inspection ended and that extensive correction actions had been developed for discussion at the enforcement conference. Those corrective actions included the Associate Hospital Administrator being assigned special oversight responsibility for the radiation safety program and the formation of a special nuclear medicine radiation safety review group reporting to the Radiation Safety Committee.

To emphasize the importance of maintaining an effective radiation safety program and ensuring compliance with regulatory requirements and license conditions, I have been authorized to issue the enclosed Notice of Violation and Proposed Imposition of Civil Penalty in the amount of $3,750 for the Severity Level III problem set forth in Part I of the Notice. The base value of a civil penalty for a Severity Level III problem is $2,500.

The escalation and mitigation factors in the Enforcement Policy were considered and 50 percent escalation of the base civil penalty was warranted because the violations were identified by the NRC. Mitigation of 50 percent was warranted for corrective action to prevent recurrence because of the extensive corrective actions that were implemented or planned for implementation such as the establishment of an executive committee to review license requirements, involvement of the Associate Hospital Administrator in program overview, and the creation of new documentation logs, computer tracking capability, and designation of a new Radiation Safety Officer with time to be devoted to oversight of the program. Escalation of 50 percent was warranted for past performance because even though the last NRC inspection conducted in February 1990 did not identify any violations, the inspection conducted in August 1989, identified seven violations which were cited on December 1, 1989, under Enforcement Action 89-186. The other adjustment factors in the Enforcement Policy were considered and no further adjustments were appropriate. However, the factors of multiple occurrences and duration were considered in categorizing the violations in Part I as a Severity Level III problem.

The other violations cited in Part II of the Notice include the failure: 1) to properly remove labels from containers of radioactive material prior to disposal, 2) of the Radiation Safety Officer to review and initial survey records at least monthly, 3) to post documents required by 10 CFR 19.11, 4) to list the exposure rate of a dedicated check source on a survey instrument, 5) to properly maintain records of disposal of byproduct material, 6) to properly document survey records, 7) to retain records of leak tests, 8) to retain records of physical inventories, and 9) to retain records of survey meter

calibrations. Although these violations were each categorized at Severity Level V, they are of concern to the NRC because, in this case, they further reflect the scope of the programmatic breakdown at your facility.

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,

James L. Milhoan for
Stewart D. Ebneter
Regional Administrator

Enclosure:
Notice of Violation and Proposed
Imposition of Civil Penalty

cc w/encl:
Commonwealth of Puerto Rico

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

Hospital de Damas
Ponce, Puerto Rico

Docket No. 030-03521
License No. 52-10270-01
EA 92-038

During an NRC inspection conducted on February 12-13, 1992, violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C (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 violations and associated civil penalty are set forth below:

I. Violations Assessed a Civil Penalty

A. 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. The licensee's procedures for the daily operation of the byproduct material program are described in the application dated December 19, 1989, and were approved in License Condition No. 13.

Contrary to the above, from June 1991 to February 12, 1992, the licensee, through its Radiation Safety Officer, failed to ensure that radiation safety activities were being performed in accordance with the above procedures.

B. 10 CFR 35.22(b)(6) requires that, to oversee the use of licensed material, the Radiation Safety Committee (RSC) must review annually, with the assistance of the Radiation Safety Officer, the radiation safety program.

Contrary to the above, from January 1, 1991 until December 31, 1991, the licensee's RSC did not review, with the assistance of the RSO, the radiation safety program.

C. Condition 13 of NRC License No. 52-10270-01 requires that licensed material be possessed and used in accordance with the statements, representations and procedures described in the license application dated December 29, 1989, and licensee letter dated March 14, 1990.

1. Item 5 of the licensee's letter dated March 14, 1990, states that the licensee will adopt the rules for safe use of radioactive materials published in Appendix I to NRC Regulatory Guide 10.8, Revision 2.

a. Item 3 of Appendix I states that either after each procedure or before leaving the restricted area, hands are to be monitored for contamination in a low-background area with a crystal probe or camera.

Contrary to the above, from May 3, 1990 to February 12, 1992, licensee personnel routinely did not monitor their hands for contamination, after each procedure or before leaving restricted areas, in a low-background area with a crystal probe or camera.

b. Item 12 of Appendix I states that the licensee will survey with a radiation detection survey meter the generator storage, kit preparation, and injection areas daily for contamination.

Item 10 of the licensee's letter dated March 14, 1990, specifies that the licensee's trigger levels for contamination are 2000 disintegrations per minute (dpm) for restricted areas and 2000 dpm or twice background, whichever is smaller, for unrestricted areas.

Contrary to the above, from May 3, 1990 to February 12, 1992, the licensee did not adequately survey with a radiation detection survey meter the generator storage, kit preparation, and injection areas daily for contamination. Specifically, the licensee performed daily contamination surveys with a survey instrument not capable of detecting the trigger levels established by the licensee.

2. Item 8 of the license application, states that the licensee will follow the model training program in Appendix A to Regulatory Guide 10.8, Revision 2. Appendix A states, in part, that personnel who work in or frequent restricted areas will be given annual refresher training to include applicable regulations and license conditions, potential hazards associated with radioactive material in each area where the employees will work, appropriate radiation safety procedures and the licensee's in-house work rules.

Contrary to the above,

a. The licensee did not give annual refresher training in the potential hazards associated with radioactive material in each area where the employees will work, appropriate radiation safety procedures and the licensee's in-house work rules to all security personnel who work in or frequent restricted areas for the years 1990 and 1991;

b. The licensee did not give annual refresher training in applicable regulations and license conditions to all nuclear medicine personnel and the radiation physicist for the year 1991.

3. Item 5 of the licensee letter dated March 14, 1990, states that the licensee will adopt the rules for safe use of radioactive

materials in Appendix I to NRC Regulatory Guide 10.8, Revision 2. Item 9 of Appendix I states that radioactive waste be disposed of only in designated, labeled, and properly shielded receptacles.

Contrary to the above, on February 12, 1992, the licensee disposed of radioactive waste in three undesignated, unlabeled and improperly shielded receptacles.

D. 35.70(e) requires that a licensee survey for removable contamination once each week all areas where radiopharmaceuticals are routinely prepared for use, administered, or stored.

Contrary to the above, for seven separate weeks between September 17, 1990 and January 17, 1992, the licensee did not survey for removable contamination in the nuclear medicine laboratory where radiopharmaceuticals were routinely prepared for use, administered, or stored.

E. 10 CFR 35.70(a) requires that a licensee survey with a radiation detection survey instrument at the end of each day of use all areas where radiopharmaceuticals are routinely prepared for use or administered.

Contrary to the above, on numerous occasions from May 3, 1990 until February 12, 1992, the licensee did not survey with a radiation detection instrument, at the end of each day of use, all areas of the nuclear medicine department where radiopharmaceuticals were routinely prepared for use or administered. Specifically, the surveys were performed in the morning rather than at the end of each day of use.

F. 10 CFR 35.22(a)(2) requires that the Radiation Safety Committee meet at least quarterly.

Contrary to the above, the licensee's Radiation Safety Committee did not meet between March 8 and July 19, 1990 and February 19 and July 1, 1991, periods in excess of a calendar quarter.

G. 10 CFR 35.315(a)(8) requires, in part, that a licensee measure the thyroid burden of each individual who helped prepare or administer dosages of iodine-131 in amounts that required the patient to be hospitalized for compliance with 10 CFR 35.75, and that the measurements be performed within three days after the administration of the dosage.

Contrary to the above, on April 8, May 7, and June 25, 1991, the licensee administered to patients 200, 130 and 130 millicuries of iodine-131, respectively, dosages which require hospitalization for compliance with 10 CFR 35.75, and the licensee did not measure the thyroid burden of the nuclear medicine physician who administered these dosages.

H. 10 CFR 35.50(b)(3) requires, in part, that a licensee test each dose calibrator for linearity over the range of its use between the highest dosage that will be administered to a patient and 10 microcuries.

Contrary to the above, on at least eight occasions between May 3, 1990 and February 12, 1992, the licensee did not test the dose calibrator for linearity down to 10 microcuries. Specifically, the licensee performed the linearity tests only down to activities that ranged between 1.233 millicuries and 793 microcuries.

I. 10 CFR 35.50(b)(1) requires a licensee to check each dose calibrator for constancy with a dedicated check source at the beginning of each day of use on a frequently used setting.

Contrary to the above, between February 8, 1990 and February 12, 1992, the licensee did not check the dose calibrator for constancy with a dedicated check source at the beginning of each day of use on a frequently used setting.

J. 10 CFR 35.59(b)(2) requires, in part, that a licensee in possession of a sealed source test the source for leakage at intervals not to exceed six months or at other intervals approved by the Commission or an Agreement State.

Contrary to the above, the licensee did not test any of the sealed sources in its possession for leakage between July 1, 1991 and February 12, 1992, an interval in excess of six months, and no other interval was approved by the Commission or an Agreement State.

This is a Severity Level III problem (Supplement VI).
Cumulative Civil Penalty - $3,750 (assessed equally among the 13 violations).

II. Violations Not Assessed a Civil Penalty

A. 10 CFR 20.203(f)(4) requires that, prior to disposal of an empty, uncontaminated container to an unrestricted area, the radioactive label be removed or defaced, or the container otherwise be indicated as no longer containing radioactive material.

Contrary to the above, on February 13, 1992, containers labeled as containing iodine-131, inside a package labeled RADIOACTIVE YELLOW-III, were transferred for disposal without removing, defacing or marking the labels, or otherwise indicating that they no longer contained radioactive material.

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

B. Condition 13 of NRC License No. 52-10270-01 requires that licensed material be possessed and used in accordance with the statements,

representations and procedures described in the license application dated December 29, 1989, and licensee letter dated March 14, 1990.

Item 10.12 of the license application, states that the licensee will establish and implement the model procedure for area surveys in Appendix N to NRC Regulatory Guide 10.8, Revision 2. Appendix N states, in part, that the Radiation Safety Officer (RSO) will review and initial area survey records at least monthly.

Contrary to the above, from December 9, 1991 until February 12, 1992, a period in excess of a month, the RSO did not review and initial area survey records.

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

C. 10 CFR 19.11(a) and (b) require, in part, that the licensee post current copies of Part 19, Part 20, the license, license conditions, documents incorporated into the license, license amendments and operating procedures, or that a licensee post a notice describing these documents and where they may be examined.

Contrary to the above, as of February 12, 1992, the licensee did not post copies of the regulations, nor maintain any of the required documents in the nuclear medicine department area of the hospital as described in the notice posted in the nuclear medicine laboratory.

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

D. 10 CFR 35.51(a)(3) requires that a licensee conspicuously note the apparent exposure rate from a dedicated check source, as determined at the time of calibration, and the date of calibration on any survey instrument used to show compliance with 10 CFR Part 35.

Contrary to the above, as of February 12, 1992, the licensee did not have the apparent exposure rate from a dedicated check source as determined at the time of calibration noted on a survey instrument, and the licensee was using this survey instrument to show compliance with 10 CFR Part 35.

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

E. 10 CFR 35.92(b) requires that a licensee retain for three years a record of each disposal of byproduct material permitted under 10 CFR 35.92(a), and that the record include the date of the disposal, the date on which the byproduct material was placed in storage, the radionuclides disposed, the survey instrument used, the background dose rate, the dose rate measured at the surface of each waste container, and the name of the individual who performed the disposal.

Contrary to the above, as of February 12, 1992, the licensee's records of disposal of byproduct material permitted under

10 CFR 35.92(a) did not include the date on which the byproduct material was placed in storage, the survey instrument used, the background dose rate, and the dose rate measured at the surface of each waste container.

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

F. 10 CFR 35.70(h) requires, in part, that a licensee retain for three years a record of daily radiation detection and weekly removable contamination surveys required by 10 CFR 35.70, and that the records include the date of the survey, a plan of each area surveyed, the trigger level established for each area, the detected dose rate at several points in each area expressed in millirem per hour or the removable contamination in each area expressed in disintegrations per minute per 100 square centimeters, the instrument used to make the survey or analyze the samples, and the initials of the individual who performed the survey.

Contrary to the above,

1. From December 14, 1991 until February 12, 1992, the licensee's records of daily radiation detection surveys required by 10 CFR 35.70(a) did not include the initials of the individual who performed the survey;

2. From May 3, 1990 until February 12, 1992, the licensee's records of daily radiation level and weekly removable contamination surveys required by 10 CFR 35.70(a) and (e) did not include a plan of each area surveyed.

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

G. 10 CFR 35.59(d) requires, in part, that a licensee in possession of a sealed source retain leakage test records for five years.

Contrary to the above, as of February 12, 1992, the licensee did not retain records of leakage tests performed after May 3, 1990, on all of the licensee's sealed sources in its possession, which constitutes a retention period of less than five years.

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

H. 10 CFR 35.59(g) requires, in part, that a licensee retain for five years records of quarterly physical inventories of sealed sources and brachytherapy sources in its possession.

Contrary to the above, as of February 12, 1992, the licensee did not retain records of physical inventories of its sealed sources performed after May 3, 1990, a retention period of less than five years.

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

I. 10 CFR 35.51(d) requires, in part, that a licensee retain records of each survey instrument calibration for three years.

Contrary to the above, as of February 12, 1992, the licensee did not retain records of annual survey instrument calibrations for two survey instruments calibrated in 1989 and 1990, which constitutes a retention period of less than three years.

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

Pursuant to the provisions of 10 CFR 2.201, Hospital de Damas (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 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 response noted above (Reply to Notice of Violation, letter with payment of civil penalty, and Answer to a Notice of Violation) should be addressed to: Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555 with a copy to the Regional Administrator, U.S. Nuclear Regulatory Commission, Region II.

Dated at Atlanta, Georgia
this 27th day of March 1992

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION V

1450 MARIA LANE
WALNUT CREEK, CALIFORNIA 94596-5368

January 13, 1992

Docket No. 030-19521
License No. 50-19913-01
EA 91-146

Ketchikan General Hospital
3100 Tongass Avenue
Ketchikan, Alaska 99901

Attention: Ed Mahn
Hospital Administrator

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY - $2500
(NRC Inspection Report No. 030-19521/91-01)

This refers to the inspection conducted on October 10 and 18, and December 9-13, 1991, of the Ketchikan General Hospital, Ketchikan, Alaska. The results of the inspection were reported in NRC Inspection Report No. 030-19521/91-01, dated November 8, 1991. Twelve violations of NRC requirements were identified by the NRC during this inspection . The violations, their causes, and your corrective actions were discussed with you during an Enforcement Conference on November 21, 1991. The results of the Enforcement Conference were documented in Inspection Report No. 030-19521/91-02, dated December 20, 1991.

The violations are described in the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice). Collectively, the twelve violations set forth in the enclosed Notice represent a breakdown in your management control system designed to provide adequate oversight of your radiation safety program.

The violations include: (1) failure to conduct annual reviews of the radiation safety program; (2) failure to conduct dose calibrator linearity tests; (3) failure to conduct a dose calibrator geometry test upon installation; (4) failure to perform survey meter calibrations; (5) failure to label syringes or syringe shields; (6) failure to conduct quarterly inventories of sealed sources (repeat violation from the NRC inspection conducted on August 17-18, 1988); (7) failure to check the ex[illegible]port of the xenon system; (8) failure to record the dose calibrator mod[illegible]d serial number on daily constancy and quarterly linearity records; (9) failure to include the Radiation Safety Officer's signature on records for dose calibrator accuracy tests, leak tests and physical inventories; (10) failure to include trigger levels and survey meter identification on records for daily surveys and weekly wipe tests; (11) failure to show the ratio of the measurements expressed in microcuries of molybdenum per millicurie of technetium for molybdenum breakthrough tests; and, (12) failure to record surveys of previously contaminated waste destined for non-radioactive disposal.

The violations involving failure to conduct dose calibrator linearity tests and survey meter calibrations are considered especially significant because they were identified by your health physics consultant prior to the

inspection. An audit on September 27, 1990 identified a missing dose calibrator linearity test in 1989, and the audit on September 4, 1991 identified additional missing tests in 1990 and 1991, but you failed to correct these deficiencies. The 1990 audit also noted that survey meters should have been calibrated annually. Minutes of the December 14, 1990 Radiation Safety Committee (Committee) meeting documented that the Committee acknowledged the need for annual calibrations of instruments and for linearity testing of dose calibrators every ninety days, but the Committee failed to ensure that these tasks were accomplished.

The number of violations, the repetition of one violation, your failure to promptly correct two other violations identified by your consultant and your failure to ensure implementation of corrective actions called for by the Committee, denote a breakdown in the control of the radiation safety program by licensee management, collectively representing 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 (1991), the violations are classified in the aggregate as a Severity Level III problem.

To emphasize the need for effective management and Committee oversight of your radiation safety program, I am issuing the enclosed Notice of Violation and Proposed Imposition of Civil Penalty in the amount of $2500 for the Severity Level III problem. The base value of a civil penalty for a Severity Level III problem is $2500. The escalation and mitigation factors in the Enforcement Policy were considered.

The base civil penalty was increased by 50% for "Identification and Reporting" because the NRC identified the violations and, in certain cases noted above, you should have reasonably discovered and taken corrective action on the violations before identification by the NRC. The base civil penalty was decreased by 50% for "Corrective Action To Prevent Recurrence" because you took timely and comprehensive corrective action. The other factors listed in the Enforcement Policy were also considered, but no further adjustments were deemed appropriate.

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

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

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

Sincerely,

for John B. Martin
Regional Administrator

Enclosure:
Notice of Violation and
Proposed Imposition of Civil Penalty

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

Ketchikan General Hospital
3100 Tongass Avenue
Ketchikan, Alaska 99901

Docket No. 030-19521
License No. 50-19913-01
EA 91-146

During an NRC inspection conducted on October 10 and 18 and December 9-13, 1991, 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 (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 violations and associated civil penalty are set forth below:

A. 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 August 18, 1988 until October 10, 1991, the licensee's Radiation Safety Committee did not review, with the assistance of the Radiation Safety Officer, the licensee's radiation safety program.

B. 10 CFR 35.50(b)(3) requires, in part, that the licensee test each dose calibrator for linearity at least quarterly.

Contrary to the above, the licensee did not test its dose calibrator for linearity during the fourth quarter of 1989, third quarter of 1990 and second quarter of 1991.

C. 10 CFR 35.50(b)(4) requires, in part, that a licensee test each dose calibrator for geometry dependence upon installation over the range of volumes and volume configurations for which it will be used.

Contrary to the above, the licensee did not test its dose calibrator for geometry dependence at the time of installation, which occurred on September 18, 1991.

D. 10 CFR 35.51(a) requires that a licensee calibrate the survey instruments used to show compliance with 10 CFR Part 35 before first use, annually, and following repair.

Contrary to the above, at the time of the inspection, the licensee was using a Technical Associates Model PUG-1 (serial no. 2268) and Victoreen Minimonitor II (serial no. c290107000) survey instrument to show compliance with 10 CFR Part 35, and these instruments had not been calibrated since September 28, 1989 and October 7, 1989 respectively.

E. 10 CFR 35.59(g) requires, in part, that a licensee in possession of a sealed source or brachytherapy source conduct a quarterly physical inventory of all such sources in its possession.

Contrary to the above, the licensee did not conduct physical inventories of its sealed sources at any time between January 1, 1991 and October 10, 1991, a period in excess of a calendar quarter.

This is a repeat violation.

F. 10 CFR 35.60(b) requires that, to identify its contents, a licensee conspicuously label each syringe, or syringe radiation shield that contains a syringe with a radiopharmaceutical, and that the label show the radiopharmaceutical name or its abbreviation, or the clinical procedure to be performed, or the patient's name.

Contrary to the above, since August 18, 1988, the licensee did not label syringes or syringe radiation shields containing a syringe with radiopharmaceuticals used at the licensee's facility.

G. Condition 16.A of the license references the licensee's application dated December 17, 1986. Item 21, paragraph 6 of the application describes, in part, the procedure for checking quarterly the exhaust port of the Pulmonex Xenon System with a Xenon Gas Monitor attached directly to the port.

Contrary to the above, as of the time of the inspection, the licensee had failed to check the exhaust port of the Pulmonex Xenon System with a Xenon Gas Monitor since August 18, 1988.

H. 10 CFR 35.50(e)(1) and (3) require, in part, that a licensee retain records of dose calibrator daily constancy checks and quarterly linearity tests for three years unless directed otherwise, and that the records include the model and serial number of the dose calibrator.

Contrary to the above, as of October 10, 1991, the licensee's record of dose calibrator daily constancy checks and quarterly linearity tests performed on March 21, 1990, June 26, 1990, December 13, 1990, February 19, 1991 and September 28, 1991 did not include the dose calibrator model and serial number.

I. 10 CFR 35.50(e)(2), 35.59(d) and 35.59(g) require, in part, that a licensee retain records of dose calibrator annual accuracy tests, sealed source leak tests and sealed source physical inventories, respectively, and that the records include, in part, the signature of the Radiation Safety Officer.

Contrary to the above, as of October 10, 1991, the licensee's records of annual accuracy tests of its dose calibrator, sealed source leak tests and sealed source physical inventory did not include the signature of the Radiation Safety Officer.

J. 10 CFR 35.204(b) states that a licensee that uses molybdenum-99/technetium-99m generators for preparing a technetium-99m radiopharmaceutical shall measure the molybdenum-99 concentration in each eluate or extract.

10 CFR 35.204(c) requires, in part, that a licensee that must measure molybdenum concentration retain records that include, for each elution or extraction of technetium-99m, the ratio of microcuries of molybdenum per millicurie of technetium, and the initials of the individual who made the measurement.

Contrary to the above, from August 18, 1988 to October 10, 1991, the licensee used molybdenum-99/technetium-99m generators for preparing technetium-99m radiopharmaceuticals, and the licensee's records of elutions of technetium-99m did not include the ratio of microcuries of molybdenum per millicurie of technetium.

K. 10 CFR 35.70(a) and (e) require, in part, that a licensee survey all areas where radiopharmaceuticals are routinely prepared for use or administered. 10 CFR 35.70(h) requires, in part, that a licensee retain a record of the trigger level and survey meter used for the surveys required by 10 CFR 35.70 (a) and (e).

Contrary to the above, as of October 10, 1991, the licensee did not record trigger levels or the survey meter used for surveys of all areas where radiopharmaceuticals are routinely prepared for use or administered.

L. 10 CFR 35.92(b) requires that a licensee retain for three years a record of each disposal of byproduct material permitted under 10 CFR 35.92(a), and that the record include, in part, the dose rate measured at the surface of each waste container.

Contrary to the above, as of October 10, 1991, the licensee's records of disposal of byproduct material permitted under 10 CFR 35.92(a) did not include the dose rate measured at the surface of each waste container.

Violations A through L above constitute a Severity Level III problem (Supplement VI).
Civil Penalty - $2500, assessed equally among Violations A through E.

Pursuant to the provisions of 10 CFR 2.201, Ketchikan General Hospital 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, the Commission may issue an order or a demand for information 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 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 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, 1450 Maria Lane, Suite 210, Walnut Creek, California 94596.

Dated at Walnut Creek, California
this 13th day of January 1992

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

MAY 04 1992

Docket No. 030-19521
License No. 50-19913-01
EA 91-146

Ketchikan General Hospital
ATTN: Mr. Ed Mahn
Hospital Administrator
3100 Tongass Avenue
Ketchikan, Alaska 99901

Gentlemen:

SUBJECT: ORDER IMPOSING CIVIL MONETARY PENALTY - $1,000

This refers to your letters dated February 5 and 26, 1992 in response to the Notice of Violation and Proposed Imposition of Civil Penalty (Notice) sent to you by our letter dated January 13, 1992. Our letter and Notice described twelve NRC-identified violations that were considered a Severity Level III problem.

To emphasize the need for effective management oversight of your radiation safety program, a civil penalty of $2,500 was proposed.

In your response, you admitted each of the violations, but requested mitigation of the penalty from $2,500 to $1,000.

After consideration of your response, we have concluded for the reasons given in the appendix attached to the enclosed Order Imposing Civil Monetary Penalty that the penalty should be mitigated to $1,000. Accordingly, we hereby serve the enclosed Order on Ketchikan General Hospital, imposing a civil monetary penalty in the amount of $1,000. We will review the effectiveness of your corrective actions during a subsequent inspection.

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

Sincerely,

Hugh L. Thompson, Jr.
Deputy Executive Director for
Nuclear Materials Safety, Safeguards
and Operations Support

Enclosures: As stated

UNITED STATES
NUCLEAR REGULATORY COMMISSION

In the Matter of	)	
KETCHIKAN GENERAL HOSPITAL	)	Docket No. 030-19521
Ketchikan, Alaska	)	License No. 50-19913-01
	)	EA 91-146

ORDER IMPOSING CIVIL MONETARY PENALTY

I

Ketchikan General Hospital(Licensee) is the holder of Materials License No. 50-19913-01 issued by the Nuclear Regulatory Commission (NRC or Commission) on April 6, 1989. The license authorizes the medical use of radioactive materials by the licensee in accordance with the conditions specified therein.

II

An inspection of the Licensee's activities was conducted on October 10 and 18 and December 9-13, 1991. The results of this inspection indicated that the Licensee had not conducted its activities in full compliance with NRC requirements. A written Notice of Violation and Proposed Imposition of Civil Penalty (Notice) was served upon the Licensee by letter dated January 13, 1992. 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 in letters dated February 5 and 26, 1992. In its response, the Licensee admitted the violations but requested mitigation of the civil penalty.

III

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

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 $1,000 within 30 days of the date of this Order, by check, draft, money order, or electronic transfer, payable to the Treasurer of the United States and mailed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555.

V

The Licensee may request a hearing within 30 days of the date of this Order. A request for a hearing should be clearly marked as a

"Request for an Enforcement Hearing" and shall be addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555. Copies also shall be sent to the Assistant General Counsel for Hearings and Enforcement at the same address and to the Regional Administrator, NRC Region V, 1450 Maria Lane, Suite 210, Walnut Creek, California 94596.

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

In the event the Licensee requests a hearing as provided above, the issues to be considered at such hearing shall be whether on the basis of the violations admitted by the Licensee, this Order should be sustained.

FOR THE NUCLEAR REGULATORY COMMISSION

Hugh L. Thompson, Jr.
Deputy Executive Director for
Nuclear Materials Safety, Safeguards
and Operations Support

Dated at Rockville, Maryland
this 11th day of May 1992

APPENDIX TO ORDER IMPOSING CIVIL PENALTY
EVALUATION AND CONCLUSION

On January 13, 1992, a Notice of Violation and Proposed Imposition of Civil Penalty (Notice) was issued for violations identified during an NRC inspection. Ketchikan General Hospital responded to the Notice in a letter dated February 5, 1992, admitting all of the violations, but requesting mitigation of the civil penalty from $2,500 to $1,000 on the grounds that it is a small, rural, isolated facility with limited financial resources. In a letter dated February 26, 1992, the licensee provided further information to justify the mitigation request, specifically noting that it engages in nuclear medicine as a community service and not for profit.

NRC Evaluation of Licensee's Request for Mitigation

The basis for mitigation is that the licensee is a small, rural, isolated facility with limited financial resources. The information provided on February 6, 1992, indicated that the licensee operated its nuclear medicine department at a loss. However, the licensee being a non profit hospital normally operates on a break even basis (expenditures balancing revenue).

In the staff's view, the licensee's ability to pay is not so marginal that collection of the full civil penalty either in a lump sum or permitting payment over time with appropriate interest would adversely affect the ability for this licensee to safely run its nuclear medicine department. However, the licensee is clearly a small rural hospital (44 beds) with a very small nuclear medicine program (10 to 15 diagnostic treatments a month). The revenue from the nuclear medicine department is about $70,000 a year which has been declining for the past several years. The expenditures for the department including overhead expenses are about $85,000. The closest hospitals with nuclear medicine departments are in Seattle 600 miles away and in Anchorage 860 miles away. Access to Ketchikan is only by boat or airplane.

In the staff's view, application of the normal civil penalty process to this small hospital is not warranted. Given the range of the sizes of hospitals covered by the normal base penalty of $2500, this hospital is clearly at the low range. A civil penalty of $1000 appears to be a fairer penalty. This penalty should be sufficient to emphasize the need for the licensee to maintain lasting corrective action.

NRC Conculsion

Therefore, in accordance with section VII.B.6 of the Enforcement Policy the Staff, after notification of the Commission, is exercising enforcement discretion and imposing a civil penalty of $1000.

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

APR 2 2 1992

Docket Nos. 030-00571 and 030-19502
License Nos. 52-13598-01 and 52-13598-03
EA 92-039

Mayaguez Medical Center
ATTN: Dr. Elba Morales de Roman
Director, Western Region
Department of Health
Commonwealth of Puerto Rico
Mr. Angel Franceschi
Medical Center Administrator
Road Number 2, Kilometer 157
Mayaguez, Puerto Rico 00708

Dear Dr. Morales de Roman and Mr. Franceschi:

SUBJECT: NOTICE OF VIOLATION AND ORDER MODIFYING LICENSES (NRC INSPECTION REPORT NOS. 52-13598-01/92-01 AND 52-13598-03/92-01)

This refers to the Nuclear Regulatory Commission (NRC) inspection conducted by Messrs. H. Bermudez and W. Loo at the Mayaguez Medical Center, Mayaguez, Puerto Rico on February 10-11, 1992. The inspection included a review of the activities conducted under your licenses with respect to radiation safety and compliance with NRC regulations and the conditions of your licenses. The report documenting this inspection was sent to Mr. A. Franceschi, Administrator, Mayaguez Medical Center, by letter dated March 5, 1992. As a result of this inspection, significant failures to comply with NRC regulatory requirements were identified. An enforcement conference was held on March 11, 1992, at the Mayaguez Medical Center with you and members of your staff to discuss the violations, their causes, and your corrective actions to preclude recurrence. A summary of the enforcement conference was sent to you by letter dated March 27, 1992.

The violations described in the enclosed Notice of Violation (Notice) involve both your nuclear medicine license and your teletherapy license and include significant and continuing problems in the areas of management controls, program organization, personnel radiation protection, facilities and equipment, control and accountability of licensed materials, and patient protection during treatment. This matter is of significant concern to the NRC because of the potential safety implications represented by the collective violations and your facility's poor recent inspection history. With regard to past inspection history, on April 18, 1989, a Notice of Violation and Proposed Civil Penalty in the amount of $5000 was issued to your facility as a result of an NRC inspection conducted on January 25, 1989. The civil penalty was subsequently mitigated to $500, based on your inability to pay the full proposed civil penalty. That enforcement action (EA 89-033) addressed multiple violations that were categorized as a Severity Level III problem because of a breakdown in the control of licensed activities based on a significant lack of management oversight and lack of attention in the use of licensed materials. On January 23, 1991, a Notice of Violation was issued to your facility as a result of an

NRC inspection conducted on December 17, 1990, which resulted in the identification of eight violations associated with the teletherapy program conducted under NRC License No. 52-13598-01.

As a result of the latest inspection, we continue to see unacceptable performance. Adequate management oversight is vital to achieving and maintaining the desired level of performance for your radiation safety program. Our concern in this regard is supported by the fact that your part-time Radiation Safety Officer (RSO), in addition to performing RSO duties, serves as the physicist for both the nuclear medicine and the teletherapy departments, and serves as the lead individual on the Radiation Safety Committee. Apparently, as a result of his various work assignments both inside and outside the facility, the RSO has not been effective in implementing and maintaining the radiation safety program.

An enforcement conference was held at the Mayaguez Medical Center on March 11, 1992. The corrective actions taken for the individual violations were discussed. During the enforcement conference discussion, you acknowledged the advantages of providing increased daily involvement by supervisory personnel in radiation safety activities as well as designating a technically qualified manager other than the RSO as Chairperson of the Radiation Safety Committee. You also acknowledged the need to recruit a full-time radiation safety specialist to assist the part-time RSO in performing the daily functions associated with the RSO position. The NRC agrees that these issues are important and that they need to be carefully considered during the assessment directed by the attached Order, especially in view of the inadequate independence that results when the same person performs duties as both the RSO and Chairperson of the Radiation Safety Committee.

Therefore, because of the collective significance of the violations and because of the continuing lack of management attention to the program, 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 (1991), a civil penalty is considered for a Severity Level III problem. However, I have decided to issue the enclosed Order modifying your licenses in lieu of a civil penalty in light of your past difficulty in paying a civil penalty. We have taken into consideration the fact that yours is the only public hospital providing nuclear medicine and teletherapy services in western Puerto Rico and that a substantial civil penalty could adversely impact your ability to provide these services.

After careful review and consideration of the inspection findings, your past compliance history, and your continuing lack of management control and oversight of the radiation safety program, and in order to ensure that your program will be conducted in a manner that protects the health and safety of your patients and employees, I have determined that the public health, safety, and interest requires issuance of the enclosed Order Modifying Licenses. This Order is effective immediately. The Order requires, in part, that you obtain independent consulting services, submit a written Performance Improvement Plan (Plan), and submit monthly reports until the Performance Improvement Plan is completed. Failure to comply with this Order may result in further enforcement actions in the future.

You are required to respond to this letter and the enclosed Notice and should follow the instructions specified in the 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 actions required by the Order, including your proposed corrective actions and the results of future inspections, the NRC will determine whether further enforcement action is necessary to ensure compliance with NRC regulatory requirements.

Should you have any questions on this Order, please contact the undersigned at (301) 504-2741, or the Region II Deputy Division Director, Bruce S. Mallett, at (404) 331-5514.

In accordance with Section 2.790 of the NRC's "Rules of Practice," Part 2, Title 10, Code of Federal Regulations, a copy of this letter and its enclosures will be placed in the NRC Public Document Room.

The responses directed by this letter and its enclosures 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 Lieberman, Director
Office of Enforcement

Enclosures:
1. Notice of Violation
2. Order Modifying Licenses

cc w/encls:
Commonwealth of Puerto Rico

NOTICE OF VIOLATION

Mayaguez Medical Center
Mayaguez, Puerto Rico

Docket Nos. 030-00571, 030-19502
License Nos. 52-13598-01,
52-13598-03
EA 92-039

During an NRC inspection conducted on February 10-11, 1992, violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C (1991), the violations are listed below:

I. VIOLATIONS ASSOCIATED WITH LICENSE NO. 52-13598-03

A. 10 CFR 35.315(a)(8) requires, in part, that a licensee measure the thyroid burden of each individual who helped prepare or administer dosages of iodine-131 in amounts that required the patient to be hospitalized for compliance with 10 CFR 35.75.

Contrary to the above, on September 10 and November 4, 1991, the licensee administered to patients 98.1 and 199.9 millicuries of iodine-131, respectively, dosages which required hospitalization of these patients for compliance with 10 CFR 35.75, and the licensee did not measure the thyroid burden of the nuclear medicine technologist who helped prepare and administer these dosages.

B. 10 CFR 35.70(a) requires a licensee to survey with a radiation detection survey instrument at the end of each day of use all areas where radiopharmaceuticals are routinely prepared for use or administered.

Contrary to the above, on at least 10 occasions between January 11 and December 20, 1991, the licensee did not survey with a radiation detection survey instrument at the end of each day of use any areas in the nuclear medicine department where radiopharmaceuticals were prepared for use or administered.

C. 10 CFR 35.70(e) requires that a licensee survey for removable contamination once each week all areas where radiopharmaceuticals are routinely prepared for use, administered, or stored.

Contrary to the above, for 14 weeks between January 29, 1990 and August 2, 1991, the licensee did not survey for removable contamination the nuclear medicine laboratory, an area where radiopharmaceuticals were routinely prepared for use, administered, or stored.

D. 10 CFR 35.50(b)(3) requires that a licensee test each dose calibrator for linearity at least quarterly.

Contrary to the above, the licensee did not test its dose calibrator for linearity from December 13, 1990 until May 1, 1991, a period in excess of a calendar quarter.

This is a repeat violation.

E. 10 CFR 35.59(g) requires, in part, that a licensee in possession of a sealed source or brachytherapy source conduct a quarterly physical inventory of all such sources in its possession.

Contrary to the above, during the periods from March 7 to September 21, 1990, from September 21, 1990 to April 26, 1991, and from April 26, 1991 to October 7, 1991, periods in excess of a calendar quarter, the physical inventories that the licensee performed failed to account for a strontium-90 eye applicator.

F. 10 CFR 35.59(b)(2) requires, in part, that a licensee in possession of a sealed source test the source for leakage at intervals not to exceed six months or at other intervals approved by the Commission or an Agreement State.

Contrary to the above, the licensee did not test any of the sealed sources in its possession for leakage between September 21, 1990 and April 26, 1991, an interval in excess of six months, and no other interval was approved by the Commission or an Agreement State.

G. Condition 21 of NRC License No. 52-13598-03 requires, in part, that licensed material be used and possessed in accordance with the statements, representations and procedures described in the license application dated November 3, 1981, and in licensee letters dated February 15, 1991, January 23, 1987, and October 30, 1979.

1. Item 15 of the license application states that the licensee will implement the general rules for the safe use of radioactive material described in Appendix G to Regulatory Guide 10.8, Revision 1. Item 3 in Appendix G states that licensee personnel monitor hands and clothing for contamination after each procedure or before leaving the area.

   Contrary to the above, on February 10, 1992, a nuclear medicine technologist did not monitor her hands and clothing for contamination after each procedure or before leaving the nuclear medicine laboratory area.

2. Licensee letter dated January 23, 1987, states, in part, that the strontium-90 eye applicator sealed source will be physically maintained in the Nuclear Medicine Laboratory for safety reasons, used in the surgery room once a week and then returned to the laboratory.

   Contrary to the above, between January 24, 1990 and February 11, 1992, the strontium-90 eye applicator sealed source was maintained in the surgery room, and not in the Nuclear Medicine laboratory.

3. Licensee letter dated October 30, 1979, states, in part, that the 100 millicurie cesium-137 survey instrument calibration source will be stored in a cabinet under lock in the radiation physicist's laboratory, and used in that laboratory.

Contrary to the above, from December 17, 1990 to February 10, 1992, the licensee did not store the cesium-137 calibration source in a cabinet under lock in the radiation physicist's laboratory.

4. Licensee letter dated February 15, 1991, states, in part, that the licensee will change the charcoal filter cartridge in the iodine "mini-hood" every six months and will maintain records after each cartridge replacement.

Contrary to the above, between April 15, 1991 and February 10, 1992, an interval in excess of six months, the licensee did not change the charcoal filter cartridge in the iodine "mini-hood."

H. 10 CFR 19.11(a) and (b) require, in part, that the licensee post current copies of Part 19, Part 20, documents incorporated into the license, license amendments and operating procedures, or that the licensee post a notice describing these documents and where they may be examined.

Contrary to the above, on February 10, 1992, the licensee did not post any of the above referenced documents, or a notice describing these documents and where they could be examined.

This is a repeat violation.

I. 10 CFR 20.203(e) requires that rooms in which specified amounts of licensed material are used or stored be conspicuously posted "Caution Radioactive Material."

Contrary to the above, on February 10, 1992, the nuclear medicine laboratory, which contained millicurie quantities of technetium-99m labeled radiopharmaceuticals and a molybdenum-99 radiopharmaceutical generator, was not posted as required.

J. 10 CFR 35.51(a)(3) requires that a licensee conspicuously note the apparent exposure rate from a dedicated check source, as determined at the time of calibration, and the date of calibration on any survey instrument used to show compliance with 10 CFR Part 35.

Contrary to the above, as of February 10, 1992, the licensee did not have the apparent exposure rate from a dedicated check source as determined at the time of calibration noted on its survey instrument, and the licensee was using the survey instrument to show compliance with 10 CFR Part 35.

K. 10 CFR 35.92(b) requires that a licensee retain for three years a record of each disposal of byproduct material permitted under 10 CFR 35.92(a), and that the record include the date of the disposal, the date on which the byproduct material was placed in storage, the radionuclides disposed, the survey instrument used, the background dose rate, the dose rate measured at the surface of each waste container, and the name of the individual who performed the disposal.

Contrary to the above, as of February 10, 1992, the licensee's records of disposal of byproduct material permitted under 10 CFR 35.92(a) did not include the radionuclides disposed and the background dose rate.

II. VIOLATION ASSOCIATED WITH LICENSE NO. 52-13598-01

A. 10 CFR 35.632(a)(3) requires that full calibration measurements on each teletherapy unit be conducted at intervals not to exceed one year.

Contrary to the above, as of February 10, 1992, the licensee had not performed full calibration measurements of its teletherapy unit since January 15, 1991, an interval in excess of one year.

This is a repeat violation.

B. 10 CFR 35.634(f) requires, in part, that the licensee retain a record of each spot check required by 10 CFR 35.634(a) and (c), and that the record include, among other things, notations indicating the operability of the treatment room doors from inside and outside the treatment room.

Contrary to the above, as of February 10, 1992, the licensee's spot check records did not include notations indicating the operability of the treatment room door from inside and outside the treatment room.

This is a repeat violation.

The violations in Parts I and II constitute a Severity Level III problem (Supplement IV).

Pursuant to the provisions of 10 CFR 2.201, Mayaguez Medical Center (Licensee) is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555, with a copy to the Regional Administrator, Region II, 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 Rockville, Maryland
this 21st day of April, 1992

UNITED STATES
NUCLEAR REGULATORY COMMISSION

In the Matter of		
MAYAGUEZ MEDICAL CENTER	)	Docket Nos: 030-00571, 030-19502
Mayaguez, Puerto Rico	)	License Nos: 52-13598-01,
	)	52-13598-03
	)	EA 92-039

ORDER MODIFYING LICENSES
(EFFECTIVE IMMEDIATELY)

Mayaguez Medical Center (Licensee) is the holder of Byproduct/Source Material License Nos. 52-13598-01 and 52-13598-03 issued by the Nuclear Regulatory Commission (NRC or Commission) pursuant to 10 CFR Part 35. License No. 52-13598-01 authorizes possession and use of cobalt-60 sealed sources having activities up to 6,700 curies for performing radiation teletherapy on humans. This license, originally issued on March 12, 1970, was most recently renewed on February 22, 1991, with an expiration date of February 28, 1996. License No. 52-13598-03 authorizes the use of certain radiopharmaceuticals and sealed sources for the diagnosis and treatment of disease and radiation survey instrument calibrations. License No. 52-13598-03 was originally issued on February 24, 1982, was renewed on March 4, 1987, and was most recently amended on February 15, 1991; at the time of the inspection, this license was in timely renewal status.

II

The Licensee's medical facility is located at Road No. 2, Kilometer 157, Mayaguez, Puerto Rico 00708. The medical facility is operated by the Department of Health of the Commonwealth of Puerto Rico and is the only public hospital

providing teletherapy and nuclear medicine services in the western part of Puerto Rico. The teletherapy department treats approximately 700 patients per month using cobalt 60 radiation. The nuclear medicine department performs approximately 350 diagnostic and therapeutic procedures per month using radiopharmaceuticals. In nuclear medicine diagnostic procedures, the morphology and physiology of certain target organs are determined quantitatively and qualitatively using scintillation camera systems. In addition, the Licensee's ophthalmology department uses a strontium-90 eye applicator to treat superficial eye diseases after surgery at a frequency of approximately 50 times per month.

A routine unannounced inspection of the Licensee's activities was performed on February 10-11, 1992. The inspection findings were documented in a letter to the Licensee dated March 5, 1992. An enforcement conference was held with the Licensee at the Mayaguez Medical Center on March 11, 1992.

As a result of this inspection, 16 violations were identified. In particular, and as emphasized at the enforcement conference, the violations of greatest safety significance related to: (1) the full calibration and checks of the teletherapy unit, (2) numerous required radiation surveys, and (3) the quality assurance testing of the dose calibrator. With respect to the full calibration and checks of the teletherapy unit, the Licensee failed to perform the full calibration of the teletherapy unit at intervals not to exceed one year. With respect to radiation surveys, the Licensee: (1) failed to perform evaluations of potential thyroid uptakes of iodine 131 in a technician involved in the administration of therapeutic dosages, (2) on numerous occasions failed to

perform the required daily radiation level surveys of the nuclear medicine laboratory, (3) on numerous occasions failed to perform the required contamination level surveys at the nuclear medicine laboratory, and (4) failed to ensure that its technologists monitored their hands and clothing for contamination after handling radioactive materials. With respect to quality assurance testing of the dose calibrator, the Licensee failed to test its dose calibrator for linearity at the required quarterly frequency. The violations are more fully set forth in the Notice of Violation issued concurrently with this Order.

The Licensee's past inspection history reflects violations similar to several of the violations identified during the NRC inspection conducted on February 10-11, 1992, and documented in the Notice of Violation. The failure to perform the full calibration of the teletherapy unit at intervals not to exceed one year was previously cited as one of eight violations identified during the December 17, 1990 inspection (Inspection Report 52-13598-01/90-02), and as one of 15 violations identified during the January 25, 1989 inspection (EA 89-33, Inspection Report Nos. 52-13598-01/89-01 and 52-13598-03/89-01). In fact, since at least 1987, the Licensee has not performed a full calibration of the teletherapy unit at the required 12-month frequency. In addition, during the January 1989 inspection, the NRC noted that the full calibration performed in September 1988 was incomplete due to the Licensee's failure to determine the uniformity of the radiation field and its dependence on the orientation of the useful beam. The failure to maintain complete records of the output and safety systems checks of the teletherapy facility equipment was also identified during

the December 1990 inspection and is a repeat violation. The failure to perform evaluations of potential thyroid uptakes of iodine 131 in a technician involved in the administration of therapeutic dosages is similar to a January 1989 violation involving the Licensee's inadequate thyroid uptake evaluations for technicians involved in the administration of therapeutic dosages of iodine 131. The failure to perform a dose calibrator linearity test at the required quarterly frequency and the failure to post required information were also identified during the January 1989 inspection. As a result of the January 1989 inspection, a civil penalty in the amount of $5000 was proposed on April 18, 1989. The civil penalty was subsequently mitigated to $500 based on the Licensee's inability to pay the full proposed civil penalty.

Additionally, of the 23 violations cited against the Licensee between 1989 and 1991, three were related to the Radiation Safety Committee's lack of oversight of licensed activities, five were related to inadequate radiation safety instrumentation (including the dose calibrator), four were related to the Licensee's failure to perform radiation surveys or perform radiation surveys adequately, and five were related to inadequate recordkeeping. The NRC is concerned that current similar violations have occurred which should have been precluded by the Licensee's implementation of effective corrective actions, by management oversight of programs, and by conducting adequate required annual program reviews.

Based on the most recent violations of NRC requirements, the recurrence of prior similar violations, and information disclosed during the enforcement conference regarding the lack of clear assignments of responsibility for

the various individuals involved in the Licensee's radiation safety program, it appears that the radiation safety program is fragmented and lacks adequate management direction. This is further demonstrated by the fact that the Licensee employs a part-time Radiation Safety Officer who, with little oversight from technically-qualified individuals, spends only two days per week at the facility overseeing both the nuclear medicine and teletherapy programs, and performing the duties of teletherapy physicist, overseeing other non-licensed activities, and acting as the lead individual on the Radiation Safety Committee.

III

Based on the above information, and after the NRC inspection of licensed activities conducted since previous inspections of the nuclear medicine and teletherapy programs in January 1990 and December 1990, respectively, it appears that the Mayaguez Medical Center has operated while in violation of numerous NRC requirements and has failed to provide adequate oversight of its licensed programs. Consequently, absent additional requirements, I lack the requisite reasonable assurance that the Licensee's nuclear medicine and teletherapy programs can be conducted in the long term in compliance with Commission requirements and that the health and safety of the public, including the Licensee's employees, will be protected. Therefore, the public health, safety, and interest require that License Nos. 52-13598-01 and 52-13598-03 be modified to require the licensee to implement the requirements specified in Section IV of this Order. Furthermore, pursuant to 10 CFR 2.202, I find that the public health, safety and interest require that this Order be immediately effective.

IV

Accordingly, pursuant to Sections 81, 161b, 161c, 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, EFFECTIVE IMMEDIATELY, THAT LICENSE NOS. 52-13598-01 AND 52-13598-03 ARE MODIFIED AS FOLLOWS:

A. Within 30 days of the date of this Order, the Licensee shall submit to the Regional Administrator, NRC, Regior II, for approval, the credentials of an independent Health Physics Consultant (Consultant), with expertise in planning and implementing nuclear medicine and teletherapy programs. Upon approval, the Consultant shall be retained to perform, independent of the Licensee's staff, an assessment of the Licensee's nuclear medicine and teletherapy radiation safety programs. The assessment shall include an analysis of the adequacy of the Licensee's current organizational structure, staffing levels, audits, training, assignment of responsibilities within the nuclear medicine and teletherapy departments and the RSO function. The Consultant shall also assist in the Licensee's implementation of corrective actions for all violations specified in the Notice of Violation. Within 30 days of NRC approval, the Consultant shall provide the Hospital Administrator a written report of his or her assessment which describes the weaknesses identified during the assessment and recommendations for improvement. A copy of this report shall be provided to the Regional Administrator, Region II, at the same time that it is transmitted to the Licensee.

B. The Consultant shall:

1. Spend a minimum of 10 hours on site per week conducting assessment or audit activities for a period of 90 days after being hired by the Licensee.

2. After the initial 90 day period, perform an audit at least once per month on site until all the actions of the Performance Improvement Plan required by Section IV.E of this Order are completed.

3. Provide, within the 90 day period, 40 hours of training in radiation safety and procedures as defined in 10 CFR Parts 19, 20, and 35, and the respective license conditions, to the responsible nuclear medicine and teletherapy technologists. The training shall include a complete review of the respective byproduct materials licenses including the procedures incorporated into the licenses by reference to the Licensee's applications and related correspondence. The 40 hours of training to be provided by the Consultant is in addition to the minimum of 10 hours per week on site required by Section IV.B.1 above. The training hours and curriculum shall be documented and maintained on file in the nuclear medicine department.

C. The Licensee shall document the number of hours per week spent by the Consultant in the nuclear medicine and teletherapy departments and the types and kinds of corrective measures implemented. All documentation shall be maintained on file in the nuclear medicine department until two years after it is inspected by the NRC.

D. Within 45 days of the date of this Order, the Licensee shall independently measure the output of the teletherapy unit on the same field sizes measured during the full calibration performed on February 15, 1992. A report comparing the two sets of measured outputs and accounting for radioactive decay since the February 1992 full calibration shall be submitted along with the report required by Section IV.A of this Order.

E. Within 30 days of the completion of the Consultant's assessment required by Section IV.A of this Order, the Licensee shall develop, with the assistance of the Consultant, a written Performance Improvement Plan (Plan) that ensures an upgrade in the performance of the nuclear medicine and teletherapy programs and a consistent high level of compliance with NRC requirements. This Plan shall be submitted to the Regional Administrator, NRC, Region II, for review and shall be implemented upon the NRC's approval. As a minimum, the Plan shall include and/or address:

1. Provisions for ensuring that professional staffing levels within the nuclear medicine and teletherapy departments and RSO function are adequate to meet the radiological safety requirements and will remain so in view of the departments' workloads.

2. Provisions for increased involvement by the Hospital Administrator in the oversight and management of the nuclear medicine and teletherapy departments.

3. Provisions for safety audits of the nuclear medicine and teletherapy departments by a qualified auditor who is independent of the Mayaguez Medical Center organization at intervals not to exceed 12 months.

4. Hospital management's program for review and follow-up action on problems identified during the independent audits.

5. Training program descriptions and plans which will ensure that the members of the Radiation Safety Committee are familiar with all applicable NRC regulations, terms of the licenses and information submitted in support of the licenses and their amendments, and that the RSO, nuclear medicine technologists, teletherapy technologists, and other nuclear medicine and teletherapy specialists are knowledgeable of regulatory requirements, equipment operations and analytical techniques.

6. Schedules for correcting the organizational problems identified during the February 10-11, 1992 inspection, including those associated with the need for separating the positions of RSO and Chairman of the Radiation Safety Committee, which were discussed during the March 11, 1992 enforcement conference.

7. Methods for incorporating the recommendations contained in the Consultant's assessment report in the Performance Improvement Plan or justification for alternative corrective action or not taking action if any specific recommendations are not adopted.

8. Milestones for completing the action items specified in the Performance Improvement Plan.

F. The Licensee shall submit a monthly report to the Regional Administrator, NRC, Region II, beginning on the 15th day of the month following the first 30 day period after the NRC's approval of the Performance Improvement Plan and thereafter on the 15th day of each month, until the Plan is implemented, which addresses:

1. The progress that has been made towards carrying out the provisions of this Order and the Performance Improvement Plan during the past calendar month.

2. In the event that a milestone date set forth in this Order or Plan is not met during the period covered by the monthly report, the report shall indicate: (1) the date by which the Licensee expects to accomplish the activity, (2) the reason for the Licensee's failure to meet the milestone date, and (3) the impact that the failure to meet the milestone date will have on the schedules provided in this Order or the Plan.

3. Those actions required under the Order and Plan which the Licensee expects to accomplish within the next 30 days.

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

V

In accordance with 10 C.F.R. 2.202, the Licensee 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 the Licensee 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, D.C. 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 NW, Atlanta, GA 30323, and to the Licensee if the answer or hearing request is by a person other than the Licensee. If a person other than the Licensee 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 the Licensee 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 a hearing shall be whether this Order should be sustained.

In the absence of any request for hearing, the provisions specified in Section IV above shall be final 30 days from the date of this Order without further order or proceedings. AN ANSWER OR REQUEST FOR A HEARING SHALL NOT STAY THE IMMEDIATE EFFECTIVENESS OF THIS ORDER.

FOR THE NUCLEAR REGULATORY COMMISSION

James Lieberman, Director
Office of Enforcement

Dated at Rockville, Maryland
this 22nd day of April 1992

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

OCT 03 1991

Docket No. 40-8027
License No. SUB-1010
EA 91-067

Sequoyah Fuels Corporation
ATTN: James J. Sheppard
President
Post Office Box 610
Gore, Oklahoma 74435

Gentlemen:

SUBJECT: ORDER MODIFYING LICENSE (EFFECTIVE IMMEDIATELY) AND DEMAND FOR INFORMATION

The enclosed Order Modifying License (Effective Immediately) and Demand for Information is being issued to the Sequoyah Fuels Corporation (SFC) to address a number of significant safety violations and regulatory problems identified at the facility by NRC inspections and investigations that have been conducted since the August 1990 solvent extraction tank excavation. This Order and Demand is based on the NRC's conclusions that certain SFC managers failed to follow NRC requirements and the conditions of the NRC license, that a certain SFC employee made false statements and withheld information from the NRC, and that your Health & Safety and Environmental Programs are in need of substantial improvement to assure the health and safety of the general public, SFC employees, contractor personnel who work at the site, and protection of the environment.

This Order modifies SFC's license to remove Carolyn L. Couch from supervisory or managerial responsibilities over NRC-regulated activities for a period of one year from the date of the enclosed Order, effective immediately. Additionally, if Ms. Couch remains involved in NRC-regulated activities, she is not to be supervised by any of the individuals named in the Demand for Information. You are also required to perform an in-depth review of the administrative control and implementing procedures in your Health & Safety and Environmental Programs by qualified personnel from outside SFC approved by the NRC. A plan that provides for an appropriate scope of the review and prioritization of items to be covered, along with an implementing schedule, must be submitted to, and approved by, the NRC prior to your restart from the September 1991 plant shutdown.

While the NRC cannot conclude that other SFC managers provided false information, there are serious questions as to whether the Senior Vice President, the Vice President of Regulatory Affairs and the Health Physics Supervisor, who have not assured that past licensed or safety responsibilities were carried out, can in the future, adequately perform the organizational responsibilities and authorities, especially those outlined in SFC's License. Therefore, you are required to respond to the enclosed Demand for Information in accordance with the instructions provided therein. This information is necessary to determine whether to modify, suspend or revoke your NRC License, and whether to renew your License.

Questions concerning this Order and Demand for Information should be addressed to James Lieberman, Director, Office of Enforcement, who can be reached at (301) 492-0741.

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

Sincerely,

Hugh L. Thompson, Jr.
Deputy Executive Director for
Nuclear Materials Safety, Safeguards
and Operations Support

Enclosure: As Stated

cc: James Mestepey
Kenneth Simeroth
Lee Lacey
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UNITED STATES
NUCLEAR REGULATORY COMMISSION

In the Matter of	)	
	)	Docket No. 40-8027
SEQUOYAH FUELS CORPORATION	)	License No. SUB-1010
Gore, Oklahoma	)	EA 91-067

ORDER MODIFYING LICENSE
(EFFECTIVE IMMEDIATELY)
AND
DEMAND FOR INFORMATION

I

Sequoyah Fuels Corporation (SFC or Licensee) is the holder of Source Material License No. SUB-1010 issued by the Nuclear Regulatory Commission (NRC or Commission) pursuant to 10 CFR Part 40. The license authorizes possession and use of source material in the production of uranium hexafluoride (UF6) and depleted uranium tetrafluoride (DUF4) in accordance with the terms and conditions of the license. The license was due to expire on September 30, 1990, but currently remains in effect based on a timely renewal application submitted by the Licensee.

II

The NRC requires its licensees to adhere to the safety standards that are contained in its regulations and the conditions specified in the facility license. The Licensee described its management organization and the responsibilities assigned to key personnel in SFC's license renewal application dated August 23, 1985, as supplemented. The NRC expects those Licensee managers holding the key positions described in the application to ensure compliance with the regulations that are within their area of licensed

responsibility so as to protect the health and safety of the general public, the Licensee's workers, any contractors that work at the facility, and the environment. Furthermore, the NRC must be able to rely upon the integrity of those Licensee managers in their conduct of licensed activities and their provision of complete and accurate information to NRC.

At the time of the solvent extraction tank excavation, SFC described its management organization and the responsibilities and authorities assigned to key personnel in its license as follows:

A. The President, Sequoyah Fuels Corporation (Mr. Reau Graves at the time), shall have overall responsibility for the safe operation of the Sequoyah Facility. Additional responsibility has been assigned to the Senior Vice President, the Vice President, Business Development, the Controller, the Manager, Regulatory Compliance and Quality Assurance, and the Manager, Health, Safety, and Environment for various functions as described in this license. These individuals report directly to the President, Sequoyah Fuels Corporation.

B. The Senior Vice President (Mr. James H. Mestepey) shall be responsible for all nuclear manufacturing activities, which includes operations, maintenance, engineering, and the process laboratory. He specifically oversees the operations, modifications, and process and equipment criteria. He shall be responsible for safe and efficient plant operations. He reviews all operating procedures, plant modifications and processes.

equipment criteria and other general and administrative matters. Mr. Mestepey reports to the President, SFC. (The organization chart shows that Mr. Mestepey is also responsible for the Training Department.)

C. The Manager, Regulatory Compliance and Quality Assurance (Mr. Lee R. Lacey), who reports to the President, SFC, is responsible for the development and implementation of a Facility Quality Assurance Plan to assure that all operations and safety-related activities are performed in accordance with facility procedures. He is also responsible for maintaining the company's NRC licenses and preparing correspondence and reports submitted to the NRC. He advises management on nuclear regulatory issues and provides regulatory compliance oversight in environmental compliance and other regulatory areas. (In September 1990, Mr. Lacey was promoted to Vice President, Regulatory Affairs, and now has additional responsibilities which include oversight of the health and safety programs, the environmental compliance [protection] programs, and the environmental laboratory.)

D. The Manager, Health, Safety, and Environment (formerly Mr. Michael M. Nichols, who resigned on April 19, 1991), who reports to the President, SFC, shall be responsible for developing and implementing programs, procedures and guidance in the functional areas of health physics, industrial hygiene, industrial safety, physical security, and environmental analyses. He shall be responsible for the effluent monitoring program, the respiratory protection program, the bioassay program, the health and safety program, the environmental laboratory, and the program for surveillance of all plant activities related to these areas.

E. The Manager, Environmental (Ms. Carolyn L. Couch), who reports to the Manager, Health, Safety and Environment, shall be responsible for developing and implementing programs and procedures to comply with all environmental monitoring requirements required by federal and state agencies. This includes the maintenance of environmental records required by SFC and by regulatory agencies.

Another key individual involved with the solvent extraction tank excavation, but whose position is not described in the license, is the Health Physics Supervisor/Assistant Radiation Safety Officer (Mr. Kenneth G. Simeroth). He reports to the Manager, Health, Safety, and Environment. During the August 1990 SX excavation activities his prime responsibility was oversight of the SX excavation for Health & Safety (H&S) Department. All of the H&S technicians reported to him at the time. After September 1990 he was assigned special programs in the H&S department, and was no longer responsible for oversight of H&S technicians.

Since August 1990, several events have occurred that demonstrate a failure on the part of key SFC managers to ensure that NRC requirements were met in their area of responsibility and indicate that a certain SFC manager failed to provide complete and accurate information to the NRC during an inspection and subsequent investigation. The first event involved the identification and reporting to the NRC on August 22, 1990, of uranium contaminated soil and water during excavation work near the solvent extraction building from approximately August 1 through August 29, 1990. An Augmented Inspection Team (AIT) conducted an onsite review of the event from August 27-29, 1990. The AIT found that concerns involving uranium contaminated water in the excavation pit were expressed by the Manager, Environmental to the Senior Vice President as early

as August 7, 1990. The AIT also found that responsible personnel did not become aware of the actual elevated sample results until August 17, 1990. Another five days elapsed before this information was communicated to the NRC. Test results for several water samples taken prior to August 8, 1990, that showed elevated levels of uranium, had apparently been lost during this time period. The Licensee was unable to determine the reason for the loss of the sample results. The AIT concluded that the Licensee's staff did not demonstrate the necessary sensitivity to the potential for uranium contamination, or understand the urgency and potential significance of such a problem. A formal investigation was initiated by the NRC on September 4, 1990, to determine whether willful violations of NRC regulations occurred.

As a result of the AIT's findings, in a letter dated August 30, 1990, the Licensee committed to: (1) assure the integrity of the solvent extraction building floor, (2) characterize the quantity and location of licensed material under the solvent extraction building, (3) identify potential migration pathways, and (4) control contaminated soil and water from the excavation. These commitments were reviewed by an AIT follow-up inspection from September 10-13, 1990. That inspection determined that the Licensee's actions taken to satisfy those commitments were appropriate. Therefore, on September 13, 1990, the NRC verbally concurred on the restart of the solvent extraction process, and documented this concurrence in a letter dated September 14, 1990. The AIT followup inspection also found that no evaluations were performed to assess the potential for worker exposure prior to workers entering the excavation, and that the radiological surveys performed were inadequate to meet 10 CFR 20.201(b) requirements. These findings, however, had no significant impact on the safe operation of the facility and were evaluated for appropriate enforcement action when the AIT followup inspection report was issued.

The second event concerned the licensee's identification and reporting of uranium contaminated water beneath the main process building (MPB) on September 14, 1990, a few hours after restart activities began. Information pertaining to the contamination under the MPB had been known to the Licensee since the 1970's. This information was of concern to the NRC because it indicated that there could be extensive contamination under the MPB. Due to the location of the MPB and lack of monitoring wells around the MPB, licensed material could have migrated into the unrestricted area and contaminated ground-water. Because the NRC did not believe the Licensee exhibited a sense of urgency for this potentially larger problem, an Order Modifying License was issued on September 19, 1990. The September 19, 1990 Order required SFC to characterize the site, take actions to prevent further releases of contaminated water, and conduct appropriate monitoring of ground water. Additional inspection coverage was instituted to verify the activities performed by the Licensee in response to the Order.

By early November 1990, those followup NRC inspections progressed to the point where the NRC was concerned that certain aspects of the SFC Safety and Environmental Programs were not being performed in full accord with NRC requirements. Consequently, a Demand for Information was issued on November 5, 1990, to have the Licensee describe (1) an oversight program it was willing to put into place while management deficiencies and weaknesses in the permanent organization were being remedied, and (2) plans for an independent written appraisal of site and corporate programs and activities, that would develop recommendations for improvements in management controls and oversight to provide assurance that personnel would comply with regulatory requirements and site procedures. The Licensee responded to the Demand in a letter dated November 20, 1990.

SFC contracted with a consulting company to perform the independent assessment of SFC's management, in accordance with the Demand, and the assessment was transmitted to the NRC via a letter dated May 15, 1991. SFC responded to the management assessment on July 15, 1991. In its response SFC stated that "the assessment gave the facility a positive bill of health in many respects, provided numerous valuable insights into our operation, and contained many useful recommendations for continual improvements." In many of the responses to the recommendations, SFC did not provide an analysis of the recommendations, but merely quoted the assessment. Additionally, neither the independent assessment nor SFC's response included a discussion and analysis of the causes of the deficiencies referenced in the Demand. SFC has agreed to implement most of the recommendations contained in the assessment over the next 18 months. In the meantime, the NRC is concerned that there continues to be observed deficiencies and weaknesses in the licensee's safety program.

NRC investigation activities concluded on June 28, 1991. The investigation concluded that certain Licensee managers failed to provide complete and accurate information to the NRC, willfully failed to comply with NRC regulations, and made false statements during NRC inspection and investigation activities.

III

As a result of a series of events at the Sequoyah facility, a number of violations and weaknesses were identified that indicate a significant management breakdown has occurred. Beginning with the August 1990 SX excavation, it became evident that significant communication weaknesses existed within the SFC organization, key licensee managers did not fully understand licensed responsibilities, and a complete failure occurred on the part of the Health & Safety

organization to assure that adequate radiological controls were implemented. NRC investigation activities related to the SX event identified a number of willful violations of NRC requirements. Increased NRC inspection efforts have identified indications that the Licensee continues to experience problems with control over activities involving licensed materials.

A. SX Excavation Activities

To comply with EPA regulations for underground storage tanks, the Licensee planned to excavate two underground tanks adjacent to the solvent extraction (SX) building during the August 1990 annual plant shutdown, and encase them in a concrete vault. One of the tanks contained licensed material (uranium bearing solvent) and was identified by the Licensee as being under NRC jurisdiction. Messers. Mestepey and Lacey and Ms. Couch stated that prior to the August 1990 annual plant shutdown, the possibility of encountering uranium contamination around the tank excavation was discussed in staff and other Operational Departmental meetings. A number of plant supervisors and managers interviewed stated that the reason that they believed that contamination could be present was due to past process fluid seepage through the SX building floor prior to its 1983/1984 repair. On August 1, 1990, the Licensee began excavating soil around the two underground tanks.

The Hazardous Work Permit (HWP) covering the excavation required the assignment of Health & Safety (H&S) technicians to provide extensive hexane monitoring due to the explosive potential of the vapors trapped in the ground. However, the HWP did not specify any contamination control measures for the workers or require that radiation surveys be made; and no provisions existed to modify the HWP to account for new or changing radiological conditions at the worksite.

During the week of August 1-6, 1990, Licensee personnel observed surface rocks coated with uranium. Mr. Nichols stated that he was notified of this condition by Ms. Couch and had operations personnel gather the material. A followup interview with Mr. Lacey, then the Manager of Regulatory Compliance & Quality Assurance, indicated that Ms. Couch had also notified him of the yellow rock discovery between August 1-4, 1990, but he failed to follow facility operating procedure HS-010, paragraph 4.7, "Visual Detection of Uranium", and forward a contamination report to the Health & Safety office.

Ms. Couch, Manager, Environmental, testified that her sole responsibility for the SX excavation project was the collection of two soil samples in conjunction with the EPA underground storage tank enclosure regulations. The samples were only required to be analyzed for total petroleum hydrocarbon (TPH) content. Those soil samples were obtained on August 7, 1990, and submitted to a laboratory for TPH analysis. Ms. Couch also obtained additional soil samples, however; no request for a uranium analysis was made for any of the soil samples until August 22-23, 1990.

Liquid samples were taken from the excavation site on August 1, 4, 6 and 7, 1990. The August 1 sample, obtained by an engineer, indicated 0.02 grams uranium/liter (g-U/l) and was known to the Licensee on August 2, 1990. Ms. Couch had liquid samples taken on August 4, 6 and 7, 1990. She testified that Mr. Nichols had not directed her to obtain the samples; but that she had done so out of curiosity. An additional liquid sample was taken on August 7 by Mr. Barrett, the SFC Safety Engineer. Mr. Knoke, the Facility Laboratory Manager, told NRC investigators that on August 7, he reviewed the August 6 sample results which indicated about 3 g-U/l, and brought it to the attention of several individuals, including Mr. Lacey,

who was responsible for regulatory compliance. In a subsequent interview, Mr. Lacey stated that he did not recall Mr. Knoke discussing this item with him. In addition, Mr. Nichols, who was responsible for health and safety, claims that he was not aware of the results of the August 4-7 liquid sampling until about August 22, 1990. Throughout the project, no liquid samples were required to be taken by the Health & Safety group to evaluate the potential hazards to workers from licensed material (uranium).

It was the Licensee's practice to have the Operations Department obtain all liquid samples and H&S obtain all air samples for laboratory analyses. However, no plant procedure existed that required the Operations Department to forward the results of the liquid sample analysis to the H&S Department. After H&S had sampled the air (alpha monitoring) around the excavation site on August 3 and 4, 1990, no further radiological evaluations of the potential worker exposure occurred until August 22, 1990, even though workers continued to move dirt or work in the excavation throughout that time.

The SX excavation job was the critical project scheduled for completion during the 1990 annual plant shutdown. As a consequence, key management and supervisory personnel, including Mr. Mestepey, often visited the site. The H&S supervisor, Mr. Simeroth, stated that he was frequently present at the excavation, and that his immediate supervisor, Mr. Nichols, the Manager of Health, Safety, and Environment, was also at the excavation on an almost daily frequency. Mr. Lacey stated that he occasionally visited the work site and saw water in the excavation during the week of August 6, 1990.

Messers. Mestepey and Simeroth and Ms. Couch accompanied two NRC inspectors on a general facility tour that included the excavation site on August 6,

1990. During this tour an NRC inspector received no reply when he casually asked what was "in the water" in the excavation around the underground tanks. In subsequent testimony, Mr. Mestepey stated that he had not heard the question. However, both Ms. Couch and Mr. Simeroth stated that they had heard the question. Ms. Couch first stated in a September 4, 1990 interview that she did not respond to the inspector's question because she did not feel it was her responsibility since Mr. Mestepey was present, and she felt that she would be chastised for speaking up. However, she later testified on March 1, 1991, that Mr. Mestepey was not in the immediate group when the question was asked, and that she gave a flippant reply to the inspector because in her view it was not a serious question and if the inspector really wanted an answer, it would be addressed formally. She also testified that she did not answer the question because Mr. Mestepey was at the entrance meeting and was well aware of the contamination in the pit and the question was not addressed specifically to her. Mr. Simeroth stated that he did not respond because he felt it was Ms. Couch's responsibility. He also stated that after the tour he discussed the question with Ms. Couch, they both agreed it had not been answered, and Ms. Couch said she was waiting to see if the inspector would pursue it. Further NRC investigation revealed that Ms. Couch met later with Mr. Lacey to discuss the inspector's question. However, neither contacted the inspector to provide a response during the course of the inspection.

Mr. Mestepey stated in an interview that the presence of yellow water as a "rule of thumb" indicates 1 gram per liter (g/l) of uranium contamination. Other Licensee personnel, including Messers. Lacey and Nichols and Ms. Couch, acknowledged that yellow water at the site was considered contaminated. Although Mr. Nichols testified that he did not see any

"yellow water" during his almost daily site visits until August 22, 1990, all of the contractor and other Licensee personnel interviewed (including the H&S supervisor, Mr. Simeroth, who claims to have discussed the matter with Mr. Nichols during the first week) indicated they observed the presence of yellow water by approximately August 4, 1990. Mr. Lacey testified that he had been at the excavation site several times during the first week and had seen standing water in the pit.

Both SFC and contractor employees involved in this project worked in close proximity to this contaminated liquid, coming into contact with it on numerous occasions. After the August 1, 1990 sample, taken during the first day of the excavation, the next analysis results (for the August 4 sample, at 2.06 g/l) were available in the laboratory on August 7. On that same day, one day after the NRC inspector's question went unanswered, Ms. Couch observed a black liquid (potential hydrocarbons that are not releasable) in the pit and ordered the workers out. She also ordered that the liquid be drummed. Work in the pit was resumed later that day.

In addition to the expected ground water seepage, significant amounts of water entered the excavation due to the heavy rainfall of August 11 and 12, 1990. On August 13, 1990, at the direction of Mr. Mestepey, about 3,000 gallons of accumulated water were pumped from the excavation to the north ditch. This water was pumped onto the ground and allowed to follow the natural terrain, contaminating the ground along the way. The north ditch feeds the facility's combination stream, which is the normal monitored plant effluent path. The next day, SFC resumed pumping water into barrels.

The results of the August 6 and 7 samples requested by Ms. Couch ranged from 0.02 to 8.2 g-U/l. The result of the August 7 sample taken by

Mr. Barrett, available that same day, was not expressed as g-U/l, but as a percentage (1% uranium). However, no action was taken to evaluate the potential radiological hazards until the results were sent to the UF6 Area Manager (Acting Manager, Operations) on August 17, 1990. Even then, the results were not forwarded to the H&S group until about August 22, 1990. Ms. Couch told various inspectors in the Augmented Inspection Team (AIT) during the week of August 27, 1990, that she had seen an August 4, 1990 laboratory analysis showing 2.06 g/l uranium and had informed Mr. Mestepey of the contamination in the pit. During interviews with NRC investigators on September 3 and 4, 1990, Ms. Couch stated that on August 7, 1990, she had taken two soil samples from around the tanks, and showed them to Messrs. Nichols, Lacey, and Mestepey because the samples appeared contaminated (yellow). In discussions with Mr. Mestepey on that day, she indicated that the material on the excavation wall made it obvious that the water was contaminated. However, she made no mention to the NRC inspectors of reviewing laboratory analysis of the liquid samples taken on August 6 and 7, 1990.

During a followup interview on September 5, 1990, and in sworn testimony on September 12, 1990, Ms. Couch stated that she had no specific knowledge of the uranium contamination levels in the SX excavation water during her August 7 discussion with Mr. Mestepey. She further stated that she was not aware of the sample concentrations until August 22, 1990. During a subsequent sworn interview on March 1, 1991, Ms. Couch stated she might have seen the August 4, 1990, laboratory report.

However, during a subsequent OI telephone interview on March 19, 1991, (with SFC's attorney present) Ms. Couch then admitted that on August 7 or 8, 1990, she had seen an August 7, 1990, laboratory report (for the

sample taken by Mr. Barrett) which indicated the presence of uranium contamination in SX excavation liquids. Because the uranium level was expressed in percentages, Ms. Couch claimed this laboratory report was meaningless to her, and later admitted she never asked anyone what this percentage would equate to in g-U/l. Ms. Couch said that even though she received this laboratory report shortly after the NRC inspector asked his August 6, 1990, question, she did not inform the NRC inspectors of this result because she thought the inspector's question was informal. She also stated that she had a copy of the August 7 laboratory analysis taken by Mr. Barrett with her during the March 1 and 19, 1991, OI interviews, but forgot to bring it to the investigator's attention.

NRC investigative inquiries revealed that several contractor employees working in the SX excavation site did not receive the instructions required by 10 CFR Part 19. The training that five contractor employees who worked in the excavation received consisted of only viewing a short visitor orientation video that appeared to be designed for visitors who were to tour the facility or possibly work in areas that did not involve exposure to hazardous materials. It did not provide adequate instructions about potential hazards and potential health effects from exposure to licensed materials in the excavation pit. The NRC interviewed about 13 of the contractor employees. Most of the contract workers interviewed stated that they did not know that uranium was present in the SX excavation where they were working. One individual indicated that he asked a H&S technician what was in the liquid and was told that it contained a very small amount of uranium that was not harmful. These contract workers informed the NRC, as verified by other SFC employees, that liquids from the excavation were routinely in contact with their skin, that these liquids burned their skin for a short period of

time (burning sensation would not be due to uranium), and that they complained to various SFC individuals. One individual stated that he was sprayed in the face with contaminated liquid while pumping liquid out of the pit on August 4, 1990. They further stated that they obtained some boots and rubber gloves only through their own initiative. The excavation site was roped off for industrial safety purposes, but not posted as a radiation or contaminated area.

The air samples taken on August 3 and 4, 1990, were not adequate to detect worker exposure to airborne contamination from August 6-22, 1990 because of changing conditions in the pit. Further, the Licensee failed to evaluate the need to obtain bioassay samples from contract workers (see NRC Inspection Reports 40-3027/90-05 and 90-06, dated November 20, 1990 and February 21, 1991). Although bioassay samples were obtained for some SFC personnel, NRC interviews of SFC employees indicated that none of them had experienced working conditions similar to the contractors who had been assigned to work in the SX excavation (uranium-contaminated liquids potentially in contact with the skin for several hours per day, for two to four weeks). SFC failed to evaluate the need for bioassays and as a consequence the contractors did not submit urine samples between August 1 and 22, 1990, and many did not submit any urine samples.

NRC investigation and inspections found that SFC Health & Safety employees failed to conduct adequate radioactive contamination surveys of articles leaving the facility. The surveys conducted were deficient in that the licensee monitored only for alpha activity, and not for beta/gamma. Although SFC maintained that no equipment went off-site that exceeded permissible release limits, on November 15, 1990, the NRC found articles

that had been contaminated to approximately ten times the SFC license limit in the cab of a truck parked at the residence of one of the contractor employees. The following day the Licensee surveyed the truck and other items at the employee's residence. However, the Licensee's survey instrument was not sensitive enough to identify all contamination above the release limits of the license (see NRC Inspection Report 40-8027/90-06).

SFC asserted that the contaminated equipment discovered under the seat of the truck was in a location not ordinarily surveyed and that the responsibility for the equipment going off-site rested with the contractor, not with the Licensee. The NRC, however, holds its licensees, not contractors, responsible for ensuring that adequate release surveys are performed. The failure of SFC's managers to understand this fundamental principle resulted in contaminated articles being removed from the site by its contractor employees.

Testimony from Messers. Mestepey, Lacey, and Nichols established that Licensee management was aware of the elevated uranium concentrations on August 17, 1990. However, the Licensee did not inform NRC Region IV by telephone of its discovery until August 22, 1990. This report was not made within 24 hours, as required by 10 CFR 20.403(b). In its November 20, 1990 response to NRC's November 5, 1990 Demand for Information, the Licensee asserted that "A release of radioactive material did not occur; the water was in an excavation, well within the restricted area boundary." Notwithstanding the Licensee's rationale, the NRC has determined that the discovery of the elevated uranium concentrations in the SX excavation constituted a reportable event because it was apparent even then that it might have

caused or threatened to cause property damage in excess of $2,000. Specifically, the cost of decontamination activities (characterization and remediation) to address contamination related to the SX excavation clearly exceeded $2,000. In its May 1, 1990, response to a similar reporting violation that occurred in March 1990, SFC had stated "SFC now has a much better understanding of NRC notification requirements and recognizes that conservative standards are to be applied in determining whether an event should be reported." Although Mr. Mestepey was present at the enforcement conference where the violation was discussed, he failed to assure that the SX excavation event was promptly reported. (see NRC Inspection Report 40-8027/90-05).

Additionally, none of SFC's managers took actions to stop work in the excavation once the contamination levels were known, and work was allowed to progress to the extent of placing the concrete floor in the vault over contaminated soil even after the issue was reported to the NRC (see NRC Inspection Report 40-8027/90-04 dated October , 1990).

In response to NRC concerns during the AIT inspection of August 27-29, 1990 (see NRC Inspection Report 40-8027/90-04), SFC drilled five boreholes with an air auger to determine if contamination had spread through the ground away from the SX building. However, it was not until February 1991, that an NRC inspector identified that SFC had existing "SX sandwells" in utility trench sand backfill zones that essentially already provided this information. SFC personnel had sampled these "sandwells" since the late 1970s and the data clearly indicate that uranium contamination had migrated away from the SX building.

Information about the existence of the pre-1990 "sandwells" was sent to Mr. Lacey on August 30, 1990, by memorandum from the Manager, Process Laboratory in response to an internal SFC investigation of the SX excavation issues. Mr. Lacey in turn sent the information to Ms. Couch. However, neither Mr. Lacey nor Ms. Couch informed NRC inspectors of the existence of this data. In fact, NRC identified this information in February 1991 only through its inspection efforts. At no time did SFC personnel advise the NRC of this relevant data that clearly demonstrated the migration of licensed materials away from the SX building over an extended period of time. Furthermore, information about the SX sandwells was not in SFC's decommissioning file (required by 10 CFR 40.36(f)).

B. Notification of Contamination Under the Main Process Building (MPB)

After the AIT was initiated, SFC agreed to perform several tasks prior to the restart of the facility (reference the letter from Reau Graves, former President of SFC to Robert Martin, Regional Administrator, NRC Region IV, dated August 30, 1990). An AIT Followup Inspection occurred on September 10-13, 1990, and NRC verbally concurred on restart of the Sequoyah facility on September 13, 1990. A few hours after restart on September 14, 1990, SFC informed NRC about a "well" in the denitration area that penetrated the floor of the MPB to the ground beneath it. Since the mid-1970s, SFC operators had routinely pumped uranium-contaminated liquids from under the MPB using this well (see NRC Inspection Reports 40-8927/90-05, 90-06, and 90-07 dated November 20, 1990, February 21 and March 1, 1991, respectively).

NRC investigation determined that Mr. Lacey was informed about the "well" (later called the "subfloor process monitor") by a former SFC manager on or about August 31, 1990. Mr. Lacey subsequently discussed this information with Mr. Mestepey sometime during the week of September 3, 1990. The presence of liquids under the MPB indicated the potential for floor degradation and significant contamination, which were similar to the NRC's concerns regarding the SX event. However, Mr. Lacey neither requested that a sample of the liquid be taken and analyzed, nor that further investigation of the issue be undertaken until September 14, 1990, just prior to informing NRC after the restart of the facility. After the notification, SFC managers did not promptly evaluate the contamination problem.

Since the Licensee could not assure the NRC that all migration pathways to the unrestricted area were known or that the ground water had not been contaminated, the NRC issued an Order Modifying License (Order) on September 19, 1990 (see the letter dated September 20, 1990, from James M. Taylor of NRC to Reau Graves of SFC and attached Order dated September 19, 1990), to require a plan that would quantify and locate the contamination under the MPB.

C. NRC Demand For Information and Related Activities

In response to concerns resulting from the identification of contamination in, around, and under the SX building and the MPB, SFC implemented an Interim Compliance Oversight Team. This action was taken as a result of NRC concerns involving the SX excavation issues. NRC issued a Demand For Information (Demand) (letter from Hugh L. Thompson, Jr., of NRC to Reau Graves, of SFC dated November 5, 1990) which requested, among

other things, that SFC describe an oversight program it was willing to put into place while management deficiencies and weaknesses in the permanent organization were remedied. The Demand also requested SFC to submit a plan for an independent appraisal of site and corporate organizations and activities that would develop recommendations for improvements in management controls and oversight.

SFC responded to the Demand on November 20, 1990 and agreed to set up a Sequoyah Oversight Team (SOT) to provide NRC additional assurance that NRC's regulations would be satisfied during operations of the Sequoyah facility. Secondly, SFC agreed to provide an impartial comprehensive management assessment and proposed the details for its implementation.

In that response, SFC made several statements that were subsequently found by the NRC to be inaccurate or misleading. This is significant because it demonstrates that as of November 20, 1990, SFC still did not understand the extent of its problems. Examples of such statements and related problems are as follows:

"Significant steps were taken to prevent any kind of problem that could have resulted from elevated levels of uranium..."

A. "Discolored water was tested immediately on August 4... ordered the water to be drummed;"

This part of the Licensee's assertion is misleading because the water sample was not obtained as part of any pre-planned requirement by the Health & Safety Department, but rather due to Ms. Couch's curiosity.

Additionally, 3,000 gallons that accumulated in the pit were not drummed, but pumped directly on the ground on August 13, 1990.

B. "Health & Safety technicians took air samples on August 3 and 4, which did not show any unusual level of contamination;"

This assertion is misleading because a significant amount of work occurred from August 4-22, 1990. Additionally, air sampling is not an adequate method for identifying and quantifying liquid contamination.

C. "Many soil samples were taken;"

This statement is misleading in that the Licensee did not require any soil samples to be taken for uranium analysis. Ms. Couch was only required to take two soil samples for TPH analysis to meet EPA requirements. Other soil samples that she obtained (not required) were not analyzed for uranium until August 23, 1990.

D. "Although special urinanalysis of the contract workers began on August 22, routine urine samples were taken from Sequoyah personnel working in the excavation prior to August 22;"

This assertion is misleading because most of the contractors were finished with their work at SFC by August 22, 1990, and had been discharged. Additionally, the working conditions differed significantly between SFC and contractor personnel, as the contractors actually came into contact with the contaminated liquid.

IV

NRC inspection efforts have identified numerous weaknesses and violations of NRC requirements since the August 1990 SX contamination event in SFC's Health & Safety and Environmental Protection Programs. In total, NRC concludes that these weaknesses and deficiencies indicate a significant failure of the management control program at the Sequoyah facility.

A. Overflow of the Solvent Rework Centrifuge

On September 15 and 16, 1990, an NRC inspector observed operations personnel draining process liquids on the floor of the SX building (see NRC Inspection Report 40-8027/90-05). These activities were contrary to statements that SFC managers, including Messers. Graves, Lacey and Mestepey, had made to NRC that the floor of the SX building would no longer be used as part of the process operation. Under a previous owner, this type of operational activity apparently contributed to the degradation of the SX floor in the early 1980s.

An NRC inspection conducted in February 1991 (see NRC Inspection Report 40-8027/91-03 dated April 29, 1991) described an event where operations personnel were unaware of a SFC internal requirement to clean the solvent rework centrifuge every 24 hours. The operations personnel apparently cleaned the centrifuge "when needed." Because the requirement to clean the solvent rework centrifuge every 24 hours was not adhered to, process solutions overflowed onto the floor. This event was noteworthy given SFC's commitments to improve contamination controls.

B. Depleted Uranium Tetrafluoride (DUF4) Facility Contamination Event

On June 5, 1991, NRC inspectors observed workers who were visibly contaminated and were not adhering to procedural requirements or appropriate health physics practices, while changing filters in the Depleted Uranium Tetrafluoride (DUF4) facility (See NRC Inspection Report 40-8027/91-10 dated July 22, 1991). The most significant problems identified were:

(1) Responsible Licensee personnel failed to adequately review the planned work activity to develop a Hazardous Work Permit appropriate for the control of the task.

(2) The workers' lapel air sampler failed to function properly.

(3) Appropriate protective clothing was not worn, resulting in head, neck, abdomen, thigh, hand, and other skin contamination.

(4) The plastic "tent" erected for the job was not posted as either an airborne or contamination area.

(5) No step-off pad was used to prevent the spread of contamination (as a result, the area outside the tent was also visibly contaminated where the workers had walked with contaminated boots).

(6) One of the workers exited the tent, removed his respiratory protection and then re-entered the tent without it.

(7) No provisions were made to change out of contaminated clothing at the job site (to change or shower, the workers would have had to walk over 100 yards to the Main Process Building).

(8) No health physics coverage was provided for a maintenance activity involving a system that had not been previously opened.

These problems were particularly significant because they demonstrated that the corrective actions undertaken by the Licensee to strengthen its Health and Safety Program since the SX event were not yet effective.

C. Radiation Safety Program

The following items, some of which have been discussed above, demonstrate a significant failure in SFC's radiation safety program.

- An NRC inspector observed on September 16, 1990, operators draining process solutions onto the floor in the SX building to the point that liquids overflowed the sump and dispersed on the floor (see NRC Inspection Report 40-8027/90-05). Interviews with Licensee personnel indicated that the floors were made, and used, as a method of secondary containment of process fluids. This occurred despite a previous Licensee commitment to minimize contaminated solutions on the floor.

- NRC investigation identified that the Licensee had no mechanism to identify visitors who were minors in order to take the extra precautions required by NRC regulations to limit their exposures. In fact, NRC investigation revealed that one minor worked in the SX excavation.

- On October 23, 1990, a shift supervisor, in the presence of an NRC inspector, wiped the bottom of a valve with his bare hand, while looking for leaks of potentially contaminated liquids in the SX building (see NRC Inspection Report 40-8027/90-06).

- On November 23, 1990, an NRC inspector observed an operator not wearing respiratory protection (as required by procedures) when manually unclogging a conveyor that transported yellowcake (see NRC Inspection Report 40-8027/90-06).

- On December 1, 1990, an NRC inspector found that an SFC shift supervisor turned off a malfunctioning frisker, but did not inform the responsible H&S personnel. Later two female employees did not

frisk themselves prior to exiting the change room, because the frisker was turned off (see NRC Inspection Report 40-8027/90-06).

- NRC inspectors found an ash receiver area high radiation area door left unlocked and unattended in January 1991. This problem has reoccurred on three separate occasions within a 3-month period (see NRC Inspection Reports 40-8027/90-06, 91-01 and 91-02).

- On February 15, 1991, NRC inspectors observed poor contamination control practices during an ash receiver change-out, when the activity resulted in visible contamination in a hallway. No attempts were made to limit access to the area to control highly contaminated equipment. Ash receivers were changed out at least two to three times per day, and appropriate contamination controls had never been instituted (see NRC Inspection Report 40-8027/91-02). In May 1991, an inspector identified that SFC provided no training, guidance, or procedures that describe to workers how to undress from highly contaminated protective clothing in a manner so as to prevent skin contamination. As a result, the hands of two workers were contaminated during removal of highly contaminated protective clothing, after changing out ash receivers (see NRC Inspection Report 40-8027/91-09).

- During the week of May 6, 1991, an NRC inspector observed poor contamination controls when a highly contaminated cart outside the ash receiver area was not attended or controlled (see NRC Inspection Report 40-8027/91-08).

- On May 16, 1991, an NRC inspector observed a worker outdoors near the clarifiers (in the restricted area) dressed in protective clothing and a full face respirator sawing on PVC pipes on the ground. Although SFC's H&S staff took action to protect the worker from potential contamination by requiring the use of a respirator, they failed to adequately consider the potential for this activity to contaminate the ground adjacent to the work area (see NRC Inspection Report 40-8027/91-09).

- SFC's license requires only surveying for alpha contamination inside the restricted area; however, the Licensee identified a problem with beta contamination in the spring of 1990, and informed NRC that the problem would be evaluated (see NRC Inspection Report 40-8027/90-03). In November 1990, SFC again committed to evaluating the issue after NRC found contaminated materials at a private residence off-site (see NRC Inspection Report 40-8027/90-06). However, by May 1991 the Licensee still had no limits for beta contamination inside the restricted area, approximately one year after the problem was first identified (see NRC Inspection Report 40-8027/91-09).

- In June 1991, NRC inspectors identified that SFC has failed to survey laundered protective clothing, as required by procedure, for over a year. This failure is potentially significant in that workers continually overloaded the washers with protective clothing which provided the potential for inadequate decontamination. SFC identified that potential in March 1991, yet took no corrective actions to assure that laundered protective clothing was suitably free of contamination until NRC inspectors identified this same problem (see NRC Inspection Report 40-8027/91-10).

- Health and Safety technicians receive little to no formal health physics training, with most having only on-the-job experience. H&S technicians frequently depended on operations and maintenance personnel to establish the protection requirements described in a hazardous work permit (see NRC Inspection Reports 40-8027/90-04 and 91-10). This is contrary to the intent of a hazardous work permit which is to independently establish worker protection requirements appropriate to a specific hazardous task.

D. Environmental Protection Program

The NRC was aware that some ground contamination existed at the Sequoyah facility, as documented in NUREG 1157 "Environmental Assessment for Renewal of Special Nuclear Material License No. SUB-1010" dated August 1985, and NRC Inspection Report 40-8027/88-03. However, the NRC was unaware of the magnitude or the extent of the contamination. NRC investigation and inspections found that SFC had many indications of the magnitude of the ground contamination, and found that SFC had a number of weaknesses in its environmental protection program. The following six items demonstrate these failures and weaknesses:

- As discussed in Section III of this Order, NRC's investigation and inspections determined that SFC had monitored and analyzed the water from "sandwells" in the vicinity of the SX building. This data indicated contamination levels below the ground surface of the restricted area that averaged about 100 times above SFC's environmental action level for unrestricted areas and at least 20,000 times above background. However, prior to August 1990, the Licensee had taken no action to evaluate the extent of this contamination, develop remedial actions, or identify the areas in their decommissioning file. The sandwells provided the Licensee with data that indicated that SFC's environmental action level had been exceeded by as much as four orders of magnitude. Nevertheless, the Licensee discontinued the sampling of the sandwells in June 1989.

- The SX sandwells, which monitored utility trench sand backfill zones, provided SFC with data for several years which indicated that these zones were potential migration pathways for licensed material. As a result of the failure to investigate available data, SFC managers Couch, Lacey, Nichols, and Simeroth were unaware that licensed materials below the ground surface had migrated to the unrestricted area although still within the owner-controlled area.

- Operators often discharged process solutions to the north ditch, relying on dilution in the combination stream to assure release limits were satisfied. Intentional dilution, without any attempt to treat contaminated water, is a poor practice to limit releases to levels as low as reasonably achievable (see NRC Inspection Report 40-8027/90-07).

- As discussed in Section III of this Order, operators routinely recovered contaminated process liquids from under the main process building through the "subfloor process monitor" since the mid-1970s and Licensee personnel had never attempted to characterize the contamination under the building. Mr. Mestepey stated that he had been aware of this activity since about 1988, yet did not question the activity.

- The current characterization of the site has identified concentrations of uranium in the Sewage Lagoon as high as 16 g-U/l. These high values are apparently the result of discharges from the laundry. Uranium has been identified to a depth of about 40 ft in some monitoring wells inside the restricted area.

- Outside the restricted area fence but still inside the Licensee's property, uranium has been found in at least four locations. Uranium has also been found in the streambed of one formerly used outfall, outside SFC's property.

V

Based on the above, it appears that a number of significant deficiencies and weaknesses exist in the Licensee's Health & Safety and Environmental programs. These deficiencies include a failure on the part of Licensee management to fully understand and exercise their licensed responsibilities; poor communication within the SFC organization, particularly between the H&S and operations (production) staff; numerous inadequacies with regard to Licensee procedures and failures on the part of SFC employees to comply with SFC procedural requirements and health and safety practices; deficiencies in training and instruction of SFC personnel working in restricted areas; and serious weaknesses in the Licensee's contamination control practices, including failures to exercise basic controls to prevent contamination to the environment and to adequately evaluate contamination. The foregoing deficiencies in the Licensee's Health & Safety and Environmental Programs are significant and adversely impact health and safety.

In addition, the Licensee's Manager, Environmental, Carolyn L. Couch, intentionally provided false testimony to OI investigators. Specifically, notwithstanding

knowledge of the scope of the NRC investigation and the relevance of the liquid samples and analyses, and after informing the AIT that she first saw the August 4 analysis result of 2.06 g-U/l on August 7, 1990, and then discussed the contamination in the SX area with Mr. Mestepey, 1) on September 5, 1990, Ms. Couch stated to OI investigators that she was unaware of the exact yellow water sample concentrations of uranium until August 22, 1990, and 2) on September 12, 1990, she stated to OI investigators that she did not remember specifically looking at any laboratory results concerning the excavation prior to approximately August 20, 1990, 3) on March 1, 1991, she stated to OI investigators that she might have seen prior to August 20 a laboratory analysis of a water sample which she had taken on August 4 which indicated approximately 1 g/l of uranium, 4) she admitted to OI investigators on March 19, 1991, that she had received and seen on August 7 or 8 a laboratory analysis of a water sample taken on August 7 which indicated a 1-percent concentration of uranium, and 5) she failed to provide OI with a copy of the August 7, 1990 analysis until March 19, 1991 although OI had previously requested all laboratory results regarding the SX excavation. These communications indicate a pattern whereby Ms. Couch either provided false information or willfully withheld material information. Furthermore, Ms. Couch did not respond to an NRC inspector on August 6 when questioned about the contents of the water in the SX excavation pit, and did not subsequently ensure that the inspector received a response to his question.

Finally, Ms. Couch was aware that in the past, sampling had been undertaken of water in pipes embedded in the ground known as "sandwells" to determine whether there was uranium contamination. In fact, she had discussed with Mr. Nichols in 1989 the sandwell data and whether the collected data was of value to the Health & Safety and Environment Departments. In addition, Ms. Couch had received a copy of a memorandum from Mr. Lacey, dated August 30, 1990, which

assigned selected SFC personnel certain tasks in connection with an investigation of the issues surrounding the excavation, and had received a copy of a memorandum from the Licensee's Manager, Facility Laboratory, also dated August 30, 1990, sent in response to Mr. Lacey's memorandum, which noted the existence of the data collected from the sandwell sampling. However, Ms. Couch failed to inform the NRC of the existence of the sandwells and sandwell data.

The Commission must be able to rely on its licensees to provide complete and accurate information. Licensees' willful violations of Commission requirements and Licensees' false statements to Commission officials cannot and will not be tolerated. The problem of false statements and the willful withholding of information by Ms. Couch undermine the NRC's reasonable assurance that the licensee with Ms. Couch involved in licensed activities will comply with NRC requirements, including the requirement that information provided be complete and accurate in all material respects.

Based on the foregoing, I lack the requisite reasonable assurance that the Licensee's current operations can be conducted under License No. SUB 1010 in compliance with the Commission's requirements and that the health and safety of the public, including the Licensee's employees, and the environment will be protected. Therefore, the public health, safety, and interest require that License No. SUB 1010 be modified to prohibit Ms. Carolyn L. Couch from supervisory or managerial involvement in NRC-regulated activities for a specified period of time and to require the rectification of deficiencies in the Health & Safety and Environmental Programs. Furthermore, pursuant to 10 CFR 2.202, I find the public health, safety and interest require that this Order be immediately effective.

VI

Accordingly, pursuant to sections 161b, 161c, 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 2.204, and 10 CFR Parts 19, 20, and 40, IT IS HEREBY ORDERED, EFFECTIVE IMMEDIATELY, THAT LICENSE NO. SUB-1010 IS MODIFIED AS FOLLOWS:

A.1. Carolyn L. Couch shall be removed from supervisory or managerial responsibilities over NRC-regulated activities at the SFC facility for a period of one year from the date of this Order. Additionally, if Ms. Couch remains involved in NRC-regulated activities, she is not to be directed or supervised by any of the individuals named in the Demand for Information (see section VIII). For two years after that initial period, SFC shall not reassign her to supervisory or managerial functions of NRC-regulated activities without providing 30-day prior notice to the NRC.

A.2. Sequoyah Fuels shall provide the Director, Office of Enforcement, within 30 days of the date of this Order, in writing under oath or affirmation, information to demonstrate why License No. SUB-1010 should not be modified to prohibit Ms. Couch from serving in any capacity involving the performance of any NRC-regulated activities.

B. SFC shall not operate the Sequoyah facility to produce Uranium Hexafluoride (UF6) or Depleted Uranium Tetrafluoride (DUF4) following its upcoming shutdown (currently scheduled to begin on September 23, 1991) until SFC submits and obtains NRC approval of the plan and schedule to review the adequacy of the Health & Safety and Environmental Programs, and the qualifications of the individuals from outside SFC performing the review. The purpose

of the review is to assure that the procedures provide clear instructions, are current, and are technically adequate, such that the intent of the procedure will be met. The schedule is to indicate which procedures will be reviewed, revised (as necessary) and implemented prior to startup. The dates by which the remaining procecure reviews, revisions, and implementation will be completed as well as a basis for their deferral until after start-up shall be provided. The schedule shall provide for appropriate personnel training in the procedures prior to their implementing the procedures reviewed and, as appropriate, revised. Following the review, the procedures are to be revised as necessary, and thereafter implemented. As a minimum, that review shall address the following are:

1. Health & Safety

- Measures to keep internal and external exposures As Low As Reasonably Achievable (ALARA).

- Measures to ensure confinement of licensed materials. In cases where confinement systems failed, procedures shall require evaluation of the quantity of material released outside the confinement system, the root cause of the condition, and corrective actions to prevent recurrence.

- Use of appropriate protective clothing to prevent personnel contamination.

- Measures to ensure Hazardous Work Permits (HWP) provide clear guidance and instructions for personnel protection requirements

and define responsibilities, including the qualifications of the individuals permitted to issue, approve, and modify HWPs.

- Measures to ensure personnel dosimetry and internal dose assessment programs are supplied and implemented.

- Measures to ensure radiation, contamination, and airborne activity survey instruments and equipment are properly calibrated so accurate surveys can be performed, and that the survey instruments are appropriate for the type of radiation monitoring performed.

- Measures to ensure that a respiratory protection program is implemented so that respiratory protection equipment is used to minimize personnel exposure.

- Measures to ensure that all SFC and contractor personnel receive appropriate radiation protection and contamination control training.

- The responsibilities, qualifications and reporting requirements for H&S technicians and supervisors are clearly defined and these individuals receive appropriate indoctrination and training to implement their responsibilities.

2. Environmental Program

- Measures to maintain releases of licensed material to the restricted and unrestricted area As-Low-As-Reasonably-Achievable.

- Measures for sampling of ground water monitor wells, analysis of samples, and evaluating the adequacy of the ground water monitoring program.

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

VII

The Licensee, Ms. Couch, or any other person adversely affected by this Order may submit an answer to this Order or request a hearing on this Order within 30 days of the date of this Order. The answer shall set forth the matters of fact and law on which the Licensee, Ms. Couch , or any other person adversely affected relies and the reasons as to why the Order should not have been issued. Any answer filed within 30 days of the date of this order may include a request for a hearing. 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, D.C. 20555. Copies shall also be sent to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, to the Assistant General Counsel for Hearings and Enforcement at the same address, to the Regional Administrator, NRC Region IV, 611 Ryan Plaza Drive, Suite 400, Arlington, TX 76011, and to the Licensee if the answer or hearing request is by a person other than the Licensee.

If a person other than the Licensee or Ms. Couch requests a hearing, that person shall set forth with particularity the manner in which his interest is adversely affected by this Order and shall address the criteria set forth in 10 CFR 2.714(d).

If a hearing is requested by the Licensee, Ms. Couch, or any other 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 shall be sustained.

In the absence of any request for a hearing, the provisions specified in this Order shall be final 30 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.

VIII

In addition to issuance of this Order modifying License No. SUB-1010, the Commission requires further information from the Licensee in order to determine whether the Commission can have reasonable assurance that in the future the Licensee will conduct its activities in accordance with the Commission's requirements and the below-named managers will carry out the responsibilities and authorities assigned to their respective key position descriptions as outlined in the License.

Based on the above, it appears that key SFC management officials failed to carry out their responsibilities with regard to licensed activities and have not been candid with the NRC. Specifically:

A. The Senior Vice President, James Mestepey, is responsible for all nuclear manufacturing activities, including operations, maintenance, engineering, training, and the process laboratory, and reviews all operating procedures, plant modifications and processes, equipment criteria and other general and administrative matters.

During the SX excavation, Mr. Mestepey was the senior manager onsite, and was responsible for conducting the excavation and vault construction project. Mr. Mestepey acknowledged that he had a responsibility for the health and safety of the workers involved in completing the project.

Mr. Mestepey was apparently aware of the potential for and existence of contamination in the SX excavation from the onset of the excavation project. Mr. Mestepey had attended meetings prior to and during the excavation at which the potential for or existence of contamination had been discussed; had ofter been present at the excavation and observed yellow water in the pit; had informed NRC inspectors that SFC personnel, not contractors, would perform most of the work involving contaminated material; and was aware that such water was being barrelled and acknowledged that he had assumed that if the water was discolored and was being put into drums it was contaminated. Furthermore, on approximately August 8, 1990, Mr. Mestepey had seen a laboratory analysis of a sample taken on August 7, 1990, of the water in the excavation which showed uranium contamination of approximately 1 percent. As of August 20, Mr. Mestepey was aware of the existence of laboratory analyses of water samples taken from the excavation pit indicating levels of uranium of as high as 8 g/l.

Notwithstanding Mr. Mestepey's responsibility for the excavation project, his acknowledged responsibility to ensure the health and safety of the workers involved in the project, and his awareness that the water in the excavation pit contained some uranium contamination, Mr. Mestepey failed to take any action to notify his Health and Safety personnel of such contamination or to assure that workers were being adequately protected, and with at least careless disregard for regulatory requirements, failed

to instruct the workers as to the presence of uranium contamination in the excavation, in violation of 10 CFR 19.12.

Furthermore, on August 13, Mr. Mestepey made the decision to pump a large quantity of water to the north ditch, contaminating the ground. In addition, Mr. Mestepey failed to have SFC submit a report to the NRC within 24 hours of the discovery of elevated uranium levels in the excavation, in violation of 10 CFR 20.403(b)(4).

In addition, as fully described in Sections III and IV of this Order, the NRC investigation and inspections determined that there were serious deficiencies in the Licensee's radiation safety, environmental protection and operation safety programs. As Mr. Mestepey was responsible for such matters as operations, training, and review of operating procedures, it appears that Mr. Mestepey has failed to adequately exercise his responsibilities to ensure that these activities were in compliance with NRC and license requirements.

B. The Vice President, Regulatory Affairs, Lee R. Lacey, is responsible for the oversight of the Licensee's health and safety programs, the environmental protection program, the environmental laboratory, the quality assurance program and the licensing program. He is responsible for the implementation of the Facility Quality Assurance Plan to assure that all operations and safety related activities are performed in accordance with facility procedures. Mr. Lacey advises SFC management on nuclear regulatory issues and provides regulatory compliance oversight in environmental monitoring and other regulatory areas. He is also responsible for the timely, accurate, and comprehensive flow of information from the Licensee to the NRC. Mr. Lacey had formerly held the position of Manager, Health, Safety and Environment.

Mr. Lacey was apparently aware of the potential for and existence of contamination in the SX excavation from the onset of the excavation project. Mr. Lacey had attended meetings prior to and during the excavation at which the potential for and existence of contamination had been discussed, and had often been present at the excavation and observed yellow water in the pit, but failed to complete a "visual detection for uranium" form (HS-010).

Mr. Lacey also was aware that one of the tanks to be excavated was under NRC jurisdiction. Mr. Lacey had also observed solidified uranium on the surface of the ground in the excavation area. By August 17, 1990, Mr. Lacey was aware of the existence of laboratory analyses indicating levels of uranium in the water of the excavation pit as high as 8 g/l.

Notwithstanding his responsibility for the environmental protection and QA programs and his awareness that the water in the excavation pit contained uranium contamination, Mr. Lacey, with at least careless disregard, violated the provisions of 10 CFR 19.12 by failing to ensure that contractor personnel working in the SX excavation were provided with information regarding the contamination in the excavation and with radiological protection. In addition, notwithstanding Mr. Lacey's responsibility for interfacing with the NRC and providing the NRC with timely, accurate and comprehensive information, Mr. Lacey took no action to inform the NRC of the contamination in the excavation, or any matters associated with the excavation, until August 22, 1990. Although Mr. Lacey was aware that the NRC inspector had inquired as to the contents of the water in the excavation pit, Mr. Lacey took no action to ensure that the inspector was provided with a response. Although Mr. Lacey was aware by August 17 of the laboratory analyses showing elevated levels of uranium in the water in the excavation,

he failed to have SFC submit a report to the NRC within 24 hours of the discovery of these elevated uranium levels, in violation of 10 CFR 20.403(b)(4).

In addition, Mr. Lacey was aware that SFC was conducting an internal investigation regarding the SX excavation. In fact, OI interviews established that the investigation was his responsibility. Mr. Lacey sent other management officials a memorandum dated August 30, 1990, requesting information in connection with this investigation and, in response to this request, received a memorandum from the Manager, Process Laboratory, also dated August 30, that there had been a series of samples taken from sandwells and that the data might be valuable in the investigation of the SX history. However, Mr. Lacey failed to investigate this data, which demonstrated the migration of licensed materials away from the SX building over an extended period of time, and failed to inform the NRC of the existence of the data.

Furthermore, on August 31, 1990, Mr. Lacey was informed about the existence of a subfloor process monitor in the SFC Process Building which had been used to pump uranium-contaminated liquids from under the building. However, Mr. Lacey failed to evaluate the contamination of the liquids under the floor, to further investigate the issue, or to inform the NRC of this matter until September 14, 1990, following restart of the facility.

Finally, Mr. Lacey was responsible for the Licensee's regulatory compliance and quality assurance programs, and had previously been responsible for the health and safety programs. As described in Sections III and IV of this Order, the NRC has identified serious deficiencies in the Licensee's radiations safety, environmental protection and operation safety program. Consequently, it appears that Mr. Lacey has failed to adequately exercise

his responsibilities to ensure that the Licensee has conducted these activities in compliance with NRC and license requirements.

C. The Health Physics Supervisor/Assistant Radiation Safety Officer, Kenneth G. Simeroth, was responsible for oversight of the SX excavation for the H&S Department, and the physical safety of the workers in the excavation. At the time of the excavation, all of the H&S technicians reported to him.

Mr. Simeroth apparently was aware of the potential for and existence of contamination in the SX excavation pit. Mr. Simeroth was at the excavation frequently, and observed "off-colored" water in the pit, and indicated that he was aware that it was very likely that the water would have some uranium in it.

Mr. Simeroth had also been the principal individual who had sampled the SFC sandwells and, during the period that such sampling was conducted, was aware that there was uranium contamination in the water that leaked into the surrounding area of the SX building. Nevertheless, Mr. Simeroth, together with Mr. Nichols, made the decision to discontinue the sampling because the numbers meant nothing to him, as he had no knowledge of any limit levels pertaining to them.

Notwithstanding Mr. Simeroth's responsibility for the safety of the workers in the excavation and his awareness that the water in the excavation contained some uranium contamination, Mr. Simeroth, with at least careless disregard, failed to instruct the workers as to the presence of uranium contamination, or to assure that these workers were being adequately protected, in violation of 10 CFR 19.12. In addition, Mr. Simeroth stated that he had received no technical, formal training regarding the radiation

protection of employees and that he did not feel qualified to be Assistant Radiation Safety Officer because of his lack of training in radiological protection.

Furthermore, notwithstanding Mr. Simeroth's awareness that the water in the excavation contained some uranium contamination, Mr. Simeroth failed to respond when the NRC inspector inquired on August 6, 1990, as to contents of the water in the excavation. Although Mr. Simeroth and Ms. Couch later discussed the fact that they had not answered the inspector's question, Mr. Simeroth took no further action to ensure that the inspector received a response to his question.

D. The former Manager, Health, Safety, and Environment, Michael M. Nichols, had been responsible for developing and implementing programs, procedures and guidance in the areas of health physics, industrial hygiene, industrial safety, and physical security. During the SX excavation activities, Mr. Nichols was responsible for the effluent monitoring program, the respiratory protection program, the bioassay program, the health and safety program, and the program for surveillance of all plant activities related to those areas.

Mr. Nichols apparently was aware of the potential for and existence of contamination in the SX excavation pit. Mr. Nichols was frequently at the excavation site, and numerous SFC employees, as well as NRC inspector, stated that, from early on in the excavation project, there was yellow water in the pit, indicating the presence of some level of uranium contamination, although Mr. Nichols denied seeing yellow water prior to approximately August 22, 1990, when the walls were poured. In any event, Mr. Nichols had observed solidified uranium on the surface of the ground in the excavation area, had been made

aware of low levels of contamination in the excavation from early on in the excavation project, and was told by Mr. Lacey on August 17 that there had been rumors of lab analyses of the water which indicated high readings of contamination.

Notwithstanding Mr. Nichols' responsibilities as described above, and notwithstanding his awareness of potential and actual contamination, Mr. Nichols, with at least careless disregard violated the provisions of 10 CFR 19.12 by failing to ensure that contractor personnel working in the SX excavation were provided with information regarding the contamination in the excavation and with radiological protection. In addition, Mr. Nichols, whose department informed the training department of contractors who were to receive training, admitted that he had seen contractor personnel around the SX excavation with only visitor badges, and did not question their being in the area without assurances that they had received the proper training.

Furthermore, Mr. Nichols failed to evaluate the contamination in the excavation to adequately survey articles used at the excavation, and to obtain bioassays. Specifically, Mr. Nichols never instructed or ensured that his staff performed sampling of the water and soil in the excavation and report to SFC management any laboratory test results, even after he was aware of low levels of uranium-contaminated water in the excavation. Mr. Nichols' staff took only airborne samples on August 3 and 4, 1990, although workers continued to move dirt in the excavation throughout an extended time period, and Mr. Nichols admitted that, due to moisture in the soil, these airborne samples may not have been adequate. In addition, articles that had been contaminated in excess of the limits in the SFC license were released from the facility and found at the home of one of the contractor employees, and the NRC determined that the instrumentation

used by SFC personnel to survey these materials was not adequate to satisfy license requirements. Although he was informed on August 18, 1990 that the contractor's concrete forms were too contaminated to release, Mr. Nichols took no action to determine the root cause of these elevated contamination survey results.

Moreover, bioassay samples were not obtained for some contract workers until August 22, 1990, and were not obtained at all for the remaining contract workers. In addition, although Mr. Nichols was informed by Mr. Lacey on August 17, 1990, about "rumors" of elevated uranium contamination readings at the excavation area, Mr. Nichols never contacted the Facility Laboratory or took any further action to determine the validity of this information.

Finally, Mr. Nichols was aware that the sandwells had been sampled for uranium contamination, and had made the decision to discontinue the sampling because he did not understand the data that was being collected. He also had apparently received a copy of the memorandum from the Manager, Process Laboratory, dated August 30, 1990, that referenced the sandwell data. Although Mr. Nichols was extensively questioned during early September 1990 by OI regarding the potential source of the contaminated water in the excavation, he never advised the NRC of the existence of the sandwell data prior to late February or March, 1991.

Accordingly, pursuant to sections 161c, 161o, 182, and 186 of the Atomic Energy Act of 1954, as amended, 10 CFR 2.204 and 10 CFR Part 40, in order for the Commission to determine whether your license should be further modified, suspended or revoked, or other enforcement action taken to ensure compliance with NRC regulatory requirements, the Licensee is required to submit to the Director,

Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, within 30 days of the date of this Order and Demand for Information, the following information, in writing and under oath or affirmation:

Sequoyah Fuels Corporation shall provide information to demonstrate why License No. SUB-1010 should not be modified (1) to prohibit Messers. Mestepey Lacey, and Simeroth from serving in any capacity involving the performance or supervision of any NRC-regulated activities, and (2) to require 30 days prior notice to the NRC of reinvolvement of Mr. Nichols by SFC in any capacity in NRC-regulated activities.

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.

After reviewing your response, the NRC will determine whether further action is necessary to ensure compliance with regulatory requirements.

FOR THE NUCLEAR REGULATORY COMMISSION

Hugh L. Thompson, Jr.
Deputy Executive Director for
Nuclear Materials Safety, Safeguards,
and Operational Support

Dated at Rockville, Maryland
this 3 day of October 1991

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

JAN 13 1992

Docket No. 40-8027
License No. SUB-1010
EA 91-196

Sequoyan Fuels Corporation
(Subsidiary of General Atomics)
ATTN: James J. Sheppard
President
P.O. Box 610
Gore, Oklahoma 74435

Gentlemen:

SUBJECT: CONFIRMATORY ORDER MODIFYING LICENSE (EFFECTIVE IMMEDIATELY)

The enclosed Order is being issued to confirm the commitments made in your December 18, 1991 letter to notify the NRC should you to desire to utilize certain individuals for the performance or supervision of licensed activities.

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. Any questions concerning this Order should be addressed to James Lieberman, Director, Office of Enforcement, at (301) 504 - 2741.

Sincerely,

Hugh L. Thompson, Jr.
Deputy Executive Director for
Nuclear Materials Safety,
Safeguards, and Operations Support

Enclosure:
Order

cc: (See next page)

Sequoyah Fuels Corporation

Oklahoma Radiation Control Program Director

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Suite 1000
Washington, D.C. 20036

UNITED STATES
NUCLEAR REGULATORY COMMISSION

In the Matter of	)	
	)	Docket No. 40-8027
Sequoyah Fuels Corporation	)	License No. SUB-1010
Gore, Oklahoma	)	EA 91-196

CONFIRMATORY ORDER MODIFYING LICENSE (Effective Immediately)

I

Sequoyah Fuels Corporation (SFC or Licensee) is the holder of Source Material License No. SUB-1010 issued by the Nuclear Regulatory Commission (NRC or Commission) pursuant to 10 CFR Part 40. The license authorizes possession and use of source material in the production of uranium hexafluoride (UF_6) and depleted uranium tetrafluoride (DUF_4) in accordance with the terms and conditions of the license. The license was due to expire on September 30, 1990, but currently remains in effect based on a timely renewal application submitted by the Licensee.

II

The Commission issued an Order Modifying License (Effective Immediately) and Demand for Information to SFC (EA 91-067) on October 3, 1991, to address a number of significant safety violations and regulatory problems that occurred at the facility since the August 1990 solvent extraction tank excavation. The Order removed Ms. Carolyn L. Couch, who then held the position of Manager, Environmental, from supervisory and managerial

responsibilities over NRC - related activities at the SFC facility for one year and required the Licensee for a two year period to inform the NRC 30 days prior to reassigning her to supervisory or managerial functions for NRC-regulated activities. The Order also requested information as to why the License should not be modified to prohibit Ms. Couch from serving in any capacity involving the performance of NRC-regulated activities at the SFC facility. The purpose of the Demand was to obtain further information from the Licensee in order to determine whether the Commission can have reasonable assurance that (1) in the future the Licensee will conduct its activities in accordance with Commission requirements and (2) certain individual managers identified in Section VIII of EA 91-067 holding key positions described in the License will carry out their responsibilities and authorities. Because it appeared that these key SFC management officials failed to carry out their responsibilities with regard to licensed activities and have not been candid with the NRC, the Demand specifically required the Licensee to provide information to demonstrate why the License should not be modified (1) to prohibit Messrs. Mertepey, Lacey, and Simeroth from serving in any capacity involving the performance or supervision of any NRC-regulated activities at the SFC facility, and (2) to require 30 days prior notice to the NRC of reinvolvement of Mr. Nichols by SFC in any capacity in NRC-regulated activities. The Licensee responded to the Order and Demand in two letters, both dated December 2, 1991.

In those responses, the Licensee asserted that, based on the information available to SFC, SFC believed that the individuals named the Demand neither acted in careless disregard of their respective responsibilities for licensed activities nor failed to be candid with the NRC. However, the Licensee admitted that the individuals made errors in judgement, missed opportunities to identify and correct deficiencies at an earlier stage, and could have done more to assure that the NRC was fully informed of SFC activities. While not admitting the allegations in the Order regarding Ms. Couch, SFC stated that Ms. Couch did not wish to continue to be involved in the performance or supervision of NRC-regulated activities at the SFC facility, and SFC, therefore, consented to the Order as to Ms. Couch.

In a letter dated November 15, 1991, the Licensee described management changes that included the reassignment of several of the individuals named in the Order and the Demand to other assignments at SFC or General Atomics, parent company of SFC. By letter dated December 18, 1991, the Licensee stated that, as a matter of clarification, SFC does not intend to use any of the named individuals in the performance or supervision of NRC-licensed activities, or to reemploy Mr. Nichols. The Licensee further stated that should it desire to utilize any of the named individuals in the performance or supervision of NRC-licensed activities, it will provide the NRC notice 30 days prior to such utilization.

III

In view of the information contained in the December 18, 1991 letter, the NRC finds that it is not necessary at this time to further address the past performance of these individuals. If at a future date the Licensee decides to utilize one or more of these individuals in the performance or supervision of NRC-licensed activities, NRC would then determine if the individual(s) should be performing or supervising licensed activities after considering, among other things, the position in which the individual would be used, changes in circumstances since August 1990, if any, additional training, and the degree of management oversight.

Accordingly, I find that the public health, safety and interest require that License No. SUB-1010 be modified by order to confirm the Licensee's commitment of December 18, 1991 and that pursuant to 10 CFR 2.202 (56 FR 40664, August 15,1991) this Order be effective immediately. The Licensee consented to this order in a discussion between L. J. Callan, Director, Division of Radiation, Safety, and Safeguards, Region IV, and J. J. Sheppard, President, SFC, on January 8, 1992.

IV

Accordingly, pursuant to sections 62, 161b, 161c, 161i, 161o, 182 and 186 of the Atomic Energy Act of 1954, as amended, and the

Commissions regulations in 10 CFR 2.202 and 10 CFR Part 40, IT IS HEREBY ORDERED, EFFECTIVE IMMEDIATELY, THAT LICENSE NO. SUB-1010 IS MODIFIED AS FOLLOWS:

SFC shall provide the NRC at least 30 days notice prior to SFC's reassignment of Ms. Couch or Messrs. Mestepey, Lacey, or Simeroth, to directly perform or supervise NRC-licensed activities, or rehiring Mr. Nichols for the purpose of performing or supervising NRC-licensed activities.

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

V

In accordance with 10 CFR 2.202, any person other than the licensee adversely affected by this Order may submit an answer to this Order within 20 days of this order. Within the same time period, such persons may request a hearing on this Order. The hearing request may be included in the answer. The answer may consent to the Order. Unless the answer consents to the Order, the answer shall, in writing, under oath or affirmation, specifically admit or deny each allegation or charge made in the Order and shall set forth the matters of fact and law on which such 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, D.C. 20555. Copies shall be sent to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555 and to the Assistant General Counsel for Hearings and Enforcement at the same address, to the Regional Administrator, NRC Region IV, and to the Licensee. If such a person requests a hearing, that person shall set forth with particularity the manner in which his interest is adversely affected by this Order and shall address the criteria set forth in 10 CFR 2.714(d).

If a hearing is requested by a person whose interest is adversely affected, the Commission will issue an Order designating the time and place of any hearing. If a hearing is held, the issue to be considered at such hearing shall be whether this Order should be sustained.

VI

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 13th day of January 1992

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

MAR 13 1992

Docket No. 40-8027
License No SUB-1010
EA 92-045

Sequoyah Fuels Corporation
(Subsidiary of General Atomics)
ATTN: James J. Sheppard
President
Post Office Box 610
Gore, Oklahoma 74435

Gentlemen:

SUBJECT: ORDER MODIFYING LICENSE (EFFECTIVE IMMEDIATELY) AND DEMAND FOR INFORMATION

The enclosed Order is being issued to impose as new license conditions reporting requirements intended to give the NRC added assurance that issues of potential safety and regulatory significance are promptly brought to our attention. While these conditions lower your reporting threshold, as with all of our licensees, we expect that you will keep the NRC informed of issues of potential regulatory or safety concern, whether or not a specific reporting requirement is involved.

In addition, this letter also addresses an issue which is part of the NRC investigation being conducted by the Office of Investigations (OI) into certain health physics activities at the Sequoyah Fuels Corporation (SFC). As a result of that investigation, questions have arisen as to the performance of your Vice President for Regulatory Affairs. Our concerns are addressed below.

As you are aware, on January 7, 1992, NRC inspectors received an allegation that 1) required surveys may have been recorded as complete when they had not been performed; 2) survey readings that were above release limits may have been recorded as below release limits; and 3) smearable swipes from trucks may not have been counted until trucks departed from the site, though records indicated that counts had been made before the trucks had left the site. These allegations, if true, could have raised current safety concerns because they may have been ongoing practices. On January 8, 1992, L. Joseph Callan, Director, Division of Radiation Safety & Safeguards, Region IV, NRC, discussed these issues with your contract Vice President for Regulatory Affairs. It was our understanding that the alleger had already notified SFC of these allegations and, therefore, we intended to refer them to SFC for investigation and reporting back to the NRC. However, your Vice President gave no indication that he was aware

of any alleged improprieties involving surveys or records of surveys. Notwithstanding two later telephone calls to Mr. Callan, it was not until sometime after the second call that NRC became aware that while your Vice President was not necessarily aware of who had made the allegation, he was aware of the issues on January 2, 1992, and had directed that an internal investigation be initiated.

There may have been several reasons for the failure of your Vice President to provide information during the January 8, 1992 discussion, such as a failure to recall the information, a failure to associate the issues of NRC concern with the information provided him on January 2nd, or a desire to assure that he had more facts or that the investigation be further along before he spoke to the agency. However, those reasons would not have excused the failure to provide full information in the subsequent communications.

Issues concerning improper health physics practices are of regulatory concern, especially at SFC. As you know, this is a site that has remained shut down under an order to address health physics issues and has been subject to two Demands for Information related to, among other things, the candor and sensitivity of your managers in providing information to the NRC. In fact, SFC itself has recognized that the former Vice President for Regulatory Affairs exercised poor judgment in this area. Consequently, the current contract Vice President, effective November 25, 1991, replaced the former Vice President pending the selection of a permanent officer. Thus, we would have expected SFC to be informing us in response to our concerns that it, SFC, recognized issues and was responsibly looking into them.

For these reasons, the staff is very concerned that at this stage of the regulatory process, your Vice President for Regulatory Affairs exhibited a lack of sensitivity to the need to keep the NRC informed of ongoing issues of regulatory concern. This is reminiscent of the communications of the previous SFC management team rather than what we have been led to believe is the expectation of the current management.

It is our understanding that you are in the process of finding a permanent replacement for this Vice President since he is a contract officer. However, for a position of such importance, it may take time to obtain the appropriate replacement. Therefore, further information is required pursuant to section 182 of the Atomic Energy Act of 1954, as amended, 10 CFR 2.204 and 10 CFR 40.31(b), to determine whether further regulatory action is required to assure that we have confidence that your Vice President for Regulatory Affairs will fully communicate with the NRC on matters related to licensed activities at SFC. Specifically, please provide in writing and under oath or affirmation, within 10 days of the date of this Demand for

Information, SFC's basis for having confidence that your Vice President for Regulatory Affairs will communicate fully with the NRC on issues concerning potential conditions that may impact on the public health and safety.

The response 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.

A copy of this Demand is being sent to your Vice President to provide him an opportunity to respond if he so desires.

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. Any questions concerning this Order should be addressed to James Lieberman, Director, Office of Enforcement, at (301) 504-2741.

Sincerely,

Hugh L. Thompson, Jr.
Deputy Executive Director for
Nuclear Materials Safety,
Safeguards, and Operations Support

Enclosure:

cc:
Oklahoma Radiation Control Program Director

Vice President for Regulatory Affairs, SFC

Diane Curran, Esq.
Harmon, Curran & Tousley
2001 S Street, N.W., Suite 430
Washington, D.C. 20009

Brita Haugland-Cantrell, Esq.
2300 North Lincoln Boulevard
112 State Capitol Building
Oklahoma City, OK 73105-4894

UNITED STATES
NUCLEAR REGULATORY COMMISSION

In the Matter of

Sequoyah Fuels Corporation
Gore, Oklahoma

Docket No. 40-8027
License No. SUB-1010
EA 92-045

ORDER MODIFYING LICENSE (EFFECTIVE IMMEDIATELY)

I

Sequoyah Fuels Corporation (SFC or Licensee) is the holder of Source Material License No. SUB-1010 issued by the Nuclear Regulatory Commission (NRC or Commission) pursuant to 10 CFR Part 40. The license authorizes possession and use of source material in the production of uranium hexafluoride (UF6) and depleted uranium tetrafluoride (DUF4) in accordance with the terms and conditions of the license. The license was due to expire on September 30, 1990, but currently remains in effect based on a timely renewal application submitted by the Licensee.

II

On November 5,1990, NRC issued a Demand for Information to SFC (EA 90-158) for the purpose of obtaining information to determine whether there was reasonable assurance that SFC could properly manage licensed activities in accordance with Commission requirements. This Demand was based in part on the failure by key managers at SFC to accurately and completely inform the NRC of material facts in a prompt manner.

On October 3,1991, the NRC issued an Order Modifying License (Effective Immediately) and Demand for Information to SFC (EA 91-067) to address a number of significant safety violations and regulatory problems. Significantly, the Order was based, in part, on the failure of a responsible licensee official to fully provide complete and accurate information to the NRC. The purpose of the Demand was to obtain further information from the Licensee in order to determine whether the Commission could have reasonable assurance that certain individual managers holding key positions described in the License would properly carry out their responsibilities and authorities. That Demand was issued, in part, because it appeared that these key SFC management officials were not candid with the NRC concerning regulatory matters.

The Licensee responded to the Demand in two letters dated December 2, 1991. In those responses, the Licensee asserted its belief that the individuals named in the Demand neither acted in careless disregard of their responsibilities for licensed activities nor failed to be candid with the NRC. However, the Licensee admitted that the individuals made errors in judgment, missed opportunities to identify and correct deficiencies at an earlier stage, and could have done more to assure that the NRC was fully informed of SFC activities.

By letter dated December 18, 1991, the Licensee stated that it did not intend to use any of the named individuals in the

performance and supervision of NRC-licensed activities, and should it desire to use any of the named individuals in such capacities in the future, it would provide the NRC at least 30 days notice. The NRC confirmed this commitment in a Confirmatory Order dated January 13, 1992 (EA 91-196).

On January 7, 1992, an employee approached NRC inspectors with allegations involving potential wrongdoing. Specifically, it was alleged that an SFC health physics (HP) supervisor was condoning, if not encouraging, the falsification of records and improper vehicle surveys. Subsequent discussions with an HP technician raised further concerns regarding the adequacy of surveys performed on vehicles prior to their release from the site.

On January 8, 1992, a senior NRC official on site discussed this matter with the Vice President for Regulatory Affairs, a contractor hired by the Licensee as an interim replacement for one of the key positions recently vacated as a consequence of the October 3, 1991 Order. This discussion was for the purpose of advising SFC of the allegations and potential safety issues so that SFC could investigate the matter and take appropriate corrective action. The Vice President did not, however, convey to the NRC official during that discussion or the subsequent telephone calls, that he had been aware of the substance of the allegations since January 2, 1992 and that he had directed that

SFC initiate an investigation into the specific matters identified by the senior NRC official.

Finally, on January 20, 1992, SFC notified the NRC of the discovery of contamination in the plant warehouse, an unrestricted area. An NRC inspection team subsequently determined that the Licensee had first become aware of the contamination as early as November 22, 1991. In addition, the NRC team also found that the Licensee had also discovered contamination in the SFC Carlile Training Center, an unrestricted offsite facility, as early as November 13, 1991. However, until the NRC inspection, the Licensee failed to either control the contaminated material or take action to restrict access to the areas where the contaminated material was stored.

III

Based on the above, it appears that the Licensee has not been able to overcome and correct SFC's history of lack of candor in bringing potential safety and regulatory issues to NRC's attention. It is recognized that each of the failures to bring forward information to the NRC was not necessarily a violation of NRC requirements. Nevertheless, given the regulatory issues at SFC, it is imperative that NRC be kept fully and promptly informed of potential safety and regulatory issues occurring at this facility. Without this information, NRC could be

significantly hampered in its ability to properly regulate activities at SFC.

Consequently, to further assure SFC's management will keep the NRC fully informed of potential safety and regulatory concerns and to provide additional assurance that NRC will be able to effectively carry out its regulatory oversight of the activities at SFC, it is necessary to require that License No SUB-1010 be modified to include additional reporting requirements. Furthermore, pursuant to 10 CFR 2.202, I find that the public health, safety and interest require that this Order be immediately effective.

IV

Accordingly, pursuant to sections 63, 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 Part 40, IT IS HEREBY ORDERED, EFFECTIVE IMMEDIATELY, THAT LICENSE NO. SUB-1010 IS MODIFIED AS FOLLOWS:

The Licensee shall, to the extent not covered by any other reporting requirement, including but not limited to 10 CFR 40.9(b), inform the Regional Administrator, Region IV, in writing, within five working days of awareness of the following:

A. Failure to follow procedures or other requirements where there are indications that the cause was a deliberate failure to meet requirements. A deliberate failure is a failure caused by deliberate misconduct as defined in 10 CFR 40.10(c).

B. Spills or other unusual occurrences involving the spread of contamination in and around the SFC's facility, equipment, or site, subject to 10 CFR 40.36(f)(1), even if the contamination has been or will be cleared up.

C. Any failure of equipment or facilities, or failure to follow procedures, which leads to 1) offsite release or contamination in unrestricted areas in excess of SFC's administrative limits; 2) any contamination in restricted areas that requires activities in an area to be suspended for more than twenty four hours pending decontamination; or 3) any personnel contamination in excess of SFC's administrative limits which within one hour of detection is not reduced to within limits.

D. Employee concerns or allegations that any of the above failures may have occurred unless it is determined within the above f rking days that the concern or allegation is not valid.

E. Any other matter that the President, SFC, believes rises to a regulatory or safety concern that warrants NRC notification.

The Regional Administrator, Region IV, 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, the Licensee must, and any other person adversely affected by this order may, submit an answer to 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 the Licensee or other person adversely affected relies and the reasons as to why the Order should not have been issued. Any answer filed within 20 days of the date of this Order may include a request for a hearing. Any answer or request for a hearing shall be submitted to the Secretary, U.S. Nuclear Regulatory Commission, ATTN: Chief, Docketing and Services Section, Washington, D.C. 20555. Copies shall also be sent to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, to the Assistant General Counsel for Hearings and Enforcement at the same address, to the

Regional Administrator, NRC Region IV, 611 Ryan Plaza Drive, Suite 400, Arlington, Texas 76011 and to the Licensee if the answer or hearing request is by a person other than the Licensee. If a person other than the Licensee requests a hearing, that person shall set forth with particularity the manner in which his interest is adversely affected by this Order and shall address the criteria set forth in 10 CFR 2.714(d).

If a hearing is requested by a Licensee or a person whose interest is adversely affected, the Commission will issue an Order designating the time and place of any hearings. If a hearing is held, the issue to be considered at such hearing shall be whether this Order should be sustained.

VI

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

ANSWER OR REQUEST FOR A HEARING SHALL NOT STAY THE IMMEDIATE EFFECTIVENESS OF THE ORDER.

FOR THE NUCLEAR REGULATORY COMMISSION

Hugh L. Thompson, Jr.
Deputy Executive Director
for Nuclear Material Safety, Safeguards,
and Operations Support

Dated at Rockville, Maryland
this 12th day of March, 1992.

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

APR 03 1992

Docket No. 40-8027
License No. SUB-1010
EA 92-059

Sequoyah Fuels Corporation
(Subsidiary of General Atomics)
ATTN: James J. Sheppard
President
Post Office Box 610
Gore, Oklahoma 74435

Gentlemen:

SUBJECT: CONFIRMATORY ORDER MODIFYING LICENSE (EFFECTIVE IMMEDIATELY)

The enclosed Order is being issued to modify Section IV.C of the March 13, 1992 Order (EA 92-045) which imposed as new license conditions reporting requirements intended to give the NRC additional assurance that issues of potential safety and regulatory significance are promptly brought to our attention. The purpose of the modification is to clarify the staff's intent regarding reporting thresholds, as discussed during the March 26, 1992 public meeting.

In a letter dated March 24, 1992, and during the public meeting, you identified a number of concerns regarding interpretation of several provisions in the Order. You specifically noted that Section IV.B did not establish any cutoff threshold for reporting minor contamination events that are reasonably expected in the course of normal operation that have no safety or regulatory concern. I have determined that relaxation of this portion of the Order is appropriate based on the revisions to Section IV.C, as discussed in the attached Order (EA 92-059), and am therefore relaxing Section IV.B of the March 13, 1992 Order by dropping the phrase "even if the contamination has been or will be cleaned up." The lead-in phrase of Section IV.C is being modified from "Any failure of equipment or facilities, or failure to follow procedures which leads to..." to read "Any occurrence which leads to..." as the staff is interested in these type of events, regardless of cause. In addition, Subsection (2) of Section IV.C is changed to require the reporting of any contamination in restricted areas that requires activities in the area to be suspended for more than 8 hours in order to decontaminate.

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. Any questions concerning this Order should be addressed to James Lieberman, Director, Office of Enforcement, at (301) 504-2741.

Sincerely,

Hugh L. Thompson, Jr.
Deputy Executive Director
for Nuclear Materials Safety, Safeguards,
and Operations Support

cc:
Oklahoma Radiation Control Program Director

Vice President for Regulatory Affairs, SFC

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UNITED STATES
NUCLEAR REGULATORY COMMISSION

In the Matter of

SEQUOYAH FUELS CORPORATION
Gore, Oklahoma

Docket No. 40-8027
License No. SUB-1010
EA 92-059

CONFIRMATORY ORDER MODIFYING LICENSE
(EFFECTIVE IMMEDIATELY)

I

Sequoyah Fuels Corporation (SFC or Licensee) is the holder of Source Material License No. SUB-1010 issued by the Nuclear Regulatory Commission (NRC or Commission) pursuant to 10 CFR Part 40. The license authorizes possession and use of source material in the production of uranium hexafluoride (UF6) and depleted uranium tetrafluoride (DUF4) in accordance with the terms and conditions of the license. The license was due to expire on September 30, 1990, but currently remains in effect based on a timely renewal application submitted by the Licensee.

II

The Commission issued an Order Modifying License (Effective Immediately) to SFC (EA 92-045) on March 13, 1992, to impose as new license conditions reporting requirements intended to give the NRC added assurance that issues of potential safety and regulatory significance are promptly brought to the NRC's attention. By letter dated March 16, 1992, SFC consented to the Order. The Licensee subsequently identified a number of questions with regard to application or interpretation of the new reporting requirements.

Examples of those questions were provided to the NRC by letter dated March 24, 1992, and a public meeting was held on March 26, 1992, to discuss SFC's understanding of the new reporting requirements.

III

Based on information developed during the March 26, 1992, public meeting, modification of the March 13, 1992 Order is necessary to clarify the intent of Section IV.C. Section IV.C required, in part, the reporting of "Any failure of equipment or facilities, or failure to follow procedures, which leads to..." (one of three types of contamination events). The NRC is interested in being informed of any of those contamination events, whether caused by the specified failures or any other inadequacy, such as an inadequate procedure. Changing that phrase to "Any occurrence which leads to ..." clarifies the NRC's intent. Subsection (2) of Section IV.C addressed reporting of "any contamination in restricted areas that requires activities in an area to be suspended for more than 24 hours pending decontamination." By modifying the 24 hour time period for decontamination to 8 hours, an appropriate threshold for reporting onsite contamination events that require at least one shift to clean up is established. This ensures that the Licensee will report items of potential safety or regulatory significance to the NRC.

Consequently, for the reasons given in the March 13, 1992, Order and explained above, it is necessary to require that License No. SUB-1010 be modified to clarify the intent of the new reporting requirements. The Licensee's president agreed to the terms of this Order in a meeting on April 1, 1992. Furthermore, pursuant to 10 CFR 2.202, for the reasons stated in the March 13, 1992 Order, I find that the public health, safety and interest require that this Order be effective immediately.

IV

Accordingly, pursuant to sections 63, 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 Part 40, IT IS HEREBY ORDERED, EFFECTIVE IMMEDIATELY, THAT SECTION IV.C TO THE ORDER ISSUED MARCH 13, 1992 IS MODIFIED TO READ AS FOLLOWS:

C. Any occurrence which leads to (1) offsite release or contamination in unrestricted areas in excess of SFC's administrative limits; (2) any contamination in restricted areas that requires activities in an area to be suspended more than 8 hours pending decontamination; or (3) any personnel contamination in excess of SFC's administrative limits which within one hour of detection is not reduced to within limits.

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

V

Any person other than the Licensee adversely affected by this Confirmatory Order may request a hearing within 20 days of its issuance. Any request for a hearing shall be submitted to the Secretary, U.S. Nuclear Regulatory Commission, ATTN: Chief, Docketing and Service Section, Washington, D.C. 20555. Copies also shall be sent to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, to the Assistant General Counsel for Hearings and Enforcement at the same address, to the Regional Administrator, NRC Region IV, 611 Ryan Plaza Drive, Suite 400, Arlington, Texas 76011 and to the Licensee. If such a person requests a hearing, that person shall set forth with particularity the manner in which his interest is adversely affected by this Order and shall address the criteria set forth in 10 CFR 2.714(d).

If a hearing is requested by a person whose interest is adversely affected, the Commission will issue an Order designating the time and place of any hearing. If a hearing is held, the issue to be considered at such hearing shall be whether this Confirmatory Order should be sustained.

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 3rd day of April 1992

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

June 2, 1992

Docket Nos. 030-14754; 030-00128
License Nos. 08-07398-03; 08-07398-01
EA 92-080

Sibley Memorial Hospital
ATTN: Robert L. Sloan
Chief Executive Officer
5255 Loughboro Road, N.W.
Washington, D.C. 20016

Dear Mr. Sloan:

Subject: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY - $2,50[illegible] (NRC Inspection Report Nos. 030-14754/92-001 and 030-00128/92-001)

This letter refers to the NRC inspection conducted on April 23, 1992, at Sibley Memorial Hospital, Washington, D.C., of activities authorized by NRC License Nos. 08-07398-03 and 080-07398-01. The inspection report was sent to you on May 11, 1992. During the inspection, sixteen apparent violations of NRC requirements were identified. On May 19, 1992, an enforcement conference was conducted with you and members of your staff to discuss the apparent violations, their causes and your corrective action. Based upon your presentation at the conference, three of the apparent violations are being withdrawn, for the reasons set forth in the enforcement conference report. A copy of that report was sent to you on May 22, 1992.

The remaining thirteen violations that are being cited are described in the enclosed Notice of Violation and Proposed Imposition of Civil Penalty. Those violations include, but are not limited to, the failures to: (1) maintain records of certain disposals of radioactive waste contaminated with iodine-131 from a radioiodine patient; (2) ensure that a patient's room was suitable for release for unrestricted use prior to such release (contamination levels were still above the regulatory limit at the time of the release); (3) provide adequate training to the nuclear medicine supervisor; (4) perform certain required constancy, linearity, and accuracy checks of the dose calibrator; (5) bioassay all individuals participating in the administration of therapeutic doses of iodine-131; (6) perform certain surveys, as required; and (7) perform a physical inventory of sealed sources at the required frequency.

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

The violation involving the release of the radioiodine patient's room for unrestricted use with contamination levels above the limit is of particular concern to the NRC because it could have resulted in contamination of members of the public. Three of the other violations are also of particular concern to the NRC since they were identified during previous NRC inspections in 1990 and 1988. Viewed collectively, the violations identified during the April 23, 1992, inspection indicate that neither management, the Radiation Safety Committee (RSC), nor the Radiation Safety Officer (RSO) provided sufficient attention to the radiation safety program to ensure that it was being properly implemented.

Although the RSO and the RSC reviewed the nuclear medicine program annually, they did not identify the numerous violations or the inefficient management attention to the program that existed at the facility. In addition, the corrective actions for the violations cited in 1990 and 1988 appeared to have been narrowly focused on the specific issues rather than a broader interpretation of the root causes of the violations, such that the corrective actions would be effective in preventing recurrence. If adequate audits, reviews, or observations of activities at the facility were conducted prior to this most recent inspection, these violations would probably have been identified.

The NRC license issued to Sibley Memorial Hospital entrusts responsibility for radiation safety to the management of the hospital; therefore, the NRC expects effective oversight of its licensed programs. 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 any potential violations of NRC requirements are identified and expeditiously corrected. Given the number of violations that existed and their diversity across most areas of the radiation safety program at the facility, the violations are classified in the aggregate as a Severity Level III problem in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C (Enforcement Policy).

The NRC recognizes that subsequent to this recent inspection, prompt and comprehensive actions were taken or planned to correct the violations and effect improvements in the control and implementation of the radiation safety program. These actions, which were described at the enforcement conference, included: (1) more direct involvement by the RSO, and less reliance on the chief technician, in monitoring implementation of the program; (2) development of additional procedures and checklists to aid in implementation of the program; (3) training and instruction to personnel, both verbally and in writing, regarding implementation of regulatory requirements; (4) close coordination between management and the retained consultant regarding actions needed to improve the program; and (5) plans to move the Nuclear Medicine Department from the Pathology Department to the Radiology Department and name a new RSO at that time. The NRC also recognizes that management was in the process, at the time of the inspection, of retaining a consultant to assist in evaluating and improving the radiation safety program.

Notwithstanding those actions, to emphasize the importance of adequate attention to, and oversight of, the radiation safety program, so as to ensure that (1) licensed activities are conducted safely and in accordance with requirements, and (2) violations, when they exist, are promptly identified and corrected, I have been authorized to issue the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice) in the amount of $2,500 for the thirteen violations set forth in the enclosed Notice.

The base civil penalty amount for a Severity Level III problem is $2,500. The escalation and mitigation factors set forth in the enforcement policy were considered, and on balance, no adjustment of the base civil penalty amount was deemed appropriate because: (1) the violations were identified by the NRC, and therefore, 50 percent escalation of the base civil penalty on this factor is warranted; (2) your corrective actions, as described herein, were considered prompt and comprehensive, and therefore, 50 percent mitigation of the base civil penalty on this factor is warranted; and (3) your past performance includes a total of eight violations being identified during the last two NRC inspections in 1990 and 1988, three of which were repetitive during the most recent inspection, and therefore, no mitigation of the base civil penalty on this factor is warranted; in addition, since those violations were of minor safety significance, no escalation is warranted; (4) although some of the violations included multiple examples which existed for an extended duration, no adjustment on these factors is warranted since these factors were considered in the determination to classify the violations in the aggregate at Severity Level III; and (5) although there were prior opportunities to identify these violations if adequate attention was provided to the program, and NRC Information Notice 90-71 provided prior notice of the importance of effective use of Radiation Safety Committees to exercise control over medical use programs, the NRC has decided not to escalate the base civil penalty amount on this factor since your chief technologist had recognized the need for more health physics support, and management had retained a consultant shortly before the inspection.

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

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

The responses directed by this letter and the enclosed Notice are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, Pub. L. 96-511.

Sincerely,

Thomas T. Martin
Regional Administrator

Enclosure: Notice of Violation and Proposed Imposition of Civil Penalty

cc:
Public Document Room (PDR)
Nuclear Safety Information Center (NSIC)
District of Columbia

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

Sibley Memorial Hospital
Washington, D.C. 20016

Docket Nos. 030-14754; 030-00125
License Nos. 08-07398-03; 08-[illegible]98-01
EA 92-05[illegible]

During an NRC inspection conducted on April 23, 199[illegible] violation[illegible] of NRC requirements were identified. In accordance with the "General State[illegible] of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C, the Nuclear Regulatory Commission proposes to impose a civil penalty pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (Act), 42 U.S.C. 2282, and 10 CFR 2.205. The particular violations and associated civil penalty are set forth below:

A. 10 CFR 35.21(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 concerning training of personnel are described in the application dated September 30, 1983, and were approved by License Condition 14.

Item No. 12 of the September 30, 1983 application requires, in part, that all radiation workers be instructed initially on the regulations and licensee procedures.

Contrary to the above, as of April 23, 1992, the supervisor of nuclear medicine had not received initial training on the regulations and licensee procedures, even after being an employee of the hospital for approximately 6 months.

B. 10 CFR 35.315(a)(8) requires, in part, that a licensee measure the thyroid burden of each individual who helped prepare or administer a dosage of iodine-131 for each patient receiving radiopharmaceutical therapy and hospitalized for compliance with 10 CFR 35.75, within three days after administering the dosage.

Contrary to the above, on November 13, 1991, the licensee administered to a patient 174 millicuries of iodine-131, a dosage which requires hospitalization for compliance with 10 CFR 35.75, and as of April 23, 1992 (a period in excess of 3 days), the licensee did not measure the thyroid burden of the nuclear medicine technologist who helped prepare this dosage.

C. 10 CFR 35.92(b) requires that a licensee retain for three years a record of each disposal of byproduct material permitted under 10 CFR 35.92(a), and that the record include the date of the disposal, the date on which the byproduct material was placed in storage, the radionuclides disposed, the survey instrument used, the background dose rate, the dose rate measured at the surface of each waste container, and the name of the individual who performed the disposal.

Contrary to the above, the licensee did not maintain records of disposal, on September 6, 1990, and December 28, 1991, of byproduct material permitted under 10 CFR 35.92(a). Specifically, the byproduct material waste generated from iodine-131 therapy treatment of a patient was disposed of and no record was maintained.

D. 10 CFR 35.315(a)(7) requires that, for each patient receiving radiopharmaceutical therapy and hospitalized for compliance with 10 CFR 35.75, a licensee survey the patient's room and private sanitary facility for removable contamination with a radiation detection survey instrument before assigning another patient to the room. The room must not be reassigned until removable contamination is less than 200 disintegrations per minute per 100 square centimeters.

Contrary to the above, on December 26, 1991, the licensee did not ensure that removable contamination was less than 200 disintegrations per minute per 100 square centimeters before assigning a patient to a room where another patient, who had received radiopharmaceutical therapy, had been previously assigned. Specifically, the licensee released a room for unrestricted use when the contamination wipes performed by the licensee showed contamination levels in the room as high as 700 disintegrations per minute per 100 square centimeters.

E. 10 CFR 35.50(b)(1) requires, in part, that a licensee check each dose calibrator for constancy with a dedicated check source at the beginning of each day of use.

Contrary to the above, as of March 15, 1992, the licensee was not checking the dose calibrator for constancy on weekend workdays, and the dose calibrator was used to measure patient doses of radiopharmaceuticals on those days.

F. 10 CFR 35.59(g) requires, in part, that a licensee in possession of a sealed source conduct a quarterly physical inventory of all such sources in its possession.

Contrary to the above, the licensee did not conduct a physical inventory of its sealed sources from September 11, 1991 to April 23, 1992, a period in excess of a calendar quarter.

This is a repetitive violation.

G. 10 CFR 35.50(b)(2) requires, in part, that a licensee test the dose calibrator for accuracy at least annually.

Contrary to the above, the licensee did not test its dose calibrator for accuracy from December 14, 1990 to April 23, 1992, a period in excess of one year.

H. 10 CFR 35.50(e), requires, in part, that a licensee retain records of annual accuracy tests of the dose calibrator for three years unless directed otherwise, and that the records include the signature of the Radiation Safety Officer.

Contrary to the above, as of April 23, 1992, the licensee's retained record of the annual accuracy test of its dose calibrator performed on December 13, 1990, did not include the signature of the Radiation Safety Officer.

This is a repetitive violation.

I. 10 CFR 35.50(d) requires, in part, that a licensee mathematically correct dosage readings for any linearity error that exceeds 10 percent if the dosage is greater than 10 microcuries.

Contrary to the above, from October 14, 1991 to January 6, 1992, the licensee did not mathematically correct patient dosage readings for a dose calibrator linearity error of 28 percent as shown on the October 14, 1991 linearity record, and the patient dosages were greater than 10 microcuries.

J. 10 CFR 35.50(b)(3) requires, in part, that a licensee test each dose calibrator for linearity at least quarterly.

Contrary to the above, the licensee did not test its dose calibrator for linearity from April 8, 1991 until October 14, 1991, a period in excess of a calendar quarter.

K. 10 CFR 35.70(a) requires that a licensee survey with a radiation detection survey instrument at the end of each day of use all areas where radiopharmaceuticals are routinely prepared for use or administered.

Contrary to the above, on numerous occasions from February 12, 1990 to April 23, 1992, the licensee did not survey with a radiation detection instrument at the end of the day areas where radiopharmaceuticals were routinely prepared for use or administered. Specifically, the licensee did not routinely survey the nuclear medicine camera rooms, areas where radiopharmaceuticals were administered. Also, the licensee did not perform required surveys of camera rooms and the hot lab on weekend workdays.

L. 10 CFR 35.53(c) requires, in part, that a licensee retain records of the measurement of radiopharmaceutical dosages for three years, and that the record contain the radiopharmaceutical lot number and expiration date.

Contrary to the above, the licensee's records of the measurement of radiopharmaceutical dosages did not contain the radiopharmaceutical lot number or expiration date for measurements performed on weekend workdays between February 12, 1990 and April 23, 1992.

This is a repetitive violation.

M. 10 CFR 35.70(b) requires, in part, that a licensee survey with a radiation detection survey instrument at least once each week all areas where radiopharmaceutical waste is stored.

Contrary to the above, from September 6, 1990 to December 26, 1992, the licensee did not survey weekly with a radiation detection survey instrument the iodine-131 waste storage area.

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

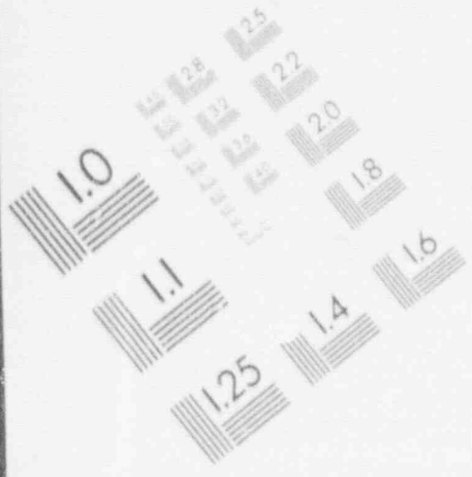
Cumulative Civil Penalty - $2,500 (assessed equally among the thirteen violations)

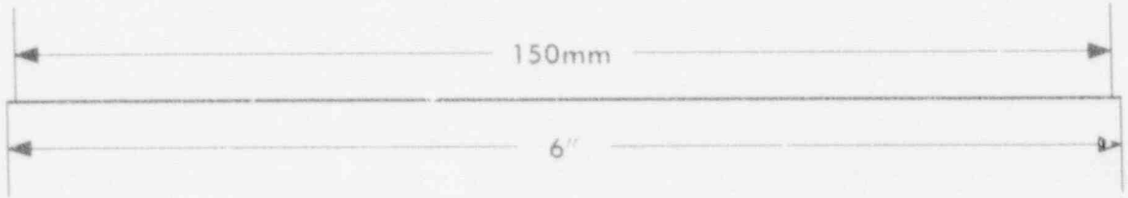
Pursuant to the provisions of 10 CFR 2.201, Sibley Memorial Hospital (Licensee) is hereby required to submit a written statement or explanation to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, within 30 days of the date of this Notice of Violation and Proposed Imposition of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

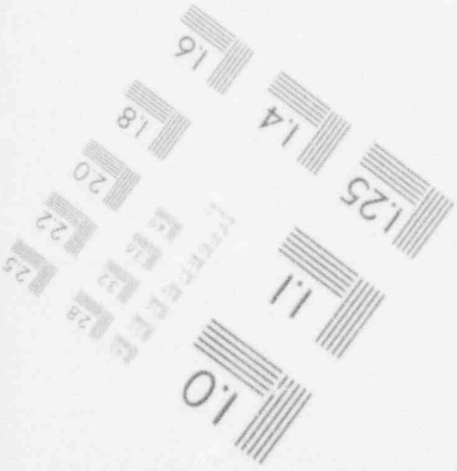
Within the same time as provided for the response required above under 10 CFR 2.201, the Licensee may pay the civil penalty by letter addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, with a check, draft, money order, or electronic transfer payable to the Treasurer 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

2

IMAGE EVALUATION TEST TARGET (MT-3)







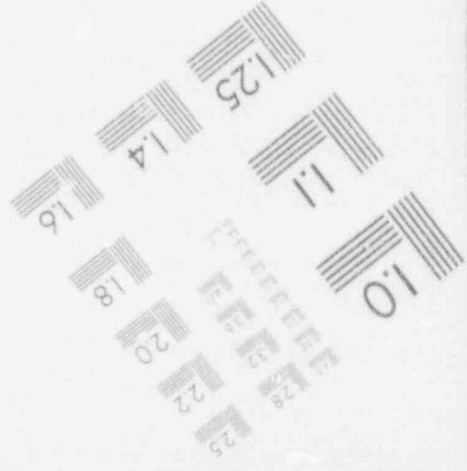


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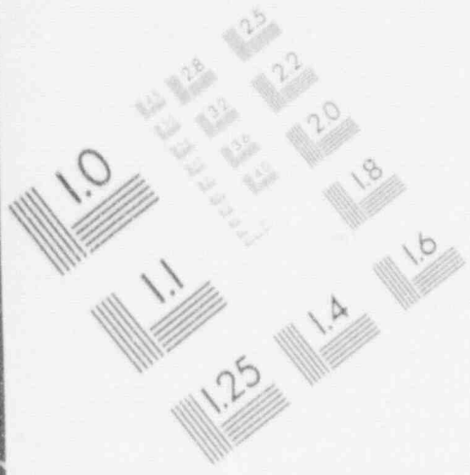
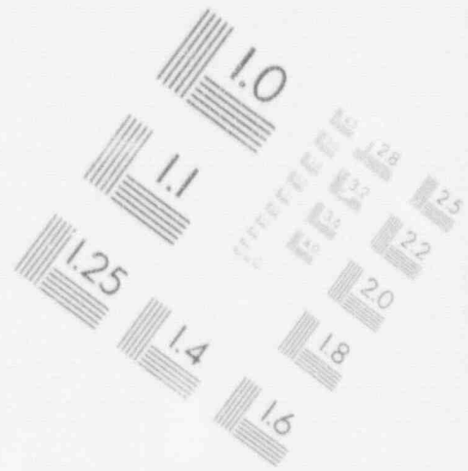
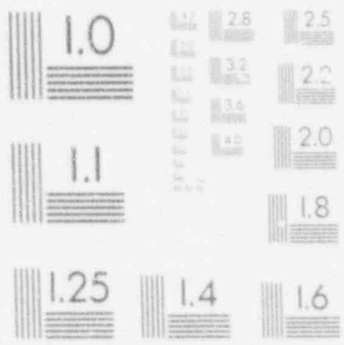
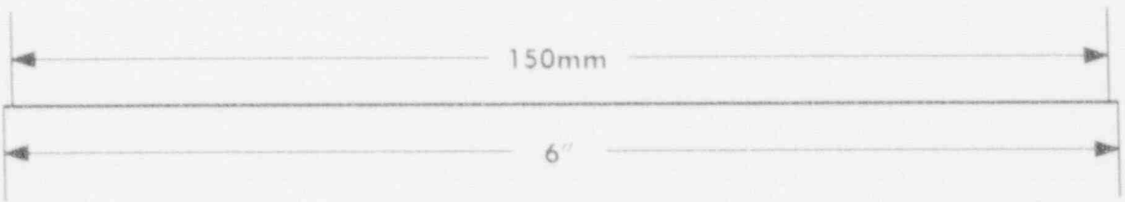
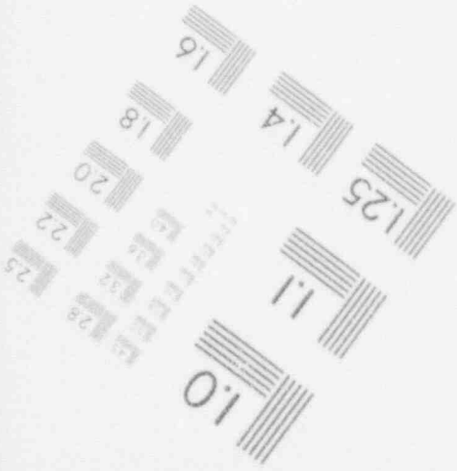
IMAGE EVALUATION TEST TARGET (MT-3)

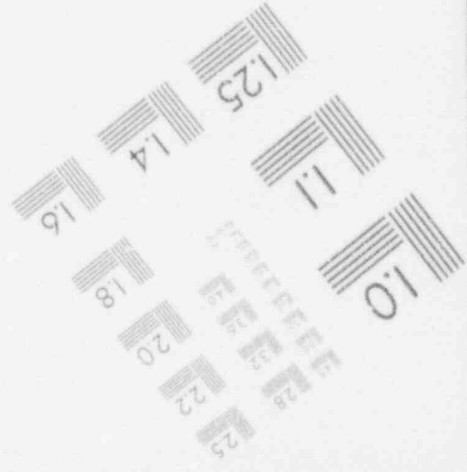












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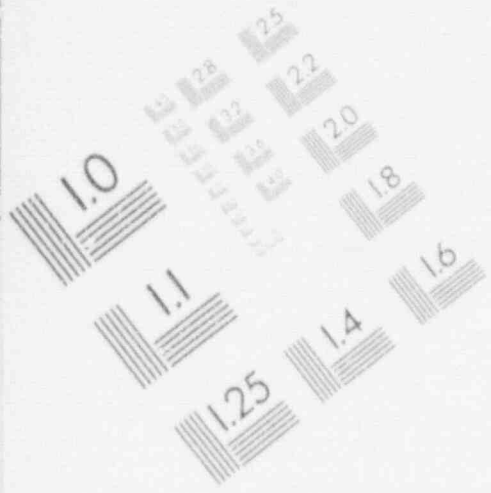
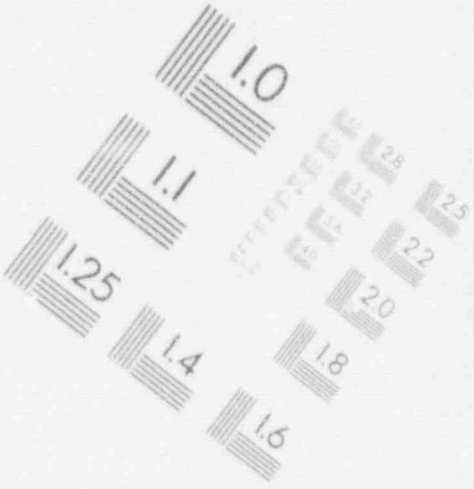
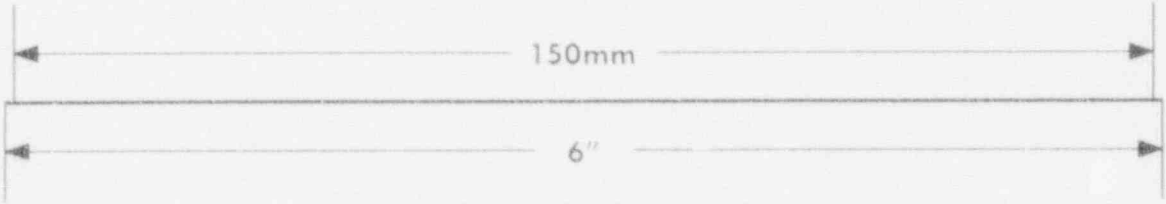
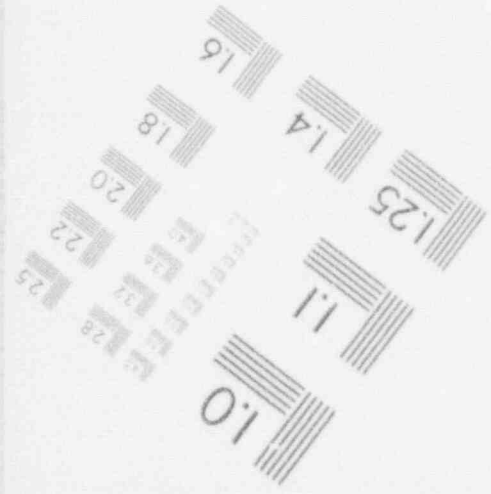
2

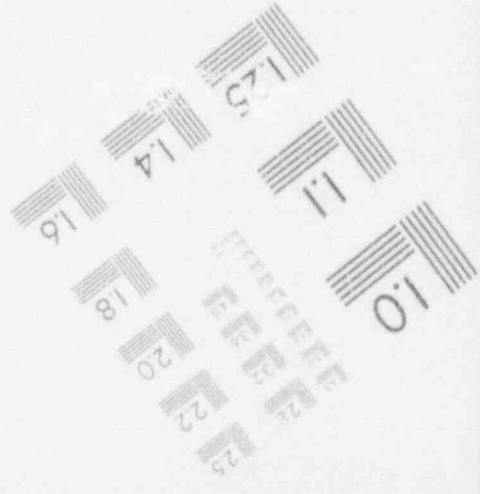
IMAGE EVALUATION TEST TARGET (MT-3)











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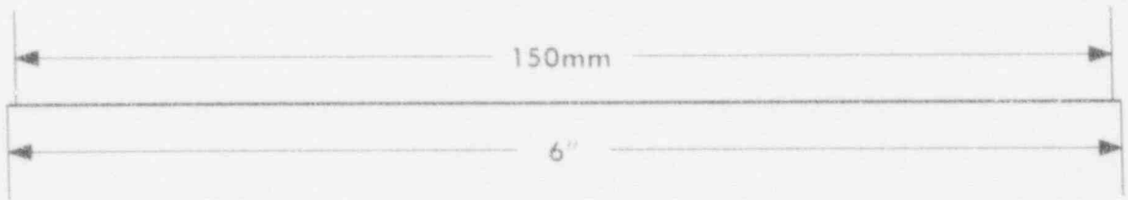

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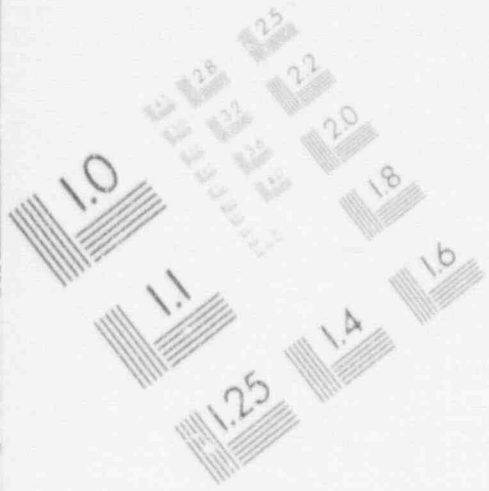
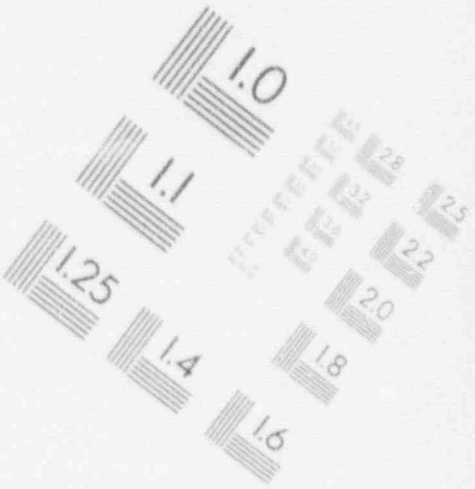
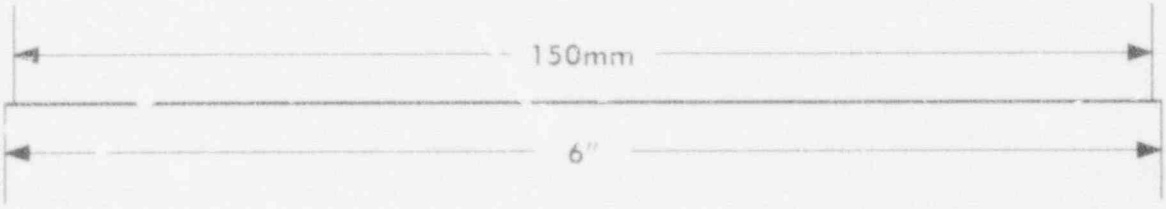
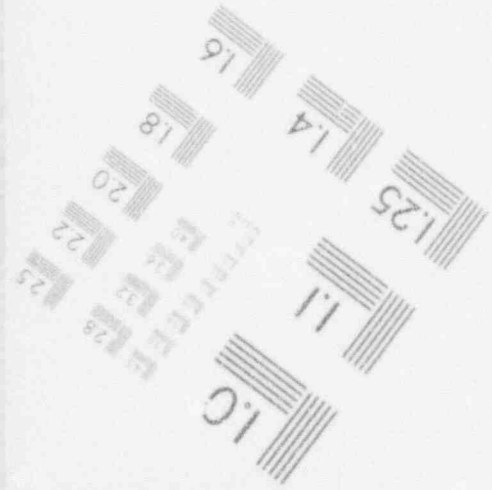
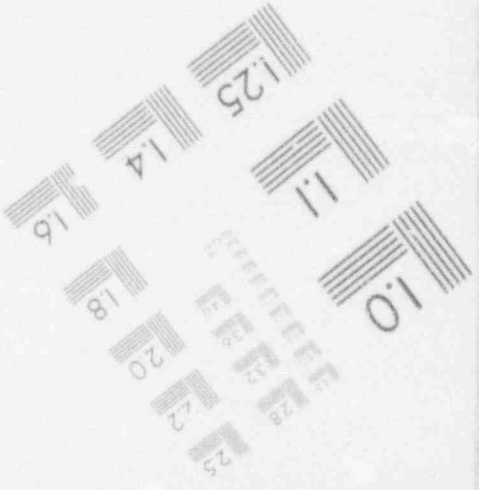
IMAGE EVALUATION TEST TARGET (MT-3)











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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 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 response noted above (Reply to Notice of Violation, letter with payment of civil penalty, and Answer to a Notice of Violation) should be addressed to: Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555 with a copy to the Regional Administrator, U.S. Nuclear Regulatory Commission, Region I, 475 Allendale Road, King of Prussia, Pennsylvania 19406.

Dated at King of Prussia, Pennsylvania
this 29th day of June 1992

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

FEB 1 1992

Docket No. 030-02526
License No. 29-10191-02
EA 92-013

St. Joseph's Hospital and Medical Center
ATTN: Sister Jane Frances Brady
President
703 Main Street
Paterson, New Jersey 07503

Dear Sister Brady:

Subject: CONFIRMATORY ORDER MODIFYING LICENSE
(EFFECTIVE IMMEDIATELY)

Enclosed is a Confirmatory Order Modifying License (Effective Immediately) which confirms certain commitments made to the NRC in your letter dated December 27, 1991, in response to an Order Modifying License and Demand for Information issued by the NRC on December 3, 1991. The basis for this action is provided in the Confirmatory Order. On February 5, 1992, in a telephone conversation with Dr. Ron Bellamy of the Region I staff, Mr. Eugene Mortensen, your Chief Operating Officer agreed to this Order on your behalf.

This letter also acknowledges receipt of your payment of $10,250 for the civil penalties proposed by NRC in a letter dated December 3, 1991 (EA 91-128).

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," Part 2, Title 10, Code of Federal Regulations, 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 Operation Support

Enclosure: Confirmatory Order

cc: State of New Jersey
Thomas M. Herskovic, M.D.

UNITED STATES
NUCLEAR REGULATORY COMMISSION

In the Matter of	)	
	)	Docket No. 030-02526
ST. JOSEPH'S HOSPITAL	)	License No. 29-10191-02
AND MEDICAL CENTER	)	EA 92-013
Paterson, New Jersey	)	

CONFIRMATORY ORDER MODIFYING LICENSE
(EFFECTIVE IMMEDIATELY)

I

St. Joseph's Hospital and Medical Center (Licensee) is the holder of NRC Byproduct Material License No. 29-10191-02 (License) issued by the Nuclear Regulatory Commission (NRC or Commission) pursuant to 10 CFR Part 30. The License authorizes the Licensee to use certain byproduct materials for certain diagnostic and therapeutic medical purposes, including for use in a Nucletron Corporation Microselectron-High Dose Rate (HDR) remote afterloading brachytheraphy unit for the treatment of humans. The License was issued on January 2, 1970, has been renewed on several occasions since that date, and had an expiration date of July 31, 1991. The License remains in effect, pursuant to 10 CFR 30.37(b), since the Licensee has submitted, prior to the expiration date, a timely request to renew the License.

II

On January 24, 25 and 28, 1991, an NRC inspection was conducted at the Licensee's facility in Paterson, New Jersey to review the Licensee's use of the HDR unit. On January 23, 1991, the day prior to the initiation of the NRC inspection, NRC Region I staff were

involved in two telephone conversations with Thomas M. Herskovic, M.D. (Dr. Herskovic), the then Chairman of the Radiation Safety Committee (RSC), concerning possible movement and use of that HDR unit. Dr. Herskovic had been assigned additional duties as Acting Radiation Safety Officer (RSO) in December 1990 when the former RSO left the facility. As a result of concerns regarding the completeness and accuracy of the information provided by Dr. Herskovic during those telephone conversations, an investigation was initiated by the NRC Office of Investigations to review this matter.

III

During the NRC inspection and investigation of this matter, several violations of NRC requirements were identified. The violations included, but were not limited to: (1) the unauthorized movement of the HDR unit from the cobalt room to the radium storage room on two occasions, and the unauthorized movement of the HDR unit to the linear accelerator room where the HDR unit was used to treat patients on 18 occasions, in careless disregard of NRC requirements; (2) the failure, while the unit was used in the linear accelerator room to treat patients, to have interlocks installed on the door to that new location, thereby creating the possibility that someone could enter the room with the source exposed and not retracting to its shielded position; and (3) the deliberate failure by the then Chairman of the RSC to provide

complete and accurate information to the NRC during the two telephone conversations with the NRC on January 22, 1991 relative to the movement and use of the HDR unit.

As a result of those findings, a Notice of Violation and Proposed Imposition of Civil Penalties in the amount of $10,250 was issued to the Licensee on December 3, 1991. In addition, an Order Modifying License and a Demand for Information were also issued on that date which (1) modified License No. 29-10191-02 for a period of three years from the date of that order such that Dr. Herskovic may not be appointed or act as the RSO or serve on the Radiation Safety Committee; and (2) required the Licensee to provide to the NRC in writing, under oath or affirmation, an explanation as to why Dr. Herskovic should not also be precluded from any involvement in NRC licensed activities for a period of three years, including acting as an authorized user or under the supervision of an authorized user.

IV

In a letter dated December 27, 1991, the Licensee responded to the Civil Penalty, Order, and Demand for Information referenced in Section III above. With respect to the civil penalty, the Licensee paid the penalty, described the causes of the violations, and provided its corrective actions.

With respect to the Order Modifying License, the Licensee indicated that Dr. Herskovic has been replaced as the RSO, has stepped down as the RSC Chairman, and is no longer a voting member of the RSC (although he will remain on the committee as an ex-officio member to ensure that he stays informed of all changes and developments pertinent to the safe use of licensed materials and the Licensee's commitment to the conditions of the License).

With respect to the Demand for Information, the Licensee provided numerous reasons why it believes that Dr. Herskovic should not be precluded from acting as an authorized user or under the supervision of an authorized user. These reasons included his having practiced as a Radiotherapist for 17 years without question of his skills, ability, and integrity; his recognition in the medical community as a dedicated, skilled physician, as evidenced by the continued high number of patient referrals to his service; that he is an essential component of the Licensee's oncology program; the fact that removal of Dr. Herskovic would have a significant impact on the Licensee's ability to serve its patient population, especially the poor, and would compromise a significant portion of the Licensee's cancer treatment program; and that a series of checks and balances have been put in place to prevent these problems from occurring again. In particular, the Licensee described several steps that would be taken concerning Dr. Herskovic's role in licensed activities to ensure full compliance. Specifically, the Licensee stated the following:

1. Dr. Herskovic has agreed to take a tutorial designed to prepare health professionals to meet regulatory requirements of the NRC, and use licensed materials safely. Dr. Herskovic wishes to improve his proficiency and acquire an adequate level of knowledge so as to re-establish his competency in the field of radiation safety.

2. Dr. Herskovic's role in the treatment of the patients will be limited to clinical activities. Dr. Herskovic will always be accompanied by a physicist staff member while he handles radioactive materials. In the event that the radioactive sources have to be transferred from the Radioactive Safe Room to the operating room or to a patient's room, the physicist staff will carry the sources and will assist in the loading, unloading and transfer of the radioactive sources. Dr. Herskovic will not load or unload the sources from a patient unless accompanied by a physicist staff member.

3. In case of emergency during the implant of radioactive materials in a patient, the nursing staff are informed and trained to contact the R.S.O. However, if there is a need for Dr. Herskovic to remove the sources from the patient, he will place the sources into the porta-pig radioactive source transfer cart that is left in the

patient room during implant procedures. After the removal of the sources, Dr. Herskovic will contact the R.S.O. or his designee. The physicist staff will be called immediately for the completion of the survey, inventory of the sources and for the transfer of the sources to the safe.

4. Neither Dr. Herskovic nor any of the physicians will have the key to the Radioactive Safe Room. The key is issued only to the Physicist staff and to the chief technologist (for emergencies only). The hospital security has been instructed not to open the Radioactive Safe Room for any personnel other than approved physicist staff and the Radiation Therapy Chief Technologist.

V

The NRC staff has reviewed the Licensee's submittal, dated December 27, 1991, and concluded that implementation of commitments described in the Licensee's submittal would provide enhanced assurance that licensed activities by Dr. Herskovic would be performed in accordance with requirements, and that any information provided to the NRC concerning those activities would be complete and accurate. The staff has also concluded that these commitments are sufficient to protect public health and safety so that is is not necessary to completely preclude Dr. Herskovic's involvement in

licensed activities. As a result, I find that the Licensee's commitments set forth in its December 27, 1991 letter, as restated in Section IV of this Confirmatory Order, are acceptable and necessary, and conclude that with these commitments, the public health and safety are reasonably assured. In view of the foregoing, I have determined that the public health and safety require that the Licensee's commitments be confirmed by this Order. The Licensee has agreed to this action in a telephone call on February 5, 1992 between Dr. Ron Bellamy of Region I and Mr. Eugene Mortensen, the Chief Operating Officer. Pursuant to 10 CFR 2.202, I have also determined that the public health and safety require that this Order be immediately effective.

VI

Accordingly, pursuant to Sections 84, 161b, 161i, 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 Part 35, IT IS HEREBY ORDERED, EFFECTIVE IMMEDIATELY, THAT LICENSE NO. 29-10191-02 IS MODIFIED, FOR A PERIOD OF THREE YEARS FROM THE DATE OF THIS ORDER, AS FOLLOWS:

1. Dr. Herskovic will take a tutorial designed to prepare health professionals to meet regulatory requirements of the NRC and use licensed materials safely.

2. Dr. Herskovic's role in the treatment of patients will be limited to clinical activities. Dr. Herskovic will always be accompanied by a physicist staff member while handling radioactive materials. If the radioactive sources must be transferred from the Radioactive Safe Room to the operating room or to a patient's room, the physicist staff member will carry the sources and assist in the loading, unloading and transfer of the radioactive sources. Dr. Herskovic will not load or unload the sources from a patient unless accompanied by a physicist staff member.

3. In case of emergency during the implant of radioactive materials in a patient, the nursing staff will be informed and trained to contact the R.S.O. However, if there is a need for Dr. Herskovic to remove the sources from the patient, he will place the sources in the portapig radioactive source transfer cart that is to be left in the patient room during implant procedures. After the removal of the sources, Dr. Herskovic will contact the R.S.O. or his designee. The physicist staff will be called immediately for the completion of the survey, inventory of the sources, and for the transfer of the sources to the safe.

4. Neither Dr. Herskovic nor any of the physicians will have the key to the Radioactive Safe Room. The key will be issued only to the Physicist staff and to the chief technologist (for emergencies only). The hospital security will not open the Radioactive Safe Room for any personnel other than approved physicist staff and the Radiation Therapy Chief Technologist.

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

VII

Dr. Herskovic and any person other than the Licensee adversely affected by this Confirmatory Order may request a hearing within 20 days of its issuance. Any request for a hearing shall be submitted to the Secretary, U.S. Nuclear Regulatory Commission, ATTN: Chief, Docketing and Service Section, Wash gton, D.C. 20555. Copies also shall be sent to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, to the Assistant General Counsel for Hearings and Enforcement at the same address, to the Regional Administrator, NRC Region I, 475 Allendale Road, King of Prussia, Pennsylvania, 19406, and to the Licensee. If such a person other than Dr. Herskovic 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 Dr. Herskovic 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 the hearing shall be whether this Confirmatory Order should be sustained. In the absence of any request for hearing, the provisions specified in Section VI 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 10th day of February 1992

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

May 1, 1992

Docket No. 30-17757
License No. 37-16507-02
EA 92-064

Taylor Hospital
Attn: William Tomlinson
President
East Chester Pike
Ridley Park, Pennsylvania 19078

Dear Mr. Tomlinson:

Subject: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY - $1,250
(NRC Inspection Report No. 030-17757/92-001)

This letter refers to the NRC inspection conducted on March 2, 1992, at the above mentioned facility in Ridley Park, Pennsylvania, of activities authorized by NRC License No. 37-16507-02. The inspection report was sent to you on April 9, 1992. During the inspection, violations of NRC requirements were identified, including the improper transfer (and subsequent improper disposal), in June 1990, of a Siemens Gamma Camera which contained a 14 millicurie americium-241 source wand. On April 20, 1992, an enforcement conference was conducted with you and other members of your staff to discuss the loss, the related violations, their causes and your corrective actions. A copy of the Enforcement Conference Report is enclosed.

The transfer of the camera containing the source occurred in June 1990 when it was shipped to Medical Data Information Services (MDIS) located in Horsham, Pennsylvania. MDIS does not have a license to receive or possess radioactive material. Apparently, the camera was sold by your administrative staff who were not aware of the presence of the radioactive material within the device. Furthermore, the consultant, upon whom you relied for much of the implementation of the radiation safety program, was present at the Radiation Safety Committee (RSC) meetings that discussed the purchase of a new camera, but apparently did not inquire regarding the transfer of the old camera.

The improper transfer of this camera, and the apparent improper disposal of the encapsulated source after the unit was disassembled by MDIS, constitutes a significant regulatory concern. Particularly disturbing is the apparent lack of knowledge by the Radiation Safety Officer (RSO) that the radioactive source contained in the camera was missing. In addition, the

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

americium-241 source was not included on your inventory of radioactive sources at your facility, and was not added to the quarterly inventory list when 10 CFR 35.59(g) became effective on April 1, 1987, thereby requiring that all sealed sources be subject to quarterly inventories. As a result, the apparent improper transfer of the source contained in the camera was not identified until after the NRC inquired about the status of the source during a prior inspection in October 1991. Although your staff indicated at that time that the camera had been transferred, your staff was unable to locate the necessary paperwork to determine who had received the camera and source wand until January 1992.

In addition to the failure to inventory the sealed source in the camera at the required frequency, the NRC is also concerned that the source apparently was not leak tested as required between May 13, 1989 and June 14, 1990. The failure to perform the required quarterly inventories of the source, as well as leak testing the source at the required frequency, constitute two other violations of NRC requirements. These violations raise serious questions regarding the adequacy of the involvement of the RSO in the functioning of the radiation safety program, as well as the adequacy of the RSC in providing oversight of that program.

The NRC recognizes that the significance of the improper disposal was minimized by the fact that the radioactive source was in an encapsulated condition, and if the material was released, it was unlikely that the release would occur in such a way that a significant dose to an individual would result. Nonetheless, these violations demonstrate a lack of adequate control of radioactive material that you were authorized to possess under the terms of your license. The failure to maintain such control could have resulted in misuse of the material by, and could have created a potential for unnecessary exposure to, members of the public. In view of the above, the violations are classified in the aggregate as a Severity Level III problem in accordance with the revised "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C (Enforcement Policy), published in the Federal Register on February 18, 1992.

The NRC also recognizes that subsequent to the inspection, actions were initiated to correct the violations and effect improvements in the control of radioactive material. These actions, which were described either during the inspection or at the enforcement conference, included: (1) revision of the procedures for maintaining inventory lists; (2) requiring technologists, the RSO, and RSC to sign off on all purchases of radioactive material; and (3) review of reports from the physics consultant by the RSC.

Notwithstanding those corrective actions, to emphasize the importance of management, the RSC, and the RSO maintaining proper control of radioactive material at the facility, I have been authorized to issue the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice) in the amount of $1,250 for the violations set forth in the enclosed Notice. The base civil penalty amount for a Severity Level III problem is $2,500. The escalation and mitigation factors set forth in the enforcement policy were considered, and on balance, 50 percent mitigation of the base civil penalty was deemed appropriate because: (1) the

violations were identified by the NRC, and therefore, 50% escalation of the civil penalty on this factor is warranted; (2) your corrective actions, as described herein, although acceptable, did not include measures to ensure adequate management oversight of the program (and activities of your physics consultant) in areas other than physical control of material, and therefore, no adjustment of the base civil penalty on this factor is warranted; and (3) your performance in the past indicates only two minor violations were identified during the prior two NRC inspections in 1991 and 1989, and therefore, 100% mitigation of the civil penalty on this factor is warranted. The other escalation/mitigation factors set forth in the policy were considered and no further action is warranted because there were no prior opportunities to identify the improper disposal (since the source was not included on the inventory list), and the improper disposal did not involve multiple examples nor did it exist for an extended duration. Although the inventory and leak test violations involved multiple examples over an extended duration, those two violations were limited to this individual source wand, and in themselves, would normally be classified individually at Severity Level IV.

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

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

The responses directed by this letter and the enclosed Notice are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, Pub. L. 96-511.

Sincerely,

Thomas T. Martin
Regional Administrator

Enclosures:
1. Notice of Violation and Proposed Imposition of Civil Penalty
2. Enforcement Conference Report

cc:
Public Document Room (PDR)
Nuclear Safety Information Center (NSIC)
Commonwealth of Pennsylvania

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

Taylor Hospital
Ridley Park, Pennsylvania 19078

Docket No. 030-17757
License No. 37-16507-02
EA 92-064

During an NRC inspection conducted on March 2, 1992, violations of NRC requirements were identified. In accordance with the revised "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C, issued in the Federal Register on February 18, 1992, the Nuclear Regulatory Commission proposes to impose a civil penalty pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (Act), 42 U.S.C. 2282, and 10 CFR 2.205. The particular violations and associated civil penalty are set forth below:

A. 10 CFR 20.301(a) requires that no licensee dispose of licensed material except by certain specific procedures. 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, on June 14, 1990, the licensee disposed of a sealed source containing fourteen millicuries of americium-241 housed in a Siemens Gamma Camera by transfer to Medical Data Information Service, a person not authorized to receive such byproduct material under the terms and conditions of a specific license issued by the Commission or an Agreement State, and therefore, a disposal method not authorized by 10 CFR 20.301.

B. 10 CFR 35.59(g) requires, in part, that a licensee in possession of a sealed source or brachytherapy source conduct a quarterly physical inventory of all such sources in its possession.

Contrary to the above, the licensee did not conduct a physical inventory of a americium-241 sealed source in its possession from April 1, 1987 to June 14, 1990, a period in excess of a calendar quarter.

C. 10 CFR 35.59(b)(2) requires, in part, that a licensee in possession of a sealed source test the source for leakage at intervals not to exceed six months or at other intervals approved by the Commission or an Agreement State.

Contrary to the above, the licensee did not test a sealed source containing 14 millicuries of americium-241 for leakage between May 13, 1989 and June 14, 1990,

an interval in excess of six months, and no other interval was approved by the Commission or an Agreement State.

These violations are classified in the aggregate as a Severity Level III problem. (Supplements IV and VI)

Cumulative Civil Penalty - $1,250 (assessed equally among the three violations)

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

Within the same time as provided for the response required above under 10 CFR 2.201, the Licensee may pay the civil penalty by letter addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, with a check, draft, money order, or electronic transfer payable to the Treasurer of the United States in the amount of the civil penalty proposed above, or 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 V.B of 10 CFR Part 2, Appendix C, issued in the Federal Register on February 18, 1992, should be addressed. Any written answer in accordance with 10 CFR 2.205 should be set forth separately from the statement or explanation in reply pursuant to 10 CFR 2.201, but may incorporate parts of the 10 CFR 2.201 reply by specific reference (e.g., citing page and

paragraph numbers) to avoid repetition. The attention of the Licensee is directed to the other provisions of 10 CFR 2.205, regarding the procedure for imposing a civil penalty.

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

The response noted above (Reply to Notice of Violation, letter with payment of civil penalty, and Answer to a Notice of Violation) should be addressed to: Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555 with a copy to the Regional Administrator, U.S. Nuclear Regulatory Commission, Region I, 475 Allendale Road, King of Prussia, Pennsylvania 19406.

Dated at King of Prussia, Pennsylvania
this 1st day of May 1992

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

MAY 01 1992

Docket No. 030-02764
License No. 04-06903-05
EA 91-071

University of Cincinnati
ATTN: Donald Harrison, M.D.
Senior Vice President and
Provost for Health Affairs
141 Health Professions Building
Mail Location 663
Cincinnati, Ohio 45267-0063

Dear Dr. Harrison:

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY - $2,000 AND DEMAND FOR INFORMATION (NRC INVESTIGATION REPORT NO. 3-89-011)

This refers to the U. S. Nuclear Regulatory Commission (NRC) radiation safety program inspection conducted at the University of Cincinnati from August 25, 1989, through October 6, 1989, and to the subsequent investigation conducted by the NRC Office of Investigations. The investigation concerned sealed source inventory records that were concealed from the inspector during an August 1988 NRC inspection of the University of Cincinnati's radiation safety program. The investigation also concerned potentially discriminatory policies that were established within the Radiation Safety Office which may have prevented radiation protection personnel from reporting radiation safety concerns. During the investigation, a violation of NRC requirements was identified, and on January 29, 1992, an enforcement conference was held in the Region III office between you and other members of your staff, and Carl Paperiello, and other members of the NRC staff. A copy of the enforcement conference report was mailed to you on February 7, 1992.

The violation, which is described in the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice), concerns the concealment of sealed source inventory records from an NRC inspector during an August 1988 inspection. Approximately one month before the NRC inspection, a licensee radiation protection technician was assigned the task of performing leak tests on two nickel-63 sealed sources used in a gas chromatograph located in Wherry Hall at the University of Cincinnati. The technician could not locate either of the nickel-63 sources. Prior to the August 22-25, 1988, NRC inspection, the former Deputy RSO handed the sealed source leak test/inventory cards for the two nickel-63 sources which could not be located to a radiation protection technician, and said "Here, do something with these." This was

witnessed by two other technicians. The technician placed the cards in his desk where they remained throughout the NRC inspection.

During the inspection, the NRC inspector requested that the former RSO provide inventory records of the licensee's sealed sources. The former RSO instructed the former Deputy RSO to bring the inventory records into his office. The former Deputy RSO produced the inventory records, with the exception of the cards on the two missing sources, and the former RSO gave the NRC inspector the inventory cards. The NRC inspector was not told that the records for the two missing sources were not included or that the licensee could not account for the two nickel-63 sealed sources.

The deliberate actions to conceal information which indicated that the licensee could not account for all of the sealed sources of licensed byproduct material in its possession, including two nickel-63 sealed sources, constitute a violation of 10 CFR 30.9(a), "Completeness and Accuracy of Information." This violation has been categorized at Severity Level II in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy) 10 CFR Part 2, Appendix C (1988), Supplement VII.

Deceptive practices by licensee representatives during an NRC inspection are of very significant concern to the NRC and raise questions about the integrity of the individuals involved. Therefore, to emphasize the need for total candor of licensee representatives in their dealings with the NRC, 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 II violation.

The base value of a civil penalty for a Severity Level II violation at academic and medical institutions is $4,000. The escalation and mitigation factors in the Enforcement Policy were considered. A reduction of the base civil penalty was considered appropriate for your identification and reporting of the violation and your immediate corrective action. In this case, you identified the potential violation through an employee allegation to management, immediately evaluated the circumstances surrounding the violation, and took prompt corrective action by relieving the involved employees from their duties under the NRC licensed program at the University of Cincinnati. As a result of those actions, the civil penalty is being mitigated 50%. Full mitigation is not appropriate because of the willful nature of the violation involving a Deputy RSO.

As stated above, we understand that Mr. Jason was removed from NRC-licensed activities at the University of Cincinnati in August 1989 and that his employment has since been terminated. Because of our concern regarding this individual, we are issuing the enclosed Demand for Information. The Demand directs the University of

Cincinnati to provide the NRC with prior notice should Mr. Jason be reinvolved in licensed activities authorized under any of the NRC licenses issued to the University of Cincinnati.

The investigation also indicated that the former RSO may have had knowledge of the missing sources at the time of the inspection and participated in the withholding of the records. The staff is not pursuing that matter at this time because there is insufficient evidence to take enforcement action based on his conduct.

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 responses, including your proposed corrective actions and the results of future inspections, the NRC will determine whether further NRC enforcement action is necessary to ensure compliance with NRC regulatory requirements.

The NRC investigation also verified information that the former RSO and an administrative director issued two memoranda, dated July 1, 1986, and June 30, 1988, which were viewed by some members of the radiation protection staff as restricting their communications with licensee managers outside of the radiation protection program and communications with the NRC. Such a policy is void and unenforceable as against the public policy reflected in Section 210 of the Energy Reorganization Act of 1974, as amended. This would have been a violation of 10 CFR 30.7(g) if that requirement had been in effect at the time of the action. However, while a violation of 10 CFR 30.7 was not established in this case, the NRC is, nonetheless, concerned about the perceptions that University employees may have formed from those policies, and that the members of the radiation protection staff may not have notified licensee management or the NRC of any unresolved radiation safety issues because of the policies. Therefore, in addition to the response required by the Notice, you are requested to describe what actions you are taking to determine if any radiation safety concerns might not have been identified as a result of the potential "chilling effect" the discriminatory policies may have created, whether identified concerns were properly handled, and why the NRC should have confidence that current employees feel free to identify safety issues to licensee management and to the NRC.

Questions concerning the Demand should be addressed to 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 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,

Hugh L. Thompson, Jr.
Deputy Executive Director for
Nuclear Materials Safety, Safeguards,
and Operations Support

Enclosures: As Stated

cc w/enclosures:
State of Ohio
Prince Jason
University of Cincinnati
Marc D. Mezibov

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

University of Cincinnati
Cincinnati, Ohio

Docket No. 030-02764
License No. 34-06903-05
EA 91-071

During an NRC inspection conducted on August 25, 1989, through October 6, 1989, and a subsequent NRC investigation, 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 (1988), 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:

License Condition No. 14 of NRC Byproduct Materials License No. 34-06903-05 requires the licensee to conduct a physical inventory every six months to account for all sources and/or devices received and possessed under the license. Records of the inventories shall be maintained for two years from the date of each inventory.

10 CFR 30.9 requires, in part, that information provided to the Commission by a licensee be complete and accurate in all material respects.

Contrary to the above, information provided to an NRC inspector during an August 22-25, 1988, inspection was not complete and accurate in all material respects. The information was not complete and accurate in that a licensee representative provided leak test and inventory records to the inspector knowing that the records were incomplete because he had previously removed leak test and inventory records associated with two nickel-63 sealed sources, and because he failed to disclose this fact to the inspector. The information was material because the concealed records would have demonstrated that NRC-licensed material could not be accounted for by the licensee.

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

Pursuant to the provisions of 10 CFR 2.201, the University of Cincinnati (Licensee) is hereby required to submit a written statement of explanation to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, within 30 days of the date of this Notice of Violation and Proposed Imposition of Civil Penalty (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each alleged violation: (1) admission or denial of the alleged violation, (2) the reasons for the violation if admitted, and if denied, the reasons why, (3)

the corrective steps that have been taken and the results achieved, (4) the corrective steps that will be taken to avoid further violations, and (5) the date when full compliance is achieved. If an adequate reply is not received within the time specified in this Notice, an order or demand 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 circumsta , (3) show error in this Notice, or (4) show other reasons w he penalty should not be imposed. In addition to protesti 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 (1988), 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 Rockville, Maryland
this 17 day of May 1992

UNITED STATES
NUCLEAR REGULATORY COMMISSION

In the Matter of	)	Dockets No. 030-02764;
	)	030-11331; 030-18949;
UNIVERSITY OF CINCINNATI	)	030-20526; 040-02678;
Cincinnati, Ohio	)	and 070-00539
	)	Licenses No. 34-06903-05;
	)	34-06903-09; 34-06903-11;
	)	34-06903-13; SUD-265; and
	)	SNM-490
	)	EA 91-071

DEMAND FOR INFORMATION

I

The University of Cincinnati, Cincinnati, Ohio (Licensee) is the holder of six licenses issued by the Nuclear Regulatory Commission (NRC or Commission), including Byproduct Material License No. 34-06903-05 (License) issued pursuant to 10 CFR Part 30. The license, originally issued on May 21, 1986, was last amended on August 3, 1990, and was due to expire on May 31, 1991. A timely license renewal application is pending.

II

A routine NRC inspection was conducted during the period August 22-25, 1988. During the inspection, the NRC inspector requested that the former Radiation Safety Officer (RSO) provide the sealed source inventory records. The former RSO asked Mr. Prince Jason, the former Deputy Radiation Safety Officer (DRSO), to bring the records to the former RSO's office and Mr. Jason complied. However, Mr. Jason brought the inventory records for all sealed sources except the two nickel-63 sources, thus creating the appearance that the Licensee could account for all sealed sources. Mr. Jason did not

tell the nspector that the records did not contain the records for the two nickel-63 sources or that the Licensee could not account for those sealed sources. A subsequent NRC investigation (Investigation No. 3-89-011) was conducted into this matter. During this investigation, Mr. Jason admitted that he concealed records of sealed source leak tests and inventories from an NRC inspector during an August 22-25, 1988, NRC inspection.

The concealment of these records is a violation of 10 CFR 30.9, "Completeness and Accuracy of Information," as described in the Notice of Violation and Proposed Imposition of Civil Penalty issued this date.

In August 1989, Mr. Jason was removed from his position in the NRC licensed programs at the University of Cincinnati and he was subsequently terminated.

On January 10, 1992, NRC sought to have an enforcement conference with Mr. Jason to further discuss the matter. However, he declined to participate in a conference.

III

Based on the results of the NRC inspection and investigation, the staff has questions whether Mr. Jason will provide complete and accurate information to the Commission concerning potential health

and safety issues and otherwise comply with the regulations. Therefore, advance notice of any reinvolvement of Mr. Jason in licensed activities is required so that the staff can determine at that time whether further regulatory action is warranted.

Accordingly, 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 Part 30, the Licensee is required to provide the NRC Regional Administrator, Region III, written notice at least one week prior to Mr. Prince Jason's reinvolvement in activities authorized under Licenses No. 34-06903-05, 34-06903-09, 34-06903-11, 34-06903-13, SUD-265, and/or SNM-490. The notice shall include a statement from the Licensee explaining its basis for concluding that, in light of Mr. Jason's prior conduct described in this Demand, he can be expected to provide complete and accurate information to the Commission and to otherwise comply with NRC requirements. This condition expires five years from its effective date.

Copies shall also be sent to the Director, Office of Enforcement, and the Assistant General Counsel for Hearings and Enforcement, both at U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

After reviewing any notice and statement in response to this Demand, the NRC will determine whether further action is necessary to ensure compliance with regulatory requirements.

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 1st day of May 1992

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

MAY 21 1992

Mr. Prince Jason
1246 Avon Drive
Cincinnati, Ohio 45229

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY AND DEMAND FOR INFORMATION SENT TO THE UNIVERSITY OF CINCINNATI

Dear Mr. Jason:

Enclosed for your information is a Notice of Violation and Proposed Civil Penalty and Demand for Information issued to the University of Cincinnati. These actions arise out of your activities at the University when you were the Assistant Radiation Safety Officer in 1988.

These actions do not prohibit you from being involved in licensed activities in the future at the University. However, the Demand for Information does require the University to provide at least one week notice before permitting your reinvolvement in licensed activities at the University. At that time the NRC can decide if further regulatory action is appropriate.

You are not required to respond to these actions. If you do desire to provide a response to the NRC concerning your involvement in the activities that underlie these actions or to address the information requirements in section III of the Demand for Information, you may provide a written response within 30 days of the date of this letter to the Regional Administrator, Region III, 799 Roosevelt Road, Glen Ellyn, Illinois 60137, with a copy to the Director, Office of Enforcement, and the Assistant General Counsel for Hearing and Enforcement, both at the U. S. Nuclear Regulatory Commission Washington, D.C. 20555.

Should you have any questions on this matter, please call James Lieberman, Director, Office of Enforcement, at 301-504-2741.

Sincerely,

Hugh L. Thompson, Jr.
Deputy Executive Director for
Nuclear Materials Safety, Safeguards,
and Operations Support

Enclosure: As Stated

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

DEC 20 1991

Docket No. 030-06402
License No. 42-02964-01
EA 91-121

Western Atlas International
ATTN: Bill Rose
Radiation Protection Officer
P.O. Box 1407
Houston, Texas 77251

Gentlemen:

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY - $10,000 (NRC INSPECTION REPORT NO. 30-06402/91-01)

This is in reference to NRC's September 6-7 and 11, 1991, inspection of the circumstances surrounding a September 5, 1991 incident involving the loss of a nominal two curie cesium-137 sealed source being transported with other radioactive sources from Yukon, Oklahoma to Houston, Texas. An inspection report was issued on September 23, 1991. Based on the results of this inspection, which disclosed violations of NRC and United States Department of Transportation (DOT) requirements, an enforcement conference with you and other company representatives was conducted in NRC's Arlington, Texas office on October 1, 1991.

As discussed at the enforcement conference, NRC attributes the loss of this material during transport to two violations of NRC and DOT requirements. These include Western Atlas International's failure to properly block and brace the shielded source container on the transport vehicle and failure to ensure that all closure mechanisms on the shielded container were in place.

These requirements are designed to prevent serious safety incidents, such as the incident that occurred on September 5, 1991. Western Atlas International's failure to meet these requirements resulted in the accidental loss of the shielded container from the vehicle and the separation of the radioactive source from its shielded container.

The violations that resulted in this incident appear to have occurred because the involved Western Atlas personnel, including a manager, failed to follow established transportation procedures, failed to correct previously identified defects in transportation containers, and were inattentive to the specific

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requirements of the NRC and the DOT. It is of particular concern that, as Western Atlas indicated during the enforcement conference, a safety audit in August 1991 identified defects in the shipping containers, including missing safety pins and locking bars. The auditor directed that the containers not be used until the defects were corrected. The findings of this audit and the need to repair the containers prior to use were reportedly further discussed the following week with the responsible manager and other members of licensee management. Nonetheless, the responsible manager disregarded these instructions. If these defects had been corrected prior to the shipment, it is likely that the source would not have been separated from its shielding and the resultant exposure to a member of the general public would not have occurred.

The violations that contributed to this incident are significant from a safety and regulatory perspective in that they resulted in an incident which posed a significant potential threat to the health and safety of the general public. This is illustrated by the fact that the source was found by one member of the general public and was actually picked up and handled by another member of the general public. As a direct result of the violations: 1) radioactive material in transit was lost from the transport vehicle; 2) the radioactive material became separated from its shielding; and 3) members of the general public came into contact with the unshielded radioactive material, providing the potential for the maximum credible accident that can occur with regard to the transportation of radioactive materials of this type. It was merely fortuitous that the person who handled the source held it only for a short time and then returned it to the ground. In other events, lost sources have been found and kept by members of the general public, resulting in some cases, in serious injuries and deaths. Therefore, in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy) 10 CFR Part 2, Appendix C (1991), these violations have been classified in the aggregate at Severity Level I.

NRC recognizes that Western Atlas's past performance based on several inspections has been good and that Western Atlas took immediate steps to ensure that all Western Atlas personnel were aware of the incident and its causes so that the same mistakes would not be made. In addition, based on the discussions at the enforcement conference, NRC recognizes Western Atlas's commitment to a variety of actions, involving both physical modifications to source-transport vehicles and procedural enhancements, to ensure against a recurrence of an incident of this type. It is noted, however, that many of the corrective actions discussed at the enforcement conference were tentative and that you intended to receive NRC concurrence prior to implementing those actions. As discussed during the enforcement conference, NRC expects and urges you to initiate action on those measures that will enhance safety as soon as practicable.

To emphasize the significance of the violations that put the general public at significant risk, and to assure that your corrective actions are lasting, I have been authorized, after consultation with the Director, Office of Enforcement, the Deputy Executive Director for Nuclear Materials Safety, Safeguards and Operations Support, and the Commission, to issue the enclosed Notice of

Violation and Proposed Imposition of Civil Penalty (Notice) in the amount of $10,000 for the Severity Level I problem described above.

For well-logging licensees, the normal base value of a civil penalty for each Severity Level I violation of this type is $1,000. However, in this case, NRC has decided to assess a $10,000 base civil penalty. This decision is based on the potential consequences to the general public caused by the violations.

In the NRC's consideration of the escalation and mitigation factors described in Appendix C of 10 CFR 2, it was determined that any mitigation based on your good past performance was offset by your prior notice regarding the defects in the shipping container's closure mechanism. The other factors were considered and no further escalation or mitigation was deemed appropriate.

The violations in Part II of the Notice are not being assessed a civil penalty. We note, however, that your failure to notify the U.S. Department of Transportation would have been considered more significant had you not immediately notified the Texas Bureau of Radiation Control upon discovering the missing source. Notifying the State of Texas, however, did not relieve you of your obligation to notify the U.S. Department of Transportation.

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

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

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

Sincerely,

for John M. Montgomery
Robert D. Martin
Regional Administrator

Enclosure:
Notice of Violation and Proposed Imposition
of Civil Penalty

cc:
State of Texas Radiation Control Program Director
State of Oklahoma Radiation Control Program Director

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

Western Atlas International
Houston, Texas

Docket No. 030-06402
License No. 42-02964-01
EA 91-121

During an NRC inspection conducted on September 6-7 and 11, 1991, 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 (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 violations and associated civil penalty are set forth below:

I. Violations Assessed a Civil Penalty

A. 10 CFR 71.5(a) requires that each licensee who transports licensed radioactive material outside of the confines of its plant or other place of use, or who delivers licensed material to a carrier for transport, shall comply with the applicable requirements of the regulations appropriate to the mode of transport of the United States Department of Transportation (DOT) in 49 CFR Parts 170 through 189.

49 CFR 177.842(d) requires that packages of radioactive material must be so blocked and braced that they cannot change position during conditions normally incident to transportation.

Contrary to the above, on September 5, 1991, the licensee did not adequately block and brace a package containing licensed material to prevent the movement and subsequent accidental loss of that package from the transport vehicle. Specifically, a transport package containing a two curie cesium 137 sealed source was not sufficiently blocked and braced on the transport vehicle to prevent the accidental loss of the package under conditions normally incident to transportation while en route from Yukon, Oklahoma to Houston Texas.

B. 10 CFR 71.5(a) requires that each licensee who transports licensed radioactive material outside of the confines of its plant or other place of use, or who delivers licensed material to a carrier for transport, shall comply with the applicable requirements of the regulations appropriate to the mode of transport of the United States Department of Transportation (DOT) in 49 CFR Parts 170 through 189.

49 CFR 173.475 requires, in part, that prior to each shipment of radioactive material, the licensee ensure that the transport package is in unimpaired condition and that each closure device is properly installed and secured and free of defects.

Contrary to the above, on September 5, 1991, the licensee did not ensure that the transport package's closure device was properly installed and secured and free of defects. Specifically, the safety pin designed to secure the locking bar of the transportation package's closure device was not installed prior to the package's use in transporting a two curie cesium 137 sealed source. Subsequently, the closure device became dislodged during transport which allowed the sealed source to become separated from the transport package when the package was lost from the transport vehicle while en route from Yukon, Oklahoma to Houston, Texas.

Collectively, this is a Severity Level I problem. Cumulative Civil Penalty - $10,000 (assessed equally between the two violations).

II. Violations Not Assessed a Civil Penalty

A. 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, shall comply with the applicable requirements of the regulations appropriate to the mode of transport of the DOT in 49 CFR Parts 170-189.

49 CFR 171.15(a)(2) requires, in part, that at the earliest practicable moment, each carrier who transports hazardous materials shall give notice in accordance with paragraph (b) of this section after each accident that occurs during the course of transportation in which spillage occurs involving shipment of radioactive material.

Paragraph (b) requires, in part, that each notice required by paragraph (a) of this section be given to the DOT by telephone at (800) 424-8802.

Contrary to the above, the licensee did not give any notice to DOT after the September 5, 1991 incident involving the spillage of a nominal two curie cesium 137 sealed source, during transport from Yukon, Oklahoma to Houston, Texas.

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

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, shall comply with the applicable requirements of the regulations appropriate to the mode of transport of the DOT in 49 CFR Parts 170-189.

49 CFR 172.403(b) requires in part, that the proper label be affixed to a package of radioactive material based on the radiation level at the surface of the package and the transport index.

Contrary to the above, on September 5, 1991, the licensee transported radioactive material in transport packages incorrectly labeled as RADIOACTIVE YELLOW II. The correct label was RADIOACTIVE YELLOW III for packages containing byproduct material transported by the licensee on this date from Yukon, Oklahoma to Houston, Texas.

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

C. 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, shall comply with the applicable requirements of the regulations appropriate to the mode of transport of the DOT in 49 CFR Parts 170-189.

1. 49 CFR 172.201(d) states that a shipping paper must contain an emergency response telephone number, as prescribed in Subpart G of Part 172 of this subchapter.

   Contrary to the above, on September 5, 1991, the licensee transported radioactive material with a shipping paper that did not contain an emergency response telephone number.

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

2. 49 CFR 172.201(c) states that a shipping paper may consist of more than one page if each page is consecutively numbered and the first page bears a notation specifying the total number of pages included in the shipping paper. For example, "page 1 of 4 pages."

   Contrary to the above, on September 5, 1991, the licensee transported radioactive material with a shipping paper that consisted of more than one page and the pages of the shipping paper were not consecutively numbered.

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

3. 49 CFR 172.203(c)(2) requires the letters "RQ" to be entered on the shipping paper either before or after the basic description required by paragraph 172.202 for each hazardous substance.

   Contrary to the above, on September 5, 1991, the licensee transported radioactive material and the letters "RQ" were not entered on the shipping paper either before or after the basic description required by paragraph 172.202 for each hazardous substance.

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

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

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

In requesting mitigation of the proposed penalty, the factors addressed in Section 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 234(c) 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 December, 1991

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

JUN 05 1992

Docket No. 30-06402
License No. 42-02964-01
EA 91-121

Western Atlas International
ATTN: Bill Rose
Radiation Protection Officer
Post Office Box 1407
Houston, Texas 77251

Gentlemen:

SUBJECT: ORDER IMPOSING CIVIL MONETARY PENALTY - $10,000

This refers to your letters (Answer to a Notice of Violation and Reply to a Notice of Violation) dated January 24, 1992, in response to the Notice of Violation and Proposed Imposition of Civil Penalty (Notice) sent to you by our letter dated December 20, 1991. Our letter and Notice described several violations identified during NRC inspections conducted on September 6-7 and September 11, 1991.

Two of the violations in the Notice (Violations I.A. and I.B.) involved the failure to transport radioactive material properly and resulted in the loss of a sealed radioactive source from a vehicle. To emphasize the significance of violations that put the general public at significant risk, and to assure that your corrective actions were lasting, a civil penalty of $10,000 was proposed.

In your responses, you admitted the violations which resulted in the proposed civil penalty but requested mitigation of the penalty. After consideration of your responses, we have concluded, for the reasons given in the Appendix attached to the enclosed Order Imposing Civil Monetary Penalty, that an adequate basis was not provided for mitigation of the civil penalty.

Accordingly, we hereby serve the enclosed Order on Western Atlas International, Inc., imposing a civil monetary penalty in the amount of $10,000. We will review the effectiveness of your corrective actions during a subsequent inspection.

In imposing this civil penalty, we emphasize that your responsibility for assuring the safe use of licensed material

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extends not only to identifying potential problems that may lead to violations of NRC regulatory requirements, but also to assuring that such problems are fully corrected so that the violations do not occur. This responsibility lies with licensee management. Significant violations such as occurred in this case because of the failure of licensee management cannot and will not be tolerated.

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:
Order Imposing Civil Monetary Penalty

cc:
State of Texas Radiation Control Program Director
State of Oklahoma Radiation Control Program Director

UNITED STATES
NUCLEAR REGULATORY COMMISSION

In the Matter of	)	
	)	Docket No. 30-06402
WESTERN ATLAS INTERNATIONAL, INC.	)	License No. 42-02964-01
Houston, Texas	)	EA 91-121

ORDER IMPOSING CIVIL MONETARY PENALTY

I

Western Atlas International, Inc. (Licensee) is the holder of Materials License No. 42-02964-01 issued by the Nuclear Regulatory Commission (NRC or Commission). The license authorizes the Licensee to possess a variety of radioactive byproduct materials for use in well tracer studies and well logging activities in accordance with the conditions specified therein.

II

An inspection of the Licensee's activities was conducted on September 6-7 and September 11, 1991, to review the circumstances surrounding a September 5, 1991 incident involving the loss of a cesium-137 sealed source being transported with other sources from Yukon, Oklahoma to Houston, Texas. 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 December 20, 1991. The Notice stated the nature of the violations, the provisio. , 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 letters dated January 24, 1992. In response, the Licensee admitted the violations that resulted in the proposed civil penalty, but requested mitigation of the 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 $10,000 penalty proposed for the violations designated in the Notice should be imposed.

IV

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

The Licensee pay a civil penalty in the amount of $10,000 within 30 days of the date of this Order, by check, draft, or money order, or electronic transfer, payable to the Treasurer of the United States and mailed to the Director,

Office of Enforcement, U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555.

V

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

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

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

Whether on the basis of the violations, which were 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 5th day of June 1992

APPENDIX

EVALUATION AND CONCLUSIONS

On December 20, 1991, a Notice of Violation and Proposed Imposition of Civil Penalty (Notice) was issued for violations identified during an NRC inspection. Western Atlas International, Inc. (WAII or Licensee) responded to the Notice on January 24, 1992. The Licensee admitted the violations which resulted in the proposed civil penalty but requested mitigation of the penalty. The NRC's evaluation and conclusions regarding the Licensee's requests are as follows:

Restatement of Violations (Part I of Notice, Violations Assessed a Civil Penalty)

A. 10 CFR 71.5(a) requires that each licensee who transports licensed radioactive material outside of the confines of its plant or other place of use, or who delivers licensed material to a carrier for transport, shall comply with the applicable requirements of the regulations appropriate to the mode of transport of the United States Department of Transportation (DOT) in 49 CFR Parts 170 through 189.

49 CFR 177.842(d) requires that packages of radioactive material must be so blocked and braced that they cannot change position during conditions normally incident to transportation.

Contrary to the above, on September 5, 1991, the licensee did not adequately block and brace a package containing licensed material to prevent the movement and subsequent accidental loss of that package from the transport vehicle. Specifically, a transport package containing a two curie cesium 137 sealed source was not sufficiently blocked and braced on the transport vehicle to prevent the accidental loss of the package under conditions normally incident to transportation while en route from Yukon, Oklahoma to Houston Texas.

B. 10 CFR 71.5(a) requires that each licensee who transports licensed radioactive material outside of the confines of its plant or other place of use, or who delivers licensed material to a carrier for transport, shall comply with the applicable requirements of the regulations appropriate to the mode of transport of the United States Department of Transportation (DOT) in 49 CFR Parts 170 through 189.

49 CFR 173.475 requires, in part, that prior to each shipment of radioactive material the licensee ensure that the transport package is in unimpaired condition and that each closure device is properly installed and secured and free of defects.

Contrary to the above, on September 5, 1991, the licensee did not ensure that the transport package's closure device was properly installed and secured and free of defects. Specifically, the safety pin designed to secure the locking bar of the transportation package's closure device was not installed prior to the package's use in transporting a two curie cesium 137 sealed source. Subsequently, the closure device became dislodged during transport which allowed the sealed source to become separated from the transport vehicle while en route from Yukon, Oklahoma to Houston, Texas.

Collectively, this is a Severity Level I problem. Cumulative Civil Penalty - $10,000 (assessed equally between the two violations).

Summary of Licensee's Response and Request for Mitigation

The Licensee admitted the violations which resulted in the proposed civil penalty but requested mitigation of the penalty from $10,000 to either the basic $2,000 (referring to the normal base value alluded to on Page 3 of NRC's December 20, 1991, Notice) or to something closer to $2,000. The Licensee based its request for mitigation on its arguments that:

1) The amount of the civil penalty should not have been increased based on "prior notice" where the WAII Senior Safety Engineer performed an inspection in advance of the shipment of radioactive sources and instructed a district manager to take certain actions prior to shipping the sources.

2) WAII does not need additional punishment to get its attention, as indicated by the fact that it terminated the employment of the district manager who, according to WAII, intentionally did not follow instructions which could have mitigated the consequences of the event; and by the fact that it took corrective actions to preclude recurrence, including modifications to its carrier vehicles.

3) The penalty against WAII should reflect what actually occurred, not what could have occurred based on speculation.

4) The penalty should reflect the past good record of WAII.

NRC Evaluation of Licensee's Response

1) Prior Notice

NRC's December 20, 1991, letter stated "...it was determined that any mitigation based on your good past performance was offset by your prior notice regarding the defects in the

shipping container's closure mechanism." NRC's Enforcement Policy (Section V.B.) permits increasing a civil penalty by as much as 100% in cases where the licensee had prior knowledge of a potential problem as a result of a licensee review, and failed to take effective corrective steps.

WAII questions whether this factor should be applied when, as it argues in this case, an inspection is performed by the licensee in advance of an activity and responsible individuals ignore instructions to take steps to preclude violations. "It would appear," WAII said in its reply, "that the NRC prefers WAII had not made the preliminary inspection so that any loss would have been simply inadvertent or without knowledge ... Failing to do so should be a factor which increases the penalty, not the reverse..."

It is expected that licensees conduct appropriate audits to assure that regulatory requirements are being met. Licensees who fail to perform such audits do so at their peril since they risk escalated enforcement action for NRC-identified violations. Therefore, NRC does not accept the contention that licensee management will not conduct audits to identify safety issues because of fear of enforcement action. Such an attitude is inconsistent with the safety ethic expected of licensees.

The NRC Enforcement Policy provides that meticulous attention to detail is expected from licensees in order to assure adequate protection of the public health and safety. The preliminary inspection performed by the Licensee's Senior Safety Engineer exemplifies this approach. The issue in this case is not that the civil penalty is being escalated for performing an audit, but rather that the penalty is being escalated because there was not adequate follow up by management consistent with the safety significance of the problem that the audit uncovered.

As a result of the preliminary inspection, Licensee management had knowledge of a problem with significant health and safety implications; but subsequently, the District Manager, a Licensee official, failed to address the issue. The NRC Enforcement Policy defines a "licensee official" as a first line supervisor or above. Had the failure occurred on the part of a non-management employee, the outcome of the enforcement action would have been different.

The Licensee further seeks to distance itself from the failure of its employee by stating that "specific remedial instructions were given which were ignored by a District Manager who had no history of ignoring such instructions." NRC is not in a position to comment on whether the District

Manager had a history of ignoring instructions. It is not clear why, in the absence of a history of not following instructions, he would do so here. Nevertheless, the use of inadequately prepared shipping containers is a serious matter that should have had further follow up to assure that the problem was corrected. Considering that the District Manager failed to follow through by executing the instructions of the Senior Safety Engineer, and that the Senior Safety Engineer failed to follow up with the District Manager to assure that the instructions were executed, it is clear that Licensee management, with the knowledge available, could have taken reasonable action that would have prevented the violation from occurring. As a result of the failure to follow through on the part of Licensee management, a violation occurred that involved the potential for very significant radiation exposure, and one member of the public did receive an exposure to his fingers of 3.5 to 5.5 rem.

Under these circumstances, the NRC Staff believes that it acted appropriately in balancing mitigation for prior good performance (in this case, 100% mitigation) against escalation for prior notice (in this case, 100% escalation). The Licensee has provided no basis for any additional mitigation.

2. Incentives to Take Corrective Action

The Licensee argues that the civil penalty is not necessary to cause it to take its responsibilities seriously and to take corrective actions. NRC licensees are always expected to take their responsibilities seriously and take appropriate corrective action. Additional action would be taken if a licensee argued otherwise. Civil penalties are assessed to deter future noncompliance on the part of all licensees and to emphasize the need for lasting corrective action. The deterrent effect is achieved when licensees, in order to avoid civil penalties, take prompt and effective action in advance of any potential violation so that the violation does not occur and the NRC does not have to become involved. Thus, the NRC Staff does not believe that the Licensee's argument warrants reconsideration of the civil penalty.

3. Actual vs. Hypothetical Consequences

The Licensee argues that the penalty should reflect what actually occurred, not what could have occurred. However, the NRC Enforcement Policy takes into account both actual and potential safety consequences. In this case, the NRC

Staff, after consulting the Commission, assigned the highest possible severity level to the violations because they resulted in actual unnecessary radiation exposures to emergency response personnel and had a potential for much higher exposures to these individuals and to other members of the public. The regulations that were violated are designed to prevent licensed radioactive sources from posing this type of hazard. The entire system of containment -- consisting of the source container itself and the securing of the container to the vehicle -- failed due to these violations. As the Commission stated in X-Ray Engineering, ". . . our statutory obligation to protect the public health and safety is not subject to the condition precedent that actual injuries occur." 1 AEC 553, 555 (1960).

The Licensee also raises an issue as to whether the emergency response personnel acted reasonably and were adequately trained. However, the responsibility to adequately control licensed material so as to assure the protection of the public health and safety rests with the Licensee and not with emergency response personnel or other members of the general public. Moreover, any person could have stopped on the roadway and picked up the source. Only luck prevented that scenario, with its resulting adverse health and safety consequences, from happening.

Thus, the NRC Staff does not find that the Licensee's argument warrants reconsideration of the civil penalty.

4. Compliance History

The Licensee argues that the civil penalty should reflect the good past record of WAII. As discussed above, in proposing the penalty, NRC did take the Licensee's past performance into account and concluded that mitigation of the base penalty value was appropriate based on prior good performance. However, this mitigation was offset by the escalation of the base penalty value on the prior notice factor.

NRC Conclusion

The NRC Staff concludes that the Licensee has not provided an adequate basis for mitigation of the civil penalty. Consequently, the proposed civil penalty in the amount of $10,000 should be imposed.

II.B. MATERIALS LICENSEES, SEVERITY LEVEL III VIOLATION,
NO CIVIL PENALTY

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

May 6, 1992

Docket No. 030-12641
License No. 24-16275-02
EA 92-070

Bothwell Regional Health Center
ATTN: Richard Davidson
Assistant Administrator
601 East 14th Street
Sedalia, Missouri 65301

Dear Mr. Davidson:

SUBJECT: NOTICE OF VIOLATION
(NRC INSPECTION REPORT NO. 030-12641/92001)

This refers to the special safety inspection conducted at Bothwell Regional Health Center, Sedalia, Missouri, on March 30 and 31, 1992, to review the circumstances associated with your reported cobalt-60 teletherapy misadministration. The report documenting this inspection was mailed to you on April 17, 1992. A violation of NRC requirements was identified during the inspection, and on April 23, 1992, an enforcement conference was held with you; Mr. William L. Axelson, Deputy Director, Division of Radiation Safety and Safeguards; and other members of our respective staffs. A copy of the report documenting the enforcement conference was mailed to you by letter dated May 1, 1992.

On March 27, 1992, you notified the U. S. Nuclear Regulatory Commission (NRC) Region III Office that a misadministration occurred during the period March 18 through 27, 1992, due to an error in the treatment calculations. As a result of this error in the calculation, the patient received 340 rads during each of 8 treatments, rather than the prescribed 200 rads per treatment fraction. The error was discovered when a physicist performed a biweekly review of the treatment plan and the calculations. The remaining treatment schedule was then adjusted to accommodate the increased dose delivered during the initial eight treatments of the series.

The violation, described in the enclosed Notice of Violation, concerns failures to follow the procedures established by your quality management program. The failures include: (1) the failure to perform an adequate weekly chart check to detect arithmetic errors; and (2) the failure to review the dose calculations within three working days after administering the first teletherapy fractional dose when the prescribed dose is to be administered in

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more than three fractions. The failure to follow the procedures of your quality management program, which resulted in a therapeutic misadministration, is considered significant and in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy) 10 CFR Part 2, Appendix C (1992), this violation was categorized at Severity Level III.

In accordance with the Enforcement Policy a civil penalty is usually assessed for a Severity Level III violation in order to emphasize the need for strict adherence to regulatory requirements during teletherapy treatment. However, after considering the civil penalty adjustment factors set forth in the NRC's Enforcement Policy, I have decided that a civil penalty will not be assessed for the Severity Level III violation. Full mitigation of this penalty was appropriate because you identified the violation and your past regulatory performance is excellent.

The root causes of the violation and the subsequent corrective actions were discussed during the April 23, 1992, enforcement conference. The major factor contributing to the violation appeared to be the unique source-to-skin distance (SSD) of 70 cm, as this was only the second time that an SSD of 70 cm was used instead of the standard 80 cm SSD.

The NRC recognizes that you implemented corrective actions; however, some of those actions need further clarification. As an example, you included a requirement in your Quality Management Program that a physicist verify calculations for a treatment plan which has unusual circumstances (e.g. an SSD of other than 80 cm), but you did not specify when that review should be performed. Also, your procedure for a weekly chart check does not include a provision to detect mistakes (e.g. arithmetic errors, miscalculations or incorrect transfer of data) as outlined in Regulatory Guide, "Quality Management Program." These checks appear to be included only in the physicist's biweekly check of treatment plans and calculations.

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. Also, please ensure that you describe the actions you have taken to strengthen the above identified weaknesses in your quality management program. After reviewing your response to this Notice, including your proposed corrective actions and the results of future inspections, the NRC will determine whether further NRC enforcement action is necessary to ensure compliance with NRC regulatory requirements.

The inspection report also discussed an apparent violation of

10 CFR 35.33(a) which required you to notify the NRC Operations Center no later than one calendar day after discovering the misadministration. However, you notified the NRC Region III Office instead of the NRC Operations Center. This violation of NRC requirements would normally be categorized at Severity Level V but is not being cited because the criteria specified in Section VII(B)(1) of the NRC Enforcement Policy were satisfied.

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,

A Bert Davis

A. Bert Davis
Regional Administrator

Enclosure:
Notice of Violation

cc/enclosure:
DCD/DCB (RIDS)

NOTICE OF VIOLATION

Bothwell Regional Health Center
Sedalia, Missouri

Docket No. 030-10715
License No. 24-16275-02
EA 92-070

During an NRC inspection conducted March 30 and 31, 1992, a violation of NRC requirements was identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C (1992), the violation is listed below:

10 CFR 35.25(a) requires, in part, that a licensee that permits the receipt, possession, use, or transfer of byproduct material by an individual under the supervision of an authorized user as allowed by 10 CFR 35.11(b) of this part shall require the supervised individual to follow the instructions of the supervising authorized user and follow the written radiation safety and quality management procedures established by the licensee.

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. The quality management program must include, in part, written policies and procedures to meet the objective that each administration is in accordance with the written directive.

The Licensee's Radiation Oncology Manual section "Quality Management Program for Administering Radiation from a Radioactive Source - Policies and Procedures for Teletherapy," effective December 19, 1991, implements the requirements of 10 CFR 35.32 and requires, in part, that a weekly chart check will be performed by a qualified person under the supervision of an authorized user to detect mistakes (e.g. arithmetic errors, miscalculations, or incorrect transfer of data) that may have occurred in the daily and cumulative teletherapy dose administration from all treatment fields and when the prescribed dose is to be administered in more than three fractions, a check of the dose calculations will be performed within three working days after administering the first teletherapy fractional dose.

Contrary to the above, from March 18 until March 26, 1992, while administering radiation treatments by teletherapy, the supervised individuals failed to follow the quality management program and procedures. Specifically, the weekly chart check for a patient receiving daily teletherapy treatments did not include a check for mistakes (e.g. miscalculations) that may have occurred in the dose administrations from all treatment fields. Also, a check of the dose calculations was not performed for that patient until eight working days after administering the first teletherapy fractional dose for a prescribed dose that was administered in more that three fractions.

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

Pursuant to the provisions of 10 CFR 2.201, Bothwell Regional Health Center (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.

FOR THE NUCLEAR REGULATORY COMMISSION

A. Bert Davis
Regional Administrator

Dated at Glen Ellyn, Illinois
the 6th day of May 1992

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

April 22, 1992

Dockets No. 030-09376
and 030-02045
License No. 21-04127-06
and 21-04127-02
EA 92-069

Harper Hospital Division
ATTN: Mark L. Penkhus
Executive Vice President
and Chief Operating Officer
3990 John R Street
Detroit, Michigan 48201

Dear Mr. Penkhus

SUBJECT: NOTICE OF VIOLATION (NRC INSPECTION REPORTS NO. 030-09376/92001 AND 030-02045/92001)

This refers to the special safety inspection conducted on March 26 and 27, 1992, to review the circumstances associated with a cobalt-60 teletherapy misadministration occurring on February 24, 1992 at the Harper Hospital, Detroit, Michigan. The report documenting this inspection was mailed to you by letter, dated April 14, 1992. Significant violations of NRC requirements were identified during the inspection, and on April 17, 1992, a telephonic enforcement conference was held with you; Mr. John A. Grobe, Chief, Nuclear Materials Safety Branch, and other members of our respective staffs. A copy of the enforcement conference report is attached.

A misadministration, involving the wrong treatment site, occurred on February 24, 1992, when radiation therapists erroneously treated a patient's left supraclavicular area with a cobalt-60 teletherapy unit instead of treating the right supraclavicular area, as prescribed. The error was realized when the radiation therapists began to set-up the teletherapy unit to treat the right tangential fields of the patient's breast following the treatment to the left supraclavicular area. The misadministration was reported in accordance with your established internal procedures, including notification of the attending physicians. However, you did not report the misadministration to the NRC until March 16, 1992.

The violations pertaining to your teletherapy license are described in Section I of the enclosed Notice of Violation and include: (a) the failure of the radiation therapists to follow the procedures of your quality management program; and (b) the failure to notify the NRC of the misadministration within one calendar day of discovery. The failure of the radiation therapists to follow the procedures of

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your quality management program, which resulted in a therapeutic misadministration, is considered significant and in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy) 10 CFR Part 2, Appendix C (1992), this violation was categorized at Severity Level III. The violation for failing to notify the NRC of the misadministration within one calendar day of discovery was categorized at Severity Level IV.

The root causes of those violations and the subsequent corrective actions were discussed during the April 17, 1992, enforcement conference. The major factor contributing to the violations appeared to be the radiation therapists' failure to follow the established procedures requiring them to check the details of the treatment for agreement with the prescription and the treatment site. The similarities of the tatoos and difficulties with the patient also contributed to the misadministration. The NRC recognizes, as described in your letter of April 13, 1992, that you took both immediate and long term corrective actions.

In accordance with the Enforcement Policy a civil penalty is usually assessed with a Severity Level III violation in order to emphasize the need for strict adherence to regulatory, license, and procedural requirements because of the significant potential for adverse effects to the health of the patient associated with teletherapy treatment. However, after considering the civil penalty adjustment factors set forth in the NRC's Enforcement Policy, I have decided that a civil penalty will not be assessed for the Severity Level III violation. Full mitigation of this penalty was appropriate because you identified the violation, your corrective actions were immediate and comprehensive, and your past performance is good.

Section II of the enclosed Notice concerns your May 1991 change of the Radiation Safety Officer for your NRC broad scope medical license. This violation was categorized at Severity Level IV in accordance with the NRC Enforcement Policy (1991).

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 do not have to repeat the actions you previously described in your letter of April 13, 1992. 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,

Carl J. Paperiello for

A. Bert Davis
Regional Administrator

Enclosures:
1. Notice of Violation
2. Enforcement Conference
   Report 030-09376/92002

cc/enclosures
DCD/DCB (RIDS)

NOTICE OF VIOLATION

Harper Hospital Division
Detroit, Michigan

Dockets No. 030-09376
and 030-02045
Licenses No. 21-04127-06
and 21-04127-02
EA 92-069

During an NRC inspection conducted March 26 and 27, 1992, violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C (1991 and 1992), the violations are listed below:

I. Violations Associated with License No. 21-04127-06

A. 10 CFR 35.25(a) requires, in part, that a licensee that permits the receipt, possession, use, or transfer of byproduct material by an individual under the supervision of an authorized user as allowed by 10 CFR 35.11(b) of this part shall require the supervised individual to follow the instructions of the supervising authorized user and follow the written radiation safety and quality management procedures established by the licensee.

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. The quality management program must include, in part, written policies and procedures to meet the objective that each administration is in accordance with the written directive.

Radiation Oncology Center Policy No. 125.1. "Identifying Patients and Confirming Prescription Before Treatment," effective January 1, 1992, implements the requirements of 10 CFR 35.32 and requires, in part, that before a radiation treatment is administered by external beam teletherapy, the details of the treatment must be checked for agreement with the prescription and plan of treatment.

Contrary to the above, on February 24, 1992, prior to administering a radiation treatment by external beam teletherapy, the supervised individuals failed to follow the quality management program procedures. Specifically, the details of the treatment were not checked for agreement with the prescription and plan of treatment.

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

B. 10 CFR 35.33(a) requires, in part, that the licensee notify by telephone the NRC Operations Center no later

than the next calendar day after discovery of a misadministration. 10 CFR 35.2 defines "misadministration," in part, to mean the administration of a teletherapy radiation dose to the wrong treatment site.

Contrary to the above, on February 24, 1992, the licensee discovered that it had administered a teletherapy radiation dose to the wrong treatment site, a misadministration, and the licensee did not report the misadministration to the NRC until March 16, 1992.

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

II. Violation Associated with License No. 21-04127-02

10 CFR 35.13(c) requires that a licensee apply for and must receive a license amendment before it changes Radiation Safety Officers (RSO).

Contrary to the above, sometime in May 1991, the licensee changed its named RSO, and the licensee did not receive a license amendment authorizing the change.

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

Pursuant to the provisions of 10 CFR 2.201 Harper Hospital Division (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.

FOR THE NUCLEAR REGULATORY COMMISSION

Carl J. Paperiello for
A. Bert Davis
Regional Administrator

Dated at Glen Ellyn, Illinois
the 27 day of April 1992

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

April 15, 1992

Docket No. 030-01244
License No. 06-00819-03
EA No. 92-052

Yale-New Haven Hospital
Attn: Norman G. Roth
Assistant Administrator
20 York Street
New Haven, Connecticut 06504

Dear Mr. Roth:

Subject: NOTICE OF VIOLATION
(NRC Inspection Report No. 030-01244/92-001)

This letter refers to the NRC inspection conducted on March 4 and 5, 1992, at Yale-New Haven Hospital, New Haven, Connecticut, of activities authorized by NRC License No. 06-00819-03. The inspection report was sent to you on March 25, 1992. The inspection was conducted to review the circumstances associated with violations of NRC requirements identified by your staff and reported to the NRC involving a radiation exposure in the amount of approximately 40 rem to the tip of the left index finger of an individual at the facility, as well as two other violations of NRC requirements that contributed to the overexposure, namely, several examples of the failure to follow procedures, and the inadequate survey (evaluation) by the individual of the radiological conditions and hazards that led to the overexposure. On April 1, 1992, 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.

The overexposure occurred on February 26, 1992, during the implementation of a procedure for replacement of the iridium-192 source located in a High Dose Rate (HDR) afterloader device. The used 3 curie source had already been removed from the HDR device, and your Radiological Engineer (RE) was in the process of transferring the replacement 8.5 curie source from its shielded source container to the HDR device. While the source change procedure was being performed, the new source slipped out of its shielded unlocked container when the RE attempted to attach the guide tube to the HDR device. (The shielded source container should have been locked since the source exchange procedure required that the last step in the setup phase prior to actual source exchange is that the shielded source container be unlocked.) Since the RE was having trouble getting the source back into the shielded container because of unsteadiness of the guide wire, he moved his hand to the tip of the guide wire to which the source is attached, steadied the source with his index finger, and was able to replace the source in the shielded container. Touching the source for a fraction of a second resulted in the overexposure.

The NRC is concerned that several examples of failure, by the RE, to properly follow the source change procedure contributed to the source slipping out of the shielded container. Specifically, (1) the source exchange was performed by the RE without either the Radiation Safety Officer or the Medical Physicist being present, as required; therefore, there was not another certified individual in the area to directly observe the activity and prevent the overexposure from occurring; (2) the shielded source container well was unlocked without first completing all of the other required procedure steps, including connection of the source guide tube to the HDR port first, as required by the procedure; and (3) the RE, although determining that the procedure had not been followed in the exact required sequence, nonetheless, continued the activity. These failures to follow the procedure in the proper sequence directly led to the source slipping out of the shielded container, and constitutes a second violation of NRC requirements which contributed to the overexposure.

The NRC is also concerned that once the source slipped out of the shielded container, and a radiation alarm was received, the RE did not immediately cease all activities and leave the area until the Radiation Safety Officer was contacted so that an appropriate evaluation of the hazards present was first performed, and plans were established to retrieve the source under controlled conditions. Rather, the RE touched the iridium-192 source with his finger in the process of returning it back to the shielded condition without an evaluation of the possible radiation hazards inherent in retrieving the source. This failure to perform an appropriate survey (evaluation) of the radiation hazards present prior to attempting to retrieve the source, constitutes a third violation of NRC requirements, which also contributed to the overexposure.

These violations indicate that adequate control over this licensed activity was not exercised, and resulted in an overexposure at the facility, as well as the creation of a substantial potential for a much higher exposure to the worker's hands and whole body (and other workers in the area). Therefore, the violations are classified in the aggregate as a Severity Level III problem in accordance with the revised "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Pa.' 2, Appendix C (Enforcement Policy) published in the Federal Register on February 18, 1992.

The NRC recognizes that subsequent to this event, actions were taken to correct the violations and preclude recurrence. These actions, which were described during the inspection and at the enforcement conference, included: (1) precluding the RE from performing any source exchange for a period of one year; (2) review and documentation of the entire source change procedure; (3) development of shortened stepwise procedures for all critical activities, as a checklist to ensure critical operations are followed in proper sequence; (4) retraining of all members of the source exchange team on the revised procedures; (5) required review of the procedure before starting any source exchange; (6) placement of forceps with the source exchange equipment so that a source can be handled remotely if it accidentally dislodges; and (7) instruction to all HDR personnel on responding to emergency conditions. These corrective actions were considered prompt and comprehensive.

Notwithstanding those corrective actions, the NRC considered issuance of a civil penalty in this case to emphasize the importance of proper conduct of licensed activities at the facility, including strict adherence to procedural requirements, to ensure that such activities are conducted safely and in accordance with requirements. However, after consideration of the escalation/mitigation factors in this case, the NRC has decided that it is appropriate to mitigate the penalty in its entirety.

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

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

The responses directed by this letter and the enclosed Notice are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, Pub. L. 96-511.

Sincerely,

Thomas T. Martin
Regional Administrator

Enclosures:
1. Notice of Violation
2. Enforcement Conference Report

cc:
Public Document Room (PDR)
Nuclear Safety Information Center (NSIC)
State of Connecticut

NOTICE OF VIOLATION

Yale New Haven Hospital
New Haven, Connecticut 06504

Docket No. 030-01244
License No. 06-00819-03
EA 92- 052

During an NRC inspection conducted on March 4-5, 1992, violations of NRC requirements were identified. In accordance with the revised "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C, published in the Federal Register Notice on February 18, 1992, the particular violations are set forth below:

A. 10 CFR 20.101(a) requires that the licensee limit the radiation dose to the hand of an individual in a restricted area to 18.75 rems per calendar quarter.

Contrary to the above, the licensee did not limit the radiation dose to the hand of an individual in the area housing the High Dose Rate afterloader device, a restricted area, to 18.75 rems per calendar quarter. Specifically, the individual received a dose of approximately 40 rems to the tip of the left index finger during the first calendar quarter of 1992, when he handled an 8.5 curie iridium-192 source for a fraction of a second.

B. 10 CFR 30.33(a)(4) requires, in part, that applications for a specific license will be approved if the applicant satisfies any special requirements contained in Parts 32 through 35 and 39.

10 CFR 35.21(b)(2)(v) requires, in part, that the Radiation Safety Officer establish written policy and procedures for using byproduct material safely.

The Radiation Safety Officer established the written policy and procedures for the exchange of sources (byproduct material) in the High Dose Rate (HDR) afterloader unit in a letter dated November 2, 1988. The RSO also incorporated additional instructions in the procedure as necessary in accordance with 10 CFR 35.21.

The letter dated November 2, 1988, and other RSO established procedures, entitled, "GammaMed II and IIi GammaMed IIi GamUhr Card For Real-Time Control and Source Replacement," require, in part, the following:

1. A source exchange would not be performed unless two of the following individuals were present: the Radiation Safety Officer, the Medical Physicist, or the Radiological Engineer;

2. The following procedure sequence is to be followed:

   a. Insert the probe for two seconds [this ensures that the source guide tube end (source-advance tube probe inserter) is first inserted in the HDR unit port (channel 1) for approximately 2 seconds after which the guide wire (cable) can be inserted];

   b. Insert the cable into channel 1 and wait approximately 10 seconds;

   c. Move the cable and insert the probe;

   d. Unlock the new source (this necessitates the shielded source container that houses the new source be unlocked only after all other procedures are completed, prior to transfer of the new source to the HDR unit);

   e. Close the door and start the key.

3. If the motor does not retract the cable, the probe inserter should be re-introduced into channel 1 for 2 seconds, subsequent to which the rest of the procedure should be repeated. (This necessitates that the individual exchanging the source determine the error and begin the procedure again if it is determined that the error occurred because the procedure was incorrect).

Contrary to the above, on February 26, 1992, the procedures for the exchange of sources in the HDR unit, as set forth in the letter dated November 2, 1988, and other established procedures, were not followed in that:

1. A source exchange was performed with only the Radiological Engineer present (the Radiation Safety Officer and the Medical Physicist were both absent at the same time during a portion of the source exchange procedure conducted on February 26, 1992);

2. The source container was unlocked without other required procedural steps first being completed, including the source guide tube not being inserted in the HDR unit port for 2 seconds as required;

3. The motor did not retract the cable and the probe inserter was not introduced into channel 1 for 2 seconds and the procedure was not repeated as required.

C. 10 CFR 20.201(b) requires that each licensee make 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, on February 26, 1992, the licensee did not make surveys to assure compliance with that part of 10 CFR 20.101 that limits the radiation exposure to the extremities. Specifically, a Radiological Engineer handled an 8.5 curie iridium-192 source (after it slipped out of its shielded source container during a source exchange of a High Dose Rate afterloader device) without consulting with other members of the source change team to assess the extent of the possible radiation hazards inherent in retrieving the source.

These violations are classified in the aggregate as a Severity Level III problem. (Supplements IV and VI)

Pursuant to the provisions of 10 CFR 2.201, the Yale New Haven Hospital (Licensee) is hereby required to submit a written statement or explanation to the Regional Administrator, Region I, U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555, within 30 days of the date of the letter transmitting this Notice of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each violation: (1) the reason for the violation or if contested the basis for disputing the violation, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken to avoid further violations, and (4) the date when full compliance will be achieved. If an adequate reply is not received within the time specified in this Notice, an order or a demand for information may be issued as to why the license should not be modified, suspended, or revoked or why such other action as may be proper should not be taken. Consideration may be given to extending the response time for good cause shown. 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 15th day of April 1992

PART III. INDIVIDUAL ACTIONS

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

NOV 12 1991

Docket No. 30-31570
License No. 35-27026-01
IA 91-001

Patrick K. C. Chun, M.D.
HOME ADDRESS DELETED
UNDER 10 CFR 2.790

Gentlemen:

SUBJECT: TERMINATION OF NRC LICENSE AND ORDER PROHIBITING CERTAIN INVOLVEMENT IN NRC-LICENSED ACTIVITIES FOR ONE YEAR

This is in reference to your January 11, 1991 request for termination of NRC License No. 35-27026-01 and to the results of an investigation conducted by the NRC's Office of Investigations (OI) to determine whether you had provided false information to NRC in February 1990 when applying for this license.

Based on OI's conclusion that you willfully provided false information about your association with the Tulsa Heart Center, NRC is issuing the enclosed Order to prohibit you for one year from the date of the Order from obtaining an NRC license or being named on an NRC license in any capacity.

Should you wish to obtain an NRC license or be named on an NRC license as an authorized user after this one-year period, you will be required to provide NRC assurances, either in person or in writing, that you can be relied upon to provide NRC complete and accurate information and abide by other requirements incumbent on a license holder.

In addition to the Order, NRC is enclosing an amendment to terminate License No. 35-27026-01 as you requested in January 1991, and a copy of the synopsis from the investigative report prepared by OI.

Questions concerning this Order should be addressed to James Lieberman, Director, Office of Enforcement, who can be reached at (301) 492-0741.

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

Sincerely,

Hugh L. Thompson, Jr.
Deputy Executive Director for
Nuclear Materials Safety,
Safeguards, and Operations Support

Enclosures:
1. Order
2. Amendment No. 03 to License No. 35-27026-01
3. Synopsis from Report of Investigation 4-91-001

cc: State of Oklahoma

UNITED STATES
NUCLEAR REGULATORY COMMISSION

In the Matter of	)	
	)	Docket No. 30-31570
Patrick K.C. Chun, M.D.	)	License No. 35-27026-01
HOME ADDRESS DELETED UNDER 10 CFR 2.790	)	IA 91-001

ORDER PROHIBITING INVOLVEMENT IN CERTAIN NRC-LICENSED ACTIVITIES
(EFFECTIVE IMMEDIATELY)

I

Patrick K.C. Chun, M.D., (Licensee) is the holder of Materials License No. 35-27026-01 (License) issued by the Nuclear Regulatory Commission (NRC or Commission) pursuant to 10 CFR Parts 30 and 35. The License authorizes the possession and use of radiopharmaceuticals in nuclear medicine activities described in 10 CFR 35.100 and 35.200. The License, which was scheduled to expire on March 31, 1995, is being terminated, as requested by the Licensee in January 1991, by the issuance of a license amendment enclosed with this Order.

II

In an application dated February 14, 1990, Patrick K. C. Chun, M.D., requested an amendment to NRC License No. 13-23664-01, which was issued in his name, to reflect the fact that he was relocating his medical practice from Terre Haute, Indiana, to Tulsa, Oklahoma. In subsequent conversations and correspondence between NRC personnel in NRC's Region IV office in Arlington, Texas, and the Licensee, the Licensee was asked to clarify his association with the Tulsa Heart Center (THC), with which the

Licensee's practice appeared to be affiliated. NRC's interest in this matter was based on its attempt to determine the person to be responsible for licensed activity and whether the License should be issued in Dr. Chun's name, as he requested, or in the name of the THC, a corporation.

On several occasions in February and March 1990, the Licensee told NRC personnel that his nuclear cardiology practice was separate from the THC. To support this, he told NRC personnel that the technologist who worked for him was employed by him, and that his patients would be billed in his name, not that of the THC. In a letter to NRC Region IV dated March 23, 1990, the Licensee stated, "This is not a medical institution, but a private practice." Based on the Licensee's representations, NRC Region IV issued a new License on March 27, 1990, in Dr. Chun's name. On the date the license was issued, NRC called the Licensee and was assured again that his practice was independent of the THC. During an NRC inspection in August 1990, the Licensee told an NRC inspector that he (the Licensee) owned the nuclear cardiology equipment, that he paid the technologist, that patients were billed in his name and that his practice was completely separate from the THC.

In January 1991, the Licensee requested termination of NRC License No. 35-27026-01. In subsequent conversations between representatives of the THC, who were interested in obtaining an NRC license for another nuclear cardiologist, and NRC Region IV

personnel, it became apparent that the Licensee had misrepresented his association with the THC. THC officials told NRC that the Licensee was an employee of the THC, that the THC owned the building in which the Licensee had practiced, and that the THC paid all of the bills associated with the Licensee's practice, including the costs of obtaining a license in Dr. Chun's name and the salary of the Licensee's technologist. Based on this information, NRC's Office of Investigations (OI) opened an investigation to determine whether the Licensee had willfully misrepresented his association with the THC in applying for his NRC license. OI interviewed the Licensee, several THC representatives and NRC personnel and concluded that the Licensee had willfully provided false information to the NRC during the licensing process.

III

NRC must be able to rely on the accuracy of information provided it by applicants for licenses and by licensees. The integrity of NRC's regulatory programs rests, to a large degree, on the integrity of its licensees. NRC regulations in 10 CFR 30.9, entitled "Completeness and accuracy of information," require information provided to the Commission by an applicant for a license or by a licensee to be complete and accurate in all material respects. The Licensee's misrepresentations to the NRC violated this requirement and have raised serious doubt as to whether he can be relied upon to adhere to the requirements that

apply to any license holder. A licensee's willful violation of Commission requirements and false statements to Commission officials cannot and will not be tolerated.

Consequently, I lack the requisite reasonable assurance that Dr. Chun would conduct NRC-licensed activities in compliance with the Commission's requirements, and that the health and safety of the public would be protected, if Dr. Chun were permitted at this time to hold an NRC license or be named in any capacity on an NRC license. Therefore, the public health, safety and interest require that the Licensee be prohibited from holding an NRC license or being named on an NRC license in any capacity for a period of one year from the date of this Order. Furthermore, pursuant to 10 CFR 2.202, I find that the public health, safety and interest require that this Order be immediately effective.

IV

Accordingly, pursuant to sections 81, 161b, 161c, 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 Part 30, IT IS HEREBY ORDERED, EFFECTIVE IMMEDIATELY, THAT:

A. PATRICK K. C. CHUN, M.D., IS PROHIBITED FOR ONE YEAR FROM THE DATE OF THIS ORDER FROM HOLDING AN NRC LICENSE OR BEING NAMED ON AN NRC LICENSE IN ANY CAPACITY; AND

B. FOR THE FOLLOWING TWO YEARS, DR. CHUN SHALL PROVIDE THE FOLLOWING NOTICE TO THE NRC:

1. FOR WORK ACTIVITIES THAT REQUIRE DR. CHUN BEING NAMED ON AN NRC LICENSE (e.g. RADIATION SAFETY OFFICER OR AUTHORIZED USER), DR. CHUN SHALL PROVIDE A COPY OF THE LICENSE APPLICATION OR AMENDMENT TO THE DIRECTOR, OFFICE OF ENFORCEMENT (OE), AT THE SAME TIME THAT THE APPLICATION OR AMENDMENT IS SENT TO THE NRC LICENSING OFFICE ALONG WITH THE INFORMATION REQUIRED BELOW.
2. FOR WORK ACTIVITIES THAT DO NOT REQUIRE DR. CHUN TO BE NAMED ON AN NRC LICENSE, DR. CHUN SHALL PROVIDE THE DIRECTOR, OE, WITH TWO WEEKS NOTICE PRIOR TO PERFORMING ANY ACTIVITIES AS AN AUTHORIZED USER.

IN BOTH INSTANCES, THE NOTICE SHALL INCLUDE ASSURANCES THAT HE CAN BE RELIED UPON TO COMPLY WITH ALL COMMISSION REQUIREMENTS, INCLUDING THAT OF PROVIDING COMPLETE AND ACCURATE INFORMATION TO THE COMMISSION, THE NATURE AND LOCATION OF THE LICENSED ACTIVITIES, AS WELL AS THE TYPE OF MATERIAL INVOLVED.

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

V

Dr. Chun 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 shall set forth the matters of fact and law on which the Licensee or other person adversely affected relies and the reasons as to why the Order should not have been issued, and shall comply in all other respects with 10 CFR 2.202. Any answer filed within 20 days of the date of this Order may include a request for a hearing. 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, D.C. 20555. Copies also shall be sent to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, to the Assistant General Counsel for Hearings and Enforcement at the same address, to the Regional Administrator, NRC Region IV, 611 Ryan Plaza Drive, Suite 400, Arlington, Texas 76011, and to Dr. Chun if the answer or hearing request is by a person other than Dr. Chun. If a person other than Dr. Chun requests a hearing, that person shall set forth with particularity the manner in which his interest is adversely affected by this Order and shall address the criteria set forth in 10 CFR 2.714(d).

If a hearing is requested by Dr. Chun 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.

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 12th day of November 1991

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

NOV 27 1991

Docket No. 30-31570
License No.35-27026-01
IA 91-001A

Patrick K. C. Chun, M.D.
4417 West Gore Blvd
Suite 5
Lawton, Oklahoma 73505

Gentlemen:

SUBJECT: ORDER MODIFYING ORDER PROHIBITING CERTAIN LICENSED ACTIVITIES

In reviewing the Order issued to you on November 12, 1991, the NRC staff noted an inconsistency between ordering provisions IV.A and B. Ordering provision IV.B requires, among other things, that you provide the Director, OE with two weeks notice prior to performing activities as an authorized user under a broad scope license, for the specified time frame. Said notice is not required if the use of licensed material is under the supervision of an authorized user. Ordering provision IV.A prohibits you, for one year from November 12, 1991, from holding an NRC license or being named on an NRC license, but does not address performing as an authorized user under a broad scope license. This inconsistency was unintentional, as it was always the staff's intention that, for one year from November 12, 1991, you only be permitted to work with licensed material under the supervision of another authorized individual. Therefore, Section IV.A of the Order is being modified to add this prohibition. As provided in the attached Order, Section IV.A of the Order issued November 12, 1991, is replaced by Section IV.A of this Order.

We have received your hearing request of November 16, 1991. Therefore, you do not need to request an additional hearing for this modified Order. However, your request did not meet the terms of 10 CFR 2.202 (copy enclosed) for an Answer in that it did not specifically admit or deny each allegation or charge made in the Order nor set forth the matters of fact and law on which you rely and the reasons as to why the Order should not have been issued. See Section V of the attached Order. If you desire to continue with your hearing request, you must revise your answer to address the issues discussed above and in Section V of the attached Order and submit it within 20 days of the date of this modified Order.

In addition, as to your request for an informal meeting, a representative from Region IV will contact you to make arrangements.

Also enclosed are License Amendment No. 03 terminating your License and a copy of the OI Report Synopsis, which were inadvertently not included with the November 12, 1991 Order. If you have any questions on the provisions of the modification to the Order, the original Order, or any other information provided by this letter, please contact either me at (301) 492-0741 or Gary Sanborn, Region IV, at (817) 860-8222.

All other provisions of the November 12, 1991 Order remain in effect.

Sincerely,

James Lieberman, Director
Office of Enforcement

Enclosures:
1. Order
2. Amendment No. 03 to License No. 35-27026-01
3. Synopsis from OI Report of Investigation 4-91-001
4. 10 CFR 2.202

cc: State of Oklahoma

UNITED STATES
NUCLEAR REGULATORY COMMISSION

In the Matter of	)	
	)	Docket No. 30-31570
Patrick K.C. Chun, M.D.	)	License No. 35-27026-01
HOME ADDRESS DELETED UNDER 10 CFR 2.790	)	IA 91-001

ORDER MODIFYING ORDER PROHIBITING INVOLVEMENT IN CERTAIN NRC-LICENSED ACTIVITIES (EFFECTIVE IMMEDIATELY)

I

Patrick K.C. Chun, M.D., (Licensee) was the holder of Materials License No. 35-27026-01 (License) issued by the Nuclear Regulatory Commission (NRC or Commission) pursuant to 10 CFR Parts 30 and 35. The License authorized the possession and use of radiopharmaceuticals in nuclear medicine activities described in 10 CFR 35.100 and 35.200. The License was terminated on November 12, 1991, by the issuance of a license amendment, as requested by the Licensee in January 1991,

II

On November 12, 1991, an Order Prohibiting Involvement In Certain NRC-Licensed Activities (Effective Immediately) was issued to the Licensee. In reviewing the Order, the NRC staff noted an inconsistency between the ordering language in paragraphs IV.A and B that was unintentional. As a result, Section IV.A of the Order is being modified to also prohibit Dr. Chun from performing activities as an authorized user for a period of one year from the date of the original Order.

III

Consequently, for the reasons stated in the original Order, I lack the requisite reasonable assurance that Dr. Chun would conduct NRC-licensed activities in compliance with the Commission's requirements, and that the health and safety of the public would be protected, if Dr. Chun were permitted at this time to perform licensed activities as ar authorized user. Therefore, the public health, safety and interest require that the Order be modified to also prohibit Dr. Chun from performing activities as an authorized user for a period of one year from the date of the original Order. Furthermore, pursuant to 10 CFR 2.202, I find that the public health, safety and interest require that this Order be immediately effective.

IV

Accordingly, pursuant to sections 81, 161b, 161c, 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 Part 30, IT IS HEREBY ORDERED, EFFECTIVE IMMEDIATELY, THAT SECTION IV.A OF THE ORDER OF NOVEMBER 12, 1991, IS HEREBY MODIFIED TO PROVIDE THAT:

PATRICK K. C. CHUN, M.D., IS PROHIBITED FOR ONE YEAR FROM THE DATE OF THIS ORDER FROM HOLDING AN NRC LICENSE, BEING NAMED ON AN NRC LICENSE IN ANY CAPACITY, OR PERFORMING ACTIVITIES AS AN

AUTHORIZED USER.

All other provisions of the Order of November 12, 1991, remain as stated therein.

V

In accordance with 10 CFR 2.202 (56 FR 40664, August 15,1991), Dr. Chun must, and any other person adversely affected by this Order may, submit an answer to the Order dated November 12, 1991, as modified by this Order, and may request a hearing on the Order, as modified by this Order, within 20 days of the date of this Order. The answer may consent to the Order. If not consenting to the Order, the answer shall in writing, under oath or affirmation, specifically admit or deny each allegation or charge made in the Order, set forth the matters of fact and law on which the Licensee or other person adversely affected relies and the reasons as to why the Order should not have been issued. Any answer filed within 20 days of the date of this Order may include a request for a hearing. 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, D.C. 20555. Copies also shall be sent to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, to the Assistant General Counsel for Hearings and Enforcement at the same address, to the

Regional Administrator, NRC Region IV, 611 Ryan Plaza Drive, Suite 400, Arlington, Texas 76011, and to Dr. Chun if the answer or hearing request is by a person other than Dr. Chun. If a person other than Dr. Chun requests a hearing, that person shall set forth with particularity the manner in which his interest is adversely affected by this Order and shall address the criteria set forth in 10 CFR 2.714(d).

If a hearing is requested by Dr. Chun 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 the Order dated November 12, 1991, as modified by this Order, should be sustained.

In the absence of any request for hearing, the provisions specified in Section IV of the Order dated November 12, 1991, as modified by 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

James Lieberman, Director
Office of Enforcement

Dated at Rockville, Maryland
this 27th day of November 1991

UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

ATOMIC SAFETY AND LICENSING BOARD

Before Administrative Judges:

Morton B. Margulies, Chairman
Thomas D. Murphy
Harry Rein

In the Matter of	Docket No. 30-31570-EA
PATRICK K. C. CHUN, M.D.	ASLBP No. 92-657-02-EA
	(Materials License No. 35-27026-01)
	May 26, 1992

ORDER
(Approving Settlement Agreement and Terminating Proceeding)

On May 19, 1992, the parties to this enforcement proceeding, the NRC Staff and Patrick K. C. Chun, M.D., filed with the Atomic Safety and Licensing Board (1) a Settlement Agreement that has been accepted and signed by both parties and (2) a joint motion requesting the Board's approval of the Agreement and entry of an order terminating this proceeding, together with a proposed Order. The Board has reviewed the Settlement Agreement under 10 C.F.R. § 2.203 to determine whether approval of the Settlement Agreement and consequent termination of this proceeding is in the public interest. Based upon its review, the Board is satisfied that approval of the Settlement Agreement and

termination of this proceeding based thereon is in the public interest.

Accordingly, the Board approves the Settlement Agreement attached hereto and, pursuant to §§ 81 and 161 of the Atomic Energy Act of 1954, as amended (42 U.S.C. §§ 2111 and 2201), incorporates the Settlement Agreement by reference into this Order. Pursuant to 10 C.F.R. § 2.20[illegible], the Board hereby terminates this proceeding on the basis of the Settlement Agreement.

THE ATOMIC SAFETY AND LICENSING BOARD

Morton B. Margulies, Chairman
ADMINISTRATIVE LAW JUDGE

Thomas D. Murphy
ADMINISTRATIVE JUDGE

Harry Rein, M.D.
ADMINISTRATIVE JUDGE

Bethesda, Maryland
May 26, 1992.

ATTACHMENT

SETTLEMENT AGREEMENT

On November 12, 1991, the NRC Staff (Staff) issued Order Prohibiting Involvement in Certain NRC-Licensed Activities (Effective Immediately) to Patrick K. C. Chun, M.D., 56 Fed. Reg. 56716 (November 21, 1991). That Order was subsequently modified on November 27, 1991, to correct an unintentional inconsistency. Order Modifying Order Prohibiting Involvement in Certain NRC-Licensed Activities (Effective Immediately). 56 Fed. Reg. 63985 (December 6, 1991).

On November 18, 1991, Dr. Chun, in response to the first Order, requested a hearing on the Order. On December 1, 1991, in response to both the Order and the Modified Order, Dr. Chun filed an answer denying all "allegations and charges made in the Orders," and requested that the Orders be rescinded. Dr. Chun also requested a hearing. In response to Dr. Chun's hearing request, an Atomic Safety and Licensing Board was established on January 14, 1992. 57 Fed. Reg. 2795 (January 23, 1992).

After discussions between the Staff and Dr. Chun, the Staff and Dr. Chun agree that it is in the public

interest to terminate this proceeding without further litigation and without reaching the merits of the underlying orders, and agree to the following terms and conditions.

1. The Staff agrees to withdraw the Orders issued to Dr. Chun, dated November 12 and 27, 1991. Such withdrawal will become effective upon approval of this Settlement Agreement by the Atomic Safety and Licensing Board.

2. Dr. Chun agrees to withdraw his request for a hearing dated November 18, 1991. Such withdrawal will become effective upon approval of this Settlement Agreement by the Atomic Safety and Licensing Board.

3. Dr. Chun agrees that from November 12, 1991, the date of the issuance of the original order, until November 11, 1992, he will not apply for or hold an NRC license, will not be named on an NRC license in any capacity, and will not perform any activities as an authorized user either under a broad scope license, issued pursuant to 10 C.F.R. Part 33, or as a visiting authorized user pursuant to 10 C.F.R. § 35.27.

4. Dr. Chun agrees that from November 12, 1992 until November 11, 1994, he will provide the following notice to the NRC:

A. For work activities that require Dr. Chun being named on an NRC license (e.g., Radiation Safety Officer or Authorized User), Dr. Chun shall provide a copy of the license application or amendment to the Chief, Medical Use Safety Branch, Office of Nuclear Material Safety & Safeguards at the same time that the application or amendment is sent to the NRC licensing office.

B. For work activities performed by Dr. Chun as an authorized user under a broad scope license or as a visiting authorized user, Dr. Chun shall provide the Chief, Medical Use Safety Branch, Office of Nuclear Material Safety & Safeguards, with two weeks notice prior to performing any such activities.

5. Dr. Chun assures the NRC that he can be relied upon to comply with all Commission requirements, including that of providing complete and accurate information to the Commission.

6. The Staff agrees, with regard to information relating to this proceeding, that it will comply with all existing federal statues, Commission regulations and policy regarding the dissemination of information.

7. The Staff and Dr. Chun shall jointly move the Atomic Safety and Licensing Board for an Order approving this Settlement Agreement and terminating this proceeding. This agreement shall become effective upon Approval by the Licensing Board.

FOR THE NUCLEAR REGULATORY COMMISSION

Marian L. Zobler
Counsel for NRC Staff

FOR PATRICK K.C. CHUN, M.D.

Dale Joseph Gilsinger
Counsel for Patrick K. C. Chun, M.D.

Dated May 19, 1992.

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. 11, No. 2

2. TITLE AND SUBTITLE

Enforcement Actions: Significant Actions Resolved
Quarterly Progress Report
April - June 1992

3. DATE REPORT PUBLISHED

MONTH	YEAR
August	1992

4. FIN OR GRANT NUMBER

5. AUTHOR(S)

Office of Enforcement

6. TYPE OF REPORT

Technical

7. PERIOD COVERED (Inclusive Dates)

8. PERFORMING ORGANIZATION – NAME AND ADDRESS (If NRC, provide Division, Office or Region, U.S. Nuclear Regulatory Commission, and mailing address; if contractor, provide name and mailing address.)

Office of Enforcement
U.S. Nuclear Regulatory Commission
Washington, DC 20555

9. SPONSORING ORGANIZATION – NAME AND ADDRESS (If NRC, type "Same as above"; if contractor, provide NRC Division, Office or Region, U.S. Nuclear Regulatory Commission, and mailing address.)

Same as above

10. SUPPLEMENTARY NOTES

11. ABSTRACT (200 words or less)

This compilation summarizes significant enforcement actions that have been resolved during one quarterly period (April - June 1992) 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

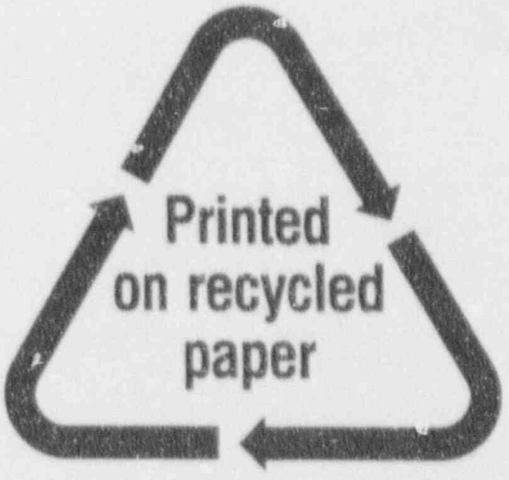
Unlimited

14. SECURITY CLASSIFICATION

(This Page)
Unclassified
(This Report)
Unclassified

15. NUMBER OF PAGES

16. PRICE



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WASHINGTON, D.C. 20555-0001

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