NUREG-0940
Vol. 10, No. 4

# Enforcement Actions: Significant Actions Resolved

Quarterly Progress Report
October–December 1991

U.S. Nuclear Regulatory Commission

Office of Enforcement

Avi ible 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 availsble from National Technical
Information Service, Springfield, VA 22161

NUREG-0940
Vol. 12, No. 4

# Enforcement Actions: Significant Actions Resolved

Quarterly Progress Report
October-December 1991

U.S. Nuclear Regulatory Commission

Office of Enforcement

Available from

Superintendent of Documents
U.S. Government Printing Office
Mail Stop SSOP
Washington, D.C. 20402-9328

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

NUREG–0940
Vol. 10, No. 4

# Enforcement Actions: Significant Actions Resolved

Quarterly Progress Report
October–December 1991

Manuscript Completed: March 1992
Date Published: March 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 (October - December 1991) 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.

CONTENTS

CONTENTS (Continued)

# ENFORCEMENT ACTIONS: SIGNIFICANT ACTIONS RESOLVED

October - December 1991

## INTRODUCTION

This issue of NUREG-0940 is being published to inform NRC licensees about significant enforcement actions and their resolution for the fourth quarter of 1991. 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 Administrator. The Director, Office of Enforcement, may act for the DEDS in the absence of the DEDS or DEDR or as directed. The actions involved in this NUREG involve NRC's civil penalties as well as significant Notices of Violation.

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

A brief summary of each significant enforcement action that has been resolved in the fourth quarter of 1991 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, 53 Fed. Reg. 40019 (October 13, 1988). 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 a copy of a Notice of Violation that has been issued to material licensees, but for which no civil penalty was assessed.

SUMMARIES

## I. REACTOR LICENSEES

### A. Civil Penalties and Orders

Alabama Power Company, Birmingham, Alabama
(Farley Nuclear Plant) Supplement I, EA 91-102

A Notice of Violation and Proposed Imposition of Civil Penalty in the amount of $25,000 was issued September 23, 1991 to emphasize the importance of ensuring operability of equipment important to safety. The action was based on the startup and operation of Unit 1 with the Turbine Driven Auxiliary Feedwater Pump (TDAFWP) flow path inoperable from May 17-22, 1991. The licensee failed to reclose a recirculation isolation valve after running a time response test on the TDAFWP. The mispositioned valve was not detected prior to startup due to the operations staff's failure to properly log the condition. The proposed civil penalty for this Severity Level III problem was mitigated 50% for good past performance. The licensee responded and paid the civil penalty on October 14, 1991.

Consumers Power Company, Covert, Michigan
(Palisades Nuclear Generating Station) Supplement I, EA 91-126

A Notice of Violation and Proposed Imposition of Civil Penalty in the amount of $50,000 was issued November 14, 1991 to emphasize the need to verify that systems designed to prevent or mitigate a serious safety event are available to perform their intended safety function. The action was based on (1) the failure to establish adequate procedures to energize and verify operability of the containment spray pumps and the High Pressure Safety Injection Pumps during startup, and (2) operating the reactor with an inoperable containment spray pump. The licensee responded and paid the civil penalty on December 13, 1991.

Duquesne Light Company, Shippingport, Pennsylvania
(Beaver Valley Power Station) Supplement I, EA 91-038

A Notice of Violation and Proposed Imposition of Civil Penalty in the amount of $25,000 was issued October 8, 1991 to emphasize the need to promptly follow up and correct conditions adverse to quality. The action was based on the licensee's failure to adequately assess the scope of a problem in which certain piping welds had not been included in the inservice inspection program. Two violations were identified, one for the failure to take adequate corrective action, and another for the failure to inspect the welds as part of the ISI program. The base civil penalty was mitigated 50% after partially offsetting mitigation for corrective action and past performance with escalation for NRC identification and prior notice of the corrective action violation. The licensee responded and paid the civil penalty November 4, 1991.

Gulf States Utilities, St. Francisville, Louisiana
(River Bend Station) Supplement I, EA 91-132

A Notice of Violation and Proposed Imposition of Civil Penalty in the amount of $75,000 was issued November 26, 1991 to emphasize the significance of the inability of a safety system to perform its post-accident function, and the importance of ensuring that design changes are properly reviewed and documented. The action was based on the discovery by the licensee of wiring errors in the control system for the plant's primary containment/drywell hydrogen mixing system that had existed since initial plant operations. In the absence of operator intervention, these errors would have prevented both trains of the system from performing their intended function. The resulting violation of the plant Technical Specifications has been categorized at Severity Level III. A 50 percent escalation of the base civil penalty of $50,000 was warranted after partially offsetting 100 percent escalation for the duration of the violation with 50 percent mitigation for licensee identification and reporting. The licensee responded and paid the civil penalty on December 20, 1991.

Northeast Nuclear Energy Company, Hartford, Connecticut
(Millstone Nuclear Power Station) Supplement I, EA 91-107

A Notice of Violation and Proposed Imposition of Civil Penalty in the amount of $50,000 was issued October 2, 1991 to emphasize the importance of effective and long lasting corrective action to resolve the weaknesses for prompt identification and resolution of safety significant deficiencies. The action was based on the licensee's failure to promptly identify and correct the root cause of degraded flow indications on the service water system that were received over a one month period. Subsequently, in response to NRC inspector concerns, the licensee discovered an extensive buildup of mussels along an 80 ft section of service water piping. The licensee responded and paid the civil penalty on October 30, 1991.

Public Service Company of New Hampshire, Seabrook, New Hampshire
(Seabrook Station) Supplement II, EA 91-144

A Notice of Violation and Proposed Imposition of Civil Penalty in the amount of $100,000 was issued November 25, 1991 to emphasize the importance of radiographs meeting all ASME Code requirements to fully demonstrate the quality of welds. The action was based on the licensee's failure to have sufficient radiographic records for a number of safety-related welds. The licensee responded and paid the civil penalty on December 23, 1991.

The Cleveland Electric Illuminating Company, Perry, Ohio
(Perry Nuclear Power Plant) Supplement I, EA 91-118

A Notice of Violation and Proposed Imposition of Civil Penalty in the amount of $100,000 was issued October 30, 1991 to emphasize the need for effective management control and oversight of NRC licensed activities, including the development and implementation of the licensee's emergency operating procedures. The action was based on (a) the failure to fully implement the Plant Emergency Instruction

Verification Plan, developed to upgrade the emergency procedures, and (b) certain technical inadequacies with selected emergency procedures. The base civil penalty was escalated 50 percent for NRC identification of the programmatic problem and 100 percent for prior notice. Once the licensee was put on notice of the problem, its corrective actions were prompt and comprehensive, and the base civil penalty was mitigated 50 percent. The licensee responded and paid the civil penalty November 22, 1991.

Virginia Electric and Power Company, Glen Allen, Virginia
(Surry Power Station) Supplement I, EA 91-114

A Notice of Violation and Proposed Imposition of Civil Penalties in the amount of $125,000 based on two violations was issued October 21, 1991 to emphasize the importance of ensuring that safety systems are fully operable and capable of performing their intended safety function following maintenance and modification. The first violation involved the inoperability of EDG No. 3 which is common to both units. Improper maintenance and failure to perform adequate post-maintenance testing resulted in the EDG being unable to automatically assume emergency electrical loads if required to do so. The second violation involves the operation, over an extended period of time, of the charging pumps in an electrical configuration in which manual actions would be required in some scenarios to ensure high pressure safety injection flow. The base civil penalty for the first violation was increased 50 percent for the licensee's initially inadequate corrective actions. The licensee responded and paid the civil penalty on November 20, 1991.

B. Severity Level III Violation, No Civil Penalty

GPU Nuclear Corporation, Middletown, Pennsylvania
(Three Mile Island Nuclear Station, Unit 1) Supplement I, EA 91-143

A Notice of Violation was issued December 18, 1991 based on a violation involving the movement of a fuel assembly at a time when the reactor building was not isolated while the reactor was in the refueling mode. A civil penalty was not proposed because the licensee identified and reported the violation and the licensee had good past performance in all areas, as evidenced by Category I ratings in all SALP areas, including the operations and outage planning areas.

Tennessee Valley Authority, Chattanooga, Tennessee
(Browns Ferry Nuclear Plant) Supplement III, EA 91-120

A Notice of Violation was issued October 29, 1991 based on violations involving the failure to perform an adequate physical inventory of licensed SNM. The violation was identified on September 7, 1991, when the licensee found SNM which had not been previously not listed in the inventory of items in the spent fuel pool. Previously, on August 21, 1991, the licensee determined that an item located in the spent fuel pool was tagged as containing SNM, when in actuality it did not. Discretion was exercised and a civil penalty was not proposed because

of the licensee's efforts to correct past problems in the licensee's SNM program for which enforcement action, including a civil penalty, had already been taken.

## II. MATERIALS LICENSEES

### A. Civil Penalties and Orders

Consolidated NDE, Incorporated, Woodbridge, New Jersey
Supplement VII, EA 91-058

A Notice of Violation and Confirmatory Order Modifying License (Effective Immediately) was issued October 11, 1991. The order confirms that an individual would be allowed to act only as an assistant radiographer, and not as a radiographer, until such time as the licensee submits, and the NRC accepts, the licensee's basis for being satisfied that the individual should act as a radiographer as defined in 10 CFR 34.2. The action was taken because the individual, when he was acting as a radiographer, failed to provide complete and accurate information to NRC during and following an NRC inspection and created an inaccurate utilization record. A civil penalty was not proposed in this case because a Confirmatory Action Letter, a civil penalty and an Order Suspending Operation had previously been issued for the underlying problem. The order was issued following the staff's evaluation of the OI Report that arose from the inspection.

Construction Engineering Consultants, Inc., Pittsburgh, Pennsylvania
Supplement VI, EA 91-077

A Notice of Violation and Proposed Imposition of Civil Penalty in the amount of $1,250 was issued July 30, 1991 to emphasize the importance of the use of the alarm ratemeters during the performance of radiographic operations. The action was based on a violation involving the failure of licensee radiographers to wear alarm rate dosimeters while performing radiography. The base civil penalty was escalated because NRC identified the violations and mitigated for the licensee's corrective action and good past performance. The licensee responded and requested termination of license; therefore, a letter withdrawing the civil penalty was issued November 6, 1991, concurrent with the termination of the license.

Fewell Geotechnical Engineering, Ltd., Pearl City, Hawaii
Supplements IV, V, VI, and V, EA 90-196

A Notice of Violation and Proposed Imposition of Civil Penalties in the amount of $20,000 was issued February 7, 1991 to emphasize the importance of complying with license and regulatory requirements, and of ensuring management oversight of the licensed program. The action was based on multiple willful radiation safety violations by a radiographer, including failure to survey after exposures, failure to adequately post the restricted area, failure to secure the source after exposures, and failure to prevent entry into the restricted area. In addition, the radiographer provided false information to

NRC personnel as to his activities. A letter was issued October 18, 1991 that withdrew the civil penalty.

Humana Hospital Greenbrier Valley, Ronceverte, West Virginia
Supplements VI and VII, EA 91-082

A Notice of Violation and Proposed Imposition of Civil Penalties in the amount of $21,500 was issued November 1, 1991 to emphasize the importance of ensuring (1) that all information communicated to the NRC is both complete and accurate, and (2) that licensed activities are conducted in strict compliance with regulatory requirements and license conditions. The action was based on two instances of inaccurate and incomplete information being submitted by senior management officials and the use of licensed material without the proper supervision or authorization by six physicians and a technologist. The licensee responded and paid the civil penalty on November 26, 1991.

Lancaster General Hospital, Lancaster, Pennsylvania
Supplements IV and VI, EA 91-137

A Notice of Violation and Proposed Imposition of Civil Penalties in the amount of $6,250 was issued November 8, 1991 to emphasize the importance of long-lasting corrective actions with respect to the management attention and oversight provided to the radiation safety program, including oversight by the Radiation Safety Officer, so as to ensure that (1) licensed activities are conducted safely and in accordance with requirements, and (2) appropriate corrective measures are taken when problems exist at the facility. The action was based on (1) multiple examples of unsecured radioactive materials at the facility, and (2) eleven other violations that, in the aggregate, represent a significant lack of management attention to, and oversight of, licensed activities. The licensee responded and paid the civil penalties on December 5, 1991.

P.X. Engineering Company, Inc., Boston, Massachusetts
Supplements VI and VII, EA 90-065

A Notice of Violation and Proposed Imposition of Civil Penalty in the amount of $7,500 was issued February 21, 1991 to emphasize the importance of the licensee's responsibility for ensuring that (1) licensed activities are conducted safely and in accordance with the conditions of the license, and (2) all information communicated to the NRC is complete and accurate in all material respects. The action was based on the licensee's former radiation safety officer, who was also the licensee's radiographer, failing to provide adequate supervision of an individual acting as a radiographer's assistant on a number of occasions between November 1987 and June 28, 1988, and the RSO's failure to provide accurate information in response to inspector's questions regarding his physical presence during the performance of radiography. The licensee responded in letters dated April 5, 1991 and May 29, 1991. After consideration of the

licensee's responses the staff concluded the violations did occur as stated and an Order Imposing Civil Penalty was issued October 1, 1991. The licensee paid the penalty on December 2, 1991.

Rutgers, The State University of New Jersey, New Brunswick, New Jersey
Supplements IV, V, and VI, EA 91-070

A Notice of Violation and Proposed Imposition of Civil Penalty in the amount of $6,250 was issued July 1, 1991 to emphasize the importance of adequate management attention to and oversight of the radiation safety program, including proper oversight of the Director/Radiation Safety Officer, to ensure that (1) licensed activities are conducted safely and in accordance with requirements, and (2) appropriate corrective measures are taken when problems exist at the facility. The action was based on numerous violations that represent a significant lack of management attention to licensed activities. The licensee responded to the Notice in letters dated July 29, 1991. After consideration of the response, one violation and one example of another violation were withdrawn. An Order Imposing Civil Penalty in the amount of $5,535 was issued November 5, 1991. The licensee paid the civil penalty on December 2, 1991.

St. Joseph's Hospital and Medical Center, Paterson, New Jersey
Supplements IV, VI, and VII, EAs 91-128 and 91-168

A Notice of Violation and Proposed Imposition of Civil Penalties in the amount of $10,250 and Order Modifying License and Demand for Information were issued December 3, 1991 to emphasize the need for management to ensure that (1) all employees provide complete and accurate information to the NRC, and (2) activities at the facility are conducted safely and in accordance with regulatory requirements. The action was based on the failure of the individual serving as Chairman of the Radiation Safety Committee and acting Radiation Safety Officer to provide complete and accurate information to the NRC, unauthorized movement of a High Dose Rate afterloader, and failure to have interlocks on the door to the linear accelerator room. The Order Modifying License precludes use of the responsible individual as RSO or from serving on the RSC for three years. The licensee responded and paid the civil penalty on December 27, 1991.

University of Cincinnati, Cincinnati, Ohio
Supplements IV and VI, EA 91-001

A Notice of Violation and Proposed Imposition of Civil Penalty in the amount of $8,750 was issued March 22, 1991 to emphasize the need for strict adherence to NRC requirements and the implementation of timely, effective, and lasting corrective actions. The action was based on numerous violations which, when considered in the aggregate, indicate a lack of management control over licensed activities. The violations include, but are not limited to, the failure to: (a) monitor the amounts of licensed material possessed by the University of Cincinnati; (b) ensure that hourly burn limits of radioactive material incineration were not exceeded; (c) evaluate the gross quantity of licensed material discharged into the sanitary

sewer system; (d) properly instruct the incinerator operator in incineration of radioactive materials and ancillary staff members in the handling of radioactive materials; and (e) audit research laboratories at required intervals. The licensee responded in a letter dated May 17, 1991 and after consideration of the response, an Order Imposing Civil Penalty was issued September 20, 1991. The licensee paid the civil penalty on October 16, 1991.

University of Missouri - Columbia, Columbia, Missouri
Supplements V and VI, EA 91-113

A Notice of Violation and Proposed Imposition of Civil Penalty in the amount of $1,875 was issued October 29, 1991 to emphasize the importance the NRC places on attention to detail while preparing byproduct material for distribution, and ensuring that byproduct material is properly shipped in accordance with NRC and DOT requirements. The action was based on two incidents in which a shipping technician inadvertently switched containers. As a result of these errors, packages were shipped with the wrong contents listed on the shipping papers and the radioactive labels; and recipients received the wrong byproduct material. The licensee responded and paid the civil penalty on November 27, 1991.

Veterans Administration Medical Center, Albany, New York
Supplements VI and VII, EA 91-050

A Notice of Violation and Proposed Imposition of Civil Penalty in the amount of $2,500 was issued November 4, 1991 to emphasize to licensee management that they have a fundamental responsibility in assuring that NRC requirements are met, including the accuracy of required records; and that trained and qualified staff, as well as adequate resources, are essential to maintaining such assurance. The action was based on the failure to perform required physical inventories of sealed sources and creation of inaccurate records indicating that the inventories had, in fact, been performed. The licensee responded and paid the civil penalty.

Watertown Memorial Hospital, Watertown, Wisconsin
Supplement VI, EA 91-138

A Notice of Violation and Proposed Imposition of Civil Penalty in the amount of $6,250 was issued November 7, 1991 to emphasize the need for effective management and oversight of NRC licensed activities. The action was based on 11 violations collectively representing a Severity Level III problem in the control of the licensee's radiation safety program. The violations included for example the following: 1) failure to provide written procedures for the receipt of packages containing radioactive material during off-duty hours; 2) failure to provide annual refresher training from January 1990 through September 26, 1991; and 3) failure to test the dose calibrator for linearity for a period in excess of a calendar quarter. The licensee responded and paid the civil penalty on November 25, 1991.

Westinghouse Environmental & Geotechnical Services, Inc.,
Raleigh, North Carolina
Supplements IV, V, and VI, EA 91-140

A Notice of Violation and Proposed Imposition of Civil Penalty in the amount of $1,750 was issued November 14, 1991 to emphasize the importance of adequate program oversight and compliance with regulatory requirements and license conditions. The action was based on seven violations involving the licensee's radiation safety program. One of the more significant violations involved the licensee establishing a permanent commercial operation without obtaining a license amendment for that establishment. The licensee responded and paid the civil penalty on December 12, 1991.

Winona Memorial Hospital, Indianapolis, Indiana
Supplement VI, EA 91-124

A Notice of Violation and Proposed Imposition of Civil Penalty in the amount of $1,250 was issued October 16, 1991 to emphasize the need for effective management and oversight of NRC licensed activities. The action was based on violations involving the periodic failure to: a) perform the quarterly linearity and the annual accuracy tests of the dose calibrator; b) conduct semiannual leak tests of a sealed source; c) survey at the end of each day the areas where radiopharmaceuticals are used; d) check the operation of the radioactive gas collection system and measure the ventilation rates in areas where radioactive gasses area used; e) hold quarterly meetings of the Medical Isotopes Committee and have the Radiation Safety Officer in attendance in such meetings; f) post certain required documents; and g) retain certain required documents. The licensee responded and paid the civil penalty on October 29, 1991.

Wrangler Laboratories, Larsen Laboratories, and Orion Chemical Company
Provo, Utah, EA 87-223

An Order Suspending Licenses (Effective Immediately) was issued February 25, 1988 to the above firms. The action was based on an NRC investigation that indicated that the firms had: 1) failed to fulfill commitments made to the NRC, 2) made contradictory statements to the NRC and the State of Utah authorities, and 3) processed uranium in an unsafe manner with inadequate contamination controls. The licensee responded to the Order on March 18, 1988. After consideration of the response, an Order Revoking License was issued August 15, 1988. A Hearing was requested and, after an initial decision, a Memorandum and Order (Terminating Proceeding) was issued September 26, 1991.

B. Severity Level III Violation, No Civil Penalty

Lippincott Engineering Associates, Riverside, New Jersey
Supplements IV, V, and VI, EA 91-150

A Notice of Violation was issued November 25, 1991 based on violations involving the failure to maintain proper security of licensed radioactive material located at the field site in Willow Grove. Specifically, an OSHA inspector observed a moisture/density gauge unattended within the perimeter of the fence of the field site. In addition, NRC inspectors determined that the gauge did not have a lock or an outer container that was locked, so as to prevent unauthorized or accidental removal of the sealed source from its shielded position. Other violations were also noted in the radiation safety area. A civil penalty was not proposed because of the licensee's prompt and comprehensive corrective actions, as well as its past good history.

I.A. REACTOR LICENSEES, CIVIL PENALTIES AND ORDERS

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

SEP 23 1991

Docket Nos. 50-348, 50-364
License Nos. NPF-2, NPF-8
EA 91-102

Alabama Power Company
ATTN: Mr. W. G. Hairston, III
Senior Vice President
Nuclear Operations
40 Inverness Center Parkway
P. O. Box 1295
Birmingham, AL 35201

Gentlemen:

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY - $25,000 (NRC INSPECTION REPORT NOS. 50-348/91-17 AND 50-364/91-17)

This refers to the Nuclear Regulatory Commission (NRC) inspection conducted by Mr. M. Hunt on July 23 - 24, 1991, at the Farley Nuclear Plant. The inspection included a review of the facts and circumstances related to a recent valve misalignment which resulted in Unit 1 changing modes while the turbine driven auxiliary feedwater pump (TDAFWP) flowpath was inoperable during the period May 17-22, 1991. The problem was identified by the plant staff and subsequently reported in Licensee Event Report No. 1-91-005 dated June 14, 1991. The report documenting this inspection was sent to you by letter dated August 7, 1991. As a result of this inspection, significant violations of NRC requirements were identified. An enforcement conference was held on August 22, 1991, in the NRC Region II office to discuss the violations, their cause, and your corrective actions to preclude recurrence. A summary of this conference was sent to you by letter dated August 29, 1991.

On May 17, 1991, at approximately 1:30 a.m., with Unit 1 in Mode 3 (Hot Standby), auxiliary feedwater recirculation valve Q1N23V008, which is normally locked closed, was unlocked and opened to allow for a time response test to be performed on the TDAFWP following a refueling outage. The valve was not closed when the test was completed. Violation A, described in Part I of the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice), occurred when Unit 1 changed operational modes from Mode 3 to Mode 1 on May 18-19, 1991, with auxiliary feedwater recirculation valve Q1N23V008 misaligned to the open position in the TDAFWP recirculation line which caused the system flowpath to be inoperable.

Violation A was caused by ineffective procedural controls and communications. The procedure step for closing the valve did not provide assurance of valve closure because it did not explicitly direct operations personnel to close the valve and did not require a verification signature by operations. Instead, the procedure directed maintenance personnel to request operations to close the valve with a maintenance sign-off. Following completion of the test, maintenance personnel informed a plant operator that the test had been completed and that the valve could be closed and locked. However, because of ineffective

communication between the personnel involved, the valve was not returned to the closed and locked position. It was not until May 22, 1991, at approximately 4:15 a.m., with Unit 1 at 41 percent power, that the improperly positioned valve was discovered by the licensee and immediately corrected.

Violation B in Part I of the Notice addresses the failure of the operations staff to follow administrative procedures which required the initiation of a Limiting Condition of Operation (LCO) Status Sheet for the LCO created when AFW valve Q1N23V008 was unlocked and placed in the open position for the time response test. This failure to initiate the LCO Status Sheet contributed to the mispositioned valve remaining undetected for an extended period because the LCO Status Binder containing the LCO Status Sheet would have been reviewed and the TDAFWP flowpath restored to operable condition prior to any mode change. This apparent lack of attention to detail, which is evidenced by other missed opportunities to identify and correct the problem, impacts your operations staff's ability to control plant evolutions. One opportunity to correct and identify the problem was the review of the key checkout book performed on May 20 and 21, 1991, which would have identified that the valve was in the wrong position. A second opportunity was missed when shift operators standing the rover position failed to identify the mispositioned valve.

The staff recognizes that immediate corrective action was taken when the violation was identified and that action was taken to return the valve to its proper alignment. In addition, we understand that you plan to review procedures to determine if similar verification errors exist.

The violations in Part I of the Notice have been considered together to be a Severity Level III problem in accordance with the NRC Enforcement Policy. To emphasize the importance of ensuring operability of equipment important to safety, 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 $25,000 for the Severity Level III problem because of the safety importance of the affected components and the clear operability requirements provided for in your Technical Specifications.

The base value of a civil penalty for a Severity Level III problem is $50,000. The escalation and mitigation factors in the Enforcement Policy were considered. Neither escalation nor mitigation was warranted for identification and reporting. The fact that your staff identified the violation and submitted an LER was offset by several missed opportunities to detect the violation earlier; those included the numerous system operator tours conducted in the vicinity of TDAFWP that failed to detect the unlocked open valve, where the locking chain was hanging from the valve. Neither escalation nor mitigation was warranted for corrective action to prevent recurrence. Your immediate corrective actions to properly align the valve and return the system to operable status, modify the procedure to ensure that operations verifies the valve closed and locked, and counsel the individuals involved addressed those important immediate concerns. However, prior to the enforcement conference, your long-term corrective actions did not include plans to revise the procedure writer's guide to ensure that future procedure revisions would require an operations verification sign-off for similar valve manipulations.

Additionally, actions focused on one individual were not viewed as sufficient to prevent the potential recurrence of the failure of operations to prepare an LCO Status Sheet when the valve was unlocked and opened. Mitigation of 50 percent was warranted for the SALP 1 rating in Plant Operations over previous SALP periods and your good prior enforcement history. Additional mitigation was not warranted for this factor because of a number of problems identified in the past nine months that involve plant configuration control. Examples included the loss of control room HVAC caused by operation of the wrong valve (Inspection Report 50-348/91-10), startup with the reactor vessel flange leakoff valve closed (Inspection Report Nos. 50-348, 364/90-36 and 50-364/90-36), dumping approximately 4500 gallons of water to the containment sump when maintenance personnel were allowed to reposition five valves without any restrictions (Inspection Report Nos. 50-348, 364/91-10), and the potential loss of the reactor coolant system vent path as a result of overtightening the reactor head stud nuts (Inspection Report No. 50-364/90-33). The other adjustment factors in the Policy were considered and no further adjustment to the base civil penalty is considered appropriate. Therefore, based on the above, the base civil penalty has been decreased by 50 percent.

Part II of the Notice contains a violation that addresses a failure to follow procedure, which, had it been followed, may have provided for earlier detection of the misaligned valve. In this particular case, administrative procedures required that the operations shift supervisor periodically audit the locked valve and key checkout sheets. Operations Memorandum 62-05 defines the periodic interval as each Monday night shift. However, no audit was conducted from May 2, until May 21, 1991, a period of 19 days. Had the audit been performed weekly, the misaligned valve may have been discovered sooner.

Inspection Report Nos. 50-348/91-17 and 50-364/91-17 identified an apparent violation involving reporting requirements associated with 10 CFR 50.72. After further review and consultation with the Office for Analysis and Evaluation of Operational Data, the staff has determined that no violation of the reporting requirements of 10 CFR 50.72 occurred in this case.

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

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter and its enclosures will be placed in the NRC Public Document Room. The responses directed by this letter and the enclosed Notice are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, Pub. L. No. 96.511.

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

Sincerely,

Stewart D. Ebneter
Regional Administrator

Enclosure:
Notice of Violation and Proposed
Imposition of Civil Penalty

cc w/encl:
B. L. Moore
Manager, Licensing
Alabama Power Company
P. O. Box 1295
Birmingham, AL 35201

R. P. McDonald
Executive Vice President
Nuclear Operations
Alabama Power Company
P. O. Box 1295
Birmingham, AL 35201

J. D. Woodard
Vice President
Nuclear Farley Project
Alabama Power Company
P. O. Box 1295
Birmingham, AL 35201

D. N. Morey
General Manager
Farley Nuclear Plant
P. O. Box 470
Ashford, AL 36312

W. R. Bayne, Supervisor
Safety Audit and Engineering Review
Farley Nuclear Plant
P. O. Box 470
Ashford, AL 36312

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

Alabama Power Company
Farley Nuclear Plant
Unit 1

Docket No. 50-348
License No. NPF-2
EA 91-102

During an NRC inspection conducted on July 23 - 24, 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. Technical Specification 3.7.1.2 requires that at least three independent steam generator auxiliary feedwater pumps and associated manual actuation switch in the control room and flow paths shall be OPERABLE with:

1. Two auxiliary feedwater pumps, each capable of being powered from separate emergency busses, and

2. One auxiliary feedwater pump capable of being powered from an OPERABLE steam supply system.

This is applicable in Modes 1, 2, and 3.

Technical Specification 3.0.4 prohibits entry into an operational mode unless the conditions of the Limiting Condition for Operations are met without reliance on the provisions of the ACTION requirement of the Technical Specification.

Contrary to the above on May 17, 1991, the recirculation bypass valve on the Unit 1 turbine driven auxiliary feedwater pump was placed in the open position which rendered the system flow path inoperable. On May 18, 1991, Unit 1 entered Mode 2, and on May 19, 1991, entered Mode 1 while the flowpath was inoperable.

B. Technical Specification 6.8.1.1 requires that written procedures shall be established, implemented and maintained covering the applicable procedures in Appendix A, Regulatory Guide 1.33, Revision 2, February 1978. Appendix A includes administrative procedures that specify the authorities and responsibilities for safe operation and shutdown.

Administrative Procedure FNP-0-AP-16, Revision 21, Conduct of Operations - Operating Group, Section 6.4, requires the Shift Foreman Operations (SFO) to initiate a Limiting Condition for Operation (LCO) form for any LCO which cannot be met during his shift.

Contrary to the above, no LCO form was issued on valve AFW Q1N23V008 on May 17, 1991, when it was unlocked and placed in the opened position while performing 1-STP-256.18A, Turbine Driven Auxiliary Feedwater Pump (TDAFWP) Response Time Test. Opening valve Q1N23V008 rendered the TDAFWP flowpath inoperable. As a consequence, the LCO for Technical Specification 3.7.1.2 was not met.

Violations A and B have been categorized in the aggregate as a Severity Level III problem (Supplement I).

Civil Penalty - $25,000 (assessed equally between both violations)

II. Violation Not Assessed a Civil Penalty

Technical Specification 6.8.1.1 requires that written procedures shall be established, implemented and maintained covering the applicable procedures in Appendix A, Regulatory Guide 1.33, Revision 2, February 1978. Appendix A includes procedures for surveillance and test activities of safety-related equipment.

Administrative Procedure FNP-0-SOP-0, Revision 30, General Instructions to Operations Personnel, Section 7.1.10, requires the operations shift supervisor to periodically audit the locked valve and key checkout sheets. Farley Site Operations Memorandum 82-05, dated July 8, 1982, requires this audit to be performed each Monday on night shift.

Contrary to the above, the review of the locked valve and key checkout sheets and the audit cover sheet required by FNP-0-SOP-0 was conducted on May 2, 1991, and not conducted again until May 21, 1991, which was 19 days later.

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

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

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

In requesting mitigation of the proposed penalty, the factors addressed in Section 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 Farley Nuclear Plant.

FOR THE NUCLEAR REGULATORY COMMISSION

James L. Milhoan for
Stewart D. Ebneter
Regional Administrator

Dated at Atlanta, Georgia
this 23rd day of September 1991

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

November 14, 1991

Docket No. 50-255
License No. DPR-20
EA 91-126

Consumers Power Company
ATTN: Gerald B. Slade
Plant General Manager
27780 Blue Star Memorial Highway
Covert, Michigan 49043

Dear Mr. Slade:

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY - $50,000 (NRC INSPECTION REPORT NO. 50-255/91017)

This refers to the special safety inspection conducted September 10 through 20, 1991, at the Palisades Nuclear Generating Station to review the events surrounding the failure to have a containment spray pump operable when the reactor was made critical on March 10, 1991, and again on March 26, 1991. The report documenting this inspection was sent to you by letter dated October 1, 1991. As a result of the inspection, significant violations of NRC requirements were identified. An enforcement conference was held on October 9, 1991, in the Region III office to discuss the violations, their cause and your corrective actions. A copy of the enforcement conference report was mailed to you on October 18, 1991.

On May 23, 1991, the Palisades Plant staff found containment spray pump P54C in an inoperable condition when it failed to start during a routine surveillance test. The NRC inspection of this event concluded that the pump was removed from service on February 11, 1991, so the containment spray pumps would not inadvertently start while the plant was in an outage. Thereafter, pump P54C was not properly returned to service before the plant was restarted on March 10, 1991. As a consequence, the pump remained inoperable during routine plant operations from March 10, 1991, through May 23, 1991. The root cause of this problem was that appropriate written procedures or instructions were not established and implemented to ensure that safety related components, including containment spray pump P54C, were verified operable prior to returning the reactor to service.

The violations, which are described in the enclosed Notice of Violation, include: (a) failure to establish adequate written procedures or instructions to ensure that the containment spray pumps, and similarly the high pressure safety injection pumps, were verified operable; and (b) operation of the reactor at power while containment spray pump P54C was inoperable without complying with the

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

applicable technical specification. The consequence of these violations is that part of the containment cooling system, which is designed to mitigate a serious safety event, was not able to perform its intended safety function. 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.

Your corrective actions were discussed during the October 9, 1991, enforcement conference. Those corrective actions consisted of operator training, revisions to the administrative testing program and the startup procedure, institution of a preventive maintenance program on breaker fuse block assemblies, and providing electrical indication for the closing coil power. Those corrective actions appear acceptable to correct the immediate technical issue. However, the NRC is concerned that the Palisades Plant staff did not recognize that containment spray pump P54C was inoperable for a two month period because of the lack of procedures or instructions concerning the return to service of the Containment Cooling System. We are also concerned with the effectiveness of your corrective action processes as they were applied to this matter. Specifically, when the containment spray pump was found inoperable, you failed to question its previous operability history and you did not perform an aggressive review to identify any previous similar events. We believe that, absent NRC involvement in the broader issues, your corrective actions may well have been less inclusive than those actually taken or proposed.

To emphasize the need to verify that systems designed to prevent or mitigate a serious safety event are available to perform their intended safety function, I have been authorized after consultation with the Director, Office of Enforcement, and the Deputy Executive Director for Nuclear Reactor Regulation, Regional Operations and Research to issue the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice) in the amount of $50,000 for the 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 no adjustments were made to the amount of the base civil penalty. We recognize that your surveillance activities on May 23, 1991, identified that pump P54C failed to start and you reported that event to the NRC in Licensee Event Report No. 91-016. While you took immediate corrective actions to restore pump P54C to service, your actions did not include an historic evaluation of pump operability and you did not perform an aggressive review to identify any previous similar problems with other plant equipment. Further, the NRC identified the inadequacies of your start-up procedure in that the procedure did not require a demonstration of the operability of the Containment Spray System. Therefore, on balance an adjustment to the amount of the civil penalty was not made for either the identification and reporting factor or the corrective action factor. The NRC also considered both your past performance and the duration of the violation and determined that on balance, no adjustment to the base civil penalty is warranted. The remaining factors in the enforcement policy were also considered, but not deemed appropriate for this case.

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,

Carl J Paperiello for

A. Bert Davis
Regional Administrator

Enclosure:
Notice of Violation and Proposed
Imposition of Civil Penalty

cc w/enclosure:
David P. Hoffman, Vice President
Nuclear Operations
P. M. Donnelly, Safety and
Licensing Director
DCD/DCB (RIDS)
James R. Padgett, Michigan Public
Service Commission
Michigan Department of
Public Health
Palisades, LPM, NRR
SRI, Palisades
SRI, Big Rock Point

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 91-126

During an NRC inspection conducted September 10 through 20, 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. Technical Specification 6.8.1.a requires that written procedures be established, implemented and maintained covering the applicable procedures recommended in Appendix A of Regulatory Guide 1.33, "Quality Assurance Program Requirements."

Regulatory Guide 1.33, Appendix A, "Typical Procedures for Pressurized Water Reactors and Boiling Water Reactors," paragraph 3 requires, in part, that the licensee establish and follow written procedures for startup, operation and shutdown of safety-related activities, including instructions for energizing the Emergency Core Cooling System and the Containment Cooling System.

Palisades Plant Procedure No. GOP 2, "Plant Heatup (Cold Shutdown to Hot Shutdown)," Revision 10, implements the requirements of Technical Specification 6.8.1.a and Regulatory Guide 1.33, Appendix A.

Contrary to the above, as of March 10, 1991, the Licensee failed to establish adequate written procedures to energize the containment spray pumps, which are a part of the Containment Cooling System, and the high pressure safety injection pumps, which are a part of the Emergency Core Cooling System. Specifically, Procedure No. GOP 2, "Plant heatup (Cold Shutdown to Hot Shutdown)," Revision 10, which the Licensee uses to control system restoration during startup, did not have a requirement to test start the containment spray pumps and the high pressure safety injection pumps to verify operability after the breakers were racked in and appropriate plant conditions established.

B. Technical Specification 3.4.1 requires, in part, that the reactor shall not be made critical unless the equipment associated with diesel generator 1-1 is operable, including Containment Spray Pump P54C.

Technical Specification 3.4.2 requires, in part, that during power operation, one of the components listed in Specification 3.4.1 may be inoperable provided that the corresponding redundant components shall be tested to demonstrate operability. If the inoperable component is not restored to operability within 7 days, the reactor shall be placed in a hot standby condition within 12 hours. If the inoperable component is not restored to operability within an additional 48 hours, the reactor shall be placed in a cold shutdown condition within 24 hours.

Contrary to the above, the reactor was made critical and was in power operation during the period of March 10, 1991 through March 25, 1991, and from March 26, 1991, until May 23, 1991, while containment spray pump P54C was not operable. Although each period exceeded seven days, redundant component testing was not performed and the reactor was not placed in a hot standby condition nor subsequently in cold shutdown within the applicable time periods.

This is a Severity Level III problem (Supplement I).
Cumulative Civil Penalty - $50,000 (assessed equally among the two violations).

Pursuant to the provisions of 10 CFR 2.201, the 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, a demand for information 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 for the cumulative amount of the civil penalty proposed above, or may protest imposition of the civil penalty in whole or in part, by a written answer addressed to the Director, Office of Enforcement, U. S. Nuclear Regulatory Commission. Should the Licensee fail to answer within the time specified, an order imposing the civil penalty will be issued. Should the Licensee elect to file an answer in accordance with 10 CFR 2.205 protesting the civil penalty, in whole or in part, such answer should be clearly marked as an "Answer to a Notice of Violation" and may: (1) deny the 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.F 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, and a copy to the NRC Resident Inspector at the Palisades Nuclear Generating Plant.

FOR THE NUCLEAR REGULATORY COMMISSION

Carl J Paperiello for

A. Bert Davis
Regional Administrator

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

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

October 8, 1991

Docket No. 50-334
License No. DPR-66
EA 91-098

Mr. J. D. Sieber
Vice President, Nuclear Group
Duquesne Light Company
Post Office Box 4
Shippingport, Pennsylvania 15077

Dear Mr. Sieber:

Subject: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY - $25,000
(NRC Combined Inspection Report Nos. 50-334/91-09, 50-412/91-09,
50-334/91-14 and 50-412/91-14)

This letter refers to the NRC inspections conducted between April 28, 1991 and July 6, 1991, at the Beaver Valley Power Station in Shippingport, Pennsylvania. Inspection reports were sent to you on June 19, 1991 and July 29, 1991. During the inspections, the inspectors reviewed the circumstances associated with two apparent violations associated with your inservice inspection program (ISI) as well as an apparent violation of a technical specification limiting condition for operation which occurred at the facility and which was identified by a member of your staff and reported to the NRC. On August 5, 1991, an enforcement conference was conducted with you and other members of your staff to discuss these issues, the causes and your corrective actions.

With respect to the ISI issues, NRC inspector followup of them was not completed until just after the close of the inspection period. However, these issues were discussed at the enforcement conference and therefore warrant inclusion here. These violations (I.A and I.B) involved a licensee Quality Assurance auditor's finding, on June 12, 1991, that a longitudinal pipe weld on the low head safety injection (LHSI) system was not on his drawing, and was not included in the ISI program. In addition, a similar finding was made during your Safety System Functional Evaluation (SSFE) in 1989. A recent followup by your engineering personnel identified 76 longitudinal welds, of which 45 were fitting welds, on the LHSI system that had been omitted from Unit 1 isometric and vendor supplied drawings. These fitting welds were also not included in the ISI program and had not been inspected during the first ten year interval, which ended in 1988, as required by the ASME Code. This constitutes a violation of 10 CFR Part 50.55a(g), Inservice Inspection Requirements.

As of July 9, 1991, a review of other safety systems to identify similar problems with longitudinal welds had not been conducted. A subsequent review of piping spoolpiece drawings from original fabrication was performed. This review identified an additional 76 longitudinal welds, of which 66 were fitting welds, in the residual heat removal (RHR) system and another 71 longitudinal fitting welds in the high head safety injection (HHSI) system, that also had not been inspected. This failure to act in a timely manner to identify the extent of

this problem, and correct it, constitutes a violation of 10 CFR Part 50 Appendix B, Criterion XVI. While there was no impact on plant system integrity due to these violations, the NRC concludes that these violations collectively represent a Severity Level III problem. Initiatives such as your SSFE program are strongly encouraged by the NRC. However, findings that result from such a program must be properly dispositioned. While it now appears the failure to inspect the welds in question was of low safety significance based on reexamination of a selected number of welds, the failure to adequately assess the scope of the problem initially is a significant issue.

The second issue involved the finding that two Unit 1 in-series control room outside air exhaust dampers were deenergized in the open position. The dampers were required to be deenergized in the closed position due to the Unit 1 solid state protection system being out of service (Unit 1 was defueled and Unit 2 was at full power at the time of the event). The dampers were apparently opened when licensee operations personnel mistakenly closed the damper breakers after racking the breakers back into the motor control center (MCC) without noting the yellow caution tags posted on the breakers. The breakers were subsequently found open although it was not positively identified how or by whom they were opened. However, in that period of time, the dampers were energized long enough to cycle open.

Unit 1 and Unit 2 share a common control room and therefore, the control room habitability is maintained by a common ventilation system. The outside air supply and exhaust dampers are designed to close and seal with air to maintain a positive pressure in the Unit 1 and Unit 2 control room area during either an accident condition or a chlorine gas release, to preclude adverse conditions in the control room and to protect the control room operators. Disabling the automatic closure feature, even for a short period, seriously challenged the ability of the control room ventilation system to perform its intended safety function.

The NRC is concerned that when the operators were directed to restore the motor control center (MCC), the control room did not communicate to the operators the abnormal configuration for the breakers powering the two exhaust dampers. The dampers are normally closed and were required to be deenergized by having their MCC breakers in the open position. The lack of procedural control over the restoration of the MCC contributed to the incorrect positioning of the breakers. In the absence of a restoration procedure, the operators relied on their past experience of placing systems in a normal configuration during restoration. However, the operators' knowledge of control room exhaust damper operation was weak, and operations personnel were not aware that the dampers remained in the open position.

The NRC recognizes that the control room emergency bottled air pressurization system was still functional and its injection under accident conditions probably would have promoted air flow out of the control room envelope during the first hour following a significant event. In addition, a non-safety related, manual operated damper (in series with the open exhaust dampers) was fortuitously closed during the event. The NRC also recognizes that under accident conditions, self contained breathing apparatus and a filtered outside air pressurization system could be used after the first hour. Nonetheless, the violation resulted in the improper alignment of the control room ventilation

system, and the disabling of its automatic isolation feature which is cause for significant concern. Therefore, the violation (Violation II) is classified at Severity Level III in accordance with the "General Statement of Policy and Procedures for NRC Enforcement Actions," 10 CFR Part 2, Appendix C, (Enforcement Policy) (1991). The violation demonstrates the importance of (1) meticulous attention to detail during the performance of safety tagging of equipment, as well as subsequent restoration of systems to normal configuration; and (2) proper control of equipment at the facility to assure that systems designed to mitigate serious safety events are able to perform their safety function and are operated in accordance with the Technical Specifications.

The NRC also recognizes that, subsequent to the event, a thorough investigation was conducted and comprehensive actions were promptly initiated to prevent recurrence of these violations. These corrective actions, which were described either during the inspection or at the enforcement conference, included, in part: (1) conducting a detailed human performance evaluation to determine the underlying causes of this event; (2) installing padlocks on the damper breakers, when necessary, to prevent the breakers from being racked into the buses and to provide positive physical control over the breaker position; (3) providing additional information at the breaker cubicle detailing the effects of closing the breaker on the operation of the dampers; (4) performing a design evaluation of the control room ventilation system, including a review of the current damper position control and indication scheme; (5) training of operators on the control room ventilation system, with particular emphasis on the isolation function; and (6) identifying other plant technical specifications which require re-positioning of breakers or valves as compensatory action, and evaluating the feasibility of locking the components in the required position.

With respect to the ISI issues, the NRC also recognizes that subsequent to the review of other safety systems, comprehensive actions were initiated to prevent recurrence of these violations. These corrective actions, which were described during the enforcement conference, included, in part: (1) conducting a review of all class 1 and 2 piping that required NDE inservice inspection; (2) performing a programmatic review of the NDE portion of the ISI program to ensure that all documentation has been adequately reviewed; (3) performing a similar detailed review of manufacturing documentation for Beaver Valley Unit 2; and (4) performing a root cause analysis of this event to identify the need for additional corrective actions.

To emphasize the need to promptly follow up and correct conditions adverse to quality, I have been authorized, after consultation with the Director, Office of Enforcement and the Deputy Director for Nuclear Reactor Regulation, Regional Operations and Research to issue the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice) in the amount of $75,000 for the Severity Level III violation for inadequate response to the identification of ISI program problems. The base value of a civil penalty for a Severity Level III problem is $50,000. The escalation and mitigation factors in the Enforcement Policy were considered. The base civil penalty was escalated 50% for identification, because notwithstanding that your staff ultimately identified the uninspected

welds, the NRC inspector identified the fact that system operability had not been addressed as required by Technical Specifications, and the full scope of uninspected welds was not understood until after the NRC became involved. The corrective actions taken following the recognition of the violation warrant 50% mitigation as they were prompt and extensive and your past performance also warrants an additional 100% mitigation. Additional 50% escalation is warranted for the prior notice that was provided by the 1989 SSFE finding. On balance, the base civil penalty has been mitigated by 50%.

Although a civil penalty is normally issued for a Severity Level III violation, I have been authorized to mitigate the penalty in its entirety for the violation set forth in Section II of the Notice. In deciding to mitigate the penalty, the escalation and mitigation factors set forth in the enforcement policy were considered in the manner described below. The event and violation were promptly identified as a result of the questioning attitude and actions of the operating shift, and when identified, were promptly reported to the NRC. Therefore, 50% mitigation of the penalty on this factor is warranted. Your corrective actions, as described herein, were considered prompt and comprehensive and included actions to prevent recurrence, and therefore, 50% mitigation of the base civil penalty on this factor is warranted. Your past performance has been good, as evidenced by no related violations of this nature in the past two years, and a Category I rating in the operations, maintenance, and safety assessment areas during the last SALP assessment, and therefore, 100% mitigation on this factor is warranted. Adjustment of the civil penalty based on the other factors is not warranted.

You are required to respond to this letter 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, including your proposed corrective actions and the results of future inspections, the NRC will determine whether further NRC enforcement action is necessary to ensure compliance with NRC regulatory requirements.

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

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

Sincerely,

Thomas T. Martin
Regional Administrator

Enclosure: Notice of Violation
and Proposed Imposition of Civil Penalty

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

Duquesne Light Company
Beaver Valley Power Station
Unit 1

Docket No. 50-334
License No. DPR-66
EA 91-098

During NRC inspections conducted from April 28 - July 9, 1991, and subsequent NRC inspector followup on July 9, 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 Part 50 Appendix B, Criterion XVI, Corrective Action, requires that measures shall be established to assure that conditions adverse to quality and nonconformances are promptly identified and corrected.

Contrary to the above, as of July 9, 1991, the licensee did not take prompt and adequate corrective action for a quality assurance auditor's finding on June 12, 1991 that identified that a longitudinal pipe weld on the low head safety injection system (LHSI) was not on his drawing and not included in the ISI program, or for a SSFE finding in 1989 concerning similar longitudinal welds. Specifically, in neither instance had the licensee conducted sufficient additional reviews to identify and resolve similar problems with longitudinal pipe welds which were present in other safety-related piping.

B. 10 CFR 50.55a(g) requires, in part, that components shall meet the requirements of paragraph (g)(4) of this section and piping shall meet the requirements applicable to components which are classified as ASME Code Class 2.

10 CFR 50.55a(g)(4) requires, in part, that components which are classified as ASME Code Class 2 shall meet the requirements set forth in applicable editions of Section XI of the ASME Boiler and Pressure Vessel Code. The applicable edition of the Code is the 1974 Edition through Summer of 1975 addenda.

Section XI, Article IWC-2000, requires, in part, that inservice examinations be performed on longitudinal weld joints in pipe fittings such that the intervals between examinations will not exceed the 10 year inspection interval.

Contrary to the above, (1) on June 18, 1991, licensee engineering personnel identified 76 longitudinal welds (45 of which were fitting welds) on the low head safety injection system that were classified as ASME Code Class 2, and that were omitted from the Unit 1 isometric and vendor supplied drawings, resulting in the failure to include these welds in the licensee's inservice inspection (ISI) program and the failure to inspect these welds during the first 10 year ISI

interval which ended in 1988; and (2) subsequent document review, on July 11, 1991, also revealed 76 longitudinal welds (66 of which were fitting welds) in the residual heat removal and 71 longitudinal welds (71 of which were fitting welds) in the high head safety injection system which were not included and inspected in the first 10-year interval of the ISI program.

This is a Severity Level III problem (Supplement I).
Civil Penalty - $25,000 (assessed for Violation I.A.).

II. Violation Not Assessed a Civil Penalty

Technical Specification (TS) 3.7.7.1 requires that when either unit is in mode 1, 2, 3, or 4, the control room habitability system shall be operable. TS 3.7.7.1.c defines the control room emergency habitability system as OPERABLE when the series normal air exhaust isolation dampers for both units are OPERABLE, and capable of automatic closure on a control room high radiation and chlorine isolation signal, or the dampers shall be closed.

T.S. 3.0.3 requires that when a Limiting Condition for Operation is not met except as provided in the associated ACTION requirement, within one hour, action shall be initiated to place the unit in a MODE in which the specification does not apply.

Contrary to the above, on May 17, 1991, while Unit 1 was defueled and Unit 2 was in mode 1, the Unit 1 solid state protection system (SSPS) was out of service (unable to provide an isolation signal), the Unit 1 control room outside air exhaust isolation dampers (two in-series dampers) were neither operable nor closed in that they were deenergized in the open position for a period of 18 1/2 hours, with no action taken to place Unit 2 in a MODE in which TS 3.7.7.1.c does not apply.

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

Pursuant to the provisions of 10 CFR 2.201, Duquense 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 result achieved, (4) the corrective steps that will be taken to avoid further violations, and (5) the date when full compliance will be achieved. If an adequate reply is not received within the time specified in this Notice, an order may be issued to show cause why the license should not be modified, suspended, or revoked or why such other action as may be proper should not be taken. Consideration may be given to extending the response time for good cause shown. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, 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 actions 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 1, and a copy to the NRC Resident Inspector at the Beaver Valley Power Station.

FOR THE NUCLEAR REGULATORY COMMISSION

Thomas T. Martin
Regional Administrator

Dated at King of Prussia, Pennsylvania
this 8th day of October 1991

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

NOV 26 1991

Docket No. 50-458
License No. NPF-47
EA 91-132

Gulf States Utilities
ATTN: James C. Deddens
Senior Vice President (RBNG)
P.O. Box 220
St. Francisville, Louisiana 70775

Gentlemen:

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY - $75,000
(NRC INSPECTION REPORT NO. 50-458/91-26)

This is in reference to the September 19-24, 1991, inspection conducted in response to Gulf States Utilities reporting to NRC on September 18, 1991, that both trains of a subsystem of the combustible gas control system at GSU's River Bend Station (RBS) nuclear power plant were discovered to have been inoperable.

NRC's inspection, which was documented in a report issued on October 11, 1991, confirmed GSU's finding that wiring errors in the control system for the plant's primary containment/drywell hydrogen mixing system would have, in the absence of operator intervention, prevented this system from performing its intended safety function. NRC's inspection also confirmed GSU's finding that this condition had existed since the plant began operating in July 1985.

Because this discovery involved a potentially serious violation of the plant's Technical Specifications, which require both trains of this subsystem to be operable when the plant is in Operational Conditions 1, 2, and 3, this matter was discussed with you and other representatives of GSU in an enforcement conference in NRC's Arlington, Texas offices on October 23, 1991.

The primary purpose of this system is to maintain hydrogen concentrations in the drywell below flammable limits following a loss-of-coolant accident (LOCA) that results in the generation of hydrogen. The hydrogen mixing system performs this function by exhausting hydrogen in the drywell atmosphere to the larger primary containment atmosphere, thus diluting hydrogen concentrations in the drywell.

Prior to the discovery of the control wiring errors on September 18, 1991, however, had operators attempted to initiate hydrogen mixing following a LOCA, the outlet valves associated with this system would have closed after operators attempted to open them, rendering the system incapable of performing its intended function without operator intervention to override faulty system logic.

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

The discovery of this problem during a biennial procedure review by an employee under contract to the RBS operations department is indeed commendable. As GSU indicated during the enforcement conference, it is unlikely that this error would have been detected during routine periodic system testing and just as unlikely to have been detected during the biennial procedural review that this employee was performing.

This problem appears to be attributable to a problem in the design control process during plant construction, in that a design change was reflected on a system logic diagram but not on a system wiring diagram. In addition, this appears to have occurred because a complete preoperational test of this system, i.e., with a LOCA signal present, was not conducted. The system outlet valves were apparently not tested under conditions that would be expected to be present following a LOCA.

NRC has considered GSU's evaluation of the safety significance of this problem and agrees that plant operators would have recognized the problem and would, under most circumstances, have been capable of finding a solution within a time frame (four hours under assumed design basis conditions) that would restore system operability before hydrogen concentrations exceeded flammable limits.

NRC also has considered GSU's assertion that the hydrogen igniter system, a separate system that was designed to control more significant quantities of hydrogen, would control the hydrogen concentration in the drywell even in the absence of the hydrogen mixing system. GSU asserted in response to questions during the enforcement conference that either the hydrogen mixing system and its associated systems or the hydrogen igniter system would satisfy design requirements for hydrogen control in the event of a LOCA. However, it is not clear in reading plant design descriptions that the hydrogen igniter system is a redundant system to the combustible gas control system. As discussed during the conference, GSU committed to take steps to revise design documents as necessary to reflect this position.

NRC notes that, on October 24, the day after the enforcement conference, GSU informed NRC that surveillance testing of the hydrogen igniter system had not been conducted in accordance with plant Technical Specifications, a discovery that put into question the ability of that system to perform its design function. Based on your review of that issue, it does not appear that the hydrogen igniter system was ever incapable of performing its function. This matter, while related to the issue at hand, will be dealt with in a separate inspection report following NRC's review.

NRC accepts GSU's premise that the safety significance of the hydrogen mixing system problem is reduced by the possibility of operator intervention and the availability of the hydrogen igniter system. The fact remains, however, that a system that was designed and installed to mitigate the consequences of a serious safety event would not have been capable of performing its intended function from July 1985 to September 1991, without operator intervention.

This condition constitutes a significant violation of the plant's Technical Specifications, which do not permit plant operations in Operational Conditions 1, 2, and 3 with both trains of the hydrogen mixing system inoperable. 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. It should be noted that by a strict reading of the Enforcement Policy this violation could be categorized at Severity Level II. However, because the NRC staff agrees that given the amount of time that would be available, the operators would likely restore system function, and because the hydrogen igniter system could provide some degree of back-up, the Severity Level III categorization was found to be the most appropriate.

NRC notes that GSU acted promptly upon the discovery of this problem to declare the system inoperable, enter Technical Specification 3.0.3, begin an orderly plant shutdown, report the matter to NRC's Operations Center, and took immediate steps to restore the system to operability. GSU's long-term corrective action plan, which was described at the enforcement conference, consists of plans to conduct enhanced surveillance testing of this system in the future, and plans to review wiring and logic diagrams for other systems to detect similar discrepancies. While NRC finds GSU's corrective action plan adequate, NRC would have considered the plan more comprehensive had it included plans to assess the significance of the fact that preoperational testing did not identify this problem. Further, given the time that had elapsed since this problem was discovered, the NRC would have expected GSU to have been further along in implementing its long term corrective action plan than was discussed at the enforcement conference.

To emphasize the significance of the inability of a safety system to perform its post-accident function, and the importance of ensuring that design changes are properly reviewed and documented, I have been authorized, after consultation with the Director, Office of Enforcement, and the Deputy Executive Director for Nuclear Reactor Regulation, Research and Regional Operations, to issue the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice) in the amount of $75,000 for the Severity Level III violation described above and in the Notice.

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 and resulted in a net increase of $25,000. In making this decision, NRC considered GSU's discovery of this problem and prompt reporting worthy of a 50 percent reduction in the base value. However, NRC considered the fact that opportunities to discover this error were missed during the design modification and preoperational test phases, resulting in the inoperability of this system for six years, worthy of a 100 percent increase in the base value under the duration factor. The other adjustment factors in the Policy were considered and no further adjustment to the base civil penalty was considered appropriate.

GSU is required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing its response. In response, GSU should document the specific actions taken and any additional actions it plans to prevent recurrence. As indicated above, preoperational testing of the hydrogen mixing system did not identify the control logic errors that prevented this system from operating as designed. Although this single instance is not cause for suspecting fundamental flaws in the RBS preoperational testing program, NRC requests that GSU discuss in its response to the Notice its basis for confidence in preoperational testing of systems and components that, like the hydrogen mixing system, may not be routinely tested under simulated design conditions. 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,

Robert D. Martin
Regional Administrator

Enclosure:
Notice of Violation and Proposed Imposition
of Civil Penalty

cc:
Gulf States Utilities
ATTN: J. E. Booker, Manager-
Nuclear Industry Relations
P.O. Box 2951
Beaumont, Texas 77704

Winston & Strawn
ATTN: Mark J. Wetterhahn, Esq.
1401 L Street, N.W.
Washington, D.C. 20005-3502

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

Gulf States Utilities
River Bend Station

Docket No. 50-458
License No. NPF-47
EA 91-132

During an NRC inspection conducted on September 19-24, 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 violation and associated civil penalty are set forth below:

River Bend Station Technical Specification 3.6.6.2 states, in part, that two primary containment/drywell hydrogen mixing systems shall be operable in Operational Conditions 1, 2, and 3.

Technical Specification 3.6.6.2 also states, in part, that with one primary containment/drywell hydrogen mixing system inoperable, the inoperable system must be restored to operable status within 30 days or the unit must be in at least hot shutdown within the next 12 hours.

Technical Specification 3.0.3 states, in part, that when a limiting condition for operation is not met, except as provided in the associated action requirements, action shall be initiated within 1 hour to place the unit in a specified operational condition, as applicable, in which the Specification does not apply.

Contrary to the above, between July 1985 and September 18, 1991, the licensee: (a) operated the facility in Operational Conditions 1, 2 and 3 with both primary containment/drywell hydrogen mixing systems inoperable; (b) failed to restore either system to operable status during this period and failed to put the unit in at least hot shutdown as a result of such inoperability; and (c) no exceptions being applicable, failed to place the unit in an applicable operational condition as specified in Technical Specification 3.0.3.

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

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

and the results achieved, (4) the corrective steps that will be taken to avoid further violations, and (5) the date when full compliance will be achieved. If an adequate reply is not received within the time specified in this Notice, an order or 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 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, and a copy to the NRC Resident Inspector at the River Bend Station.

Dated at Arlington, Texas
this 26th day of November, 1991

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

October 2, 1991

Docket No. 50-423
License No. NPF-49
EA 91-107

Mr. E. J. Mroczka
Senior Vice President - Nuclear
Engineering and Operations
Northeast Nuclear Energy Company
P.O. Box 270
Hartford, Connecticut 06141-02

Dear Mr. Mroczka:

Subject: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY - $50,000
(NRC Inspection Report No. 50-423/91-15)

This letter refers to the NRC inspection conducted between June 16 and July 31, 1991, at Millstone Nuclear Power Station, Unit 3, Waterford, Connecticut. The inspection report was sent to you on August 8, 1991. During the inspection, a violation of NRC requirements was identified involving the failure to promptly identify and correct a condition adverse to quality at the facility. On August 29, 1991, an enforcement conference was conducted with you and members of your staff to discuss the violation, its causes and your corrective actions.

The condition adverse to quality involved the degradation of the service water system in that an 80 foot section of the "B" train of the service water piping had extensive buildup of mussel clusters, thereby inhibiting flow to certain heat exchangers, including the two heat exchangers for the associated diesel generator. Although your staff had received indications on at least eight occasions between June 27 and July 25, 1991, that service water flow was significantly reduced below Alert or Alarm limits, your staff performed cleaning operations, but did not aggressively pursue the cause of this degraded condition, nor determine whether the service water system could perform its intended design function. The mussel fouling of the service water system occurred because the chlorination system, which was designed to prevent such fouling, injected chlorine at a point downstream of where the fouling occurred.

The NRC is concerned that although there were numerous indications during the June and July 1991 timeframe, that service water flow to system components in this train was significantly degraded, you did not properly analyze this evident trend. Furthermore, although the diesel generator heat exchangers were cleaned

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

on eight separate occasions during that period, you did not verify whether system design functions were affected by the mussel fouling. When an extended flow test was ultimately performed (to confirm whether design service water functions were maintained) after concerns were raised by the NRC inspectors on July 25, 1991, you found that the B Diesel Generator would not have operated for a full 24 hours at full load, as required by the plant technical specifications, since only 15% of required service water flow was obtained.

The NRC recognizes that subsequent to the identification of this violation, prompt and comprehensive actions were initiated to resolve the specific technical concerns, and preclude recurrence of such violations. These corrective actions, which were described at the enforcement conference, and in your related Licensee Event Report, included: (1) prompt shutdown of the reactor on July 25, 1991 (which has remained down as of this date); (2) a comprehensive inspection of all the service water system piping to ascertain the extent of the problem; (3) hydrolasing the section of piping where the cluster of mussel fouling was identified; (4) planned reexamination of the system in future outages to assure any mussel biofouling is promptly identified and corrected; (5) plans to do a similar evaluation of the "A" train; and (6) a change in the Plant Incident Reporting process to ensure that relevant data banks concerning affected equipment are critically reviewed in a timely manner following an event to assure equipment operability.

These failures demonstrate weaknesses in your program for prompt identification and resolution of safety significant deficiencies. To emphasize the importance of effective and long lasting corrective action to resolve this concern, I have been authorized, after consultation with the Director, Office of Enforcement, and the Deputy Executive Director for Nuclear Reactor Regulation, Regional Operations and Research, to issue the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice) in the amount of $50,000 for the violation set forth in the enclosed Notice.

The base civil penalty amount for a Severity Level III violation is $50,000. The escalation and mitigation factors set forth in the enforcement policy were considered, as described below. The violation (failure to promptly identify and correct a condition adverse to quality) was identified by the NRC, and therefore, 50% escalation of the base civil penalty on this factor is warranted. Your corrective actions, subsequent to the identification of this violation, were prompt and comprehensive, and therefore, 50% mitigation of the civil penalty on this factor is warranted. The other adjustment factors in the policy were considered and no further adjustment of the penalty was warranted. Therefore, the civil penalty is being proposed at $50,000.

You are required to respond to the enclosed Notice 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. 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 enclosure will be placed in the NRC's Public Document Room.

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

Sincerely,

Thomas T. Martin
Regional Administrator

Enclosure:
Notice of Violation and
Proposed Imposition of Civil Penalty

cc:
W. D. Romberg, Vice President, Nuclear Operations
S. E. Scace, Nuclear Station Director
C. H. Clement, Nuclear Unit Director
R. M. Kacich, Manager, Nuclear Licensing
D. O. Nordquist, Director of Quality Services
Gerald Garfield, Esquire
Nicholas Reynolds, Esquire
Public Document Room (PDR)
Local Public Document Room (LPDR)
Nuclear Safety Information Center (NSIC)
NRC Senior Resident Inspector
State of Connecticut

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

Northeast Nuclear Energy Company
Waterford, Connecticut

Docket No. 50-423
License No. NPF-49
EA 91-107

During an NRC inspection conducted between June 16 and July 31, 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 the associated civil penalty are set forth below:

> 10 CFR Part 50, Appendix B, Criterion XVI (Corrective Action), requires, in part, that measures shall be established to assure that conditions adverse to quality, such as failures, deficiencies and deviations, are promptly identified and corrected.
>
> Contrary to the above, between June 27, 1991 and July 25, 1991 a condition adverse to quality existed at Millstone Unit 3, and the condition was not promptly identified or corrected. Specifically, mussel clusters of significant enough volume to cause operational problems had accumulated along an 80 foot section of service water system piping. On at least eight occasions during that time period actions taken by licensee personnel to correct indications of degraded service water flow neither identified nor corrected the full extent of the problem. These ineffective corrective actions resulted in significantly reduced service water flow to the "B" Diesel Generator heat exchanger which in turn resulted in a reduction in the diesel generator's electrical load carrying capability.
>
> This is a Severity Level III violation (Supplement I).
>
> Civil Penalty - $ 50,000

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

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

Within the same time as provided for the response required above under 10 CFR 2.201, the Licensee may pay the civil penalty by letter addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, with a check, draft, money order, or electronic transfer payable to the Treasurer of the United States in the amount of the civil penalty proposed above, or may protest imposition of the civil penalty in whole or in part by a written answer addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission. Should the Licensee fail to answer within the time specified, an order imposing the civil penalty will be issued. Should the Licensee elect to file an answer in accordance with 10 CFR 2.205 protesting the civil penalty, in whole or in part, such answer should be clearly marked as "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. 2282(c).

The responses 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, D.C. 20555 with a copy to the Regional Administrator, U.S. Nuclear Regulatory Commission, Region 1, 475 Allendale Road, King of Prussia, Pennsylvania 19406 and a copy to the Senior Resident Inspector, Millstone, Unit 3.

FOR THE NUCLEAR REGULATORY COMMISSION

Thomas T. Martin
Regional Administrator

Dated at King of Prussia, Pennsylvania
this 2nd day of October 1991

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

November 25, 1991

Docket No. 50-443
License No. NPF-86
EA 91-144

Public Service Company of New Hampshire
ATTN: Mr. T. C. Feigenbaum, President
and Chief Executive Officer
New Hampshire Yankee Division
Post Office Box 300
Seabrook, New Hampshire 03874

Dear Mr. Feigenbaum:

Subject: Notice of Violation and Proposed Imposition of Civil Penalty - $100,000

On December 27, 1990, the NRC was informed by New Hampshire Yankee (NHY) that the radiographic records (i.e., the film and accompanying Radiographic Inspection Report) for one safety-related weld could not be located. Region I documented this issue in NRC Inspection Report (IR) No. 50-443/90-24 as an unresolved item pending licensee completion of its evaluation and implementation of corrective measures, as well as further NRC review of the safety significance of this finding. During your subsequent evaluation, which included implementation of a NHY weld record reverification program (WRRP), the radiographic records for three additional safety-related welds could not be located.

In addition to the missing weld records, as a result of further NRC inspection follow-up of the unresolved item, the NRC also identified a weld radiographic record that did not include documentation to verify that Yankee Atomic Electric Company (YAEC) quality assurance personnel performed the procedurally required film review of one safety-related radiograph to confirm its acceptability. Furthermore, additional investigation by NHY personnel revealed one additional safety-related weld for which there was no documentation to indicate that a YAEC review of a radiograph was performed.

The NRC also notes that you initiated a weld radiograph reinterpretation program (WRRIP) to reexamine a specific population of construction field weld radiographs and their applicable records, as a result of a Notice of Violation issued to you on June 28, 1991, involving

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

deficient radiographs for six welds. The radiographs were deficient in that the requirements of the ASME Boiler and Pressure Vessel Code (ASME Code) for radiographic film sensitivity were not met (Reference: Inspection Report No. 50-443/91-12). Based on that WRRIP, the results of which were provided to the NRC in letters dated September 17 and 27, 1991 (Reference: NYN-91151 and NYN-91157), you indicated that you established a suspect population of 90 similarly configured welds which NRC had not previously reviewed, or which were re-radiographed by a different technique after you had instituted more stringent controls. Based on your review of the associated radiographs, 47 were found to have similar deficiencies to those previously found to be inadequate by the NRC. The specific deficiencies included the failure of 40 weld radiographs to meet certain ASME Code requirements for film density, the failure of three weld radiographs to meet certain ASME Code requirements for penetrameter sensitivity and the failure of four weld radiographs to meet either requirement.

With respect to the first two issues, the NRC recognizes that NHY has implemented corrective action for the four weld radiograph records that were missing, and for the two weld radiographic records for which there was no evidence of a YAEC film review. Those actions were submitted, along with the results of further inspection and review, in a letter dated August 30, 1991 (Reference: NYN-91134). In that final WRRP report, NHY indicated that for all four cases where the radiographic records were found to be missing, the welds were radiographed again and found acceptable per ASME Code requirements. Also, NHY indicated that for the other two welds where independent YAEC review of the radiographs was not in evidence, a review by a YAEC reviewer was performed, subsequent to the discovery of this discrepancy, and that review confirmed the acceptability of both weld and film quality in each case.

With respect to the third issue, the population of affected welds was limited to those welds in piping of three-inch and under diameter examined with a specific radiographic technique (namely, double wall viewing after double wall shots with source side penetrameters) and for which the initial Pullman-Higgins review signature occurred prior to October 1, 1982 (more stringent controls were put in place by you after this date). You subsequently radiographed the 47 welds whose original radiographs were found to be in question, and the resultant radiographs were verified as meeting all requisite criteria in each of the 47 cases, and confirmed the quality of the affected welds. In addition, the NRC has reviewed a sufficient number of new weld radiographs and their associated records, as well as additional populations of weld radiographs and associated records, to establish confidence that you currently meet the requirements of the ASME Code for weld and film quality.

Notwithstanding the actions taken once the deficiencies were identified, three violations have been identified as a result of the extensive review of the issues set forth above. The violations, which are described in the enclosed Notice of Violation, involved: (1) the failure to retain, and be able to retrieve for the life of the plant, the radiographs and associated records for four welds (Violation II.A); (2) the failure to document that a YAEC review was performed of the radiographic packages for two other welds as required by your procedures (Violation II.B); and, (3) the failure of 47 additional radiographs to meet the ASME Code requirements necessary to fully demonstrate the quality of the welds (Violation I).

The first two violations, which are described in Section II of the enclosed Notice, are classified at Severity Level IV.

Given the number of examples of the third violation, and the fact that they resulted in welds of indeterminate quality until the additional radiographs were taken in 1991, the third violation, which is described in Section I of the enclosed Notice, is classified at Severity Level III in accordance with Supplement II of the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy) 10 CFR Part 2, Appendix C (1991).

With respect to the third violation, the NRC recognizes that the deficiencies were limited to a small portion of the set of approximately 2700 radiographs, and that you had taken other actions to ensure the quality of construction at the facility. Furthermore, the NRC also recognizes that the subsequent radiographs in 1991 confirmed the quality of the affected welds in each case.

Nonetheless, to emphasize the importance of radiographs meeting all ASME Code requirements to fully demonstrate the quality of welds, 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 $100,000 for the Severity Level III violation set forth in Section I of the enclosed Notice. The base civil penalty amount for a Severity Level III violation is $50,000. The escalation and mitigation factors set forth in the enforcement policy were considered. The civil penalty has been escalated 100% after considering the factors of identification, corrective action, and duration. Specifically, the associated radiographic deficiencies set forth in Violation I were not identified and corrected until the 1990-1991 time frame. Those actions were not taken until after NRC inquiries concerning this matter as a result of allegations and information received from other sources.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. After reviewing your response to this Notice, including your corrective actions (which may reference prior submittals as warranted)

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 the enclosure will be placed in the NRC's Public Document Room.

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

Sincerely,

Thomas T. Martin
Regional Administrator

Enclosure:
Notice of Violation and Proposed Imposition of Civil Penalty

cc w/encl:
L. E. Maglathlin, Jr., President and Chief Executive Officer, PSNH
Senior Vice President and Chief Operating Officer, NHY
J. M. Peschel, Regulatory Compliance Manager, NHY
D. E. Moody, Station Manager, NHY
T. Harpster, Director of Licensing Services, NHY
R. M. Kacich, Manager of Generation Facilities Licensing, NUSCO
J. F. Opeka, Executive Vice President, NU
G. Garfield, Esquire
R. Hallisey, Director, Dept. of Public Health, Commonwealth of Massachusetts
S. Woodhouse, Legislative Assistant
Public Document Room (PDR)
Local Public Document Room (LPDR)
Nuclear Safety Information Center (NSIC)
NRC Resident Inspector
State of New Hampshire, SLO
Commonwealth of Massachusetts, SLO Designee

NOTICE OF VIOLATION
OF
PROPOSED IMPOSITION OF CIVIL PENALTY

Public Service Company of New Hampshire
Seabrook Station
Seabrook, New Hampshire

Docket No. 50-443
License No. NPF-86
EA 91 144

As a result of the licensee and NRC follow-up of issues set forth in the NRC Inspection Report Nos. 90-24, 91-12 and 91-21, violations of the 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 the associated civil penalty are set forth below:

I. VIOLATION ASSESSED A CIVIL PENALTY

10 CFR Part 50, Appendix B, Criterion IX, Control of Special Processes, requires that measures be established to assure that special processes, such as nondestructive testing, be controlled and accomplished by qualified personnel using qualified procedures in accordance with applicable codes, standards, specifications, criteria, and other special requirements. Pursuant to this requirement, Seabrook Station was constructed in accordance with the requirements of the ASME Boiler and Pressure Vessel Code (Code), 1977 Edition up to the Winter 1977 Addenda.

Section III of the Code delineates the requirements for the construction of piping systems, including welded joints and the radiography of welded joints. Article 2 of Section V of the Code, which is invoked by Section III of the code, delineates the requirements for radiography of piping welds. Specifically, Table T-272 of the ASME Code, requires that "the minimum radiographic quality, as displayed by a radiographic penetrameter for thicknesses up to and including 0.875," shall be 2-4T. In addition, Paragraph T-263.2(a) of Article 2 of Section V requires the density of the area of interest to be within minus 15% to plus 30% of the density through the body of the penetrameter and Paragraph T-234.1 requires a minimum density of 2.0 for radiographs made with a gamma source.

10 CFR Part 50, Appendix B, Criterion XVII, Quality Assurance Records, requires that sufficient records be maintained to furnish evidence of activities affecting quality. The records shall be identifiable and retrievable. Pullman-Higgins Procedure IX-RT-[illegible] 17 implemented this requirement for all welds reviewed to ASME Section V and Section III.

Contrary to the above, sufficient records (radiographs) under Pullman-Higgins Procedure No. RT-1-W77 were not obtained to furnish evidence that all welds met the quality standards required by ASME Section V and Section III, rendering the quality of welds indeterminate. Specifically, final code required radiographs taken for three of the welds in the early 1980's did not meet the minimum quality level of 2-4T, the radiographs taken in the same period for 40 welds did not meet the requirements for minus 15 to plus 30 percent of the penetrameter density or the 2.0 minimum density requirements and the radiographs taken in the same time frame for four welds did not meet either requirement. This condition existed until September 1991, when additional radiographs were taken and found to be acceptable.

This is a Severity Level III Violation (Supplement II)

Civil Penalty - $100,000

II. VIOLATIONS NOT ASSESSED A CIVIL PENALTY

A. 10 CFR Part 50, Appendix B, Criterion XVII, Quality Assurance Records requires, in part, that sufficient records shall be maintained to furnish evidence of activities affecting quality, and that these records be identifiable and retrievable.

Contrary to the above, between December 27, 1990 and August 1991, radiographs and their associated records, (namely, the original Radiograph Inspection Reports (RIR)), for four welds were not identifiable and retrievable, since they had not been retained for the life of the plant. The specific welds for which radiograph packages were missing were Welds 1-CS-328-02-,F0204; 1-CS-360-08,F0801; 1-CBS-1201-07,F0701; and 1-FI-188-01,F0150.

This is a Severity Level IV Violation (Supplement II)

B. 10 CFR Part 50, Appendix B, Criterion II, Quality Assurance Program requires, in part, that the program contain documented procedures and that activities be carried out in accordance with applicable procedures.

The Yankee Atomic Electric Company (YAEC) Procedure No. 5, entitled, "QEG NDE REVIEW GROUP," which implements 10 CFR Part 50, Appendix B, Criterion II, requires a YAEC quality assurance program review of all safety-related radiographs.

Contrary to the above, prior to August 1991, no YAEC quality assurance program review of two radiographic packages was conducted for Welds 1-RH-151-01,F0102 and 1-CBS-1201-01,F0103. In particular, the RIRs for these welds were not signed by the YAEC reviewer, as were those for all other welds reviewed.

This is a Severity Level IV Violation (Supplement II)

Pursuant to the provisions of 10 CFR 2.201, New Hampshire Yankee 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, including measures taken to prevent similar problems with work conducted on future modifications, and (5) the date when full compliance will be achieved. For items (3), (4) and (5) above, your reply may refer to previous actions and letters to the NRC, as appropriate and warranted. 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 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 I, 475 Allendale Road, King of Prussia, Pennsylvania 19406 and a copy to the NRC Senior Reactor Inspector, Seabrook Nuclear Power Station.

FOR THE NUCLEAR REGULATORY COMMISSION

Thomas T. Martin
Regional Administrator

Dated at King of Prussia, Pennsylvania
this 25th day of November 1991

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

October 30, 1991

Docket No. 50-440
License No. NPF-58
EA 91-118

The Cleveland Electric Illuminating
Company
ATTN: Mr. Michael D. Lyster
Vice President Nuclear - Perry
10 Center Road
Perry, Ohio 44081

Dear Mr. Lyster:

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY - $100,000 (NRC INSPECTION REPORT NO. 50-440/91013)

This refers to the special safety inspection conducted on August 19-30, 1991, at the Perry Nuclear Power Plant to review the program controls and technical adequacy of the emergency operating procedures (EOPs; also called Plant Emergency Instructions, or PEIs at the facility). The report documenting this inspection was sent to you by letter dated September 23, 1991. As a result of the inspection, significant violations of NRC requirements were identified. An enforcement conference was held on September 30, 1991, in the Region III office with you to discuss the violations, their cause and your corrective actions. A copy of the enforcement conference report was mailed to you on October 2, 1991.

It appears that a lack of effective management control and oversight of the EOP program was the major factor contributing to the violations, as evidenced by the inattention to program requirements (e.g. verification and validation) during the development and implementation of the EOPs and the limited application of resources to the EOP program. Additionally, quality assurance activities failed to identify the significant programmatic problems.

Violation A involves the failure to fully implement the PEI Verification Plan developed to comply with Technical Specification 6.8.1.b and NUREG-0737 requirements for upgraded emergency operating procedures. Specifically: (1) PEI-SPIs (Special Plant Instructions) were not verified for conformance to the Perry Plant Specific Technical Guidelines prior to issuance, (2) the first issuance of two procedures that provided new sequences of operator actions resulting from changes in methodology described in revised PEIs were not validated prior to issuance, and (3) the "Technical Adequacy" portion of the PEI Verification Checklist was not performed for PEI flow charts.

Violations B and C concern inadequate and nonexistent PEI-SPIs which resulted from the program weaknesses exemplified in the previous violation. In particular,

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

PEI-SPI 2.6, "Bypass of RWCU Isolation on SLCS Initiation" did not contain instructions for reopening system isolation valves to allow for reactor pressure control. PEI-SPI 8.2, "RPV Venting Using RCIC" failed to provide instructions to reopen isolation valves or to prevent the closure of the RCIC steam shutoff valve on a Level 8 isolation. In addition, no procedures were developed to defeat the reactor protection system and alternate rod insertion logic trips (to allow for reinsertion of a reactor scram in response to an ATWS event), or to bypass the main steam isolation valve (MSIV) high radiation isolation. When considered together, the failure to provide instructions to defeat the RCIC and MSIV isolations would have precluded all venting of the reactor pressure vessel, rendering reactor cooling through containment flooding ineffective for low probability accident scenarios beyond the plant design basis.

Corrective actions included the verification and validation of the PEI-SPIs, the technical verification of EOP flow charts, and the planned revision to your procedure controlling EOP development and implementation. Also, the evaluation by your quality assurance organization of its performance and the resulting comprehensive corrective actions in the quality assurance area that extended beyond the PEI program area are viewed as positive actions.

Violations A, B, and C collectively represent a significant breakdown in the management oversight and control during the development and implementation of the EOPs at the Perry Nuclear Power Plant. 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.

Since 1982, the NRC has issued three NUREG documents, one Information Notice, one supplement to the Information Notice, and numerous inspection reports, and held meetings with the industry addressing either EOP development or problems identified with EOP development/implementation. Comprehensive information was made available in April 1989 when NUREG-1358, "Lessons Learned from the Special Inspection Program for Emergency Operating Procedures," was issued. NUREG-1358 detailed the problems identified during NRC inspections of EOPs at 30 nuclear power plants in 1988.

In light of the information available to the Cleveland Electric Illuminating Company, the NRC is concerned that significant process and technical problems with the EOP program existed at the Perry Nuclear Power Plant at the time of the inspection. The failures of the Cleveland Electric Illuminating Company were in three critical areas. First, the individual assigned the responsibility to develop the EOPs was not knowledgeable of the components necessary to ensure a quality product. Second, line management did not provide effective oversight of the EOP process. This is particularly disturbing because the conclusions of NUREG-1358 stated that the majority of the problems with EOPS at other nuclear power plants were due to the lack of adequate implementation. And finally, the quality assurance organization was ineffective in providing senior management with assurance that the EOP process was being properly implemented.

To emphasize the need for effective management control and oversight of NRC licensed activities at the Perry Nuclear Power Plant, including the development and implementation of the EOPs, I have been authorized after consultation with the Director, Office of Enforcement, and the Deputy Executive Director for Nuclear Regulation, Regional Operations and Research to issue the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice) in the amount of $100,000 for the Severity Level III problem. The base value of a civil penalty for a Severity Level III problem is $50,000. The escalation and mitigation factors in the Enforcement Policy were considered, as described below, and on balance, 100% escalation of the civil penalty was warranted.

The base civil penalty was escalated 50% because the NRC identified the majority of the violations. While you had previously identified some of the violations (e.g. the need for an SPI to bypass the MSIV high radiation isolation), they had not yet been corrected at the time of the inspection. Additionally, you did not identify the larger programmatic implications or recognize the significance of the deficiencies. Once you were put on notice, your corrective actions were prompt and extensive. Therefore, the full 50% mitigation is warranted for this factor. The amount of the civil penalty was increased an additional 100 percent for the prior notice of similar events provided in NUREG-1358, "Lessons Learned from the Special Inspection Program for Emergency Operating Procedures." At the enforcement conference, you acknowledged that your staff received and reviewed NUREG-1358. The remaining factors in the enforcement policy were also considered and no further adjustment to the base civil penalty was considered appropriate.

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

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

See Attached Distribution

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

Cleveland Electric Illuminating Company
Perry Nuclear Power Plant, Unit 1

Docket No. 50-440
License No. NPF-58
EA 91-118

During an NRC inspection conducted on August 19 through 30, 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. Technical Specification 6.8.1.b requires that written procedures or instructions be established, implemented, and maintained covering the requirements of NUREG-0737 and supplements thereto.

NUREG-0737, Supplement No. 1, paragraph 7.1, requires, in part, the licensee to prepare technical guidelines and to implement upgraded emergency operating procedures.

Perry Plant Operations Procedure (OAP) 0507, Revision 4, "Development of Plant Emergency Instructions," dated March 28, 1991, implements the requirements of Technical Specification 6.8.1.b, and NUREG-0737 (Supplement No. 1).

Contrary to the above, as of August 19, 1991, the licensee failed to comply with the provisions of OAP-0507 as evidenced by the following examples:

1. All PEI-SPIs (Special Plant Instructions) issued on July 12, 1991, were not verified for PSTG conformance in accordance with the PEI Verification Plan, as specified by paragraph 6.4.2 of OAP-0507.

2. New sequences of operator actions resulting from a change in methodology as described in newly developed (revised) PEI-SPI 2.6, "Bypass of RWCU Isolation on SLCS Initiation" and PEI-SPI 8.2, "RPV Venting Using [illegible]" were not validated prior to issuance as specified by paragraph 6.4.3 of OAP-0507.

3. The "Technical Accuracy" portion of the PEI Verification Checklist was not performed for PEI flow charts issued on July 12, 1991, as specified by paragraph 2.4.2.2.e to Attachment 2 of OAP-0507.

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

Contrary to the above, as of August 19, 1991, Plant Emergency Instructions - Special Plant Instructions (PEI-SPIs), procedures governing activities that affect quality, were not of a type appropriate to the circumstances for implementation of the PEIs, as evidenced by the following examples:

1. PEI-SPI 2.6, "Bypass of RWCU Isolation on SLCS Initiation," Revision 0, failed to provide instructions to allow the reactor water clean-up system isolation valves to be opened had they closed on an earlier isolation. This was inappropriate to the circumstances for implementation of the PEI provision for reactor vessel pressure control.

2. PEI-SPI 8.2, "RPV Venting Using RCIC," Revision 0, failed to provide instructions to allow the RCIC steam line isolation valves upstream of the RCIC steam shutoff valve to be opened, or reopened had the isolation valves closed previously. Additionally, PEI-SPI 8.2 failed to provide procedures to prevent the closure of the RCIC steam shutoff valve on a Level 8 isolation. This was inappropriate to the circumstances for implementation of the PEI provisions for maintaining reactor system venting capability.

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

Contrary to the above, as of August 19, 1991, the PEI-SPIs issued by the licensee failed to provide procedures for plant emergencies as evidenced by the following examples:

1. No PEI-SPI was developed to defeat the reactor protection system and alternate rod insertion logic trips. This was inappropriate to the circumstances for implementation of the PEI provisions for response to an ATWS condition.

2. No PEI-SPI was developed to bypass the main steam isolation valve high radiation isolation. This was inappropriate to the circumstances for implementation of the PEI provisions for maintaining reactor system venting and reflooding capability.

Violations A, B, and C are a Severity Level III problem (Supplement I). Cumulative Civil Penalty - $100,000 (assessed equally among the three violations).

Pursuant to the provisions of 10 CFR 2.201, the Cleveland Electric Illuminating Company (Licensee) is hereby required to submit a written

statement of explanation to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, within 30 days of the date of this Notice of Violation and Proposed Imposition of Civil Penalty (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each alleged violation: (1) admission or denial of the alleged violation, (2) the reasons for the violation if admitted, and if denied, the reasons why, (3) the corrective steps that have been taken and the results achieved, (4) the corrective steps that will be taken to avoid further violations, and (5) the date when full compliance 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, and a copy to the NRC Resident Inspector at the Perry Nuclear Power Plant.

FOR THE NUCLEAR REGULATORY COMMISSION

A. Bert Davis
Regional Administrator

Dated at Glen Ellyn, Illinois
this 30th day of October 1991

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

OCT 21 1991

Docket Nos. 50-280, 50-281
License Nos. DPR-32, DPR-37
EA 91-114

Virginia Electric and Power Company
ATTN: Mr. W. L. Stewart
Senior Vice President - Nuclear
5000 Dominion Boulevard
Glen Allen, Virginia 23060

Gentlemen:

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTIES - $125,000 (NRC INSPECTION REPORT NOS. 50-280/91-24 AND 50-281/91-24)

This refers to the Nuclear Regulatory Commission (NRC) inspection conducted by Mr. M. Branch on August 2 - 26, 1991, at the Surry Power Station. The inspection included a review of the facts and circumstances related to the identification of a problem involving Units 1 and 2 operating with the common emergency diesel generator inoperable from May 9, 1991 to August 2, 1991. In addition, the inspection included a review of a problem identified by the NRC that involved the operation of Units 1 and 2 since 1980 while in a specific electrical configuration that resulted in an inoperable automatic start feature for the high head safety injection pumps. The report documenting this inspection was sent to you by letter dated August 30, 1991. As a result of this inspection, violations of NRC requirements were identified. An enforcement conference was held on September 17, 1991, in the NRC Region II office to discuss the violations, their cause, and your corrective actions to preclude recurrence. A summary of this conference was sent to you by letter dated September 30, 1991.

The violations, which are described in the enclosed Notice of Violation and Proposed Imposition of Civil Penalties (Notice), involve the two issues discussed above. Violation A concerns the failure of EDG No. 3, which is common to both units, to achieve and sustain the design nominal speed of 900 rpm following a Unit 2 safety injection with a reactor trip from 93 percent power on August 2, 1991. Following its automatic startup, EDG No. 3 stabilized at approximately 835 rpm. While the EDG was not required to tie to its respective emergency bus during the event, a nominal speed of 870 rpm is required to satisfy the output breaker closure permissive interlock which would permit automatic assumption of electrical loads on the emergency bus in the event of a loss of offsite power. NRC identified to your staff that EDG No. 3 was not running at the nominal speed of 900 rpm and that the impact of the degraded speed condition should be evaluated. As a result, EDG No. 3 was subsequently declared inoperable and the Technical Specification (TS) 3.16.B.1 was entered.

Your staff initiated a review to determine why EDG No. 3 failed to reach its required speed and that review indicated that the Woodward UG-8 governor, which controls the speed and load for the EDG, was not adjusted at the required setting. This governor setting was readjusted, and two consecutive fast starts of EDG No. 3 were performed to verify that the EDG would reach the required speed. After testing, the TS Action Statement was exited. Additional review of the EDG failure was conducted by the licensee's Corporate Nuclear Safety staff which determined that the governor on EDG No. 3 had been replaced on May 7-9, 1991, and that adjustments were made on that governor following installation without subsequent fast start testing. It was concluded that EDG No. 3 failed to reach the correct speed on August 2, 1991, because of governor adjustments made on May 9, 1991, which affected the running speed attained by the EDG after an automatic start.

An NRC review of the work package controlling the maintenance activity related to the installation of the new governor revealed that there had been no formal procedure used to accomplish this maintenance. The maintenance was accomplished by utilizing job steps outlined in the work package and Station Nuclear and Safety Operating Committee (SNSOC) approved instructions for adjustment of the governor. In addition, a vendor representative for the governor manufacturer was present during the maintenance activity to assist in the adjustment of the new governor. After the new governor was installed and the speed control adjusted, the EDG was started and additional governor adjustments made; however, the EDG would not properly load. Following more adjustments, the EDG was restarted and loaded properly, but governor drift was observed during steady state operation. With the EDG running, the vendor representative made an additional adjustment to the governor's synchronizing motor friction adjustment to stabilize EDG speed and the EDG was operated for approximately 40 minutes more with EDG speed remaining stable. The EDG was then secured and declared operable without further testing such as a fast start test. Such a test would have verified proper governor operation upon receipt of a startup demand.

The NRC is concerned with this event because its root cause was a breakdown in the management oversight and control functions related to the maintenance activities associated with this event. For example, although the SNSOC approved instruction for governor adjustment required the EDG be subjected to a fast start following governor replacement, the post-maintenance testing (PMT) follower in the work package only required that the EDG be slow started; a formal maintenance procedure was not utilized to accomplish the maintenance associated with the governor replacement; and, there was confusion and poor communications between operations, maintenance, engineering, and the vendor as to what extent maintenance was actually being performed. As a result, the automatic safety function of EDG No. 3 was inoperable and would not have performed its intended safety function without operator intervention to adjust the EDG speed.

Violation B concerns the failure to have Units 1 and 2 charging/high head safety injection (HHSI) pumps (3 per unit) configured such that the "A" and "C" pumps would automatically start for an accident requiring safety injection during a design basis accident concurrent with a loss of offsite power. This inadequate configuration was discovered by the NRC as a result of questions

raised by the NRC during discussions with plant system engineers regarding HHSI pump interlocks and the on/off sequencing of HHSI pumps from their respective emergency buses during an undervoltage condition. A review by the plant system engineering staff subsequently determined that under certain HHSI pump electrical configurations, the "A" pump would lockout on an undervoltage condition on its emergency bus. Operator action would have been required to manually start the "A" or the "C" pump. Although, the licensee's review of this event identified the lockout feature, it did not recognize the operability significance of this configuration.

This condition has existed since the implementation of Design Change No. 78-537B, during 1980, which changed the pump configuration so that only two HHSI pumps, one off each emergency bus, were aligned to automatically start upon receipt of an ECCS actuation signal. The change was made so that the low head safety injection pumps could maintain adequate net positive suction head to the HHSI pumps during the recirculation transfer mode of operation. A safety review conducted for this modification did not identify that the change actually resulted in an inappropriate disabling of the charging pumps' capacity to respond to a safety injection due to the interlocks associated with the three charging pumps.

This violation is a concern to NRC because it indicates a weakness in the engineering area as this problem should have been identified when the engineering review to support the design change was done. Further, the problem should have been corrected when a similar problem was identified at the North Anna Power Station. Specifically, in 1983 a Licensee Event Report (LER) documented the fact that the "A" HHSI pump would have locked out and failed to start automatically when in a configuration comparable to that at Surry. The corrective actions implemented at the North Anna Power Station were not implemented at the Surry Power Station, and represent missed opportunity to identify and correct this problem. As your staff discussed at the enforcement conference, there were at least two other opportunities, in the form of engineering reviews, where the problem might have subsequently been identified. Finally, the NRC is also concerned that the acceptability at Surry of allowing operator manual action to compensate for required automatic safety features contributed to the delay in identifying the significance of this configuration problem.

To emphasize the importance of ensuring that safety systems are fully operable and capable of performing their intended safety function following maintenance and modification, I have been authorized, after consultation with the Director, Office of Enforcement, and the Deputy Executive Director for Nuclear Reactor Regulations, Regional Operations and Research, to issue the enclosed Notice of Violation and Proposed Imposition of Civil Penalties in the amount of $125,000 for the violations set forth in the Notice. The violations have each been categorized at Severity Level III in accordance with the "General Statement of Policy and Procedure for Enforcement Actions," (Enforcement Policy) 10 CFR Part 2, Appendix C (1991). 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 for each violation as described below.

For Violation A, neither escalation nor mitigation was applied for the factor of identification and reporting. While the cause of the problem was fully developed by your staff and initiation of that review might have taken place had plant personnel identified the problem, in fact, the start of the detailed review was based on questions raised by the NRC Resident Inspector Staff. With regard to corrective actions, escalation of the base civil penalty by 50 percent was warranted because the immediate corrective action taken for the problem focused solely on manually compensating for the misadjusted limit switches which are designed to automatically align the governor for emergency operation. This corrective action was not comprehensive. Consequently, another problem with an EDG governor's improper manual compensation was experienced with EDG No. 2 on August 26, 1991. Although consideration was given to SALP ratings in maintenance that have shown improvement from a SALP 3 to a SALP 2, current performance does not warrant mitigation. In addition, engineering has remained a SALP 2. The other adjustment factors in the Policy were considered and no further adjustment to the base civil penalty was considered appropriate. Therefore, based on the above, the base civil penalty for Violation A has been increased by 50 percent.

For Violation B, neither escalation nor mitigation was found appropriate for identification and reporting. While your staff did identify the technical issue, they did so after discussion with the NRC inspectors. Mitigation of 50 percent was warranted for the immediate action to correct the problem and for the initiation of an Operator Action Study to review other areas where operator manual actions might be in place to fulfill safety functions. Neither escalation nor mitigation was warranted for past performance. The base civil penalty has been escalated 50 percent based on the prior notice provided by North Anna LER 83-058/03L-0. The other adjustment factors in the Enforcement Policy were considered and no further adjustments of the base civil penalty were made. Therefore, overall no adjustment to the base civil penalty was found to be appropriate.

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

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

The responses directed by this letter and the enclosed Notice are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, Pub. L. No. 96.511.

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 Penalties

cc w/encl:
E. W. Harrell
Vice President - Nuclear Operations
Virginia Electric & Power Company
5000 Dominion Boulevard
Glen Allen, VA 23060

J. P. O'Hanlon
Vice President - Nuclear Services
Virginia Electric & Power Company
5000 Dominion Boulevard
Glen Allen, VA 23060

M. R. Kansler
Station Manager
Surry Power Station
P. O. Box 315
Surry, VA 23883

M. L. Bowling, Jr., Manager
Nuclear Licensing
Virginia Electric & Power Co.
5000 Dominion Boulevard
Glen Allen, VA 23060

Sherlock Holmes, Chairman
Board of Supervisors of Surry County
Surry County Courthouse
Surry, VA 23683

Dr. W. T. Lough
Virginia State Corporation
Commission
Division of Energy Regulation
P. O. Box 1197
Richmond, VA 23209

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTIES

Virginia Electric and Power Company
Surry Nuclear Plant
Units 1 and 2

Docket Nos. 50-280 and 50-281
License Nos. DPR-32, DPR-37
EA 91-114

During an NRC inspection conducted on August 2 - 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 two civil penalties pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (Act), 42 U.S.C. 2282, and 10 CFR 2.205. The particular violations and associated civil penalties are set forth below:

A. Technical Specification (TS) 3.16.B.1 requires that when the Unit's dedicated Emergency Diesel Generator (EDG) or shared backup EDG is inoperable, the operability of the other EDG be demonstrated daily, and that the inoperable EDG be returned to service within seven days or the reactor brought to a cold shutdown.

Contrary to the above, after maintenance rendered the shared backup EDG automatic safety function inoperable on May 9, 1991, the dedicated EDGs in Units 1 and 2 were not tested daily nor were the units placed in cold shutdown within the required seven day period. The shared backup EDG automatic safety function remained inoperable until August 2, 1991. From May 9 to August 2, 1991, Unit 1 operated without satisfying the above TS Action Statement. Unit 2 operated June 1 and 2, June 5 through 11 and July 2 through August 2, 1991, without satisfying the above TS Action Statement.

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

Civil Penalty - $75,000

B. TS 3.3.B.2 requires, in part, that, if two of the three charging pumps in a unit are out of service, one of the inoperable pumps shall be restored to an operable status within 24 hours. If one of the inoperable pumps is not restored within 24 hours, then the reactor shall be shutdown.

Contrary to the above, since 1980, Units 1 and 2 charging pumps were routinely aligned such that the "A" and "C" charging pumps in each unit were inoperable in excess of 24 hours and the units were not brought to shutdown. The pumps would not automatically start during an accident that required safety injection with a loss of off-site power. Recent examples when this condition existed for Unit 1 were April 26 through May 26, June 20 through August 2, and August 19 through August 21, 1991 and for Unit 2, March 8 through 30, 1991 and July 3 through 5, 1991.

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

Civil Penalty - $50,000

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

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

FOR THE NUCLEAR REGULATORY COMMISSION

James L. Milhoan for
Stewart D. Ebneter
Regional Administrator

Dated at Atlanta, Georgia
this 21st day of October 1991

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

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

December 18, 1991

Docket No. 50-289
License No. DPR-50
EA 91-143

GPU Nuclear Corporation
ATTN: Mr. T. G. Broughton
Vice President and Director of TMI-1
Three Mile Island Nuclear Station
P. O. Box 480
Middletown, Pennsylvania 17057

Gentlemen:

Subject: NOTICE OF VIOLATION
(NRC Inspection Report No. 50-289/91-27)

This letter refers to the NRC inspection conducted between October 9-23, 1991 at the Three Mile Island Nuclear Station, Unit 1, Middletown, Pennsylvania. The inspection report was sent to you on November 6, 1991. The inspection was conducted to review the circumstances associated with an event which occurred at the facility, while the reactor was in the refueling mode, involving the movement of a fuel assembly at a time when the Reactor Building was not isolated. The event, and the associated violations of NRC requirements, were identified by your staff and reported to the NRC resident inspector shortly after its occurrence, as well as in a Licensee Event Report (LER) sent to the NRC on November 7, 1991. On November 20, 1991, an enforcement conference was conducted with you and other members of your staff to discuss the violations, the causes and your corrective actions.

The movement of fuel was done as a part of the performance of a surveillance procedure used to test the refueling system interlocks. The test is designed to verify that the refueling bridge hoist will shift to slow speed when lowered down to a certain height above the fuel and remain in slow speed while raising a fuel assembly out of the core. During the performance of this test, which lasted for approximately ten minutes, one irradiated fuel assembly was fully withdrawn from the core, then reinserted back into the core. At the time, there was a direct access path from the containment to the atmosphere and the Auxiliary Building, since the inner and outer doors of both the personnel hatch and the emergency hatch were open. This constituted a violation of a technical specification limiting condition for operation.

This violation was principally caused by the deficient performance by operations staff, including the refueling bridge crew, as well as operations staff located in the control room. Specifically, both the control room staff and refueling bridge crew (a licensed Senior Reactor Operator and Reactor Operator) did not adequately prepare for the evolution and did not have a thorough understanding of the prerequisites for the surveillance procedure. If the individuals had completely reviewed the procedure, they would have been aware that the test required the movement of a fuel assembly, and therefore would not have continued with the procedure until containment integrity had been established. Furthermore, the control room staff failed to question the refueling bridge crew's actions when they requested the location of the first fuel assembly to be moved without containment integrity established.

In addition to these concerns, the NRC is also concerned that the specific surveillance procedure performed by the refueling bridge crew did not have a specific caution or warning stating that those Reactor Building hatch doors must be closed (and other appropriate prerequisites specified in the fuel shuffle procedure met) prior to moving any fuel as part of the test. An adequate review of the procedure was not accomplished prior to its approval and issuance, particularly the required safety review performed by the Plant Review Group (PRG). This failure to conduct an adequate safety review to ensure the adequacy of the surveillance procedure, constitutes the second violation of NRC requirements, also set forth in the enclosed Notice.

The NRC recognizes that the safety consequences of the violation of the technical specification were minimal, since the condition existed for a short period, and was within those conditions assumed in the Final Safety Analysis Report (FSAR) since the FSAR does not take credit for the isolation of the Reactor Building in the analysis of the fuel handling accident, but credits the Reactor Building Purge Exhaust System for providing a filtered release path in the event of this accident. Nonetheless, the NRC has a significant regulatory concern with the deficient performance by the operations staff in this case, as well as the procedural inadequacies and inadequate safety assessments that contributed to this occurrence. These findings indicated a significant lack of attention toward licensed responsibilities. Therefore, the violations have been classified in the aggregate as a Severity Level III problem in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy), 10 CFR Part 2, Appendix C (1991). The violations demonstrate the importance of (1) appropriate performance of duties by the operations staff to ensure that equipment is properly controlled, and the facility is operated and maintained safely and in accordance with the Technical Specifications, and (2) meticulous attention to detail during the performance of safety reviews at the facility to ensure procedures are properly reviewed, and appropriate cautions are included, as warranted.

The NRC recognizes that actions were initiated to correct these violations and prevent recurrence. These corrective actions, which were described at the enforcement conference, included: (1) counseling of the operators involved, as well as all fuel handling personnel, prior to any further movement of fuel; (2) initiating a Plant Incident Report which was reviewed by all operations personnel; (3) initiating a Temporary Change Notice to the surveillance procedure incorporating additional warnings and precautions; and (4) reviewing the related surveillance procedure with the objective of strengthening the procedure, and incorporating human factors recommendations.

Although a civil penalty is normally issued for a Severity Level III problem, 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 mitigate the penalty in its entirety and issue the enclosed Notice of Violation (Notice) for these violations. In deciding to mitigate the penalty, the escalation and mitigation factors set forth in the enforcement policy were considered in the manner described below.

The event and violations were identified by your staff and the NRC was promptly notified. Therefore, 50% mitigation of the base civil penalty on this factor is warranted. Although your short term corrective actions were considered prompt and included actions to prevent recurrence, your long term corrective actions were narrowly focused on the refueling surveillance procedure, and did not include a review of other plant procedures, or the PRC procedure review process, to assure that similar problems did not exist and to prevent them from occurring in the future, therefore, no adjustment of the civil penalty on this factor is warranted. Your past performance in all areas, including the operations and outage planning areas, has been good, as evidenced by Category I ratings in all SALP areas during the last SALP assessment, and therefore, 50% mitigation of the base civil penalty on this factor is warranted. Full 100% mitigation on this factor is not warranted since three examples of deficiencies involving inadequate procedural guidance and review, similar to Violation B of the enclosed Notice, were identified in two inspection reports in 1990, and a Licensee Event Report (LER) in 1991. (Reference: Severity Level IV violation in IR 50-289/90-15; an additional example in IR 50-289/90-18; and LER 91-003-00.) The other escalation and mitigation factors were considered, and no adjustment on these factors was warranted.

As to the apparent violation associated with the reporting pursuant to 10 CFR 50.72, the NRC has considered the arguments on both sides and decided not to issue a citation. However, discussions with the Office for Analysis and Evaluation of Operational Data (AEOD) are continuing to determine if additional guidance on reporting requirements in this type matter is needed.

You are required to respond to the enclosed Notice 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. 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 enclosure will be placed in the NRC's Public Document Room.

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

Sincerely,

Thomas T. Martin
Regional Administrator

Enclosure: Notice of Violation

cc:
R. E. Rogan, TMI Licensing Director
C. W. Smyth, Manager, TMI-1 Licensing
M. Ross, Operations and Maintenance Director, TMI-1
J. A. Knubel, Licensing and Regulatory Affairs Director
E. L. Blake, Jr., Esquire
TMI-Alert (TMIA)
Public Document Room (PDR)
Local Public Document Room (LPDR)
Nuclear Safety Information Center (NSIC)
Commonwealth of Pennsylvania

NOTICE OF VIOLATION

GPU Nuclear Corporation
Middletown, Pennsylvania

Docket No. 50-289
License No. DPR-50
EA 91-143

During an NRC inspection conducted between October 9-23, 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 violations are listed below:

A. Technical Specification Limiting Condition for Operation 3.8.6, requires that during the handling of irradiated fuel in the Reactor Building, at least one door shall be closed on both the personnel and emergency hatches.

Contrary to the above, at approximately 10:40 a.m., on October 8, 1991, irradiated fuel assembly E-14 was handled when it was fully withdrawn from the core and then reinserted during testing of the Main Refueling Bridge "Fuel Hoist Fast and Slow Zones Over Core" interlocks. At the time, the inner and outer doors of both the personnel hatch and the emergency hatch were open.

B. Technical Specification 6.8.1 requires in part that written procedures shall be established, implemented and maintained covering surveillance and test activities of equipment that affects nuclear safety and refueling operations.

Technical Specification 6.8.2 requires in part that each procedure required by 6.8.1 shall be reviewed and approved as described in 6.5.1 prior to implementation and shall be reviewed periodically as set forth in administrative procedures.

Technical Specification 6.5.1.1 requires in part that each procedure required by 6.8 and other procedures which affect nuclear safety shall be reviewed for adequacy by an individual(s)/group other than the preparer.

Contrary to the above, Surveillance Procedure 1303-11.4, Refueling System Interlocks, Revision 24, was approved by the Plant Review Group (PRG) on August 7, 1991, without an appropriate review for adequacy. Specifically, this review was inadequate in that it did not assure that the procedure contained adequate warning that all prerequisites for fuel movement must be met before proceeding with the performance of Section 6.3.3.1 of the procedure, including a warning that irradiated fuel not be moved unless at least one door in both the containment personnel hatch and the emergency hatch were closed.

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

Pursuant to the provisions of 10 CFR 2.201, GPU Nuclear Corporation is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555 with a copy to the Regional Administrator, Region I and a copy to the NRC Resident Inspector within 30 days of the date of the letter transmitting this Notice of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each violation: (1) the reasons for the violations, or if contested, the basis for disputing the violation, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken to avoid further violations, and (4) the date when full compliance will be achieved. If an adequate reply is not received within the time specified in this Notice, an order or demand for information may be issued as to why the license should not be modified, suspended, or revoked, or why such other action as may be proper should not be taken. Where good cause is shown, consideration will be given to extending the response time. Under the authority of Section 182 of the Atomic Energy Act, 42 U.S.C. 2232, this response shall be submitted under oath or affirmation.

Dated at King of Prussia, Pennsylvania
this 18th day of December 1991

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

OCT 2 9 1991

Docket Nos. 50-259, 50-260, 50-296
License Nos. DPR-33, DPR- , DPR-68
EA 91-120

Tennessee Valley Authority
Mr. D. A. Nauman
Senior Vice President, Nuclear Power
6N 38A Lookout Place
1101 Market Street
Chattanooga, TN 37402-2801

Gentlemen:

SUBJECT: NOTICE OF VIOLATION
(NRC INSPECTION REPORT NOS. 50-259/91-33, 50-260/91-33
AND 50-296/91-33)

This refers to the Nuclear Regulatory Commission (NRC) inspection conducted by E. L. Clay on September 3-6, 1991. This inspection included a review of circumstances surrounding special nuclear material (SNM) accountability discrepancies identified at your Browns Ferry Nuclear Plant. The report documenting this inspection was sent to you by a letter dated September 19, 1991. As a result of this inspection, failures to comply with NRC regulatory requirements were identified. An enforcement conference was held in the Region II Office on October 4, 1991 to discuss the violation, its causes and concerns as to why your corrective actions for previous similar violations failed to prevent a recurrence. The information that you provided and a list of attendees at the conference are enclosed.

The violation described in the enclosed Notice of Violation involves a failure to perform an adequate physical inventory of licensed SNM as required by your own procedures and NRC requirements. The violation resulted on September 7, 1991, when you found SNM which was previously not listed in your inventory of items in the spent fuel pool. Previously, on August 21, 1991, you determined that an item located in your spent fuel pool was tagged as containing SNM, when in actuality it did not. Your 1990 inventories did not uncover this discrepancy.

It is our understanding, from our inspection and statements you made at the enforcement conference, that these inventory discrepancies were discovered during the clean-up of the spent fuel pools which began in July 1991. This clean-up was part of your Action Plan developed in 1989 to resolve SNM inventory discrepancies, to improve controls over inventory of nonfuel items in the spent fuel pools, and to clean-up the pools at the Browns Ferry Nuclear Plant. The search of plant areas other than the spent fuel pools was completed in 1990. The search resulted in your accounting for all SNM onsite outside the spent fuel pools. At the conference, you also indicated that you had performed a physical inventory of the SNM in the spent fuel pools according to procedures, but only examined tags on some items since you were, at the time, unable to positively identify some high dose rate items that were tangled below the water's surface.

The NRC is concerned that there was not an adequate physical inventory of SNM in your spent fuel pools. Prior to the conference, we understood, from your letter dated April 17, 1991, that you had an adequate baseline inventory and that you would be cleaning up the spent fuel pools to facilitate future inventories. The letter did state that SNM in the spent fuel pools was verified by serial number and/or a positive piece count process. However, that statement followed a number of statements indicating that all corrective actions were complete. We understand now, based on statements made during the enforcement conference, that the cleanup effort actually completes the inventory and as part of that cleanup, it was discovered that reliance on material tags was inappropriate. This improper reliance on tags rather than a physical inventory is significant in view of the two other enforcement actions, including the May 2, 1990 civil penalty, issued to Browns Ferry during the last five years concerning control of the inventory of SNM.

As implied above, the quality of your April 17, 1991 letter is also of concern to the NRC. Notwithstanding the letter's one qualifying reference to the spent fuel pools, the above referenced statements concerning corrective actions, along with the characterization of the inventory that was performed as a SNM baseline inventory, clearly would lead most readers to conclude that the inventory in the spent fuel pools had been properly addressed at the time the letter was written. Further, given the history of the SNM program at Browns Ferry, the NRC concludes that any characterization of an inventory as a baseline inventory without physically checking the material is clearly inappropriate. Finally, upon receipt of the April 17, 1991 letter, had the NRC understood that finishing the inventory was tied to the completion of the spent fuel pool activities which was scheduled for early next year, it is likely that the NRC would have required those activities to be completed sooner, which you are now doing.

We acknowledge the steps you have taken to date, to gain control of SNM inventory, including: (1) development and partial implementation of a plan and schedule for corrective actions; (2) training search teams and, except for the spent fuel pools, searching all plant site areas for nonfuel SNM; (3) except for the spent fuel pools, positive identification of each item of SNM onsite; (4) development of an action plan to dispose of current and future generated unusable SNM items; and (5) performance of dose rate measurements of items in the spent fuel pools to determine if they contained SNM. However, because of the continuing discovery of problems in the area of SNM accountability at Browns Ferry, the violation contained in the enclosed Notice of Violation has been categorized at Severity Level III.

In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy) 10 CFR Part 2, Appendix C, a civil penalty is considered for a Severity Level III violation. However, 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 the discretion provision of Section V.G.5 of the Enforcement Policy will be applied, and a civil penalty will not be proposed. Setting aside the quality of your April 17, 1991 letter, the violation was discovered as part

of your efforts to correct past problems in your SNM program for which enforcement action, including a civil penalty, has already been taken. Therefore, exercising discretion in this case is appropriate.

During the conference, you stated that you had not performed adequate physical inventories of SNM on site in the past. It is our understanding from the statements you made during the enforcement conference, that you were taking the following additional steps to gain control of SNM inventory an the Browns Ferry Nuclear Plant, including the spent fuel pools: (1) the Plant Manager will be responsible for site activities associated with the spent fuel pools; (2) when the clean-up is complete, the spent fuel pools will serve only as temporary storage for spent LPRMs and, when used for storage, the LPRMs will be stored in a manner that assures proper identification and accountability; (3) cutting and packaging operations of spent LPRMs for disposal will be performed only at a time just prior to the time of shipment to an offsite burial facility; (4) all currently known nonfuel SNM items and nonessential hardware components will be removed from all spent fuel pools, and you will refrain from using the spent fuel pools to store these items in future operations; (5) you will vacuum clean sludges and other debris from all spent fuel pools and video-tape all items remaining in the pools after the cleaning is complete; (6) you will establish and report to NRC, an accurate and credible baseline inventory of all SNM on site; (you indicated that this item would be completed by October 26, 1991) and (7) you will have an independent organization from outside the Tennessee Valley Authority evaluate the entire SNM control and accounting program at the Browns Ferry Nuclear Plant. We request that you reconfirm these commitments in your response and include the schedule when each of the actions has been or will be implemented and completed.

In view of problems discovered at the Browns Ferry Nuclear Plant during the enforcement conference, we expressed concerns about the SNM inventory control program at your Sequoyah Nuclear Plant. You stated that Sequoyah Nuclear Plant inventory control program would be evaluated in a manner similar to that planned for the Browns Ferry Nuclear Plant. You agreed to provide us with your plan and schedule for evaluating the Sequoyah Nuclear Plant. Those items were provided to the NRC Region II staff during the October 7, 1991 management meeting held in the Region II office.

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, 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", 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, Public Law No. 96-511.

Sincerely,

Stewart D. Ebneter

Stewart D. Ebneter
Regional Administrator

Enclosures:
1. Notice of Violation
2. Enforcement Conference Attendees
3. Licensee Handout at Enforcement Conference

cc w/encls:
M. Runyon, Chairman
Tennessee Valley Authority
ET 12A
400 West Summit Hill Drive
Knoxville, TN 37902

J. B. Waters, Director
Tennessee Valley Authority
ET 12A
400 West Summit Hill Drive
Knoxville, TN 37902

W. H. Kennoy, Director
Tennessee Valley Authority
ET 12A
400 West Summit Hill Drive
Knoxville, TN 37902

W. F. Willis
Senior Executive Officer
ET 12B
400 West Summit Hill Drive
Knoxville, TN 37902

D. Nunn, Vice President
Nuclear Projects
Tennessee Valley Authority
3B Lookout Place
1101 Market Street
Chattanooga, TN 37402-2801

NOTICE OF VIOLATION

Tennessee Valley Authority

Browns Ferry Nuclear Plant

Docket Nos.: 50-259, 50-260, 50-296

License Nos.: DPR-33, DPR-52, DPR-68

EA 91-120

During the Nuclear Regulatory Commission (NRC) inspection conducted on September 3-6, 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 violation is listed below:

10 CFR 70.51(d) requires, in part, that each licensee who is authorized to possess at any one time and location special nuclear material (SNM) in a quantity totaling more than 350 grams of contained uranium-235 shall conduct a physical inventory of all special nuclear material in his possession under license at intervals not to exceed twelve months.

Contrary to the above, the licensee failed to perform an adequate physical inventory in 1990. Specifically, the February and March 1990 physical inventory failed to include an item containing SNM, which was identified in the spent fuel pool on September 7, 1991.

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

Pursuant to provisions of 10 CFR 2.201, Tennessee Valley Authority is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555 with a copy to the Regional Administrator, Region II, and a copy to the NRC Resident Inspector at Browns Ferry, within 30 days of the date of the letter transmitting the Notice of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each violation: (1) the reasons for the violation if contested, the basis for disputing the violation; (2) the corrective steps that have been taken and the results achieved; (3) the corrective steps which 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 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 be taken. Where good cause is shown, consideration will be given to extending the response. 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 US NUCLEAR REGULATORY COMMISSION

Stewart D. Ebneter
Regional Administrator

Dated at Atlanta, Georgia
this 24th day of October 1991

II.A. MATERIALS LICENSEES, CIVIL PENALTIES AND ORDERS

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

OCT 11 1991

Docket No. 030-20787
License No. 29-21452-01
EA 91-058

Consolidated NDE, Incorporated
ATTN: J. Lee Ballard
Chief Executive Officer
6 Woodbridge Avenue
P.O. Box 593
Woodbridge, New Jersey 07095

Dear Mr. Ballard:

Subject: (1) NOTICE OF VIOLATION
(2) CONFIRMATORY ORDER MODIFYING LICENSE (EFFECTIVE IMMEDIATELY)

(NRC Inspection Report No. 030-20787/90-002 and Office of Investigations Report No. 1-90-010)

This letter refers to the NRC inspection conducted on April 25, 1990, at a temporary field site in East Vineland, New Jersey, of activities authorized by NRC License No. 29-21452-01. This letter also refers to the subsequent investigation conducted by the NRC Office of Investigations (OI). The inspection report was sent to you on January 2, 1991. During the inspection and investigation, violations of NRC requirements were identified. Several of the violations identified during the inspection were discussed with you during a management meeting on April 27, 1990, and also formed the basis for a Confirmatory Action Letter issued on April 26, 1990. An Order Suspending Operation and Modifying License (Effective Immediately) was issued on May 2, 1990, based, in part, on the April 1990 inspection, and a $10,000 civil penalty was also issued on that date based on similar violations that were identified during a previous inspection in March 1990. Enforcement action for two other issues involving the failure of a radiographer to provide complete and accurate information to the NRC, and the falsification of a utilization record, was held in abeyance pending completion of the investigation. Upon completion of the investigation, an enforcement conference was conducted with you and members of your staff on July 9, 1991, to discuss the additional violations, their causes and your corrective actions. A copy of the Enforcement Conference Report was sent to you on July 19, 1991.

The violations, which are described in the enclosed Notice of Violation (Notice), include a licensee employee, acting as a radiographer, providing information to the NRC that was not accurate in all material respects, in that (1) during an inspection conducted by two NRC inspectors on April 25, 1990, the employee stated he had adequately surveyed the guide tube and the exposure device, and had locked the device after each of the exposures; and (2) the employee made an entry on his utilization log, dated April 25, 1990, that he did perform surveys after each exposure, when in fact, the NRC inspectors had observed that the employee had not complied with these requirements. In addition, the employee made false statements to the NRC during the management meeting on April 27, 1990 and during an interview with a NRC Investigator on August 29, 1990, when the employee reiterated the statements given to the two NRC inspectors on April 25, 1990, concerning the survey of the guide tube and exposure device, and locking the device after each exposure.

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 not only the licensee, but also its employees, will be accurate and forthright in providing information so that the NRC may ensure that the use of licensed materials does not endanger public health and safety. This includes ensuring that all information provided to the NRC, either orally or in writing, as well as the creation of all records of performance of activities required by the license or NRC regulations, are complete and accurate in all material respects. Such accuracy is particularly important concerning the conduct of radiography, since your personnel work at sites where operations are difficult to monitor but have the potential to harm unsuspecting bystanders as well as radiography personnel. In the absence of licensee management or NRC inspectors, the NRC relies on an individual's integrity to ensure compliance with the conditions of the license and regulatory requirements.

Given their willful nature, these violations constitute a significant regulatory concern. It is extremely important that licensee management foster an appropriate culture which emphasizes the need for employees to be scrupulously accurate in all communications with the NRC. Accordingly, the violations are collectively 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) (1990).

The NRC recognizes that subsequent to the inspection and our communication of the results of OI's investigation, corrective actions were initiated to ensure that all employees possess a clear understanding of the company's policies on integrity and

forthright communications. These actions, which were described at the enforcement conference, included: (1) issuance of a letter to all employees delineating management's expectations concerning communications with the NRC; (2) posting at your business office the NRC letter dated June 26, 1991, which discussed the issues set forth in the enclosed Notice; and (3) developing plans to include 10 CFR 30.9, Completeness and Accuracy of Information in your continuing training.

In addition, with respect to the radiographer, you stated at the enforcement conference that (1) you have prohibited the radiographer from acting as a radiographer since the April 25, 1990 inspection; (2) he has only acted as an assistant radiographer during this time period and was the subject of nine management audits wherein his performance was deemed satisfactory; (3) he has completed a four hour counseling session with management concerning the issues of integrity and accuracy of information; and (4) you plan to initiate administrative controls to ensure that he is limited to performing the duties of assistant radiographer, and not acting as a radiographer, until such time as an acceptable rehabilitation program is implemented and completed. Further, during a telephone conversation with Mr. R. Cook, Deputy Director, Division of Radiation Safety and Safeguards, Region I, on August 14, 1991, your Radiation Safety Officer committed to the NRC that the individual would not be allowed to perform as a radiographer until approval was obtained from the NRC. For reasons more fully explained in the attached Confirmatory Order Modifying License (Effective Immediately), NRC has determined that your actions and commitments with respect to this individual should be confirmed by Order.

In accordance with the Enforcement Policy, a civil penalty is normally assessed for a willful violation at any Severity Level. In this case, however, a Confirmatory Action Letter, a $10,000 civil penalty, and an Order Suspending Operation were previously issued to address the underlying problem that existed at the time of the NRC inspection on April 25, 1990, namely a significant lack of attention or carelessness toward a system of NRC requirements intended to protect against exposure in excess of 10 CFR Part 20 limits. Also, extensive corrective actions regarding both the individual and the underlying problem have been implemented. We have considered these circumstances, among other factors, and have determined that the enclosed Confirmatory Order Modifying License: (1) is necessary and appropriate to maintain reasonable assurance that the public health and safety are protected and (2) emphasizes, to the licensee and the individual, the significance that NRC places on (a) assuring that communications with the NRC are complete and accurate and (b)

maintaining accurate records of licensed activities. Therefore, in this instance, a civil penalty is not being proposed to accompany the Order. However, any similar violations in the future may result in more significant enforcement action. Further, NRC considered more significant action with respect to the individual, but in view of the actions taken by the licensee, decided not to take further action.

You are required to respond to the enclosed Notice and, in preparing your response, you should follow the instructions specified therein. In your response, you should document the specific actions taken for each violation 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 your license and regulatory requirements; and (2) information communicated to, or maintained for, the NRC by all employees (in particular the responsible individual in this case), is complete and accurate. After reviewing your response to this letter and 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 enclosure will be placed in the NRC's Public Document Room.

The responses directed by this letter and the enclosure 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 Material Safety, Safeguards
and Operations Support

NOTICE OF VIOLATION

Consolidated NDE, Incorporated
Woodbridge, New Jersey

Docket No. 030-20787
License No. 29-21452-01
EA 91-058

During an NRC inspection conducted on April 25, 1990, as well as a subsequent investigation by the NRC Office of Investigations (OI), 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 (1990), the particular violations are set forth below:

A. 10 CFR 30.9(a) requires, in part, that information provided to the Commission by the licensee, or information required by the Commission's regulations to be maintained by the licensee, shall be complete and accurate in all material respects.

Contrary to the above, information provided to the Commission by the licensee, and information required by the Commission's regulations to be maintained by the licensee, were not complete and accurate in all material respects, as evidenced by the following examples:

1. A licensee employee provided inaccurate information to NRC personnel when interviewed (1) by two NRC inspectors on April 25, 1990; (2) by NRC management on April 27, 1990; and (3) by an NRC investigator on August 29, 1990, by stating that he had adequately surveyed the guide tube and the exposure device and locked the device after each of the exposures conducted during licensed radiography on April 25, 1990, at a job site in East Vineland, New Jersey. The information was inaccurate in that two NRC inspectors observed that the employee did not adequately survey and did not lock the exposure device. Regarding surveys, the two NRC inspectors observed that the employee failed to survey the radiographic exposure device, as well as the associated guide tube, on at least one occasion, and failed to perform adequate surveys on several other occasions in that those surveys did not include the entire circumference of the exposure device nor the full length of the guide tube, as required by 10 CFR 34.43(b). Regarding the locking of the device, the inspectors observed that the employee failed to lock the exposure device after each radiographic exposure on at least three occasions, as required by 10 CFR 34.22(a).

2. Information maintained by a licensee employee was not complete and accurate in all material respects when on April 25, 1990, the employee checked and signed the entry on the Utilization Log which states that a survey of the exposure device was made to ensure that the source had returned safely to the device after each exposure and prior to returning the device to the storage area. During licensed radiography on April 25, 1990 at a job site in East Vineland, New Jersey, two NRC inspectors observed that an adequate survey of the exposure device was not made for the first eleven exposures, and no survey of the device was made on the last exposure.

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

Pursuant to the provisions of 10 CFR 2.201, Consolidated NDE, Incorporated is required to submit a written statement or explanation to the Regional Administrator, Region I, with a copy to the U. S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555, within 30 days of the date of the letter transmitting this Notice of Violation (Notice) This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each violation: (1) the reason for the violation, or, if contested, the basis for disputing the violation, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken to avoid further violations, and (4) the date when full compliance will be achieved. If an adequate reply is not received within the time specified in this Notice, the Commission may issue and Order or 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. 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 11th day of October 1991

UNITED STATES
NUCLEAR REGULATORY COMMISSION

| | | |
|---|---|---|
| In the Matter of | ) | |
| | ) | Docket No. 030-20787 |
| Consolidated NDE, Inc. | ) | License No. 29-21452-01 |
| Woodbridge, New Jersey | ) | EA 91-058 |

CONFIRMATORY ORDER MODIFYING LICENSE
(EFFECTIVE IMMEDIATELY)

I

Consolidated NDE, Incorporated (Licensee) is the holder of NRC Byproduct Material License No. 29-21452-01 issued by the Nuclear Regulatory Commission (NRC or Commission) pursuant to 10 CFR Parts 30 and 34. The license authorizes the Licensee to possess numerous sealed sources of iridium-192 for industrial radiography exposure devices used for the performance of industrial radiography in accordance with the conditions specified in the license. The license was issued on October 6, 1983, was due to expire on September 30, 1988, and is currently under timely renewal.

II

On April 25, 1990, an NRC inspection was conducted of the Licensee's activities at a temporary field site in East Vineland, New Jersey, where radiography was being performed on a gas pipeline temporarily located above the ground. During the inspection, several violations of NRC requirements were identified, including the failures to:

1. survey the radiographic exposure device, as well as the associated guide tube, on at least one occasion, as well as the failure to perform adequate surveys on several other occasions in that those surveys did not include the entire circumference of the exposure device nor the full length of the guide tube, as required by 10 CFR 34.43(b); and

2. lock the exposure device after each radiographic exposure on at least three occasions, as required by 10 CFR 34.22(a).

Most of the violations, including the two set forth above, were similar to violations identified during the previous NRC inspection conducted just one month earlier in March 1990. As a result of the findings from the April 25, 1990 inspection, the NRC Region I office promptly conducted a management meeting with the licensee on April 27, 1990, to discuss those findings, including the repetitive nature of the violations, as well as their causes, and the licensee's corrective actions. The radiographer involved in the violations discussed above, Mr. Anthony Carbone, Sr. (Mr. Carbone), attended the management meeting.

III

As a result of the NRC findings in March and April 1990, an Order Suspending Operation and Modifying License (Effective Immediately) was issued to the licensee by the NRC on May 2, 1990, based, in part, on the April 1990

inspection, and a $10,000 civil penalty was also issued on that date. In addition, as a result of information obtained during the April 25 inspection and the April 27 management meeting, an investigation was conducted by the NRC Office of Investigations (OI) to determine, among other things, whether Mr. Carbone provided false information to the NRC or maintained false records of activities performed.

The OI investigation identified two additional violations as described below: First, Mr. Carbone provided information to the NRC that was not accurate in all material respects, in that on three separate occasions, he stated that he had adequately surveyed the guide tube and the exposure device, and locked the device after each of the exposures. The three occasions during which false information was provided to the NRC were during the April 25, 1990 inspection, the April 27, 1990 management meeting, and a subsequent interview by an OI investigator in August 1990. Second, Mr. Carbone made a false entry on his utilization log, dated April 25, 1990, indicating that he did perform surveys after each exposure. The information presented to the NRC, as well as the entry on the utilization log, were false in that two NRC inspectors had observed that Mr. Carbone had not complied with these requirements. As a result of these findings, an enforcement conference was conducted with the licensee on July 9, 1991, to discuss these violations, following the NRC transmittal of a description of the findings to the licensee in a letter dated June 26, 1991. The violations are described in detail in the related Notice of Violation also issued on this date.

IV

During the July 9 enforcement conference, the licensee described the corrective actions that it had initiated to ensure that all employees possess a clear understanding of the company's policies on integrity and forthright communications. These actions included: (1) issuance of a letter to all employees delineating management's expectations concerning communications with the NRC; (2) posting the NRC letter, dated June 26, 1991 (which discussed these issues) at the licensee's business office; and (3) development of plans to include the requirements for completeness and accuracy of information, as set forth in 10 CFR 30.9, in the licensee's continuing training program.

In addition, the licensee also stated at the enforcement conference that (1) the licensee has prohibited Mr. Carbone from acting as a radiographer (as defined in 10 CFR Part 34.2) since the April 25, 1990 inspection; (2) Mr. Carbone has acted only as an assistant radiographer during this time period and was the subject of nine management audits wherein his performance was deemed satisfactory; (3) Mr. Carbone has completed a four hour counseling session with management concerning the issues of integrity, as well as completeness and accuracy of information; and (4) Mr. Carbone will continue to act only as an assistant radiographer, and not as an independent radiographer, until such time as an acceptable rehabilitation program is implemented and completed. Furthermore, during a telephone conversation with Mr. R. Cooper, Deputy Director, Division of Radiation Safety and Safeguards, Region I, on August 14, 1991, the

licensee's Radiation Safety Officer committed to the NRC that Mr. Carbone would remain as an assistant radiographer, and would not be allowed to perform as a radiographer until such time as the licensee concluded that he was rehabilitated, and approval was obtained from the NRC to allow Mr. Carbone to act as a radiographer.

V

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, will be accurate and forthright in providing information so that the NRC may ensure that the use of licensed materials does not endanger public health and safety. This includes ensuring that all information provided to the NRC, either orally or in writing, as well as the creation of all records of performance of activities required by NRC regulations or the license, are complete and accurate in all material respects. Such accuracy is particularly important concerning the conduct of radiography, since personnel work at sites where operations are difficult to monitor but have the potential to harm unsuspecting bystanders as well as radiography personnel. In the absence of licensee management or NRC inspectors, the NRC relies on an individual's integrity to ensure compliance with the conditions of the license and regulatory requirements. Mr. Carbone's actions, as set forth herein, raise serious questions as to whether Mr. Carbone, if performing as an independent radiographer, will ensure compliance with those requirements.

VI

I find that the Licensee's commitments made at the enforcement conference on July 9, 1991, and in the telephone conversation with the NRC on August 14, 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 and safety require that these Licensee commitments in regard to Mr. Carbone 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 and safety require that this Order be immediately effective.

VII

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, EFFECTIVE IMMEDIATELY, THAT LICENSE NO. 29-21452-01 IS MODIFIED AS FOLLOWS:

Mr. Anthony Carbone, Sr. may not act as a radiographer until the Licensee obtains written approval from the NRC to return Mr. Carbone to a radiographer status and only after the Licensee submits, and the NRC accepts, the Licensee's basis for being satisfied that Mr. Carbone should act as a radiographer as defined in 10 CFR 34.2.

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.

VIII

Mr. Anthony Carbone, Sr. and any other person, other than the Licensee, adversely affected by this Confirmatory Order may request a hearing within 20 days of its issuance. Any request for a hearing shall be submitted to the Secretary, U.S. Nuclear Regulatory Commission, ATTN: Chief, Docketing and Service Section, Washington, D.C. 20555. Copies also shall be sent to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, to the Assistant General Counsel for Hearings and Enforcement at the same address, to the Regional Administrator, NRC Region I, 475 Allendale Road, King of Prussia, Pennsylvania 19406, and to the Licensee. If a person other than Mr. Carbone, Sr. 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, this Order 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 11th day of October 1991

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

July 30, 1991

Docket No. 030-15115
License No. 37-18456-01
EA 91-077

Construction Engineering Consultants, Inc.
ATTN: Ralph Artuso
President
7702 Edgewood Avenue
Pittsburgh, Pennsylvania 15218

Dear Mr. Artuso:

Subject: NOTICE OF VIOLATION AND IMPOSITION OF CIVIL PENALTY - $1,250 (NRC Inspection Report No. 030-15115/91-001)

This letter refers to the NRC inspection conducted on May 22-23, 1991, at your facility in Pittsburgh, Pennsylvania, as well as at a field site at the Greater Pittsburgh Airport, of activities authorized by NRC License No. 37-18456-01. The inspection report was sent to you on June 14, 1991. During the inspection, two violations of NRC requirements were identified. In addition, the inspector reviewed the circumstances associated with another violation of NRC requirements which was identified by your staff. On June 19, 1991, a telephone enforcement conference was conducted with you and members of your staff to discuss the violations, their causes and your corrective actions. A copy of the Enforcement Conference Report was sent to you on June 26, 1991.

The violations are described in the enclosed Notice. The most significant violation involved the performance of radiography since January 1991 without the radiographers wearing alarm ratemeters, as required by 10 CFR 34.33(a). Although the requirement to wear such alarm ratemeters had become effective on January 10, 1991, the two radiographers (one of whom was the Radiation Safety Officer (RSO)) informed the inspector that such meters had not been purchased and were not being used. The violation appeared to have been caused by the failure of management and the current RSO to keep abreast of this NRC requirement when it became effective, even though NRC notification was provided in both a Federal Register Notice of the new requirement, as well as an NRC Newsletter issued by the NRC Office of Nuclear Materials Safety and Safeguards and mailed directly to your address in 1990.

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

The violation is classified at Severity Level III in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C (Enforcement Policy) (1991), since it involved the failure to have, during radiography operations, one of the personnel monitoring devices required by 10 CFR Part 34. The violation is set forth in Section I of the Notice.

The NRC recognizes that subsequent to the inspection, actions were initiated to correct the violation and prevent recurrence. These actions, which were described at the enforcement conference, included (1) prompt purchasing and use, within one day, of alarm ratemeters; (2) initiation of a procedure to have all NRC correspondence signed by both the RSO and Radiation Safety Supervisor (RSS) to ensure that they stay abreast of current requirements, issues, and concerns; (3) plans to review prior NRC Newsletters and Information Notices to assure awareness of any pertinent issues; and (4) revision of the checklist for auditing radiographers to include a requirement that the audits will include a specific check to verify alarm ratemeters are being used.

Notwithstanding these corrective actions, to emphasize the importance of the use of these alarm ratemeters during the performance of radiographic operations to warn radiographers of any impending dangers, 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 $5,000. The escalation and mitigation factors set forth in the enforcement policy were considered as follows: (1) although the violations were identified by the NRC, the violations should have been identified sooner by your staff since the NRC sent notification of the new requirement in the Federal Register Notice, as well as the NMSS Newsletter, and therefore, 50% escalation of the base civil penalty on this factor is warranted; (2) your corrective actions, as described herein, were generally prompt and comprehensive, and therefore, 25% mitigation of the base civil penalty on this factor is warranted (full 50% mitigation is not warranted because (a) you had not yet verified whether there were other similar issues/requirements set forth in the Federal Register or NMSS Newsletters for which appropriate action had not yet been taken, and (b) the licensee did not commit to include checks for alarm ratemeters in audits until raised by the NRC during the enforcement conference); and (3) your past performance has been good, as evidenced by only a few minor violations being identified during the past two NRC inspections, as well as no violations being identified during the three inspections conducted before that, and therefore, 100% mitigation of the civil penalty on this factor is warranted. Although you had prior notice, via the NRC Federal Register Notice and NMSS Newsletter, of the new requirement concerning the need to wear alarm ratemeters, escalation based on the "prior notice" factor is not warranted in this case since this was a consideration in the NRC

basis for escalating the penalty based on the NRC identification of a violation that you should have reasonably identified sooner. The NRC also considered that the violation involved multiple examples and existed for an extended duration. In considering these factors, however, the NRC recognizes that the cause of the violation was ignorance of the implementation of the new rule, and the number of examples of the violations, as well as the extended period of time during which they occurred, were inevitable consequences of that lack of knowledge of the rule. While ignorance of the rule is unacceptable and you clearly have a responsibility to know and follow all requirements, the NRC has already escalated the penalty because the NRC identified the violation and you should have been aware of the requirement and identified the violation sooner. Therefore, the NRC has decided that further escalation based on the multiple example and duration factors is not warranted.

The other violation identified by the NRC is set forth in Section II of the enclosed Notice and is classified at Severity Level IV. The violation identified by your staff is set forth in the inspection report and is not being cited for the reasons described therein.

You are required to respond to the enclosed Notice 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. 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 enclosure will be placed in the NRC's Public Document Room.

The responses directed by this letter and the enclosure 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

NOTICE OF VIOLATION
AND
IMPOSITION OF CIVIL PENALTY

Construction Engineering Consultants, Inc.
Pittsburgh, Pennsylvania 15218

Docket No. 030-015115
License No. 37-18456-01
EA 91-077

During an NRC inspection conducted on May 22-23, 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

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 April 9, 1991, as well as other occasions between January and May 1991, radiographers did not wear alarm ratemeters while conducting radiographic operations at field sites.

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

Civil Penalty - $1,250

II. VIOLATION NOT ASSESSED A CIVIL PENALTY

10 CFR 71.5(a) requires, in part, that no licensee shall transport any licensed material outside the confines of its plant or other place of use, or deliver licensed material to a carrier for transport, unless the licensee complies with applicable requirements of the regulations appropriate to the mode of transport of the Department of Transportation (DOT) in 49 CFR Parts 170-189.

49 CFR 172.203(d) requires that the description on the shipping paper for a shipment of radioactive material include the transport index assigned to the package as defined in 49 CFR 173.403(bb). 10 CFR 173.403(bb) defines "transport index" as the dimensionless number (rounded up to the first decimal place) on the label of the package.

Contrary to the above, on April 9, 1991, the licensee transported approximately 80 curies of iridium-192 to Columbus, Ohio, and the associated shipping paper did not include the correct transport index assigned to the package as defined in 49 CFR 173.403(bb). Specifically, the transport index was described as "less than 2" instead of 0.6.

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

Pursuant to the provisions of 10 CFR 2.201, Construction Engineering Consultants, 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 with the time specified in this Notice, an order may be issued to show cause why the license should not be modified, suspended, or revoked or why such other action as may be proper should not be taken. Consideration may be given to extending the response time for good cause shown. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, 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 procedures 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 comprised, 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 I, 475 Allendale Road, King of Prussia, Pennsylvania 19406.

FOR THE NUCLEAR REGULATORY COMMISSION

Thomas T. Martin
Regional Administrator

Dated at King of Prussia, Pennsylvania
this 30th day of July 1991

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

NOV 06 1991

Docket No. 030-15115
License No. 37-18456-01
EA No. 91-077

Construction Engineering Consultants, Inc.
ATTN: Ralph Artuso,
President
7702 Edgewood Avenue
Pittsburgh, Pennsylvania 15218

Dear Mr. Artuso:

SUBJECT: RESCISSION OF PROPOSED CIVIL MONETARY PENALTY
(Inspection Report 91-001)

On July 30, 1991, the Nuclear Regulatory Commission issued a Notice of Violation and Proposed Imposition of Civil Penalties in the amount of $1,250 (Notice) to Construction Engineering Consultants, Inc. You answered the Notice by letter dated August 19, 1991, admitted that the violations occurred, and requested mitigation of the civil penalty based on your corrective actions. In a letter dated August 8, 1991, and in a September 16, 1991 telephone conversation between you and Mr. Paul Swetland of the NRC Region I staff, you notified the NRC of your intent to terminate your byproduct materials license. On November 5, 1991, the NRC issued an amendment terminating NRC license no. 37-18456-01.

The violations cited in the Notice of Violation are considered serious. We have reviewed your request for additional mitigation and reaffirm our position that the amount of mitigation originally considered and the resultant civil penalty proposed in our July 30, 1991 letter was appropriate. However, in light of the termination of your NRC license to conduct industrial radiography and the circumstances of this case, the Notice of Violation issued July 30, 1991 to Construction Engineering Consultants, Inc. is modified to delete the civil penalty.

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

Sincerely,

James Lieberman, Director
Office of Enforcement

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION V
1450 MARIA LANE, SUITE 210
WALNUT CREEK, CALIFORNIA 94596

FEB - 7 1991

Docket No. 030-30870
License No. 53-23288-01
EA 90-196

Fewell Geotechnical Engineering, Ltd.
ATTN: Mr. Richard B. Fewell
President
96-1416 Waihona Place
Pearl City, Hawaii 96782

Dear Sir:

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTIES - $20,000 (NRC INSPECTION REPORT NOS. 90-01 AND 90-02)

This letter refers to the Nuclear Regulatory Commission (NRC) inspection conducted by Inspectors Beth Riedlinger and Robert Pate on October 4, 1990, and to a followup NRC inspection by Inspector David D. Skov and Investigator Philip Joukoff between October 23 and November 8, 1990. The inspections examined the activities authorized by License No. 53-23288-01 as they relate to radiation safety and to compliance with NRC regulations and the conditions of your license.

Both inspections identified numerous failures to comply with NRC requirements. The October 4, 1990 inspection identified nine apparent violations, documented in Inspection Report 90-01, and sent to you on October 25, 1990. The follow-up NRC inspection included a special field inspection of your licensed activities at temporary radiography job sites on October 23 and 25, 1990 at Campbell Industrial Park, Hawaii. During this follow-up inspection, NRC inspectors identified nine additional apparent violations, documented in Inspection Report 90-02, sent to you by letter dated November 16, 1990.

On November 20, 1990, an enforcement conference was held with you to discuss the violations, their causes, and your corrective actions. At the enforcement conference, you did not dispute the inspection findings, and you acknowledged the need for increased management attention to your radiation safety program. During the conference, you proposed to implement an independent audit program to more effectively monitor your licensed operations.

Some of the violations appear to have been willfully committed by one of your radiographers, and represented a significant threat to the health and safety of the radiographer, helper personnel assisting the radiographer, and members of the public. Because of the apparent willful violations and NRC's concern for the health and safety of radiography personnel and the public, an immediately effective NRC Order Modifying License was issued to you on November 2, 1990. The Order prohibited your utilization of this employee as a radiographer, radiographer's assistant or helper in licensed activities for three years. On October 26, 1990, prior to issuance of the Order, based on a telephone conversation with the NRC, you had voluntarily agreed to temporarily remove the radiographer from licensed activities.

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

The violations, which are described in the enclosed Notice of Violation and Proposed Imposition of Civil Penalties, include the radiographer's providing false information to NRC personnel, and failures to: (1) secure the radiographic source in the shielded position after each source exposure; (2) conduct exposure device radiation surveys to ensure that the source had been returned to its shielded position after radiographic exposures; (3) rope off any portion of the restricted area boundary, post appropriate radiation warning signs for most of that boundary, and conspicuously post the high radiation area; (4) conduct instrument surveys to establish the radiation boundary; (5) prevent entry into the restricted area of individuals other than radiographers and radiographer's assistants; (6) label a shipping container with required "Radioactive" category labels; (7) check a pocket dosimeter for exposure after each radiographic exposure; (8) audit the radiation safety program once every six months; (9) audit a radiographer's performance at three month intervals; (10) check pocket dosimeters for correct response to radiation; (11) maintain records of survey meter calibration; (12) document pocket dosimeter readings; (13) maintain records of sealed source physical inventories; (14) maintain a record of an exposure device storage survey; (15) maintain required utilization logs; and (16) submit to the NRC a report of occupational radiation exposures for 1989. The large number and type of violations demonstrate the lack of effective management control of your radiation safety program.

The violation in Section I of the enclosed Notice occurred on October 25 and November 1, 1990, when your radiographer repeatedly provided false information to NRC personnel concerning his actions during the operations of October 23 and 25, 1990. The radiographer stated that he had complied with NRC requirements (and demonstrated the procedures he purportedly used) for securing the source in the fully shielded position after each exposure, for conducting surveys to assure that the source had been retracted to its fully shielded position, and for preventing the entry of unauthorized personnel into the restricted area, when in fact the radiographer had not complied with these requirements.

Licensees must be accurate and forthright in providing information to the NRC if the NRC is to ensure that licensed materials do not endanger public health and safety. This is particularly important in radiography, in which licensee personnel work at sites where operations are difficult to monitor but have the potential to harm unwary bystanders as well as radiography personnel. Licensee managers and the NRC must be able to trust licensee employees when they report they have complied with requirements designed to protect the public health and safety. Thus licensees must insist that their employees be scrupulously accurate in completing required records and in communicating with the NRC. Therefore, based on the willfulness of this violation and on the number of examples, and in accordance with the Enforcement Policy, the violation in Section I has been classified as a Severity Level II violation.

The numerous violations in Section II of the enclosed Notice demonstrate a significant lack of adequate management attention to, and oversight of, your licensed activities. The radiographer employee who was responsible for certain of the violations during field radiography on October 23 and 25, 1990, significantly degraded radiation safety and directly threatened public health and safety.

including his own. Moreover, as noted above, several of the violations committed by the radiographer were willful in that he repeatedly failed to comply with requirements of which he was well aware. However, as the licensee, you are in part responsible for these actions. These violations might have been prevented had you addressed the concerns NRC representatives discussed with you in an October 4, 1990 meeting (attended by you, your RSO, and the radiographer). During that meeting NRC stressed the need for increased management attention to the radiation safety program to ensure compliance with Commission requirements. Notwithstanding this discussion, you apparently failed to act to correct this situation, implicitly signalling to your personnel that they were free to perform licensed activities without fear of management oversight. The most significant violations occurred following the October 4 meeting. Individually, these violations would be classified at Severity Levels III, IV and V. However, taken together, with the elements of willfulness and lack of management oversight, they constitute a very significant regulatory concern. Therefore, in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions" (Enforcement Policy) 10 CFR Part 2, Appendix C (1990), the violations in Section II have been classified in the aggregate as a Severity Level II problem.

In your letter of December 17, 1990, you indicated that you will engage an independent health physics consultant to perform audits of operations and oversee the program. In addition, you stated that you are reviewing your operating procedures and will submit modified procedures in a request for license amendment.

To emphasize the importance of complying with license and regulatory requirements, and of ensuring management oversight of the licensed program, 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 Penalties (Notice) in the amount of $20,000 for the violations described in Sections I and II of the enclosed Notice.

The escalation and mitigation factors in the Enforcement Policy were considered. The base value of a civil penalty for a Severity Level II violation is $8,000. No adjustment was considered appropriate for the Severity Level II violation in Section I of the Notice. The base civil penalty for the violations in Section II was increased by 50 percent because all of the violations were NRC-identified, although they could have been discovered by you. The other adjustment factors in the Policy were considered and no further adjustment to the base civil penalties is considered appropriate.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. In your response, you should document the specific actions taken and any additional actions you plan to prevent recurrence. In addition, your response should describe the changes and actions that have been or will be implemented in your management oversight to ensure that licensed activities are conducted in accordance with your license and NRC regulatory requirements. After reviewing your response to this Notice, including your proposed corrective actions and

the results of future inspections, the NRC will determine whether further NRC enforcement action is necessary to ensure compliance with NRC regulatory requirements.

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

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

Sincerely,

John B. Martin
Regional Administrator

Enclosure:
Notice of Violation and Proposed
Imposition of Civil Penalties

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTIES

Fewell Geotechnical Engineering, Ltd.
Pearl City, Hawaii

Docket No. 030-30870
License No. 53-23288-01
EA 90-196

During NRC inspections conducted on October 4, 1990 and from October 23 to November 8, 1990, 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 (1990), 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. Incomplete and Inaccurate Information

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

Contrary to the above, when interviewed by NRC personnel on October 25 and November 1, 1990, a licensee radiographer provided false information to NRC personnel as evidenced by the following examples:

A. By stating that he never allowed any other persons inside the restricted area while a source was exposed during radiographic operations on October 23, 1990 at a pipeline job site in Campbell Industrial Park (CIP), Hawaii. Contrary to the radiographer's statement, during licensed radiography on October 23, 1990 at the CIP job site, NRC personnel observed the radiographer exposing a 54 curie iridium-192 source while two helpers and four other non-radiographer personnel entered the 2 mR/hr bounded restricted area. Although five of the unauthorized personnel were in direct view of the radiographer, the radiographer made no effort to prevent entry of the unauthorized personnel into the restricted area, or to warn personnel to immediately leave the area, or to retract the exposed source.

B. By stating that and by demonstrating how he had locked the source in the shielded position of the exposure device between source exposures during radiography on October 25, 1990 at the CIP job site. Contrary to the radiographer's statement and demonstration, during licensed radiography on October 25, 1990 at the CIP job site, NRC personnel observed that the radiographer had repeatedly failed to lock or secure the sealed source in the shielded position of the exposure device after returning the source to that position.

C. By stating that and by demonstrating how he had carried a survey meter and always conducted surveys of the exposure device and source guide tube during radiography on October 23 and 25, 1990 at the CIP job site. Contrary to the radiographer's statement, during licensed radiography on October 23 and 25, 1990 at the CIP job site, NRC personnel observed

that the radiographer had repeatedly failed to carry a survey meter and survey the exposure device and guide tube to determine that the source was returned to its shielded position inside the exposure device after each of several source exposures.

These statements were material in that they related directly to compliance with NRC requirements.

This is a Severity Level II violation (Supplement VII).
Civil Penalty - $8,000.

II. Radiation Safety Violations

A. License Condition 15 requires in part that the licensee conduct its program in accordance with the statements, representations, and procedures included in the application dated October 24, 1988 ("Application") and letter dated January 13, 1989 ("Application Letter").

1. Section IV, Paragraph 2.5, of the Operating and Emergency Procedures ("OEP"), included with the Application and the Application Letter, requires licensee personnel to conduct a survey to establish the 2 mR/hr radiation (restricted area) boundary at the start of each radiographic operation.

   Contrary to the above, at the time of the inspection on October 25, 1990, a licensee radiographer failed to conduct radiation surveys to establish the 2 mR/hr restricted area boundary during radiography at Campbell Industrial Park (CIP), Hawaii.

2. OEP Section I, Paragraph 5.0, and OEP Section IV, Paragraph 2.5, require that only radiographers and assistant radiographers be permitted inside the 2 mR/hr boundary of the restricted area and that the licensee maintain surveillance to prevent unauthorized entry into the radiation area.

   Contrary to the above, on October 23, 1990, a licensee radiographer did not prevent the unauthorized entry of six non-radiographer personnel into the 2 mR/hr bounded restricted area during radiographic exposures using a 54 curie iridium-192 source at the CIP jobsite.

3. OEP Section IV, Paragraph 2.6, included with the Application Letter, requires radiography personnel to check the readings of their dosimeters immediately after surveying and locking the exposure device following each radiographic source exposure.

   Contrary to the above, during the inspection on October 23 and 25, 1990, a licensee radiographer failed to check the reading of his dosimeter following each of several radiographic source exposures at the CIP jobsite.

B. 10 CFR 34.22(a) requires, in part, that during radiographic operations, the sealed source assembly be secured in the shielded position each time the source is returned to that position.

Contrary to the above, on October 25, 1990, a licensee radiographer did not secure the sealed source assembly in the shielded position of the exposure device after returning the source to that position on four occasions during radiography at the CIP jobsite.

C. 10 CFR 34.43(b) requires the licensee to ensure that a survey with a calibrated and operable radiation survey instrument is made after each radiographic exposure to determine that the sealed source has been returned to its shielded position. The survey must include the entire circumference of the radiographic exposure device and any source guide tube.

Contrary to the above, on October 23 and 25, 1990, a licensee radiographer did not conduct radiation surveys after each of several radiographic source exposures to determine that the source had been returned to its shielded position inside the exposure device during radiography at the CIP jobsite.

D. 10 CFR 34.42 requires, with exceptions not here applicable, that licensees conspicuously post areas in which they are performing radiography with "Caution Radiation Area" and "Caution High Radiation Area" signs, as required by 10 CFR 20.203(b) and (c)(1).

License Condition 15 requires, in part, that the licensee conduct its program in accordance with the statements, representations, and procedures included with the Application and the Application Letter.

OEP Section IV, Paragraph 2.2, included with the Application and the Application Letter, requires the licensee to establish the boundary of the restricted area with ropes and radiation area signs.

Contrary to the above, on October 23 and 25, 1990, the licensee failed to post "Caution Radiation Area" signs at most of the restricted area boundary, and failed to rope off any portion of that boundary during radiography at the CIP jobsite. Also contrary to the above, the licensee did not conspicuously post "Caution High Radiation Area" signs in that these signs could not be read by persons entering the high radiation area from all directions.

E. License Condition 16 authorizes the licensee to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material". 10 CFR 71.5(a) requires each licensee who transports licensed material outside of the confines of its plant or other place of use to comply with the applicable requirements of 49 CFR Parts 170 through 189.

49 CFR 172.403 requires appropriate "Radioactive" category labels that identify the activity and radioactive contents of packages containing radioactive material. Determination of the proper label is based on the radiation dose rates at the surface and at one meter (transport index) from the package.

Contrary to the above, on October 25, 1990, a radiographic exposure device containing a 54 curie iridium-192 sealed source was transported by a licensee radiographer to the CIP jobsite without any "Radioactive" category labels.

F. License Condition 15 requires in part that the licensee conduct its program in accordance with the statements, representations, and procedures included in the application dated October 24, 1988 ("Application") and letter dated January 13, 1989 ("Application Letter").

Paragraph 2.2 of the "Safety Program", included with the Application and the Application Letter, requires an audit of the radiation safety program once every six months.

Contrary to the above, as of October 25, 1990, the licensee had not conducted audits of the radiation safety program since issuance of the license on January 26, 1989.

G. 10 CFR 34.11(d)(1) requires the licensee to have an inspection program that requires observations of the performance of each radiographer and radiographer's assistant during an actual radiographic operation at intervals not to exceed three months.

License Condition 15 incorporates in License No. 53-23288-01 the inspection program satisfying the requirements of 10 CFR 34.11(d)(1), as submitted in the Application and Application Letter.

Paragraph 2.1 of the "Safety Program," included with the Application and Application Letter, requires the licensee to conduct audits of each radiographer at least once each calendar quarter and not to exceed three months.

Contrary to the above, the licensee had not audited the performance of an individual radiographer conducting radiographic operations between February 10, 1990 and June 1, 1990, an interval exceeding three months.

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

Contrary to the above, from August 16, 1989 to October 4, 1990, an interval exceeding one year, pocket dosimeters were not checked for correct response to radiation.

I. 10 CFR 34.24 requires in part the calibration of each survey instrument used to conduct physical radiation surveys required by 10 CFR Parts 20 and 34 and requires a record to be maintained of the date and results of each calibration for three years after the date of calibration.

Contrary to the above, as of October 4, 1990, the licensee failed to maintain a record showing the date and results of calibration of the survey instrument that was used for conducting radiation surveys during radiography on April 4-10, 1990.

J. 10 CFR 34.33(b) requires that pocket dosimeters be read and exposures recorded daily.

Contrary to the above, on July 16, 1990 and on August 27, 1990, a licensee radiographer did not record his pocket dosimeter readings.

K. 10 CFR 34.26 requires, in part, that the licensee maintain, for three years, records of quarterly physical inventories that include the quantities and kinds of byproduct material, location of sealed sources, and the date of the inventory.

Contrary to the above, at the time of the inspection on October 4, 1990, the licensee had not maintained records of sealed source physical inventories that were conducted on February 9, 1990 and June 27, 1990.

L. 10 CFR 34.43(d) requires the licensee to ensure that a record of the storage survey required by 10 CFR 34.43(c) is retained for three years when that storage survey is the last one performed in the work day.

Contrary to the above, at the time of the inspection on October 4, 1990, the licensee had not retained records of the last storage survey of the radiographic exposure device following radiography on August 27, 1990.

M. 10 CFR 34.27 requires, in part, that each licensee maintain current utilization logs, which shall be kept available for three years from the date of the recorded events, for inspection by the Commission, at the address specified in the license, showing for each sealed source: the make and model number of the radiographic exposure device or storage container in which the sealed source is located; the identity of the radiographer to whom assigned; and the plant or site where used and dates of use.

Contrary to the above, as of October 4, 1990, the licensee did not maintain required utilization logs in Pearl City, Hawaii, of changes of sealed sources in exposure devices occurring on approximately March 14, 1990 and August 29, 1990.

N. 10 CFR 20.407(b), with exceptions not here applicable, requires licensees to submit to the Commission, within the first quarter of each calendar year, a report of exposures recorded for individuals under a licensed program for the preceding calendar year.

Contrary to the above, as of October 4, 1990, the licensee had not submitted the required report for calendar year 1989.

This is a Severity Level II problem (Supplements IV, V, and VI). Cumulative Civil Penalty - $12,000 (assessed $1,350 each for Violations A.1., A.2., A.3., B., C., D., F., and G.; $500 for Violation E., and $100 each for Violations H., I., J., K., L., M., and N.)

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

Within the same time as provided for the response required above under 10 CFR 2.201, the Licensee may pay the civil penalties by letter 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 cumulative amount of the civil penalties, 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 (1990) should be addressed. Any written answer in accordance with 10 CFR 2.205 should be set forth separately from the statement or explanation in reply pursuant to 10 CFR 2.201, but may incorporate parts of the 10 CFR 2.201 reply by specific reference (e.g., citing page and paragraph numbers) to avoid repetition. The attention of the Licensee is directed to the other provisions of 10 CFR 2.205, regarding the procedure for imposing civil penalties.

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

The response noted above (Reply to Notice of Violation, letter with payment of civil penalties, and Answer to a Notice of Violation) should be addressed to: Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555, with a copy to the Regional Administrator, U.S. Nuclear Regulatory Commission, Region V, 1450 Maria Lane, Walnut Creek, California, 94596.

FOR THE NUCLEAR REGULATORY COMMISSION

John B. Martin
Regional Administrator

Dated at Walnut Creek, California
this 7 day of February 1991

OCT 1 8 1991

Docket No.: 030-30870
License No.: 53-23288-01
EA 90-196

Fewell Geotechnical Engineering, Ltd.
ATTN: Mr. Richard B. Fewell
President
96-1416 Waihona Place
Pearl City, Hawaii 96782

Dear Mr. Fewell:

On February 7, 1991, the NRC issued a Notice of Violation and Proposed Imposition of Civil Penalties in the amount of $20,000 (Notice). You answered the Notice by letter dated March 19, 1991, and suggested alternative measures as corrective action. The NRC requested additional information on May 20, 1991, which you supplied by letter dated June 20, 1991. On August 23, 1991, following several telephone conversations with the Office of Enforcement, you requested termination of your NRC license. On September 27, 1991, the NRC issued an amendment terminating NRC License No. 53-23288-01.

The violations cited in the Notice of Violation are considered serious. However, in light of the termination of your NRC license to conduct radiography and the circumstances of this case, the Notice of Violation issued February 7, 1991, to Fewell Geotechnical Engineering, Ltd. is modified to delete the civil penalty. The remainder of the Notice of Violation stands as issued.

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

Sincerely, Original Signed by
James Lieberman
James Lieberman, Director
Office of Enforcement

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

NOV 01 1991

Docket No. 030-12343
License No. 47-17199-01
EA 91-082

Humana Hospital Greenbrier Valley
ATTN: Mr. David Sirk
Executive Director
Post Office Box 497
Ronceverte, West Virginia 24970

Gentlemen:

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTIES - $21,500 (NRC INSPECTION REPORT NO. 47-17199-01/90-02 AND OFFICE OF INVESTIGATIONS REPORT NO. 2-91-002)

This letter refers to the Nuclear Regulatory Commission (NRC) inspection conducted by Ms. C. Connell and Mr. W. Loo on November 29 and 30, 1990, and December 11, 1990, and the investigation conducted by Mr. R. Burch of the NRC Office of Investigations (OI) during the period December 18, 1990 through May 28, 1991, at the Humana Hospital Greenbrier Valley (HHGV), Ronceverte, West Virginia. The inspection report and synopsis of the investigation were sent to you by letter dated August 6, 1991. During the inspection and subsequent investigation, violations of NRC requirements were identified. As a result of NRC concerns with the preliminary findings of the inspection, a management meeting was held at our request in the NRC Region II office, Atlanta, Georgia, on January 30, 1991. Matters discussed included management control of licensed activities at HHGV, Radiation Safety Officer involvement in the HHGV's nuclear medicine activities, frequent turnover of authorized users as well as the use of licensed material under the supervision of an authorized user, and management actions being taken to assure that licensed activities were in full compliance with NRC requirements. A summary of that meeting was provided to you by letter dated February 22, 1991, wherein you were advised that the NRC was continuing to review the results of the inspection to determine appropriate enforcement action. On August 15, 1991, an enforcement conference was held in the NRC Region II office with you and members of your staff to discuss the specific violations, their cause, and your corrective actions to preclude recurrence. In addition, we have received and reviewed your letter dated August 29, 1991. A summary of the enforcement conference was sent to you by letter dated September 23, 1991.

The violations are described in the enclosed Notice of Violation and Proposed Imposition of Civil Penalties (Notice). Violation A in Part I of the Notice involves two examples of inaccurate and incomplete information provided to the NRC by former senior management officials of the HHGV staff. Example I.A.1. in Part I of the Notice involves a request for documentary information made by an NRC inspector during a routine inspection conducted at HHGV on August 28, 1990. During that inspection, the inspector requested to review HHGV's health physics consultant's quarterly report for June 1990, and a copy of that document was

provided to the inspector as requested. However, the NRC later determined during the OI investigation that the document provided to the inspector was incomplete in that page four had been withheld from the inspector at the time it was provided. The withholding of that particular page was significant as it contained comments by the consultant pertaining to apparent violations of NRC requirements identified by the consultant and a recommendation that the nuclear medicine department be closed unless the identified deficiencies were immediately corrected.

Example 1.A.2. in Part I of the Notice involves oral information provided to the NRC inspectors on November 29, 1990, by HHGV senior management officials and a representative of the HHGV radiology contractor, Metro Radiology Management Services (MRMS). In this particular instance, inaccurate and misleading information was provided by a Senior MRMS representative in the presence of both the former Executive Director and former Associate Executive Director of HHGV. In responding to questions by the NRC inspector as to whether MRMS physicians were performing nuclear medicine procedures, the MRMS representative stated that MRMS physicians had performed only x-ray procedures at HHGV since their arrival on October 22, 1990. Neither the former Executive Director nor the former Associate Executive Director indicated this information was incorrect when it was provided to the NRC inspectors. After it became apparent that the statement by the MRMS representative was not true, the former Executive Director was questioned about the involvement of MRMS physicians and he stated that one or two MRMS physicians may have been involved in one or two nuclear medicine procedures. The inspectors subsequently discovered, during a review of records, that six MRMS physicians had performed nuclear medicine procedures from October 29, 1990 through November 29, 1990. During the enforcement conference and in your August 29, 1991 letter in response to the conference, licensee representatives indicated that they could not attest to what was said since they were not at those discussions between your representatives and the NRC inspectors. You stated, however, that the MRMS physicians were not doing nuclear medicine procedures but were only interpreting scans. NRC interviews of hospital staff, including several MRMS physicans, evidences that the work the MRMS physicians were doing, including interpreting scans, constituted performance of nuclear medicine procedures. The failure to provide accurate information to the NRC inspectors in this instance was significant because the NRC was seeking information to verify that the licensee was adequately ensuring that physicians performing nuclear medicine procedures were qualified and authorized to perform those procedures under the NRC license issued to HHGV.

The two examples discussed above provide a basis for raising questions as to whether the NRC can rely on HHGV management officials to provide complete and accurate information in all material respects. The NRC relies on information provided by a licensee during inspections in order to assure that the licensee is complying with regulatory requirements and that it is safely using licensed radioactive materials. The NRC recognizes that the senior management officials identified above are no longer employed at HHGV; however, had they still been employed at your facility, the NRC would have given serious consideration to the issuance of an Order to preclude their further involvement in the management and oversight of licersed activities. The NRC considers their actions to reflect a careless disregard for regulatory requirements since the officials

clearly understood what was being asked by the inspectors, yet failed to demonstrate sufficent regard for the accuracy and/or completeness of the information in all material respects. During the enforcement conference and in your subsequent correspondence to the NRC dated August 29, 1991, you did not provide any substantive information to contradict the finding that inaccurate information was provided to the NRC.

Violation B in Part I of the enclosed Notice involves a period of one month during which six MRMS physicians and a nuclear medicine technologist were permitted to possess and use licensed radioactive byproduct material for medical uses (i.e., the determination and administration of dosages to specific patients) at HHGV without being supervised by an authorized user and without authorization on a specific license issued by the NRC. The NRC inspection and OI investigation determined that MRMS physicians and HHGV staff performed these licensed activities without the supervision required by 10 CFR Part 35. During the enforcement conference, you indicated that HHGV was not aware that its authorized user was not supervising those individuals. In fact, during the enforcement conference and in your August 29, 1991 letter, you indicated that MRMS physicians were only interpreting scans and that you thought the only authorized user was supervising their work. Yet, the NRC inspection and investigation found evidence that dosages were administered to patients without the authorized user's knowledge. Also, you granted nuclear medicine privileges to these physicians without limiting their activities to the interpretation of scans, and HHGV staff members were not aware that the MRMS physicians were limited to only scan interpretation. The NRC considers your actions in allowing the MRMS physicians and HHGV staff to conduct NRC licensed activities without assuring proper supervision to reflect a careless disregard for the requirements in 10 CFR Part 35.

In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy) 10 CFR Part 2, Appendix C (1990), Violation A in Part I of the Notice has been categorized at Severity Level II because it involves two examples where HHGV senior management representatives provided and/or failed to correct inaccurate and incomplete information on matters of importance to the NRC because of careless disregard for the accuracy of the information. Violation B in Part I of the Notice has been categorized at Severity Level III because of the careless disregard displayed by licensee managers for the regulatory requirements established to protect public health and safety and the significant lack of attention to and control of licensee responsibilities.

The NRC is also concerned about your failure to establish positive controls to ensure that visiting physicians or other hospital staff (i.e., nuclear medicine technologist) comply with the procedures established by the authorized user. Documents obtained during the inspection and investigation showed that physicians enjoying staff privileges were authorized to perform nuclear medicine procedures. During the enforcement conference, you indicated this authorization was confined to "reading scans." However, you also indicated you had no method to ensure that this restriction was followed.

To emphasize the importance of ensuring (1) that all information communicated to the NRC is both complete and accurate, and (2) that licensed activities are

conducted in strict compliance with regulatory requirements and license conditions, I have been authorized, after consultation with the Director, Office of Enforcement, and the Deputy Executive Director for Nuclear Materials Safety, Safeguards, and Operations Support, to issue the enclosed Notice of Violation and Proposed Imposition of Civil Penalties (Notice) in the amount of $21,500 for the violations set forth in Part I of the Notice.

The base civil penalty for a Severity Level II violation is $4,000. The escalation and mitigation factors in the Enforcement Policy were considered for Violation A in Part I. The base civil penalty has been increased by 50 percent because the violation was identified by the NRC. Neither escalation nor mitigation was warranted for corrective action to prevent recurrence, because you have not developed any formal long term action nor advised the staff of the importance of these matters. Neither escalation nor mitigation was applied for past performance. Escalation of 100 percent was applied for multiple occurrences as evidenced by the two examples cited in the violation. An Enforcement Conference was held on January 24, 1990, as a result of falsification of qualifications by a former staff physician and the NRC emphasized to licensee management the seriousness of providing false information to the NRC. Therefore, escalation of 100 percent was applied for prior notice. The other 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 250 percent resulting in a civil penalty of $14,000.

The base civil penalty for a Severity Level III violation is $2,500. The escalation and mitigation factors in the Enforcement Policy were considered for Violation B in Part I, and the base civil penalty for this violation has been increased by 50 percent because the violation was identified by the NRC. Mitigation of 50 percent was warranted for corrective action to prevent recurrence because immediate corrective action to change the credentialing process for visiting physicians so as to ensure that proper credentials were on file prior to those physicians being permitted to perform licensed activity had been initiated by the time of our January 1991 management meeting. Additionally, procedures were instituted to ensure that physicians not listed as authorized users would not perform licensed activities unless the Radiation Safety Officer or a qualified assistant was on site to supervise their activities, and procedures were implemented to ensure that the Radiation Safety Committee would take a more active role in the oversight of nuclear medicine activities. Escalation of 100 percent was warranted for prior notice of similar events in that credentialing was discussed at the January 24, 1990, Enforcement Conference and in the NRC's letter of April 2, 1990. The HHGV consultant identified the credentialing issue as a potentially serious problem that required management attention in his comments at the March 22, 1990, Radiation Safety Committee meeting. The investigation also disclosed several internal HHGV documents from the April/May 1990 time frame that cited ongoing problems related to credentialing. Also, a problem with the credentials of a locum tenens physician was discussed at the September 26, 1990, meeting of the Radiation Safety Committee. Escalation of 100 percent was warranted for multiple occurrences in that six MRMS physicians who were not properly credentialed, and the nuclear medicine technologist, were permitted to possess and use byproduct material for medical uses at HHGV while not under the supervision of an authorized user and without authorization of a specific license issued by the NRC. The other adjustment factors in the Policy were

considered and no further adjustment to the base civil penalty is considered appropriate. Therefore, based on the above, the base civil penalty has been increased by 200 percent resulting in a civil penalty of $7,500 for the Severity Level III violation.

In addition to the violations set forth in Section I of the Notice, one other violation was identified during the inspection which is described in Part II of the Notice. This violation includes the failure to: ensure that radiation safety activities were performed as required, establish and implement written policies and procedures, and establish personnel exposure investigational levels. This violation is of concern because it represents additional indications of a lack of control of licensed activities by key staff such as the Radiation Safety Officer and the Radiation Safety Committee at your facility.

You are required to respond to the enclosed Notice and, in preparing your response, you should follow the instructions specified therein. In your response, you should document specific actions taken and any additional actions you plan to prevent recurrence. This response should also focus on explaining what actions you are taking to ensure that each person involved in licensed activities understands his or her responsibilities to ensure that NRC requirements will be followed and that communications with the NRC are 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 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 enclosure will be placed in the NRC's Public Document Room.

The responses directed by this letter and the enclosure 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,

Stewart D. Ebneter

Stewart D. Ebneter
Regional Administrator

Enclosure:
Notice of Violation and Proposed
Imposition of Civil Penalties

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTIES

Humana Hospital Greenbrier Valley
Ronceverte, West Virginia

Docket No. 030-12343
License No. 47-17199-01
EA 91-082

During an NRC inspection conducted on November 29 and 30, 1990, and December 11, 1990, 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 (1990) the Nuclear Regulatory Commission proposes to impose civil penalties pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (Act), 42 U.S.C. 2282, and 10 CFR 2.205. The particular violations and associated civil penalties are set forth below:

I. Violations Assessed a Civil Penalty

A. 10 CFR 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, on the dates indicated below, the licensee provided information to the NRC during inspections that was not complete and accurate in all material respects as evidenced by the following examples:

1. During the NRC inspection conducted on August 28, 1990, the then Associate Executive Director for Humana Hospital Greenbrier Valley withheld from the NRC inspector a portion of the June 1990 health physics consultant's report which contained references to apparent violations identified by the consultant and the recommendation that the licensee's nuclear medicine department be closed until the identified deficiencies were immediately corrected. This omission was material because it directly related to potential violations of NRC requirements and served to effectively deflect any additional NRC review into the facts and circumstances of the potential violations during the inspection.

2. On November 29, 1990, a Humana Hospital Greenbrier Valley radiology contractor informed the NRC inspectors that between October 22, 1990 and November 29, 1990, all contractor radiologists who had worked at Humana Hospital Greenbrier Valley, other than the one authorized user and his associate who was working under his supervision, were performing only diagnostic x-ray procedures. Licensee officials who were present did not correct this statement. This statement was not accurate in that a review of licensee records revealed that six contractor radiologists, who were not designated as authorized users on the license nor working under the supervision of an

authorized user, had performed multiple nuclear medicine procedures from October 29, 1990 through November 29, 1990. This statement was material because it was directly related to violations of NRC requirements and to the extent of existing deficiencies.

This is a Severity Level II violation (Supplement VII).
Civil Penalty - $14,000

B. 10 CFR 35.11(a) requires, in part, that a person not possess or use byproduct material for medical use except in accordance with a specific license issued by the Commission or an Agreement State.

10 CFR 35.11(b) provides that an individual may possess or use byproduct material under the supervision of an authorized user as provided in 10 CFR 35.25.

Contrary to the above, from October 29, 1990 through November 29, 1990, the licensee permitted six contractor radiologists and a staff nuclear medicine technologist to possess and use byproduct material for medical uses (i.e., determine and administer dosages) without being authorized on a specific license issued by the NRC or an Agreement State, and while not under the supervision of an authorized user.

This is a Severity Level III violation (Supplement VI).
Civil Penalty - $7,500

II. Violation Not Assessed a Civil Penalty

10 CFR 35.21(a) requires that the licensee, through the Radiation Safety Officer, ensure that radiation safety activities are being performed in accordance with approved procedures and regulatory requirements in the daily operation of the licensee's byproduct material program.

10 CFR 35.21(b) requires, in part, that the Radiation Safety Officer establish and implement written policy and procedures, and establish personnel exposure investigational levels.

Contrary to the above, as of November 30, 1990, the Radiation Safety Officer who was authorized on the license on November 23, 1990, had not been at the hospital during this period of time, had not communicated with the hospital staff, and had not performed the activities described above.

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

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

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

Within the same time as provided for the response required above under 10 CFR 2.201, the Licensee may pay the civil penalties by letter addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, with a check, draft, money order, or electronic transfer payable to the Treasurer of the United States in the amount of the civil penalty proposed above, or the cumulative amount of the civil penalties if more than one civil penalty is proposed, or may protest imposition of the civil penalties in whole or in part, by a written answer addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission. Should the Licensee fail to answer within the time specified, an order imposing the civil penalties will be issued. Should the Licensee elect to file an answer in accordance with 10 CFR 2.205 protesting the civil penalties, in whole or in part, such answer should be clearly marked as an "Answer to a Notice of Violation" and may: (1) deny the violation 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 (1990), 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 penalties due which subsequently have been determined in accordance with the applicable provisions of 10 CFR 2.205, this matter may be referred to the Attorney General, and the penalties, unless compromised, remitted, or mitigated, may be collected by civil action pursuant to Section 234c of the Act, 42 U.S.C. 2282c.

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

Dated at Atlanta, Georgia
this 15th day of November 1991

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

November 8, 1991

Docket No. 030-03151
License No. 37-11866-01
EA 91-137

Lancaster General Hospital
ATTN: Mr. Jeffrey M. Fried
Senior Vice President
555 North Duke Street
Lancaster, Pennsylvania 17603

Dear Mr. Fried:

Subject: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTIES - $6,250
(NRC Inspection Report No. 030-03151/91-001)

This letter refers to the NRC inspection conducted on September 25-26, 1991, at Lancaster General Hospital, Lancaster, Pennsylvania, of activities authorized by NRC License No. 37-11866-01. The inspection report was sent to you on October 22, 1991. During the inspection, twelve apparent violations of NRC requirements were identified. On October 30, 1991, an enforcement conference was conducted with you and members of your staff to discuss the apparent violations, their causes and your corrective actions.

The most significant violation identified during the inspection involved three examples of the failure to maintain security of licensed radioactive material at the facility. Two of the three examples involved curie quantities of material being left in unrestricted areas at the facility in an unsecured manner, and not under constant surveillance and immediate control of the licensee. This violation is of particular concern to the NRC because it could have resulted in the loss or theft of the material, as well as unnecessary exposure of individuals to radiation. This violation is described in Section I of the enclosed Notice.

The other violations, which are described in Section II of the enclosed Notice, include, but are not limited to: (1) failure to implement several aspects of the radiation safety program through the Radiation Safety Officer (RSO), as required; (2) disposal of radioactive waste in a manner other than authorized; (3) failure to provide required training to certain personnel; (4) failure

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

to perform, within the required time frame, bioassays of individuals administering therapeutic treatments; (5) failure to evaluate radiation levels in unrestricted areas; (6) failure to perform required constancy checks of the dose calibrator; (7) failure to wear lab coats while handling radioactive material; (8) failure to perform hand monitoring, as required; and (9) failure to perform adequate surveys, as required.

These violations appeared to have been caused by the lack of adequate management oversight and control of the radiation safety program at your facility. Of particular concern was the apparent lack of a formal radiation safety organization which included sufficient staff dedicated to assuring proper implementation of radiation safety requirements. In addition, the Radiation Safety Officer (RSO), who is also the Chief of Radiation Oncology at your facility, appeared to have placed the ultimate responsibility for radiation safety on a contracted full time medical physicist who also assists with patient treatments. The RSO was apparently principally focused on implementing his responsibilities regarding radiation oncology patient treatment, without providing sufficient attention to his radiation safety oversight responsibilities.

The NRC inspection did reveal that the RSO, when informed of problems and concerns at the facility, did raise these problems and concerns at the Radiation Safety Committee (RSC) meetings, and corrective actions to address these matters were also discussed. However, there was apparently no clear assignment of the individuals responsible for implementing these corrective actions, nor for tracking these matters to assure that appropriate actions were taken. In addition, there was no evidence of a policy which designated individual responsibility for communication or implementation of the Radiation Safety Committee (RSC) policy. As a result, policy and procedural changes were not always communicated to the appropriate staff.

The violation involving unsecured material in an unrestricted area is classified at Severity Level III in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C (Enforcement Policy) (1991). In addition, the eleven other violations represent a lack of adequate management attention to, and oversight of, the radiation safety program, and therefore, are classified in the aggregate as a Severity Level III problem in accordance with the Enforcement Policy. If management had provided adequate attention to, and oversight of, the radiation safety program, the violations should have been either prevented, or identified and corrected prior to the NRC inspection.

The NRC recognizes that subsequent to the inspection, prompt and comprehensive actions were initiated 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: establishment of a Radiation Safety Office, which includes the hiring of a radiation physicist by December 1, 1991, to assume the role of the RSO for oversight and integration of all radiation safety activities at the hospital; the naming of a new supervisor of Nuclear Medicine responsible for ensuring that staff has appropriate training and knowledge

necessary to comply with NRC regulations and policies, and to communicate to the staff necessary changes, and a comprehensive review of the RSC's methodology of tracking and accountability of corrective actions. In addition, the corrective actions to address the security violation included: installation of padlocks on the Radioimmunoassay (RIA) and Hot Lab doors; institution of a form which requires signatures (initials) of both the technologist who is responsible for package receipts and placement in the Hot Lab during off-hours, as well as the morning technologist who opens the Hot Lab; and strict enforcement of a revised disciplinary policy which includes letters in personnel folders as well as dismissal from the facility. Furthermore, to address the communication deficiencies that existed regarding policies and procedures, biweekly training by the physics staff and the supervisory Nuclear Medicine Technologist has been initiated.

Nonetheless, to emphasize the importance of long-lasting corrective actions with respect to the management attention and oversight provided to the radiation safety program, including oversight by the Radiation Safety Officer, so as to ensure that (1) licensed activities are conducted safely and in accordance with requirements, and (2) appropriate corrective measures are taken when problems exist 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 $6,250 for the violations set forth in the enclosed Notice.

The base civil penalty amount for a Severity Level III violation or problem is $2,500. The escalation and mitigation factors set forth in the enforcement policy were considered and the NRC has decided that a separate civil penalty in the base amount of $2,500 should be issued for the Severity Level III violation set forth in Section I of the Notice, as well as a separate civil penalty in the amount of $3,750 for the aggregate Severity Level III problem set forth in Section II of the Notice.

With respect to the violation set forth in Section I, the NRC has determined that, on balance, no adjustment of the penalty is warranted because: (1) the violation was identified by the NRC, and should have been identified earlier by your staff, and therefore, 50% escalation of the base civil penalty on this factor is warranted; (2) your corrective actions, as described herein, are considered prompt and comprehensive, and therefore, 50% mitigation of the civil penalty on this factor is warranted; (3) your past performance in this area was good, as evidenced by only one violation being identified during the past two NRC inspections in 1988 and 1984, and therefore, 100% mitigation of the civil penalty on this factor is warranted; and (4) the violation included multiple examples of not maintaining security of licensed material which existed for a certain duration, and therefore, 100% escalation of the civil penalty on these factors is warranted. Although your staff had prior notice of some of the problems and the corrective actions for these problems were discussed at the RSC meetings, the NRC has decided to not escalate for prior notice since these management failures were indicative of the management breakdown at the facility for which a separate Severity Level III problem is being issued.

With respect to the violations set forth in Section II of the Notice, the NRC has determined that, on balance, 50% escalation of the civil penalty amount is warranted because: (1) the violations were identified by the NRC, and should have been identified by your staff if adequate management attention to the program had been provided, and therefore, 50% 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% mitigation of the base civil penalty on this factor is warranted; (3) although your past performance includes a total of only one violation during the prior two NRC inspections conducted in 1988 and 1984, it is clear that the facility's performance has significantly declined since these prior inspections such that your degraded performance constitutes an extensive rather than isolated issue, and therefore, no adjustment of the civil penalty on this factor is warranted; (4) although this case did involve prior notice of some of the deficiencies and some of the violations involved multiple examples, these factors were considered in classifying the violations in the aggregate at Severity Level III, and therefore, the NRC has decided that further escalation based on these factors is not warranted; and (5) the most significant of these violations, namely, the improper disposal and the radiation levels in unrestricted areas, existed for an extended duration, and therefore, 50% escalation based on this factor is warranted.

You are required to respond to the enclosed Notice 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. 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 enclosure will be placed in the NRC's Public Document Room.

The responses directed by this letter and the enclosure 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)
Commonwealth of Pennsylvania

NOTICE OF VIOLATION

AND

PROPOSED IMPOSITION OF CIVIL PENALTIES

Lancaster General Hospital
Lancaster, Pennsylvania 17602

Docket No. 030-03151
License No. 37-11866-01
EA 91-137

During an NRC inspection conducted on September 25-26, 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 civil penalties pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (Act), 42 U.S.C. 2282, and 10 CFR 2.205. The particular violations and associated civil penalties are set forth below:

I. VIOLATION OF SECURITY REQUIREMENTS

10 CFR 20.207(a) requires that licensed materials stored in an unrestricted area be secured against unauthorized removal from the place of storage. 10 CFR 20.207(b) requires that materials not in storage be under constant surveillance and immediate control of the licensee. As defined in 10 CFR 20.3(a)(17), an unrestricted area is any area access to which is not controlled by the licensee for purposes of protection of individuals from exposure to radiation and radioactive materials.

Contrary to the above, as of September 25, 1991,

1. licensed material consisting of 2-Curie Moly-Tech generators, millicurie quantities of iodine-131, and other radiopharmaceuticals were located in the hall adjacent to the Hot Lab, an unrestricted area, and this material was not secured against unauthorized removal, and was not under constant surveillance and immediate control of the licensee.

2. the Hot Lab, which at times was an unrestricted area when the door was left opened, contained curie quantities of licensed material, and the material was not secured and was not under constant surveillance and immediate control of the licensee.

3. the door to the Pathology Radio-immunoassay (RIA) Lab, an unrestricted area, was left opened while the storage refrigerator containing RIA test kits was unlocked, and the licensed material consisting of I-125 and chromium-51 test kits,

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 (Supplements IV and VI)

Civil Penalty - $2,500

II. VIOLATIONS OF OTHER REQUIREMENTS

A. 10 CFR 35.21(a) requires, in part, that a licensee shall appoint a Radiation Safety Officer responsible for implementing the radiation safety program, and that the licensee, through the Radiation Safety Officer, shall ensure that radiation safety activities are performed in accordance with approved procedures and regulatory requirements in the daily operation of the licensee's byproduct material program.

Contrary to the above, as of September 25, 1991, the Radiation Safety Officer did not ensure that radiation safety activities were being performed in accordance with approved procedures and regulatory requirements in the daily operation of the licensed byproduct materials program. Specifically, the RSO did not provide daily oversight to assure that established procedures and regulatory requirements were followed in many areas, including personnel training; security of radioactive materials; authorized waste disposal; weekly surveys; surveys associated with radiation levels in unrestricted areas; surveys associated with release of I-131 therapy patients' rooms; applicable retention of records; and rules for safe use of radioactive material and bioassays.

B. 10 CFR 20.301 requires that no licensee dispose of licensed material except by certain specified procedures. 10 CFR 35.92(a) permits a licensee to dispose of byproduct material with a physical half-life of less than 65 days in the ordinary trash, provided, in part, that the licensee first holds such byproduct material for decay a minimum of ten half-lives.

Contrary to the above, prior to September 25, 1991,

1. the licensee routinely sent nonexempt iodine-125 radioactive waste from the Pathology RIA Lab to the normal trash, which was incinerated, a method of disposal not authorized by 10 CFR 20.301

2. the licensee routinely disposed of iodine-131 in ordinary trash without first holding this material for decay a minimum of ten half-lives. For example, iodine-131 (whose half life is 8 days) waste from patients administered

150 mCi on July 19, 1991, 150 mCi on August 16, 1991, and 150 mCi on September 7, 1991, was incinerated with the normal trash.

C. 10 CFR 19.12 requires, in part, that all individuals working in a restricted area be instructed in the precautions and procedures to minimize exposure to radioactive materials, in the purpose and functions of protective devices employed, and in the applicable provisions of the Commission's regulations and licenses.

Contrary to the above, as of September 25, 1991, individuals working in restricted areas were not instructed in the precautions and procedures to minimize exposure to radioactive materials, in the purpose and functions of protective devices employed, and in the applicable provisions of the Commission's regulations and licenses, as evidenced by the following examples:

1. individuals who were working in the Nuclear Medicine Department and the Pathology RIA Lab, which are restricted areas, had not been instructed in the applicable provisions of the regulations and the conditions of the license, namely, in maintaining the security of radioactive materials, and the appropriate procedure for delivery and receipt of radioactive materials during off hours;

2. one individual who was working in the Nuclear Medicine Department for a period of time greater than one week had not been instructed in the precautions and procedures to minimize exposure to radioactive materials or the applicable provisions of the license;

3. individuals working in the Nuclear Medicine Department were not instructed in the appropriate hand monitoring procedures; and

4. individuals working in the Pathology RIA Lab were not instructed in the procedure for authorized disposal of radioactive waste.

D. 10 CFR 20.105(b) requires that, except as authorized by the Commission in 10 CFR 20.105(a), no licensee shall possess, use, or transfer licensed material in such a manner as to create in any unrestricted areas, radiation levels which, if an individual were continuously present in the area, could result in his receiving a dose in excess of 2 millirems in any one hour or 100 millirems in any seven consecutive days.

Contrary to the above, as of September 25, 1991, the licensee allowed the creation of radiation levels in unrestricted areas (namely, in rooms adjoining therapy patient's rooms, and in hallways contiguous to those rooms), such that if an individual were continuously present in the area, he could have received a dose in excess of 2 millirems in any one hour, or 100 millirems in any seven consecutive days, as evidenced by the following examples:

1. permissible levels in unrestricted areas, namely, in rooms adjacent to patients' rooms, or in adjourning hallways, were 3 mR/hr in an adjacent room on August 19, 1991; 6 mR/hr in adjoining rooms and 2 mR/hr in the hallway on February 25, 1991; 4.5 mR/hr in an adjoining room on January 14, 1991; 3 mR/hr in an adjoining room on September 10, 1991; 11.3 mR/hr in an adjoining room on January 24, 1991; 3.5 mR/hr in an adjoining room on January 16, 1991; 8 mR/hr in an adjoining room on January 15, 1990; 3.8 mR/hr in an adjoining room on February 4, 1991; 4 mR/hr in an adjoining room and 3 mR/hr in the hallway on January 28, 1990; 3 mR/hr in an adjoining room and 4 mR/hr in the hallway on June 5, 1989; 3.5 mR/hr in an adjoining room on December 12, 1990; and

2. prior to September 25, 1991, the levels were exceeded weekly, whenever a Moly-Tech generator was left in the hall outside of the Nuclear Medicine Hot Lab, an unrestricted area, since the generators remained in that hallway for time periods ranging from 1 to 6.5 hours, and the exposure rate at 18 inches from the generator was calculated to be between 10 and 20 mR/hr.

E. 10 CFR 35.315(a)(8) requires, in part, that licensees, for each patient receiving radiopharmaceutical therapy and hospitalized for compliance with 10 CFR Part 35.75, measure the thyroid burden of each individual who helped prepare or administer a dosage of iodine-131 within three days after administering the dosage.

Contrary to the above, on numerous occasions between January 13, 1990, and September 25, 1991, individuals who prepared and administered greater than 30 millicuries of iodine-131 did not have a thyroid burden measurement performed within 3 days of administering the dosage; rather, measurements for thyroid burdens during that time were only conducted once in each calendar quarter.

F. 10 CFR 20.201(b) requires that each licensee make such surveys as may be necessary to comply with the requirements of Part 20 and which are reasonable under the circumstances to evaluate the extent of radiation hazards that may be

present. As defined in 10 CFR 20.201(a), "survey" means an evaluation of the radiation hazards incident to the production, use, release, disposal, or presence of radioactive materials or other sources of radiation under a specific set of conditions.

Contrary to the above, as of September 25, 1991, the licensee did not make surveys to assure compliance with 10 CFR 20.301, which describes authorized means of disposing of licensed material. Specifically, as of September 25, 1991, the licensee did not survey empty radioimmunoassay (RIA) vials to assure that their radioactivity could not be distinguished from the background radiation level prior to disposal in the normal waste stream.

G. 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 (200 dpm/100 $cm^2$).

Contrary to the above, on numerous occasions prior to September 25, 1991, the licensee did not conduct an adequate survey for removable contamination of the iodine-131 therapy patients' rooms prior to assigning the room to another patient. The surveys were not adequate in that the GM survey instrument used to perform the surveys was not sufficiently sensitive to detect 200 dpm/100 $cm^2$.

H. 10 CFR 35.50(b)(1) requires that licensees check each dose calibrator for constancy with a dedicated check source at the beginning of each day of use.

Contrary to the above, on September 25, 1991, a dose calibrator was used to assay technetium-99m for kit preparations of radiopharmaceuticals, and the dose calibrator was not checked for constancy with a dedicated check source at the beginning of the day.

I. 10 CFR 35.21(a) requires that medical licensees appoint a Radiation Safety Officer responsible for implementing the radiation safety program. 10 CFR 35.21(b)(2) requires, in part, that the Radiation Safety Officer establish and implement written policy and procedures for the safe use of radioactive materials. The licensee's procedures were described in the application dated January 30, 1990 and letters dated July 11, 1990, February 27, 1991, and April 29, 1991, and were approved by License Condition No. 14.

1. The application dated January 30, 1990, states, in Item No. 10.4, that Appendix I to Regulatory Guide 10.8, Revision 2, is the required procedure for Safe Use of Radioactive Materials.

   a. Appendix I, Item 1, requires that laboratory coats or other protective clothing be worn where radioactive materials are used.

      Contrary to the above, on September 25, 1991, a technologist working with millicurie quantities of radioactive material, namely, Tc-99m, in the Nuclear Medicine Hot Lab, was not wearing a laboratory coat, or other protective clothing.

   b. Appendix I, Item 3, requires that radiation workers, either after each procedure or before leaving the area, monitor their hands for contamination in a low background area with a crystal probe or camera.

      Contrary to the above, on and prior to September 25, 1991, individuals who were working with and handling millicurie quantities of radioactive materials in the Nuclear Medicine Department did not routinely monitor their hands after each procedure or before leaving the area, as required; rather, these individuals monitored their hands only when they "suspected" contamination.

2. The letter dated July 11, 1990, states, in Item No. 3.a., that the procedure for area surveys requires that radioisotope preparation areas be surveyed and wipe tested daily, and that other areas be done weekly.

   Contrary to the above, prior to September 25, 1991, the radioisotope preparation areas were not wipe tested daily for removable contamination, as evidenced by the following examples: June 24-29, 1991; March 11-16, 1991; and July 29 through August 3, 1991. In addition, the weekly surveys for removable contamination were not performed for other specific areas (namely, Room III, a Patient Injection Area, of the Nuclear Medicine Department, and the Storage Bin in the basement of the facility), during the weeks of March 11-16, 1991; June 10-15, 1991; June 24-29, 1991; July 29-August 3, 1991; August 12-17, 1991; and August 19-24, 1991.

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 eleven violations)

Pursuant to the provisions of 10 CFR 2.201, Lancaster General 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 Penalties (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each alleged violation: (1) admission or denial of the alleged violation, (2) the reasons for the violation if admitted, and if denied, the reasons why, (3) the corrective steps that have been taken and the results achieved, (4) the corrective steps that will be taken to avoid further violations, and (5) the date when full compliance will be achieved. If an adequate reply is not received within the time specified in this Notice, an order may be issued to show cause why the license should not be modified, suspended, or revoked or why such other action as may be proper should not be taken. Consideration may be given to extending the response time for good cause shown. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, this response shall be submitted under oath or affirmation.

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

In requesting mitigation of the proposed penalties, the factors addressed in Section 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 procedures for imposing a civil penalties.

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

The response noted above (Reply to Notice of Violation, letter with payment of civil penalties, and Answer to a Notice of Violation) should be addressed to: Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555 with a copy to the Regional Administrator, U.S. Nuclear Regulatory Commission, Region I, 475 Allendale Road, King of Prussia, Pennsylvania 19406.

FOR THE NUCLEAR REGULATORY COMMISSION

Thomas T. Martin
Regional Administrator

Dated at King of Prussia, Pennsylvania
this 26th day of November 1991

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

February 21, 1991

Docket No. 030-08572
License No. 20-15102-01
EA 90-065

P.X. Engineering Company, Inc.
ATTN: Paul O'Neil
President
25 FID Kennedy Avenue
Boston, Massachusetts 02210

Gentlemen:

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY - $7,500
(NRC Inspection Report No. 88-002 and Investigation Report 1-88-016)

This letter refers to the NRC safety inspection conducted on June 28-29, 1988, at Boston, Massachusetts of activities authorized by NRC License No. 20-15102-01. This letter also refers to the subsequent investigation conducted by the NRC Office of Investigations (OI). The report of the inspection was forwarded to you on August 17, 1988. A copy of the redacted OI Report of Investigation was also forwarded to you on August 17, 1990. During the inspection and investigation, violations of NRC requirements were identified. On September 11, 1990, an enforcement conference was held with you and members 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 (Notice). The violations include the former Radiation Safety Officer (RSO): (1) failing to adequately supervise an individual acting as a Radiographer's Assistant when the individual was using a radiographic exposure device; and (2) providing information to the NRC that was not accurate in all material respects, in that during an interview with two NRC inspectors on June 28-29, 1988, the RSO stated he was personally present during the performance of all radiographic operations performed by two of your employees when, in fact, the RSO subsequently admitted to an OI investigator that he was not present at all times for a number of radiographic operations performed by one of the individuals between November 1987 and June 1988.

The NRC notes that Violation A in the Notice of Violation (NOV) enclosed with our letter dated August 17, 1988, which also transmitted the report of the NRC's June 28-29, 1988 inspection, involved two unqualified individuals acting as Radiographers Assistants in that these individuals had not completed the required tests to be qualified (one of these individuals was no longer employed by you at the time of this inspection). In your letter dated September 12, 1988, in response to Violation A of this NOV, you stated that the trainee present during the inspection had since passed the written and

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

field tests required by your license and that your company will no longer use trainees prior to becoming a Radiographer's Assistant. Subsequently, that violation was again discussed at the September 1990 enforcement conference because of OI's findings.

At the time that Violation A of the August 17, 1988 NOV was issued, the NRC believed, based on statements made by the RSO, that the safety significance of the violation was minimal because the RSO was present on all occasions when the individuals performed radiography. However, during the subsequent OI investigation (initiated after allegations were received by the NRC following issuance of that Notice of Violation), the RSO admitted to an NRC investigator that although he was present in the facility and "monitored" all radiography being performed, he was not present at all times with one of the individuals (to watch the individual's performance of operations) on every occasion when the source was being exposed. Since a person acting as a Radiographer's Assistant is required to be personally supervised by, and in the presence of, a radiographer and you allowed a trainee to act as a Radiographer's Assistant without such supervision on several occasions, a violation for the failure to supervise is being issued as Violation A in the enclosed Notice.

During the transcribed enforcement conference on September 11, 1990, the RSO asserted (in contradiction to his sworn testimony to OI on November 16, 1989), that he was monitoring every radiographic exposure made by the trainee in that, although he may not have been next to the individual cranking out the source, he was watching him from a distance. Notwithstanding the RSO's contentions at the conference, the NRC has concluded that the RSO provided inaccurate information to the NRC during the June 28-29, 1988 inspection, as set forth in Violation B of the enclosed Notice. This conclusion is based on the admissions by the RSO to OI during his sworn testimony (which was transcribed) on November 16, 1989 wherein he admitted he was occasionally in his office doing paper work, and was not present on every occasion when the source was out and radiography was being performed. The NRC recognizes that during the enforcement conference you provided an explanation of the inconsistencies in the RSO's statement, and you also stated that he was soon to be replaced.

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 that all information provided to the NRC, either orally or in writing, as well as the creation of all records of performance of activities required by the license, are complete and accurate in all material respects since the NRC relies on these statements and records to determine compliance with regulatory requirements.

False statements by the RSO to the NRC inspectors indicating that he was personally present on all occasions when one of the individuals performed radiography without his having actually been present on all such occasions,

violates the Commission's requirements. It is a significant regulatory concern for an RSO acting as a radiographer to not fully supervise radiographic operations. Being in the same building where radiography is performed is not adequate to fulfill NRC's requirement for supervision. In addition, it is of concern that during the June 28-29, 1988 inspection, the RSO could not demonstrate how radiography is performed, and was generally unfamiliar with the relevant NRC requirements. Consequently, we found it necessary to issue a Confirmatory Action Letter to assure that additional training would be given the RSO.

Therefore, these violations represent a significant breakdown in management control based on the RSO's lack of supervision, the RSO's providing erroneous information, and your continued utilization of the RSO notwithstanding his limited ability to serve as the RSO. Accordingly, the violations set forth in the Notice have been classified in the aggregate as a Severity Level III problem in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C, (Enforcement Policy) (1988), that was in effect at the time of the violations.

These violations demonstrate that licensee's management, including the RSO, did not provide the necessary level of oversight to ensure that licensed activities were performed in accordance with regulatory requirements. Therefore, 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, and (2) all information communicated to the NRC is both complete and accurate in all material respects, 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 $7,500.

The base civil penalty amount for a Severity Level III violation is $5,000. The escalation and and mitigation factors in the enforcement policy were considered and on balance a 50 percent escalation of the base civil penalty amount is appropriate because: (1) the violations were identified by the NRC and therefore, in accordance with the policy in effect at the time, no adjustment of the base civil penalty on this factor is warranted; (2) your corrective actions, (which included qualification of your only radiography trainee as a radiographer, and replacement and removal of the RSO from licensed activities) were not considered prompt and were only minimally acceptable in that you did not replace your RSO until two months after the enforcement conference and, therefore, a 50 percent escalation of the base civil penalty is warranted; (3) mitigation warranted for prior good performance was offset by the escalation warranted for multiple examples involved in the failure to adequately supervise; and (4) the remaining escalation and mitigation factors were considered and no further adjustment was considered appropriate since this case did not involve prior notice or duration.

Finally, the NRC is concerned that on a number of occasions between November 1987 and June 1988, your source utilization logs identified the RSO as the radiographer and he admitted that his signature on these logs indicated he was present during radiography, when in fact, testimony given to OI, (including that

of the RSO) established that the RSO was not present on all occasions to act as a radiographer when the source was utilized in radiographic operations. Although the NRC has decided not to include a citation for the falsification of these logs in the enclosed Notice, the NRC is placing you on notice that should such falsification occur in the future, appropriate enforcement action will be taken.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice in preparing your response. 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 your license, and (2) information submitted to the NRC, is 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 information submitted to the NRC will 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,

Thomas T. Martin

Thomas T. Martin
Regional Administrator

Enclosure:
Notice of Violation and
Proposed Imposition of Civil Penalty

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

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

P.X. Engineering Company, Inc.
Boston, Massachusetts

Docket No. 030-08572
License No. 20-15102-0,
EA 90-065

During an NRC inspection conducted on June 28-29, 1988, at the licensee's facility in Boston, Massachusetts, 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 associated civil penalty are set forth below.

A. 10 CFR 34.44 requires that whenever a Radiographer's Assistant uses radiographic exposure devices, uses sealed sources or related source handling tools, or conducts radiation surveys required by 10 CFR 34.43(b) to determine that the sealed source has returned to the shielded position after an exposure, he shall be under the personal supervision of a radiographer. The personal supervision shall include: (a) the radiographer's personal presence at the site where the sealed sources are being used, (b) the ability of the radiographer to give immediate assistance if required, and (c) the radiographer's watching the assistant's performance of the operations referred to in this section.

Contrary to the above, on a number of occasions between November 1987 and June 28, 1988, an individual acted as a Radiographer's Assistant, utilized a radiographic exposure device and was not adequately supervised by a radiographer, in that the radiographer/Radiation Safety Officer (RSO) was not watching the performance of operations including exposure of the source.

B. 10 CFR 30.9 (a) requires, in part, that information provided to the Commission by a licensee, or information required by the Commission's regulations to be maintained by the licensee, shall be complete and accurate in all material respects.

Contrary to the above, information provided by the licensee's RSO during an interview with two NRC inspectors on June 28, 1988, was inaccurate in that the RSO, in response to questions by the inspectors regarding the RSO's personal presence during the performance of radiography by two licensee employees, stated that he was personally present during all radiographic exposures performed by both individuals. This statement by the RSO was not accurate in that the RSO was not personally present at all times on all occasions when one of the individuals performed radiographic

exposures. By the admission of the RSO, on a number of occasions between November 1987 and July 1988, he did not observe all radiographic exposures in that he states that he was in his office located approximately 50 feet from the location where the radiography was being performed. This statement was material because it relates directly to an NRC requirement and also because one of the individuals acting as a Radiographer's Assistant had not been given an oral test as required by the licensee's procedures and, had the inspector been aware that this individual was not being adequately supervised by the RSO, the inspector may have determined that this situation had more than minimal safety significance, and significant enforcement action may have been taken against the licensee at that time.

These violations have been categorized in the aggregate as a Severity Level III problem. (Supplements VI and VII).

Cumulative Civil Penalty - $7,500 (assessed $4,500 for Violation A and $3,000 for Violation B).

Pursuant to the provisions of 10 CFR 2.201, P.K. Engineering Company, Inc. (Licensee) is hereby required to submit a written statement or explanation to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, within 30 days of the date of this Notice of Violation and Proposed Civil Penalty (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, and if denied, the reasons why, (3) the corrective steps that have been taken and the results achieved, (4) the corrective steps that will be taken to avoid further violations, and (5) the date when full compliance will be achieved. If an adequate reply is not received within the time specified in this Notice, an order may be issued to show cause why the license should not be modified, suspended, or revoked or why such other action as may be proper should not be taken. Consideration may be given to extending the response time for good cause shown. Under the authority of Section 182 of the Act 42 U.S.C. 2232, 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, 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 "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 (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 mitinated, may be collected by civil action pursuant to Section 234c of the Act, 42 U.S.C. 2282(c).

The responses noted above (Reply to 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 20555 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

Thomas T. Martin
Regional Administrator

Dated at King of Prussia, Pennsylvania
this 21 day of February 1991

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20666

OCT 01 1991

Docket No. 030-08571
License No. 20-15102-01
EA 90-065

P.X. Engineering Company, Inc.
ATTEN: Paul O'Neil
President
25 FID Kennedy Avenue
Boston, Massachusetts 02210

Dear Mr. O'Neil:

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

This letter refers to your letter, dated April 5, 1991, as well as your supplemental response, dated May 29, 1991, in response to the Notice of Violation and Proposed Imposition of Civil Penalty (Notice) sent to you by our letter dated February 21, 1991. Our letter and Notice describe two violations identified by the NRC during an inspection conducted on June 28-29, 1988, and during a subsequent investigation by the NRC Office of Investigations (OI). The violations involved (1) the failure of the Radiation Safety Officer (RSO) to adequately supervise an individual acting as a Radiographer's Assistant, and (2) the RSO providing information to the NRC that was not accurate in all material respects. To emphasize the importance of your responsibility for ensuring that (1) licensed activities are conducted safely and in accordance with the conditions of your license, and (2) all information communicated to the NRC is both complete and accurate in all material respects, a civil penalty of $7,500 was proposed.

In your response to the Notice, you deny both violations and contend that the RSO performed the supervision specified in the regulation and in accordance with your license, and provided information to the NRC inspectors that was true and accurate based on the questions presented to him. Further, you request a remission of the civil penalty based on your response, extenuating circumstances, and the large expenditures you indicate that you have made regarding this matter over the past two years, as well as the severe economic hardships that you state you are currently experiencing.

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

After consideration of your responses, we have concluded, for the reasons given in the Appendix attached to the enclosed Order Imposing Civil Monetary Penalty, that the violations did occur as stated in the Notice, and that an adequate basis was not provided for mitigation of the civil penalty. Accordingly we hereby serve the enclosed Order on P.X. Engineering Company, Inc., imposing a civil monetary penalty in the amount of $7,500. We will review the effectiveness of your corrective actions during a subsequent inspection.

In accordance with Section 2.790 of the NRC's "Rules of Practice," a copy of this letter 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/ encls:
Public Document Room (PRD)
Nuclear Safety Information Center (NSIC)
Commonwealth of Massachusetts

UNITED STATES
NUCLEAR REGULATORY COMMISSION

| | | |
|---|---|---|
| In the Matter of | | |
| P.X. Engineering Company, Inc.<br>Boston, Massachusetts | | Docket No. 030-08572<br>License No. 20-15102-01<br>EA 90-065 |

ORDER IMPOSING CIVIL MONETARY PENALTY

I

P.X Engineering Company, Inc., (Licensee) is the holder of License No. 20-15102-01 issued by the Nuclear Regulatory Commission (NRC or Commission) on January 26, 1983. The license authorizes the Licensee to possess and use byproduct material for the conduct of industrial radiography in accordance with the conditions specified therein.

II

An inspection of the Licensee's activities was conducted on June 28-29, 1988. Subsequently, the NRC Office of Investigations performed an investigation of licensed activities. The results of the inspection and investigation indicated that the Licensee had not conducted its activities in full compliance with NRC requirements. A written Notice of Violation and Proposed Imposition of Civil Penalty (Notice) was served upon the Licensee by letter dated February 21, 1991. 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 a letter, dated April 5, 1991, and in a

supplemental letter dated May 29, 1991. In its responses, the Licensee denied the violations. In addition, the licensee requested full remission of the civil penalty if the NRC maintains the violations occurred.

III

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

IV

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

The Licensee pay a civil penalty in the amount of $7,500 within 30 days of the date of this Order, by check, draft, money order, or electronic transfer, payable to the Treasurer of the United States and mailed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555.

V

The Licensee may request a hearing within 30 days of the date of this Order. A request for a hearing should be clearly marked as a "Request for an Enforcement Hearing" and shall be addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555. Copies also shall be sent to the Assistant General Counsel for Hearings and Enforcement at the same address and to the Regional Administrator, NRC Region I, 475 Allendale Road, King of Prussia, Pennsylvania 19406.

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

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

(a) whether the Licensee was in violation of the Commission's requirements as set forth in the Notice referenced in Section II above, and

(b) whether, on the basis of such violations, 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 15th day of October 1991

APPENDIX

EVALUATIONS AND CONCLUSION

On February 21, 1991, a Notice of Violation and Proposed Imposition of Civil Penalty (Notice) was issued for violations identified during an NRC inspection. P.X. Engineering Company, Inc., responded to the Notice in a letter, dated April 5, 1991, and in a supplemental letter dated May 29, 1991. In its responses, the licensee denies the violations. In addition, the licensee contends that full remission of the civil penalty is warranted if the NRC maintains that the violations occurred. The NRC's evaluation and conclusion regarding the licensee's requests are as follows:

1. Restatement of Violations

A. 10 CFR 34.44 requires that whenever a Radiographer's Assistant uses radiographic exposure devices, uses sealed sources or related source handling tools, or conducts radiation surveys required by 10 CFR 34.43(b) to determine that the sealed source has returned to the shielded position after an exposure, he shall be under the personal supervision of a radiographer. The personal supervision shall include: (a) the radiographer's personal presence at the site where the sealed sources are being used, (b) the ability of the radiographer to give immediate assistance if required, and (c) the radiographer's watching the assistant's performance of the operations referred to in this section.

Contrary to the above, on a number of occasions between November 1987 and June 28, 1988, an individual acted as a Radiographer's Assistant, utilized a radiographic exposure device and was not adequately supervised by a radiographer, in that the radiographer/Radiation Safety Officer (RSO) was not watching the performance of operations including exposure of the source.

B. 10 CFR 30.9 (a) requires, in part, that information provided to the Commission by a licensee, or information required by the Commission's regulations to be maintained by the licensee, shall be complete and accurate in all material respects.

Contrary to the above, information provided by the licensee's RSO during an interview with two NRC inspectors on June 28, 1988, was inaccurate in that the RSO, in response to questions by the inspectors regarding the RSO's personal presence during the performance of radiography by two licensee employees, stated that he was personally present during all radiographic exposures performed by both individuals. This statement by the RSO was not accurate in that the RSO was not personally present at all times on all occasions when one of the individuals performed radiographic

exposures. By the admission of the RSO, on a number of occasions between November 1987 and July 1988, he did not observe all radiographic exposures in that he states that he was in his office located approximately 50 feet from the location where the radiography was being performed. This statement was material because it relates directly to an NRC requirement and also because one of the individuals acting as a Radiographer's Assistant had not been given an oral test as required by the licensee's procedures and, had the inspector been aware that this individual was not being adequately supervised by the RSO, the inspector may have determined that this situation had more than minimal safety significance, and significant enforcement action may have been taken against the licensee at that time.

These violations have been categorized in the aggregate as a Severity Level III problem. (Supplements VI and VII).

Cumulative Civil Penalty - $7,500 (assessed $4,500 for Violation A and $3,000 for Violation B).

2. Summary of Licensee's Response Concerning Denial of the Violations

The licensee denies the violations. In doing so, the licensee makes numerous assertions. Of these, the principal ones which appear most directly related to the basis for its actual denial that the violations occurred are summarized as follows: First, the licensee states that the former Radiation Safety Officer (RSO) both performed the supervision specified in the regulation and fulfilled the requirements to prevent unauthorized entry as well as to monitor the areas in accordance with its license. The licensee contends that the subject license requires the Radiographer to control the perimeter of the restricted area (according to the licensee, the office area of PX Engineering at times falls within the restricted area and must be controlled); therefore, the former RSO had to provide personal supervision of the Radiographer's Assistant and also comply with the license which requires direct surveillance of the operation. The licensee further states that the former RSO was always at the site when the sealed source was being used, and was able to provide immediate assistance if needed.

The licensee believes that information provided to the NRC inspectors during the June 29, 1988 inspection was true and accurate as provided by the RSO (an engineer by training and vocation) based on the questions presented to him. In addition, the licensee believes that the explanation provided during the Enforcement Conference of September 11, 1990 regarding the presence and supervision of the Radiographer's Assistant by the RSO confirmed its compliance with the license and regulations.

With respect to corrective actions, the licensee states that the management of the company has always been seriously involved in the radiography program and was concerned with the results of the June 29, 1988 inspection and immediately increased the level of oversight by: (1) providing additional training for the RSO and ensuring that no radiography operations were performed until the RSO's refresher training was complete; (2) revising the Radiation Safety Manual to add specific limitations on Radiographer's Assistants and auditing of Radiographer and Radiographer's Assistants performance; and (3) commencing unannounced management audits during radiographic operations, including records and personnel. The licensee concluded that the corrective steps that have been taken will avoid any further alleged violations.

NRC Evaluation of Licensee's Response

The NRC does not accept the licensee's contention that the RSO performed the supervision specified in the regulation (10 CFR 34.44) as long as the RSO was in the office area when radiographic operations were being conducted. The requirement for direct surveillance of the operation (required by license condition) and for watching the performance of the operation (required by 10 CFR 34.44) cannot be fulfilled from the RSO's office, which is approximately 50 feet from the area where radiographic operations are conducted, with an interposed wall that obstructs the view. The above referenced license condition and NRC regulation require a physical presence close to the individual performing the radiographic operation.

The licensee's argument that the RSO had to be in his office to control the perimeter of the restricted area is similarly unpersuasive. All NRC requirements must be met. In situations where radiography must be performed in obstructed areas, this may be accomplished by utilizing additional personnel, locking out areas, etc.

NRC does not agree with the licensee's assertion that the explanation provided during the Enforcement Conference on September 11, 1990, confirmed compliance with the license and regulations. A review of the transcripts of the enforcement conference does not lead the NRC to conclude that compliance with the requirements was achieved; the explanation given at the enforcement conference contradicts the information provided by OI. The RSO, during the transcribed enforcement conference, stated that he was monitoring every radiographic exposure made by the trainee in that, although he may not have been next to the individual cranking out the source, he was watching him from a distance. This statement contradicts the transcribed testimony given to the OI investigator on November 16, 1989 in that, during his testimony, the RSO stated: " He (Radiographer's Assistant) let me know when he was going to be doing radiography. I'd check things. Sometimes I'd see him crank it out, watch him, monitor him there. Some times I didn't."

With respect to the inaccurate information provided to the NRC inspectors by the RSO on June 29, 1988, the licensee's explanation is that the RSO was asked if he was present and responded affirmatively because he was present at the site. The licensee points out that the RSO responded, based on the question presented to him, as an engineer by training and vocation. As NRC noted in the letter transmitting the February 21, 1991 Notice, the RSO was generally unfamiliar with the relevant NRC requirements and, consequently, NRC found it necessary to issue a Confirmatory Action Letter to assure that the RSO received additional training. While this information may explain the circumstances surrounding the inaccurate information, it does not excuse or forgive the inaccurate information. An RSO familiar with the requirements of 10 CFR 34.44 would have known of the need for a physical presence close to the individual performing the radiographic operation and would have responded accordingly.

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

The licensee requested remission of the civil penalty based on the aforementioned facts, extenuating circumstances and the large expenditures it has made regarding this matter over the past 2 years, as well as the severe economic hardship which it is experiencing in the current recession. In response to the NRC's request for additional financial information, the licensee provided a supplemental response dated May 29, 1991. The licensee contends it has not "turned a profit" in the past three years and submitted Federal Tax Returns (Form 1120) for fiscal years 1988, 1989, and 1990, as evidence. The licensee cites collusion among two of its key employees for the loss of clients as well as increased costs due to duplicate purchases and theft via falsified shipments. In addition, the licensee states that in 1990, the company incurred rate increases for labor and health insurance, and experienced an unstable work force due to labor market conditions. The licensee concludes that if the civil penalty is imposed, upper management will consider terminating this corporation.

NRC Evaluation of Licensee's Request for Remission

The NRC reviewed the merits of this case and concluues that a basis for mitigation or remission of the civil penalty has not been shown. The mitigation factors set forth in the Enforcement Policy were appropriately considered in the computation of the proposed civil penalty. Specifically, the violations were identified by the NRC, the licensee's corrective actions were not considered prompt, and the mitigation warranted for good performance was offset by the escalation warranted for multiple examples. The licensee's response does not provide any additional information that specifically rebuts the NRC method of determining the amount of the civil penalty.

The NRC has also reviewed the financial information provided by the licensee in the May 29, 1991 letter. The NRC finds that while the licensee may have been experiencing economic hardship and increased

operating costs, there is no evidence that payment of this civil penalty would place the licensee in a position where it could no longer remain in business or would substantially affect its ability to safely conduct licensed activities. This conclusion is made based on the fact that the amount of the civil penalty is small in comparison to the total company revenues (as disclosed by the 1988 and 1989 tax returns), as well as the compensation paid to the licensee officers in 1989.

4. NRC Conclusion

The NRC has concluded that the violations occurred as stated in the Notice and that the licensee has not provided an adequate basis for either withdrawal of the violations, or for mitigation of the civil penalty. Consequently, the proposed civil penalty in the amount of $7,500 should be imposed.

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

July 1, 1991

Docket Nos. 030-00883
030-06991
030-00356
070-00343

License Nos. 29-05218-28
29-05218-29
29-05218-30
SNM-314

EA 91-070

Rutgers, The State University of New Jersey
ATTN: Richard M. Norman
Associate Senior Vice President and Treasurer
Old Queen's Building
New Brunswick, New Jersey 08903

Dear Mr. Norman:

Subject: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY - $6,250
(NRC Inspection Report Nos. 030-00883/91-001; 030-06991/91-001; 030-00356/91-001; 070-00343/91-001)

This letter refers to the NRC inspection conducted on May 21-24, 1991, at Rutgers, The State University of New Jersey, New Brunswick, New Jersey, of activities authorized by NRC License Nos. 29-05218-28, 29-05218-29, 29-05218-30, and SNM-314. The inspection report was sent to you on June 7, 1991. During the inspection, numerous violations of NRC requirements were identified. On June 12, 1991, an enforcement conference was conducted with you and members of your staff to discuss the violations, their causes and your corrective actions. A copy of the Enforcement Conference Report was sent to you on June 17, 1991.

The violations, which are described in the enclosed Notice, include: (1) failure of an Authoree (authorized user) to supervise the use of radioactive materials by a Supervised User (i.e., a user who is not specifically authorized to use the material without supervision); (2) failure to provide certain training required by 10 CFR 19.12; (3) failure to refrain from smoking, eating and drinking in restricted areas, and failure to wear protective clothing in restricted areas; (4) failure to maintain radiation levels in unrestricted areas in accordance with limits; (5) failure to post or adequately post documents, as required; (6) failure of an individual to obtain authorization to receive and use Special Nuclear Materials (SNM); (7) failure to secure licensed material; (8) failure of Authorees to limit possession of radioactive material to the limits authorized ; (9) failure to assign radioactive materials to another Authoree when the responsible Authoree left the University; (10) failure to follow transportation requirements when delivering radioactive materials; and (11) failure to keep

records of iodine-125 (I-125) bioassays in the proper units. As a result of the violations involving the failure to obtain authorization to receive and use SNM, as well as an example of the failure to maintain security of this SNM, a Confirmatory Action Letter was issued to you on May 24, 1991.

The violations appeared to have been caused by the lack of adequate management oversight and control of the radiation safety program at your facility. It appears that certain established radiation safety controls are generally not followed by the authorized users and radiation workers at the facility, as evidenced by the repetitive violations associated with individuals eating, drinking and smoking in laboratories, as well as not wearing "lab coats" while in the laboratory. Although such problems had been identified by both the NRC and the State of New Jersey during prior inspections, management has been either unable or unwilling to preclude recurrence of these violations.

Furthermore, your program, under the Radiation and Environmental Health and Safety (REHS) organization, does not provide a direct link between the person responsible for the daily oversight of licensed activities and those individuals implementing the program. The operational policy and the Radiation Safety Guide (RSG) appear to place the ultimate responsibility for radiation safety on the authorized users without management and supervision (1) providing adequate control over the licensed programs, and (2) effectively tracking the use of radioactive materials by the authorized and supervised users.

In addition, the NRC is also concerned, given the size of the radiation safety program, with the apparent lack of adequate staffing dedicated specifically to the program, as well as the apparent inability of the University Health Physicist (who does not report to the Radiation Safety Officer but who is responsible for the daily oversight of licensed activities) to increase the current staff's involvement in radiation safety activities. This failure may have seriously affected management's ability to provide proper oversight and control of licensed activities, and likely contributed to a decrease in the number of audits and inspections of these activities.

The violations, if considered individually, would normally be classified at Severity Level IV or V. However, given that the violations represent a lack of adequate management attention to and oversight of the radiation safety program, the violations are collectively 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) (1991). If management had provided adequate attention to, and oversight of, the radiation safety program, the violations should have been either prevented, or identified and corrected prior to the NRC inspection. Furthermore, if the Radiation Safety Committee (RSC) had met in 1990 to review the adequacy of your program, it would have provided another opportunity to identify and correct the problems sooner.

The NRC also recognizes that subsequent to the inspection, corrective actions were initiated to effect improvements in the control and implementation of the radiation safety program. These actions, which were described at the enforcement conference, included (1) specific actions taken in response to the Confirmatory Action Letter; (2) providing proper shielding for stored radioactive sources, thereby reducing radiation levels in unrestricted areas; (3) reposting required documentation and notices in appropriate areas; (4) verifying proper operation of the computer tracking system responsible for control of the radioactive material inventory; (5) developing plans to develop a tracking system to alert the REHS Department when an authorized user leaves the University; (6) delivering radioactive materials directly to the responsible laboratory; (7) maintaining iodine-125 bioassay records in the proper units as required by Part 20; and (8) developing plans to amend the licensee so that the University Health Physicist assumes the responsibility as the Radiation Safety Officer (RSO). However, these actions were not sufficient in that they do not address management's plans for resolving the concerns with eating, drinking, smoking and not wearing lab coats in restricted areas, as well as maintaining security of licensed materials in unrestricted areas.

Therefore, to emphasize the importance of adequate management attention to and oversight of the radiation safety program, including proper oversight by the Director/Radiation Safety Officer, to ensure that (1) licensed activities are conducted safely and in accordance with requirements, and (2) appropriate corrective measures are taken when problems exist 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 $6,250 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 as follows: (1) the violations were identified by the NRC, and should have been identified by your staff if adequate management attention to the program had been provided, and therefore, 50% escalation of the base civil penalty on this factor is warranted; (2) your corrective actions, as described herein, did not include measures to prevent recurrence of all of the violations, in particular, the violations involving the eating, drinking, smoking, and failing to wear "lab coats" in laboratories, as well as the violation involving the lack of security of certain licensed materials, and therefore, 50% escalation of the base civil penalty on this factor is warranted; (3) your past performance includes a total of nine violations during the prior two NRC inspections (three of which recurred during the most recent inspection), and it is clear that the facility's performance has significantly declined since these prior inspections such that your degraded performance constitutes an extensive rather than isolated issue, and therefore, 50% escalation of the civil penalty on this factor is warranted; and (4) this case did not involve prior notice, and therefore, no adjustment of the civil penalty on this factor is warranted. The NRC also considered that some of the violations involved multiple examples or existed for an extended duration. However, since these factors were considered in

determining the severity level of the violation, the NRC has decided that further escalation based on these factors is not warranted.

You are required to respond to the enclosed Notice 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, including measures for assuring that (1) individuals do not eat, drink, or smoke in restricted areas; (2) individuals use lab coats, as required, in restricted areas; and (3) management ensures that security of licensed materials in unrestricted areas at your facility is maintained. Furthermore, your response should also describe oversight of the computer tracking system that will be employed for the inventory control of radioactive materials. 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 enclosure will be placed in the NRC's Public Document Room.

The responses directed by this letter and the enclosure 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)
State of New Jersey

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

Rutgers, The State University
of New Jersey
New Brunswick, New Jersey

Docket Nos. 030-00883
030-06991
030-00356
070-00343

License Nos. 29-05218-28
29-05218-29
29-05218-30
SNM-314

EA 91-070

During an NRC inspection conducted on May 21-24, 1991, violations of NRC requirements were identified. In accordance with the "General Statemen 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 20.207(a) requires that licensed material stored in an unrestricted area be secured against unauthorized removal from the place of storage. 10 CFR 20.207(b) requires that licensed materials in an unrestricted area and not in storage be 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, at various times between May 21-24, 1991, quantities of licensed material stored in numerous unrestricted areas were not secured against unauthorized removal and were not under constant surveillance and immediate control of the licensee. The specific cases of unsecured material consisted of:

1. Special Nuclear Material (consisting of uranium 235 (U-235) as 1 gram of uranium oxide) located in an unrestricted area of the Wright-Reiman Building, Laboratory No. 288, Chemistry Department, Busch Campus;

2. undetermined amounts of licensed materials located in numerous research laboratories on the Busch, Kilmer, and Cook Campuses, unrestricted areas;

3. an unknown quantity of licensed material in a refrigerator located in a corridor outside Laboratory No. 513, Pharmacy Department, Busch Campus, an unrestricted area; and

4. an unknown quantity of licensed material located in two 55-gallon barrels on the REHS loading dock, an unrestricted area.

B. 10 CFR 20.105(b) requires that, except as authorized by the Commission in 10 CFR 20.105(a), no licensee allow the creation of radiation levels in unrestricted areas which if an individual were continuously present in the area, he could have received a dose in excess of 2 millirems in any hour or 100 millirems in any seven consecutive days.

Contrary to the above, from May 21 to 24, 1991, the licensee allowed the creation of radiation levels on the loading dock area outside the REHS package receiving room, Building 4127, Kilmer Campus and in the REHS conference room, unrestricted areas, such that if an individual were continuously present in these areas, he could have received a dose in excess of 2 millirems in any hour or 100 millirems in any seven consecutive days.

C. 10 CFR 19.12 requires, in part, that all individuals working in a restricted area be instructed in the precautions or procedures to minimize exposure to radioactive materials, in the purposes and functions of protective devices employed, and in applicable provisions of the Commission's regulations and licenses.

Contrary to the above, as of May 21, 1991, an individual working in Laboratory 288, Chemistry Department, Busch Campus, a restricted area, had not been instructed in the applicable provisions of the Commission's regulations and conditions of the license.

D. Condition 15 of License No. SNM-314 and Condition 24 of License No. 29-05218-28 require, in part, that licensed material be possessed and used in accordance with the statements, representations, and procedures contained in a letter dated July 11, 1989, and its enclosed Radiation Safety Guide, Seventh Edition, July 1989 (Guide).

1. Condition 8.C. of License No. SNM-314, Amendment No. 10, limits the amount of uranium-235 (U-235) that may be possessed at any one time, to a total of 10 milligrams of U-235 as metal.

Sections 1.0 and 4.0, of this Guide, requires that no work with sources of ionizing radiation can be initiated until written authorization has been received specifically permitting that work.

Section 2.2 of this Guide states that the REHS Department's primary means of administering control and safety programs is by enforcing the following rules:

1. NO SOURCE OF RADIATION IS TO BE ALLOWED TO ENTER OR LEAVE THE UNIVERSITY PROPERTY OR TO BE USED OR MOVED FROM THE AUTHORIZED SITES WITHOUT THE PRIOR KNOWLEDGE AND APPROVAL OF THE REHS.

2. NO INDIVIDUAL IS TO USE A SOURCE OF RADIATION UNTIL HE OR HIS/HER SUPERVISOR RECEIVES WRITTEN AUTHORIZATION.

Contrary to the above, on May 21, 1991, the licensee possessed 1 gram of uranium oxide that was 80% enriched in the U-235 isotope, or about a total of 755 milligrams of U-235. Furthermore, this material was used by an individual without the prior knowledge and approval of the REHS, without the receipt of written authorization, and without the REHS Department's administering of their control and safety programs.

2. Appendix 4 of this Guide, requires, in part, that an Authoree (authorized user) comply with the specific conditions and limitations of his/her authorization.

Appendix 4, Item 5 of this Guide, states, in part, that each user should maintain a radioisotope log to record the receipt, use, and disposal of all radioisotopes he receives, and requires that REHS keep other records required by federal and state law.

Contrary to the above,

a. on May 21, 1991, the Authoree of Authorization No. 1222, which limits the possession of iodine-125 (I-125) to 20 millicuries at any one time, did not comply with the limitations of his authorization, in that the amount of I-125 on hand exceeded 20 millicuries. Specifically, records indicated that during April 1991, the Authoree possessed 25.9 millicuries of I-125, and had received three, 10 millicurie orders of I-125 during April 1991; and

b. as of May 21-24, 1991, computer records of receipt, transfer and disposal of radioisotopes maintained by REHS indicated that several other Authorees had materials on hand that exceeded the limits of their specific authorizations.

This is a repeat violation.

3. Section 4.4 of this Guide requires that authorization be terminated if the Authoree leaves the employment of Rutgers University or ends his/her use of the radiation sources. All sources shall be placed under the responsibility of an active Authoree or the REHS department before the authorization is terminated.

   Contrary to the above, although an Authoree's authorization was terminated at some time prior to May 21, 1991, as of May 21, 1991, sodium-22 radiation sources had not been removed from Laboratory No. 288, Chemistry Department, Wright-Reiman Labs, Busch Campus, and placed under the responsibility of another active Authoree or the REHS Department prior to assigning the laboratory to a new Authoree.

4. Appendix 4 of this Guide requires, in part, that an Authoree comply with the procedures and practices outlined in this appendix.

   Appendix 4, Item 12, of this Guide lists the "Rules for Working with Radioactive Materials", i. e., routine procedures.

   Rule 1 states that eating, drinking, smoking, or using cosmetics is not permitted in laboratories using radioactive materials.

   Rule 4 states that personnel always use rubber or plastic gloves when handling radioisotopes, and that lab coats shall be worn in the laboratory and left in the laboratory.

   Rule 13 states that personnel never keep or store beverages or foods in Radioisotope labs, especially in refrigerators or freezers with radioisotopes.

   Contrary to the above, during May 21-24, 1991, evidence of eating and drinking was observed in numerous laboratories using radioactive materials (the evidence included the presence of a coffee maker, food and soda cans); evidence of smoking (namely, cigarette packs, and trays with cigarette butts and ashes) was observed in one laboratory in Building 4127, REHS Department, Kilmer Campus; the majority of the persons observed working in these laboratories were not wearing lab coats; and refrigerators containing radioactive material in several of these posted laboratories also contained food or beverages.

   This is a repeat violation with respect to Rule 1.

5. Section 2.3 of this Guide requires, in part, that an Authoree, a person permitted to use radiation at Rutgers University by virtue of a written authorization, has the primary responsibility for the radiation safety associated with the use of the source of radiation, and must also supervise the use of his/her sources of radiation to conform to all safety conditions of his/her authorization and those of the Guide. Section 2.4 of this Guide requires that Supervised Users (i.e., a user that is not specifically authorized) use sources of radiation only under the supervision of an Authoree.

   Contrary to the above, as of May 24, 1991, an Authoree did not supervise an individual using the sources of radiation under written Authorization No. 1422. Specifically, the Authoree left for a year of sabbatical leave approximately 2 months prior to the date of the inspection, and the individual Supervised User continued to use radioisotopes without the Authoree's supervision.

E. 10 CFR 71.5(a) requires that each licensee who transports licensed material outside the confines of its facility 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.

   49 CFR 177.817(a) requires that a carrier may not transport a hazardous material unless it is accompanied by a shipping paper that is prepared in accordance with Sections 172.200, 172.201, 172.202, and 172.203 of this subchapter.

   49 CFR 172.403 requires that each package of radioactive material, unless excepted from labeling by Sections 173.421 through 173.425 of this subchapter, be labeled, as appropriate, with a RADIOACTIVE WHITE-I, a RADIOACTIVE YELLOW-II, or a RADIOACTIVE YELLOW-III label.

   49 CFR 173.411 specifies the general design requirements for packages containing radioactive materials. 49 CFR 173.412 specifies additional design requirements for Type A packages. 49 CFR 173.415(a) requires, in part, that each shipper of a Specification 7A package must maintain on file for at least one year after the latest shipment, a complete documentation of tests and an engineering evaluation or comparative data showing that the construction methods, packaging design and materials of construction comply with Specification 7A.

   49 CFR 178.350-3 requires that packaging that meets Specification 7A be marked "USA DOT 7A TYPE A" on the outside of each package.

Contrary to the above, prior to May 21, 1991,

1. the licensee, acting as a carrier, transported packages of radioactive materials over public highways from Building 4127, Kilmer Campus, to the various Authorees throughout the campuses of Rutgers University, without being accompanied by shipping papers;

2. the licensee received packages of radioactive materials from suppliers which it opened, checked, removed from the original packaging, and then repackaged in a single, styrofoam box, which was not labelled with the appropriate RADIOACTIVE WHITE I, YELLOW-II or YELLOW III label;

3. the licensee did not have on file documentation and an engineering evaluation or comparative data showing that a styrofoam box (which was used to transport radioactive material) met Specification 7A packaging requirements; and

4. the licensee did not mark the unlabeled, unevaluated styrofoam box as "USA DOT 7A Type A" on the outside of the package.

F. 10 CFR 19.11(a) and (b) requires, in part, that the licensee post current copies of Parts 19, Part 20, the license, license conditions, documents incorporated into the license, license amendments, and operating procedures, or that a notice be posted describing these documents and where they may be examined. 10 CFR 19.11(d) requires, in part, that documents, notices or forms appear in a sufficient number of places to permit individuals engaged in licensed activities to observe them on the way to or from any particular licensed activity location to which the document applies.

Contrary to the above, as of May 21-24, 1991, the licensee did not post the documents or the notices in a sufficient number of places (some laboratories did not have any of the documents posted, while some other laboratories had only some of the required documents posted) to permit individuals engaged in licensed activities to observe them on the way to or from any particular licensed activity location.

G. 10 CFR 20.401(b) requires, in part, that the licensee maintain records in the same units used in Part 20, showing results of surveys required by 10 CFR 20.201(b).

10 CFR 20.5 requires, in part, that units of radioactivity for purposes of the regulations in Part 20 be measured in terms of disintegrations per minute or in curies.

Contrary to the above, as of May 21-24, 1991, the licensee did not maintain iodine-125 bioassay records of surveys made to assure compliance with 10 CFR 20.103(b) in disintegrations per minute or curie units used in Part 20, but rather in counts per minute.

This is a repeat violation.

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

Cumulative Civil Penalty - $6,250 (assessed equally among the violations)

Pursuant to the provisions of 10 CFR 2.201, Rutgers, The State University of New Jersey (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 may be issued to show cause why the license should not be modified, suspended, or revoked or why such other action as may be proper should not be taken. Consideration may be given to extending the response time for good cause shown. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, this response shall be submitted under oath or affirmation.

Within the same time as provided for the response required above under 10 CFR 2.201, the Licensee may pay the civil penalty by letter addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, with a check, draft, money order, or electronic transfer payable to the Treasurer of the United States in the amount of the civil penalty proposed above, or may protest imposition of the civil penalty in whole or in part, by a written answer addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission. Should the Licensee fail to answer within the time specified, an order imposing the civil penalty will be issued. Should the Licensee elect to file an answer in accordance with 10 CFR 2.205 protesting the civil penalty, in whole or in part, such answer should be clearly marked as an "Answer to a Notice of Violation" and may: (1) deny the violation(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 procedures 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 comprised, 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 1, 475 Allendale Road, King of Prussia, Pennsylvania 19406.

FOR THE NUCLEAR REGULATORY COMMISSION

Thomas T. Martin
Regional Administrator

Dated at King of Prussia, Pennsylvania
this 15th day of July 1991

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

NOV 05 1991

Docket Nos. 030-00883
030-06994
030-00356
070-00343

License Nos. 29-05218-28
29-05218-29
29-05218-30
SNM-314

EA No. 91-070

Rutgers, The State University of New Jersey
ATTN: Richard M. Norman
Associate Senior Vice President and Treasurer
Old Queen's Building
New Brunswick, New Jersey 08903

Dear Mr. Norman:

SUBJECT: ORDER IMPOSING CIVIL MONETARY PENALTY - $5,535
(Inspection Report 91-001)

This refers to your two letters dated July 29, 1991 in response to the Notice of Violation and Proposed Imposition of Civil Penalty (Notice) sent to you by our letter dated July 1, 1991. Our letter and Notice describe eleven violations identified during the NRC inspection conducted on May 21-24, 1991, at your facility.

To emphasize the importance of adequate management attention to and oversight of the radiation safety program, including proper oversight by the Director/Radiation Safety Officer, to ensure that (1) licensed activities are conducted safely and in accordance with requirements, and (2) appropriate corrective measures are taken when problems exist at the facility, a civil penalty in the amount of $6,250 was proposed.

In your response, you denied a number of violations in whole or in part. Further, you protested classification of the violations in the aggregate at Severity Level III, and also requested that the civil penalty be revoked.

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 Violation C and Example E.1 of Violation E should be withdrawn, that a corresponding reduction of the civil penalty by $715 is appropriate, that all

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

the other violations did occur as stated in the Notice, and that an adequate basis was not provided for reclassification of the Severity Level of the violations. Accordingly, we hereby serve the enclosed Order on Rutgers University imposing a civil monetary penalty in the amount of $5,535. We will review the effectiveness of your corrective actions during a subsequent inspection.

In your response, you also address several concerns expressed at the enforcement conference, namely, (1) a lack of access by the Health Physicist (HP) to Health/Safety (H/S) Specialists who carry out operational aspects of the program; (2) a lack of a direct line from the HP to the Radiation Safety Officer; (3) a lack of health physics expertise in the H/S Specialist positions; and (4) concern that the violations in this case were indicative of a potential for a more serious problem or event.

With respect to these concerns, the NRC acknowledges your explanation that the H/S Specialists routinely go directly to senior staff, one of whom is the University Health Physicist (HP), on technical matters and in all emergencies. However, the NRC is still concerned because of the non-traditional structure and the size of your program. This organizational structure has the potential of adversely impacting the appropriate implementation of radiation safety requirements because (1) the H/S Specialists do not have a direct line for reporting to the University HP and (2) the H/S Specialists have a broader safety responsibility than only radiation safety. It still appears that the HP must interact with other senior staff to have routine radiation safety activities put on a higher priority rather than being allowed to redirect the Health/Safety Specialists to assure that routine radiation safety activities are carried out.

As to the lack of a direct line from the University HP to the University Radiation Safety Officer (RSO), your plan to rename the University HP position as the University RSO position may alleviate that concern. However, you need to provide information as to the placement of the RSO within the Department organization and state his authority and control of the H/S Specialists with regard to radiation safety. The designation of the University HP as the RSO must be approved by the NRC through the license amendment process.

As to the lack of health physics expertise in the H/S Specialist positions, although you state that there is a significant level of expertise within the Radiation and Environmental Health and Safety (REHS) Department, the NRC is concerned that the violations identified during the subject inspection were not identified and corrected by the H/S Specialists and University HP during their routine audits and inspections. Such failures

reflect either a lack of understanding of radiation protection principles and compliance with regulations and license conditions, or insufficient time (manpower) for more than a cursory audit/inspection of the licensed program. The NRC attaches great importance to comprehensive licensee programs for detection, correction and reporting of problems that may constitute, or lead to, violations of regulatory requirements. If the University had an aggressive self-assessment program with knowledgeable staff able to find radiation problems, you should have identified the number and type of violations found during this inspection, and this enforcement action would not have needed to be taken.

As to the NRC's finding that the violations collectively represent a potentially significant lack of management attention toward licensed responsibilities, that finding is based on the number and nature of the violations, including the repetitive violations, and is consistent with the application of the Enforcement Policy in other similar cases. Civil penalties are assessed in such cases to emphasize the need for prompt correction of not only the individual violations, but also the adverse conditions related to management control of the program, before an event occurs that could potentially affect the public health and safety. Further details concerning the classification of the violations in the aggregate at Severity Level III can be found in the Appendix.

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

Sincerely,

Hugh L. Thompson, Jr.

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

Enclosures: As Stated

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

UNITED STATES
NUCLEAR REGULATORY COMMISSION

| | | |
|---|---|---|
| In the Matter of | ) | Docket Nos. 030-00883; |
| | ) | 030-06991; |
| Rutgers University | ) | 030-00356; |
| New Brunswick, New Jersey | ) | 070-00343 |
| 08903 | ) | License Nos. 29-05218-28; |
| | ) | 29-05218-29; |
| | ) | 29-05218-30; |
| | ) | SNM-314 |
| | ) | EA No. 91-070 |

ORDER IMPOSING CIVIL MONETARY PENALTY

I

University (Licensee) is the holder of Byproduct Material
s Nos. 29-05218-28, 29-05218-29, 29-05218-30 and Special
ar Material License No. 314 last renewed by the Nuclear Regulatory Commission (NRC or Commission) on January 18, 1990; February 13, 1987; March 20, 1990; and January 3, 1990, respectively. The licenses, in accordance with the conditions specified therein, authorize the Licensee to use byproduct materials for research and development, calibration of instruments, and in gauging devices; for irradiation studies; for storage only of a cobalt-60 irradiation source; and for calibration of instruments and research and development using special nuclear materials.

II

An inspection of the Licensee's activities was conducted during May 21-24, 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 July 1, 1991. The Notice states the nature of the violations, the provision of the NRC's requirements that the Licensee had violated, and the amount of the civil penalty proposed for the violations. The Licensee responded to the Notice in two letters both dated July 29, 1991. In its response, the Licensee denied Violations A, C, D.2, D.4 in part, D.5, and G, and example E.1 of Violation E. The Licensee also stated that with respect to Violation F, it was unable to verify compliance. In addition, the Licensee protested the classification of the violations in the aggregate at Severity Level III and requested that the civil penalty, which was assessed equally among the eleven violations, be withdrawn.

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, with the exception of Violation C and example E.1 of Violation E, occurred as stated; that the penalty proposed for the violations designated in the Notice should be mitigated by $715 based on the withdrawal

of Violation C and example E.1 of Violation E.; and that a civil penalty of $5,535 should be imposed.

IV

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

The Licensee pay a civil penalty in the amount of $5,535 within 30 days of the date of this Order, by check, draft, money order, or electronic transfer, payable to the Treasurer of the United States and mailed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555.

V

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

Administrator, NRC Region I, 475 Allendale Road, King of Prussia, Pennsylvania 19406.

If a hearing is requested, the Commission will issue an Order designating the time and place of the hearing. If the Licensee fails to request a hearing within 30 days of the date of this Order, the provisions of this Order shall be 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 A, D.2, D.4, D.5, F and G in the Notice referenced in Section II above, and

(b) whether, on the basis of these violations and 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 5th day of November 1991

APPENDIX

EVALUATIONS AND CONCLUSION

On July 1, 1991, a Notice of Violation and Proposed Imposition of Civil Penalty (Notice) was issued for violations identified during an NRC inspection. Rutgers University (licensee) responded to the Notice on July 29, 1991. The licensee denied Violations A, C, D.2, D.4 in part, D.5, and G, and example E.1 of Violation E. The licensee also protested classification of the violations in the aggregate at Severity Level III, and requested that the civil penalty be withdrawn. The NRC's evaluation and conclusion regarding the licensee's requests are as follows:

Restatement of Violation A

10 CFR 20.207(a) requires that licensed material stored in an unrestricted area be secured against unauthorized removal from the place of storage. 10 CFR 20.207(b) requires that licensed materials in an unrestricted area and not in storage be 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, at various times between May 21-24, 1991, quantities of licensed material stored in numerous unrestricted areas were not secured against unauthorized removal and were not under constant surveillance and immediate control of the licensee. The specific cases of unsecured material consisted of:

1. Special Nuclear Material (consisting of uranium 235 (U-235) as 1 gram of uranium oxide) located in an unrestricted area of the Wright-Reiman Building, Laboratory No. 288, Chemistry Department, Busch Campus;

2. undetermined amounts of licensed materials located in numerous research laboratories on the Busch, Kilmer, and Cook Campuses, unrestricted areas;

3. an unknown quantity of licensed material in a refrigerator located in a corridor outside Laboratory No. 513, Pharmacy Department, Busch Campus, an unrestricted area; and

4. an unknown quantity of licensed material located in two 55-gallon barrels on the REHS loading dock, an unrestricted area.

Summary of Licensee Response

The licensee denies all four examples of this violation. With respect to the first two examples of the violation, the licensee states that it considers these laboratories to be restricted areas in accordance with 10 CFR 20.3(a)(14) because: (1) the campus is isolated from urban areas, (2) warnings are posted on the laboratory door, (3) training of employees warn against entry or work in laboratories without clearance from the Radiation and Environmental Health and Safety (REHS) organization or the laboratory (lab) user, and (4) it would take malicious intent to become exposed to radioisotopes. The licensee states that security of radioisotopes inside restricted areas is emphasized during the training sessions, and this is further scrutinized by the Health/Safety Specialists, who conduct inspections in all University labs, not just those labs using radioisotopes or other licensed material. The licensee contends that these factors provide for control of access to these labs (and other labs) for purposes of protection of individuals from exposure to radiation and radioactive materials. With respect to the third example of the violation, the licensee also considers this corridor to be a restricted area.

With respect to the fourth example of this violation, the licensee states that barrels were mislabeled and did not contain radioactive material, and the contents were below the concentration defined by the NRC Regulation as being licensable.

NRC Evaluation of Licensee Response

With respect to the first two examples of the violation, the NRC disagrees with the statements in the licensee's response that Laboratory No. 288, Chemistry Department, Busch Campus, which contained special nuclear material (Uranium-235), as well as other numerous research laboratories containing licensed materials on the Busch, Kilmer and Cook campuses, were restricted areas on the dates of the inspection. As described in 10 CFR Part 20.3(a)(14), a restricted area is any area access to which is controlled by the licensee for purposes of protection of individuals from exposure to radiation and radioactive materials. In the cases described in this violation, access to the areas was not controlled on the dates of the inspection. Although the licensee argues that in the case of Laboratory (lab) 288, the lab is isolated from urban areas, that isolation does not provide control of access to the area. In addition, the fact that the laboratory doors were posted does not provide access control to the area; rather, it only provides a warning. Finally, the licensee's statement that it would take malicious intent to become exposed to radioisotopes does not lessen the fact that access to the area was not controlled.

When laboratory doors are not locked or positive access control is not otherwise maintained, and radioactive materials are stored in a hood or within an unlocked room in the lab, that area is considered unrestricted. With respect to Example 1 of this violation, the inspectors gained access to this area through an unsecured door and were not challenged by a student in the lab. The student had no knowledge of hazards in the area or that radioactive materials were located in the hood and in another unlocked room within the laboratory. With respect to Example 2 of the violation, doors to laboratories containing radioactive material were open and unlocked, and no individuals were present in the area to provide constant surveillance or immediate control of radioactive material that was not in storage or not secured. With respect to Example 3 of the violation, the access to the hallway in which the unlocked refrigerator containing licensed material was stored, was not controlled by any means.

With respect to Example 4 of the violation, the licensee provides conflicting information as to the contents of the barrels. On the one hand, the licensee states that the barrels contained no radioactive materials. On the other hand, the licensee implies that radioactive material was present in the barrels but, quoting the licensee, "below the concentration defined by the NRC Regulation as being licensable." Contrary to the licensee's assertion, material that has been received under an NRC license remains licensed material until it has been transferred or disposed of in accordance with NRC regulations. Without further information as to the exact nature of the material, and based on the labeling of the barrels, the NRC finds no basis for retraction of this example of the violation.

Based on the above, the licensee has not provided sufficient information to withdraw any examples of Violation A. Therefore, NRC maintains that the violation occurred as stated in the Notice.

Restatement of Violation C

10 CFR 19.12 requires, in part, that all individuals working in a restricted area be instructed in the precautions or procedures to minimize exposure to radioactive materials, in the purposes and functions of protective devices employed, and in applicable provisions of the Commission's regulations and licenses.

Contrary to the above, as of May 21, 1991, an individual working in Laboratory 288, Chemistry Department, Busch Campus, a restricted area, had not been instructed in the applicable provisions of the Commission's regulations and conditions of the license.

Summary of Licensee Response

The licensee denies this violation, stating that the person identified in the inspection report has never used radioactive isotopes or special nuclear materials. The licensee noted that the individual did attend a Radiation Safety Orientation session on June 4, 1991.

NRC Evaluation of Licensee Response

After further evaluation of this violation, the NRC is withdrawing this violation because Lab 288 was an unrestricted area based on example 1 of Violation A. The NRC notes, however, that 10 CFR 19.12 requires instruction of all workers who are working in or frequenting a restricted area, whether they use licensed materials or not. Thus, if the individual had actually worked in or frequented a restricted area without appropriate training, the citation would have been valid. Since the civil penalty was assessed equally among 11 violations, NRC is reducing the civil penalty by 1/11 or $570 based on the withdrawal of Violation C.

Restatement of Violation D.2

Condition 15 of License No. SNM-314 and Condition 24 of License No. 29-05218-28 require, in part, that licensed material be possessed and used in accordance with the statements, representations, and procedures contained in a letter dated July 11, 1989, and its enclosed Radiation Safety Guide, Seventh Edition, July 1989 (Guide).

Appendix 4 of this Guide, requires, in part, that an Authoree (authorized user) comply with the specific conditions and limitations of his/her authorization.

Appendix 4 Item 5 of this Guide, states, in part, that each user should maintain a radioisotope log to record the receipt, use, and disposal of all radioisotopes he receives, and requires that REHS keep other records required by federal and state law.

Contrary to the above,

a. on May 21, 1991, the Authoree of Authorization No. 1222, which limits the possession of iodine-125 (I-125) to 20 millicuries at any one time, did not comply with the limitations of his authorization, in that the amount of I-125 on hand exceeded 20 millicuries. Specifically, records indicated that during April 1991, the Authoree possessed

25.9 millicuries of I-125, and had received three, 10 millicurie orders of I-125 during April 1991; and

b. as of May 21-24, 1991, computer records of receipt, transfer and disposal of radioisotopes maintained by REHS indicated that several other Authorees had materials on hand that exceeded the limits of their specific authorizations.

Summary of Licensee Response

The licensee denies both examples of Violation D.2.

With respect to the first example, the licensee indicates that its computer records indicated an over-possession that, in fact, did not exist. The licensee states that the activity possessed by the authoree at the time of the inspection was within authorized limits due to the fact that the waste records had not been entered into the program and thus subtracted from the total inventory. The licensee also states that the authoree had ordered three shipments of 10 mCi of I-125, and REHS computer records indicated these had been delivered; however, in fact, two of these deliveries contained no activity. The licensee states that its computer records had not been updated to reflect the appropriate activity in the laboratory.

With respect to the second example of the violation, the licensee states that in these cases, its computer records are used only as an internal control procedure. The licensee maintains that at the time of the inspection, its procedure was to not deliver radioisotopes to an authoree if the delivery would create possession above authorized limits, unless the authoree was contacted and advised the REHS that REHS' computer record was inaccurate or unless REHS had received a written request and had agreed to increase the authorization limit before delivery.

NRC Evaluation of Licensee Response

With respect to the first example (D.2.a) of the violation, the inspectors found that one Authoree, who was authorized to possess 20 millicuries of iodine-125, had 25.9 millicuries of iodine-125 on hand as of April 1, 1991. The licensee has provided no specific information, such as the Authoree's records of receipt, use and disposal, to refute this finding. Concerning the three subsequent shipments of 10 millicuries each of iodine-125 to the Authoree during April 1991, NRC has verified the licensee's statement that two of these deliveries, in fact, contained no activity. However, this does not change the fact that the Authoree was in excess of his possession limit before any of the three shipments occurred. In the absence of records to the contrary, NRC considers this to be a valid example.

With respect to the second example (D.2.b) of this violation, the licensee's computer records indicated that other Authorees also exceeded their possession limits. For example, as noted in the inspection report, Authoree No. 1443 was authorized to possess 20 millicuries of tritium (H-3), but ordered and received 25 millicuries of H-3. The inspectors verified that this example involved actual physical possession of 25 millicuries of H-3 on the part of the Authoree. Further, the licensee has provided no specific information, such as the Authoree's records of receipt, use, and disposal, to refute this finding. Therefore, NRC considers this to be a valid example.

Restatement of Violation D.4

Condition 15 of License No. SNM-314 and Condition 24 of License No. 29-05218-28 require, in part, that licensed material be possessed and used in accordance with the statements, representations, and procedures contained in a letter dated July 11, 1989, and its enclosed Radiation Safety Guide, Seventh Edition, July 1989 (Guide).

Appendix 4 of this Guide requires, in part, that an Authoree comply with the procedures and practices outlined in this appendix.

Appendix 4, Item 12, of this Guide lists the "Rules for Working with Radioactive Materials," i.e., routine procedures.

Rule 1 states that eating, drinking, smoking, or using cosmetics is not permitted in laboratories using radioactive materials.

Rule 4 states that personnel always use rubber or plastic gloves when handling radioisotopes, and that lab coats shall be worn in the laboratory and left in the laboratory.

Rule 13 states that personnel never keep or store beverages or foods in Radioisotope labs, especially in refrigerators or freezers with radioisotopes.

Contrary to the above, during May 21-24, 1991, evidence of eating and drinking was observed in numerous laboratories using radioactive materials (the evidence included the presence of a coffee maker, food and soda cans); evidence of smoking (namely, cigarette packs, and trays with cigarette butts and ashes) was observed in one laboratory in Building 4127, REHS Department, Kilmer Campus; the majority of the persons observed working in these laboratories were not wearing lab coats; and refrigerators containing radioactive material in several of these posted laboratories also contained food or beverages.

This is a repeat violation with respect to Rule 1.

Summary of Licensee Response

The licensee admits the violation as it applies to Rule 13, but denies those aspects of the violation as they apply to Rule 1 and Rule 4.

With respect to Rule 1, the licensee states that no one was observed eating, drinking, smoking or using cosmetics in the laboratory. The licensee notes, however, that action is being taken to eliminate the circumstances that may indicate that the above activities took place, including (1) increased emphasis on the prohibition of eating, drinking, and smoking in laboratories in future Radiation Notes issued to all authorees throughout the year, (2) more frequent inspections by our Health/Safety Specialists and (3) greater emphasis during training sessions. With respect to Rule 4, the licensee indicates that many people do not wear lab coats in radioisotope laboratories, contending that the Radiation Safety Officer never intended to require that all radioisotope workers use laboratory coats; rather, it was intended to require that where laboratory coats were worn, they should not be worn outside the laboratory.

NRC Evaluation of Licensee Response

As to Rule 1, the NRC agrees with the licensee's statement that no one was observed eating, drinking, or smoking in laboratories using radioactive materials. However, physical evidence was observed in numerous laboratories, including the presence of a coffee maker, food and soda cans, and at least two individuals admitted to the inspector that they did in fact eat in these laboratories. Therefore, the NRC has concluded that eating and drinking in the labs did occur. Cigarette packages, and trays with cigarette butts and ashes were found in a laboratory in Building 4127, REHS Department, Kilmer Campus which indicates that smoking did occur.

As to Rule 4, the rule clearly states that laboratory coats shall be worn in the laboratory. This rule is part of the conditions on which the license was granted; consequently, the licensee may not unilaterally relax its commitment for wearing laboratory coats without amendment of its license. Therefore, the NRC maintains this example of the violation occurred as stated.

Restatement of Violation D.5

Condition 15 of License No. SNM-314 and Condition 24 of License No. 29-05218-28 require, in part, that licensed material be possessed and used in accordance with the statements, representations, and procedures contained in a letter dated Jul

11, 1989, and its enclosed Radiation Safety Guide, Seventh Edition, July 1989 (Guide).

Section 2.3 of this Guide requires, in part, that an Authoree, a person permitted to use radiation at Rutgers University by virtue of a written authorization, has the primary responsibility for the radiation safety associated with the use of the source of radiation and must also supervise the use of his/her sources of radiation to conform to all safety conditions of his/her authorization and those of the Guide. Section 2.4 of this Guide requires that Supervised Users (i.e., a user that is not specifically authorized) use sources of radiation only under the supervision of an Authoree.

Contrary to the above, as of May 24, 1991, an Authoree did not supervise an individual using the sources of radiation under written Authorization No. 1422. Specifically, the Authoree left for a year of sabbatical leave approximately 2 months prior to the date of the inspection, and the individual Supervised User continued to use radioisotopes without the Authoree's supervision.

Summary of Licensee Response

The licensee denies this violation, claiming that "supervision" has been interpreted differently by the NRC and the licensee. The licensee does not believe that supervision requires the continual presence of the authoree for radioisotopes to be used.

NRC Evaluation of Licensee Response

The NRC agrees that "supervision" does not require the continual physical presence of the Authoree. However, supervisory responsibility does require, as defined in the preamble to Appendix 4 of the licensee's Radiation Safety Guide, that the Authoree "ascertain that all persons who use radioisotopes under the coverage of his/her authorization are supervised, properly trained and experienced, aware of the attendant radiation hazards, and observe the procedures of this Guide." Information gathered from the user in the Authoree's laboratory during the inspection, indicated that the Authoree left on sabbatical without providing for any supervision of the users covered by his/her authorization, and without either informing the RSO, or arranging for another Authoree to provide supervision for his/her users. Therefore, this Authoree could not ascertain that the users under his/her authorization were observing the procedures in the licensee's Radiation Safety Guide. The statements made by the licensee in its Radiation Safety Manual define what constitutes "supervision" and, on this basis, the NRC maintains the violation occurred as stated.

Restatement of Violation E

10 CFR 71.5(a) requires that each licensee who transports licensed material outside the confines of its facility 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.

49 CFR 177.817(a) requires that a carrier may not transport a hazardous material unless it is accompanied by a shipping paper that is prepared in accordance with Sections 172.200, 172.201, 172.202, and 172.203 of this subchapter.

49 CFR 172.403 requires that each package of radioactive material, unless excepted from labeling by Sections 173.421 through 173.425 of this subchapter, be labeled, as appropriate, with a RADIOACTIVE WHITE-I, a RADIOACTIVE YELLOW-II, or a RADIOACTIVE YELLOW-III label.

49 CFR 173.411 specifies the general design requirements for packages containing radioactive materials. 49 CFR 173.412 specifies additional design requirements for Type A packages.

49 CFR 173.415(a) requires, in part, that each shipper of a Specification 7A package must maintain on file for at least one year after the latest shipment, a complete documentation of tests and an engineering evaluation or comparative data showing that the construction methods, packaging design and materials of construction comply with Specification 7A.

49 CFR 178.350-3 requires that packaging that meets Specification 7A be marked "USA DOT 7A TYPE A" on the outside of each package.

Contrary to the above, prior to May 21, 1991,

1. the licensee, acting as a carrier, transported packages of radioactive materials over public highways from Building 4127, Kilmer Campus, to the various Authorees throughout the campuses of Rutgers University, without being accompanied by shipping papers;

2. the licensee received packages of radioactive materials from suppliers which it opened, checked, removed from the original packaging, and then repackaged in a single, styrofoam box, which was not labelled with the appropriate RADIOACTIVE WHITE I, YELLOW-II OR YELLOW III label;

3. the licensee did not have on file documentation and an engineering evaluation or comparative data showing that a

styrofoam box (which was used to transport radioactive material) met Specification 7A packaging requirements; and

4. the licensee did not mark the unlabeled, unevaluated styrofoam box as "USA DOT 7A Type A" on the outside of the package.

Summary of Licensee Response

The licensee admits examples E.2 - E.4, but denies example E.1, stating that all shipping papers accompanied each transport. The licensee notes that the papers are kept by the individual authoree as demonstrated to the inspectors during their laboratory walk-through.

NRC Evaluation of Licensee Response

The NRC has reviewed the licensee's contention and agrees that all shipping papers did accompany the licensee's transport of radioactive materials. Therefore, the NRC is withdrawing this example of the violation. Since Violation E is one of 11 violations and contained four examples, the civil penalty is being reduced by 1/44, or $145, based on the withdrawal of example E.1.

Restatement of Violation F

10 CFR 19.11(a) and (b) requires, in part, that the licensee post current copies of Parts 19, Part 20, the license, license conditions, documents incorporated into the license, license amendments, and operating procedures, or that a notice be posted describing these documents and where they may be examined. 10 CFR 19.11(d) requires, in part, that documents, notices or forms appear in a sufficient number of places to permit individuals engaged in licensed activities to observe them on the way to or from any particular licensed activity location to which the document applies.

Contrary to the above, as of May 21-24, 1991, the licensee did not post the documents or the notices in a sufficient number of places (some laboratories did not have any of the documents posted, while some other laboratories had only some of the required documents posted) to permit individuals engaged in licensed activities to observe them on the way to or from any particular licensed activity location.

Summary of Licensee Response

While the licensee does not specifically deny this violation, the licensee maintains that there were no specific locations noted in

the inspection report, and therefore, it was unable to verify compliance with this violation. The licensee also states that determining compliance with this regulation requires judgment on the traffic plan in the building as well as the specific poster location. The licensee states that at times, due to vandalism or damage to the notices, some individual labs may not have posters; however, there are typically multiple postings of all required notices in common areas of the buildings on campus.

NRC Evaluation of Licensee Response

At the time of the inspection, the inspectors determined that the subject documents did not appear in a sufficient number of places in the buildings on the Busch, Kilmer, and Cook campuses so as to permit individuals engaged in licensed activities to observe them on the way to or from the particular licensed activity to which the document applies. For example, as pointed out to the licensee's Health Physicist during the inspection, in Lab B148 Nelson Building, Busch Campus; Lab 288, Chemistry, Busch Campus; CABM Lab 124, Busch Campus; and on either end of the corridor from Lab 513, Pharmacy; there were either no postings or the posting was not adequate to meet the requirement. The inspectors noted that in some laboratories using licensed material, no documents were posted, while in others, only some of the required documents were posted. Therefore, the NRC maintains that the violation occurred as stated in the Notice.

Restatement of Violation G

10 CFR 20.401(b) requires, in part, that the licensee maintain records in the same units used in Part 20, showing results of surveys required by 10 CFR 20.201(b).

10 CFR 20.5 requires, in part, that units of radioactivity for purposes of the regulations in Part 20 be measured in terms of disintegrations per minute or in curies.

Contrary to the above, as of May 21-24, 1991, the licensee did not maintain iodine-125 bioassay records of surveys made to assure compliance with 10 CFR 20.103(b) in disintegrations per minute or curie units used in Part 20, but rather in counts per minute.

This is a repeat violation.

Summary of Licensee Response

The licensee denies the violation stating that its procedures for documenting records require activity to be recorded only if it exceeds 10 nanocuries (which, apparently, due to the counting efficiency of the licensee's equipment, corresponds to 850 counts per minute).

NRC Evaluation of Licensee Response

As Condition 24 of License No. 29-05218-28 clearly states, the NRC's regulations govern the licensee's statements, representations, and procedures unless those statements, representations, and procedures are more restrictive than the regulations. The licensee maintained its records of bioassays in counts per minute, rather than disintegrations per minute. Counts per minute is not a unit allowed in Part 20 of the Commission's regulations. The licensee's response provides no basis for withdrawal of the violation. Therefore, the NRC maintains that the violation occurred as stated in the Notice.

Summary of Licensee Response Protesting Classification of the Violations in the Aggregate at Severity Level III and Requesting Revocation of the Civil Penalty

The licensee protests the civil penalty and the classification of the violations in the aggregate at Severity Level III, stating that: (1) the violations in no way jeopardized the health and safety of the people in and outside the University, and (2) review of the NMSS Licensee Newsletter indicates that fines of the magnitude of the civil penalty assessed in this case are assigned to incidents where there is a risk to the health of employees and/or the general public, such as loss of high activity sources, release of radioactivity to the environment above the established limit, overexposure of patients or personnel, etc. The licensee also stated that it has a 30 year impeccable record in radiation safety, as documented by NRC inspections.

The licensee, in disputing the classification of the violations in the aggregate at Severity Level III, also states that (1) the Rutgers' Radiation Safety Program did not suffer from a lack of management attention or oversight and it is committed to ALARA; (2) in 1990, management reorganized its Health and Safety Department, and (3) contrary to NRC claims, it has plans for resolving concerns with evidence of eating, drinking, and smoking in laboratories, and wearing of lab coats (the licensee states that in the future, all rules, including the eating, drinking and smoking issues, will be enforced through formal written notification of the authoree and his supervisor of the

implications of rule violations noted by the licensee's staff during inspections, and if there is continued disregard of rules, the Radiation Safety Committee will act to suspend the authorization of the offender). The licensee also opines that the NRC inspection found only relatively minor violations and did not give due weight to the strengths of the Licensee's Radiation Safety program and its overall compliance with the performance standards of the NRC regulations.

NRC Evaluation of Licensee Response

The NRC disagrees with the licensee's assertion that the violations did not constitute a Severity Level III problem. The NRC views the cumulative effect of the cited violations and the lack of management attention and control that allowed the violations to occur and continue undetected and uncorrected to be more significant from a safety perspective than the individual violations if they were viewed independently.

Absent specific references for the cases that the licensee is referring to, and an understanding of how the escalation and mitigation factors in the Enforcement Policy were applied in those cases, it is not possible to address the licensee's contention that the magnitude of the civil penalty proposed in this case is unnecessarily large when compared to other civil penalties noted in the NMSS newsletter. However, civil penalties are normally assessed in accordance with the examples, tables, and guidance in the Enforcement Policy, as is true for the civil penalty in the case at hand.

The NRC agrees that the record of the licensee's performance prior to the 1987 inspection was good. However, in accordance with Section V.B.3 of the Enforcement Policy, violations that occurred within the period covered by the previous two inspections were considered in evaluating the licensee's past performance.

The NRC agrees that, although the licensee denied the aspects of Violation D.4 that applied to Rule 1, the licensee's written response, dated July 29, 1991, does address corrective actions for eating, drinking and smoking in laboratories. However, as discussed in the Enforcement Policy, Section V.B.2, the NRC assesses corrective action based on, among other things, timeliness and degree of licensee initiative. In this case, at the Enforcement Conference, which took place June 12, 1991, the licensee did not have a plan of corrective action for the violation of this Rule, or Rule 4 of Violation D.4, or the security of licensed materials in unrestricted areas (Violation A). Further, the licensee did not describe its corrective action until after the issue was raised again in NRC's July 1, 1991, Notice.

Therefore, the licensee's corrective actions were judged to be neither prompt nor comprehensive.

NRC Conclusion

Based on the NRC's evaluation of the licensee's response, the NRC has concluded that the violations occurred as stated in the Notice with the exception of Violation C and example E.1 of Violation E; that the licensee has provided no information to alter the NRC's view that the violations in the aggregate are of significant regulatory concern and warrant classification at Severity Level III. However, based on the withdrawal of Violation C and example E.1 of Violation E, a reduction of the civil penalty in the amount of $715 is warranted. Consequently, a civil penalty in the amount of $5,535 should be imposed.

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

DEC 03 1991

Docket No. 030-02526
License No. 29-10191-02
EAs 91-128 & 91-168

St. Joseph's Hospital and Medical Center
ATTN: Sister Jane Frances Brady
President
703 Main Street
Paterson, New Jersey 07503

Dear Sister Brady:

Subject: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTIES (NOTICE) - $10,250 and ORDER MODIFYING LICENSE and DEMAND FOR INFORMATION (NRC Inspection Report No. 90-001 and OI Investigation Report 1-90-018)

This letter refers to the NRC inspection conducted at your facility on January 24, 25, and 28, 1991, as well as a subsequent investigation by the NRC Office of Investigations (OI), of activities authorized by NRC License No. 29-10191-02. The inspection report and a copy of the synopsis of the OI investigation were sent to you on October 8, 1991. During the inspection and investigation, numerous violations of NRC requirements were identified. On March 27, 1991, a Notice of Violation was issued to you for some of the violations identified during the inspection. The remaining violations identified during the inspection were held in abeyance until completion of the investigation. After the investigation, the remaining violations, as well as the violation identified during the investigation, were discussed at an enforcement conference conducted with Mr. Eugene Mortensen and other members of your staff on October 18, 1991. During that conference, the NRC also discussed with your staff the causes of the violations and your corrective actions.

The violations that were discussed during the enforcement conference are described in the enclosed Notice. The violations included, but were not limited to: (1) the deliberate failure by the then acting Radiation Safety Officer, who is also the current Chairman of the Radiation Safety Committee (RSC), to provide complete and accurate information to NRC personnel during two telephone conversations on January 23, 1991 concerning the

unauthorized movement and use of the facility's High Dose Rate (HDR) afterloader unit; (2) the actual unauthorized movement of the HDR unit from its authorized location on three occasions and subsequent use of the unit on the third occasion to treat patients at the new unauthorized location, in careless disregard of NRC requirements; and (3) the failure to have interlocks on the door to the linear accelerator room while the HDR unit was used there, so as to preclude anyone from entering the room with the source exposed.

With respect to the deliberate failure by the Chairman of the RSC to provide complete and accurate information to the NRC, although the individual knew that the HDR had been moved without an NRC amendment, as required, and was used in its new location to treat patients, he did not reveal that information to the NRC inspector during the first of two telephone conversations on January 23, 1991, but instead inquired as to whether a license amendment was necessary before moving the unit the next week. During the second telephone conversation on January 23, 1991, although the individual admitted that the unit was moved, he stated that the HDR was not used at its new location, when, in fact, he knew that it had been used. In a signed and sworn statement provided to the OI investigator in March 1991, the individual admitted that he had not been straightforward with the NRC inspector, although he denied having stated that the HDR unit had not been used on patients after its relocation to the linear accelerator room. This lack of candor by the Chairman of the RSC cannot and will not be tolerated by the NRC. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C, (1991), this violation, which is set forth in Section I of the Notice, represents a very significant regulatory concern and is classified at Severity Level II.

The two other violations involving the unauthorized movement and use of the HDR unit, as well as the failure to have door interlocks at the new location, are also of significant concern to the NRC because they could have resulted in unnecessary exposure of individuals to radiation. The NRC is concerned that the Chairman of the RSC acted with careless disregard by directing hospital employees to move and operate the unit, regardless of NRC requirements, even though he admitted there was a question in his mind as to whether an amendment was needed prior to the move. These violations, which are set forth in Section II of the Notice, are classified in the aggregate as a Severity Level III problem in accordance with the enforcement policy.

The NRC recognizes that the RSC Chairman was relieved of his duties as the Radiation Safety Officer, subsequent to the inspection, and other actions have been taken to ensure that the

duties and responsibilities of the RSO position are effectively implemented, so that similar violations in the future are precluded. These actions included hiring a new qualified physicist to be the facility's RSO, and performance of a limited program audit. These actions, although acceptable, are not viewed as prompt and comprehensive in that management did not counsel all licensee staff who are engaged in NRC licensed activities on the importance of providing complete and accurate information to the NRC, the audit which was performed by your staff was limited in scope and depth, and procedures remained weak and were not revised to ensure implementation of the NRC regulations during the day-to-day conduct of licensed activities and proper handling of NRC licensing matters.

Further, the RSC Chairman appeared to be concerned that he had called the NRC to seek information without first consulting with management of the hospital, and that management lacks an articulated policy to ensure that the staff, particularly those in responsible positions such as the RSO or the RSC Chairman, will not feel inhibited about calling the NRC. Your corrective actions did not address those potential deficiencies on the part of management in this event, nor the actions taken or planned to correct those deficiencies.

To emphasize the need for management to ensure that (1) all employees provide complete and accurate information to the NRC, and (2) activities at the facility are conducted safely and in accordance with regulatory requirements, I have decided to issue the enclosed Notice of Violation and Proposed Imposition of Civil Penalties in the amount of $10,250 for the violations set forth in Sections I and II of the enclosed Notice. The base civil penalty amounts for Severity Level II and III violations or problems are $4,000 and $2,500, respectively. The escalation/mitigation factors set forth in the policy were considered, and on balance, the base civil penalty amount for the Severity Level II violation has not been increased, and the base civil penalty amount for the Severity Level III problem has been increased by 150% to $6,250.

With respect to the civil penalty for the Severity Level II violation, escalation and mitigation were considered for corrective action and past performance, but adjustment of the base civil penalty amount was not warranted since: (1) the corrective actions, although acceptable, were not viewed as prompt and comprehensive; and (2) the violation was willful, and therefore, no mitigation was warranted for your generally good past performance. The other factors were considered and no further adjustment was considered appropriate.

With respect to the civil penalty for the violations classified in the aggregate as a Severity Level III problem, 50% escalation of the penalty is warranted as the violations were identified by the NRC. Since the corrective actions, although acceptable, were not considered prompt and comprehensive, no adjustment on this factor is warranted. No mitigation based on your past performance is warranted because this violation involved willfulness and because one of the previous NRC inspections identified a violation involving the failure to have a functioning interlock between the cobalt teletherapy unit and the HDR unit to prevent both from operating at the same time. Since the violations did involve multiple examples, namely, three unauthorized moves of the HDR device, and 18 patients being treated at the unauthorized location in the linear accelerator room, full 100% escalation of the base penalty on this factor is warranted. The other factors were considered and further escalation/mitigation was not warranted.

In addition to the civil penalty, the NRC is issuing (1) the enclosed Order Modifying License which requires that you preclude the individual who provided the incomplete/inaccurate information from acting as the RSO or serving on the RSC for three years, and (2) a Demand for Information that requires you to provide reasons why the NRC should not preclude the individual from any involvement in licensed activities, including functioning as an authorized user for a period of three years.

You are required to respond to the enclosed Notice, Order, and Demand 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. Further, you should describe the actions taken or planned to strengthen procedures so as to ensure proper implementation of NRC regulations during the day-to-day conduct of licensed activities and proper handling of NRC licensing matters. After reviewing your response to this Notice, Order, and Demand, 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,

James Lieberman

James Lieberman, Director
Office of Enforcement

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

cc:
Public Document Room (PDR)
Nuclear Safety Information Center (NSIC)
State of New Jersey
Thomas M. Herskovic, M.D.

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTIES

St. Joseph's Hospital and
Medical Center
Paterson, New Jersey

Docket No. 030-02526
License No. 29-10191-02
EA 91-128

During an NRC inspection conducted on January 24, 25 and 28, 1991, as well as a subsequent investigation by the NRC Office of Investigations (OI), 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 penalties are set forth below:

I. VIOLATION INVOLVING INACCURATE INFORMATION ASSESSED A CIVIL PENALTY

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, during conversations with NRC Region I staff on January 23, 1991, the licensee's Chairman of the Radiation Safety Committee (RSC), who was also the acting Radiation Safety Officer at the time, provided information to the Commission that was not complete and accurate in all material respects as evidenced by the following examples:

a. during a telephone conversation with an NRC inspector on January 23, 1991, the Chairman of the RSC told the inspector that the High Dose Rate (HDR) afterloader unit would be moved the following week, and asked questions of the inspector concerning whether a license amendment was needed to move the unit, but did not inform the inspector that the unit had already been moved and had been used to treat patients at a new location in the linear accelerator room, as admitted by the individual in a signed and sworn statement to an NRC OI investigator on March 21, 1991; and

b. during a second telephone conversation on January 23, 1991, the Chairman of the RSC, in response to a question from an NRC Section Chief, admitted that the unit had been moved, but stated that the unit had not been used to treat patients at the new location, when

in fact it had been used, as admitted by the individual to another inspector during an inspection the next day.

(This information was material because if the NRC had known that the HDR unit had been relocated and used at an unauthorized location, immediate action would have been taken to require cessation of that activity.)

This is a Severity Level II violation.

Civil Penalty - $4,000 (Supplement VII)

II. OTHER VIOLATIONS OF NRC REQUIREMENTS ASSESSED A CIVIL PENALTY

Condition 16 of License No. 29-10191-02 requires, in part, that the licensee conduct its program in accordance with the statements, representations, and procedures contained in the letter dated February 26, 1987.

A. Sections 2.A. and 3.D. of the letter dated February 26, 1987, require, in part, that the HDR unit be housed in the Cobalt Room (i.e., Cronin Ground 2-4) and not be moved.

10 CFR 30.34(c) requires, in part, that each licensee confine his possession and use of byproduct material to the locations authorized in the license.

Contrary to the above, on certain occasions, the HDR unit was not housed in the Cobalt Room, but was moved from that location, and used at one of the other locations within the hospital as evidenced by the following examples:

1. from September 21 to 23, 1990, and December 28 to 30, 1990, the HDR unit was moved from the Cobalt Room to the radium storage room; and

2. from December 30, 1990 to January 28, 1991, the HDR unit was moved from the Cobalt Room to the linear accelerator room, and used on 18 occasions to treat patients.

B. Section 2.C.1 of the licensee's letter dated February 26, 1987, requires that the door switch be interlocked to the selectron (HDR unit) computer which will initiate the "stop" sequence if the door is opened.

Contrary to the above, between December 31, 1990 and

January 28, 1991, when the HDR unit was located and used to treat patients in the linear accelerator room, the door switch was not interlocked to the selectron (HDR unit) computer in order to initiate the "stop" sequence if the door were opened.

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

Cumulative Civil Penalty - $6,250 (assessed equally among the two violations)

III. VIOLATIONS NOT ASSESSED A CIVIL PENALTY

A. Condition 16 of License No. 29-10191-02 requires, in part, that the licensee conduct its program in accordance with the statements, representations, and procedures contained in the letter dated February 26, 1987.

Section 3.A.4. of the licensee's letter dated February 26, 1987 requires, in part, the performance of daily checks of interlocks, reproducibility of the source positioning, verification of source position indicators, and inspection of the guide tubes for kinks or imperfections.

Section 3.B.1. of the Licensee's letter dated February 26, 1987, requires, in part, the performance of a quarterly survey of the unit's output.

Contrary to the above, prior to January 28, 1991, reproducibility of the source positioning, verification of source position indicators; inspection of the guide tubes for kinks or imperfections, were performed on a weekly basis, rather than daily; and the quarterly survey of the unit's output was not done.

This is a Severity Level IV violation (Supplements IV and VI).

B. 10 CFR 20.203(c)(1) requires that each high radiation area be conspicuously posted with a sign or signs bearing the radiation caution symbol and the words: "Caution High Radiation Area."

Contrary to the above, from December 30, 1990 to January 28, 1991, a high radiation area existed in the linear accelerator room where the HDR unit had been

moved and used, but that high radiation area was not posted with a sign or signs bearing the radiation caution symbol and the words: 'Caution High Radiation Area."

This is a Severity Level IV violation (Supplements IV and VI).

Pursuant to the provisions of 10 CFR 2.201, St. Joseph's Hospital & Medical Center (Licensee) is hereby required to submit a written statement or explanation to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, within 30 days of the date of this Notice of Violation and Proposed Imposition of Civil Penalties (Notice). This reply should be clearly marked as a "Reply to 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 cumulative amount of the civil penalties, 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 (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 civil penalties.

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

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

Dated at Rockville, Maryland
this 3rd day of December 1991

UNITED STATES
NUCLEAR P"GULATORY COMMISSION

| | | |
|---|---|---|
| In the Matter of | ) | |
| | ) | Docket No. 030-02526 |
| St. Joseph's Hospital and | ) | License No. 29-?0191-02 |
| Medical Center | ) | EA 91-168 |
| Paterson, New Jeisey | | |

ORDER MODIFYING LICENSE
AND
DEMAND FOR INFORMATION

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 Iridium 192, 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, was 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.

During that inspection, the NRC determined that the HDR unit had been moved on three separate occasions from its authorized location in the cobalt room. In the first two instances, which occurred between September 21 and 23, 1990 and between December 28 and 30, 1990, the unit was temporarily moved to the radium storage room but was not used to treat patients at that location. In the third instance, which occurred between December 31, 1990 and January 28, 1991, the unit was moved to the linear accelerator room and was used to treat 18 patients at that location between January 2 and 15, 1991. These three movements of the unit and the use of the unit to treat patients at an unauthorized location were contrary to Condition 16 of the License and to 10 CFR 30.34(c), which require that the unit will be housed and used only in the existing cobalt room and will not be moved from that location, except pursuant to NRC authorization in the form of a license amendment.

On January 23, 1991, the day prior to the initiation of the NRC inspection, NRC Region I staff had two telephone conversations with the Chairman of the Radiation Safety Committee (RSC) (who had also been assigned as the acting Radiation Safety Officer (RSO) in

December 1990 when the existing RSO left the facility) concerning possible movement and use of that HDR unit. The RSC Chairman did not, during the first conversation, inform the NRC inspector that the unit had been moved, even though during the second conversation he did admit it after repeated questioning. In addition, during the second conversation, he denied that the unit had been used at the new locations. As a result of the staff's concerns regarding the completeness and accuracy of the information provided 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, several violations of NRC requirements were identified. The violations, which are described in detail in a Notice of Violation and Proposed Imposition of Civil Penalty issued on this date, included, but were not limited to, (1) the movement of the HDR unit from the cobalt room to the radium storage room on two occasions, and the 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 when the source was exposed without the source retracting to its shielded position; and (3) the deliberate failure by the Chairman of the RSC to provide

complete and accurate information to the NRC during two telephone conversations with the NRC on January 23, 1991 relative to the movement and use of the HDR unit.

The Chairman of the RSC, Thomas M. Herskovic, M.D., during a January 23, 1991 telephone conversation with an NRC inspector, inquired regarding the need for a license amendment before moving the HDR unit, but did not inform the inspector that the hospital had already moved and used the HDR unit at the new location. In a signed and sworn statement provided to an OI investigator on March 21, 1991, Dr. Herskovic admitted that he was not straightforward with that inspector by failing to volunteer that information. In addition, in a subsequent telephone conversation on January 23, 1991, with an NRC supervisor and a second NRC inspector, Dr. Herskovic admitted that the HDR unit had been moved, but in response to a question concerning whether the unit was used on patients after it was moved, stated, "No, the unit was never used on patients at the new location." Dr. Herskovic stated to a third inspector during the January 1991 NRC inspection that the unit had in fact been used on patients after it had been moved. While Dr. Herskovic denied, in his March 21, 1991 statement and at the enforcement conference on October 18, 1991, having said that the unit was "never used on patients at its new location," both the NRC supervisor and inspector affirm that this statement was in fact made.

Dr. Herskovic was the Licensee official responsible for compliance with NRC requirements. This responsibility included decisions as to movement of the HDR unit. Nonetheless, even though he was unsure as to whether the unit could be moved without a license amendment, he failed to carry out his duties and acted with careless disregard for regulatory requirements by directing that the unit be moved without further checking of the requirements and then giving false information to the NRC.

IV

A License to use radioactive material is a privilege that confers upon the Licensee, its officials and its 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, will be accurate and forthright in providing information so that the NRC may ensure that the use of licensed materials does not endanger public health and safety. This includes ensuring that all information provided to the NRC, either orally or in writing, as well as the creation of all records of performance of activities required by the License or NRC regulations, are complete and accurate in all material respects. The NRC relies on the integrity of individuals involved in licensed activities to ensure compliance with the conditions of the License and other regulatory requirements. Dr. Herskovic's willful failure to reveal to the NRC inspector during the first telephone conversation on January 23, 1991, that the HDR unit had been moved and used at a

new location, and then providing inaccurate information to the NRC during the second conversation that date by stating that the unit had not been used at the new location and his willfully authorizing movement of the HDR unit without NRC approval, raise serious questions concerning whether Dr. Herskovic will ensure compliance with those requirements while performing licensed activities at the facility. Although the Licensee subsequently replaced Dr. Herskovic as the Radiation Safety Officer, pursuant to a commitment (documented in January 25, 1991, Confirmatory Action Letter) to submit an amendment to the NRC, naming a qualified RSO, Dr. Herskovic is still the Chairman of the RSC at the facility, and is also listed on the License as an authorized user of licensed material. Therefore, I have determined that the public health and safety require that Dr. Herskovic should not be in such critical oversight positions as the Radiation Safety Officer or a member of the RSC.

V

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 (56 FR 40664, (August 15, 1991)) and 10 CFR Part 30, IT IS HEREBY ORDERED THAT LICENSE NO. 29-10191-02 IS MODIFIED AS FOLLOWS:

For a period of three years from the date of this Order, Thomas M. Herskovic, M.D. may not be appointed, or act, as the Radiation Safety Officer or serve on the Radiation Safety

Committee.

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

VI

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 under oath or affirmation, and may request a hearing on this Order, within 30 days of the date of this Order. The answer may consent to the Order and the person so consenting is not required to include in its answer the matters set forth below. Otherwise, the answer shall in writing, under oath or affirmation, specifically admit or deny each allegation or charge made in the Order, and 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 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 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 answer or hearing request is by a person other than the Licensee. If a person other than the Licensee or Dr. Herskovic 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, Dr. Herskovic, 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 should be sustained.

In the absence of any request for a hearing, the provisions specified in Section V above shall be final 30 days from the date of this Order without further order or proceedings.

VII

In addition to the issuance of this Order Modifying License No. 29-10191-02, the Commission requires further information to determine whether it can have reasonable assurance that in the future the Licensee will provide complete and accurate information to the Commission, and otherwise conduct its activities in accordance with the Commission's requirements, while Dr. Herskovic remains as an authorized user of licensed material.

Accordingly, pursuant to Sections 161c, 161o, 182 and 186 of the Atomic Energy Act of 1954, as amended, 10 CFR 2.204, (56 FR 40664 (August 15, 1991)) and 10 CFR 30.32(b), in order for the Commission to determine whether the 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 Demand for Information, the following information, in writing and under oath or affirmation:

> An explanation as to why Thomas M. Herskovic, M.D., should not be precluded from any involvement in NRC licensed activities under this License for a period of three years, including acting as an authorized user, or under the supervision of an authorized user.

Dr. Herskovic may, also, file a written answer to the Demand for Information within 30 days of the date of this Demand.

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.

After reviewing the Licensee's response, the NRC will determine whether further action is necessary to ensure compliance with regulatory requirements.

FOR THE NUCLEAR REGULATORY COMMISSION

James Lieberman, Director
Office of Enforcement

Dated at Rockville, Maryland
this 3rd day of December 1991

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

March 22, 1991

Dockets Nos. 30-02764, 30-20526
and 40-02678
Licenses Nos. 34-06903-05, 34-06903-13,
and SUD-265
EA 91-001

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 45267-0663

Gentlemen:

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY - $8,750
(NRC INSPECTION REPORT NOS. 030-02764/91001; 030-20526/91001; AND
040-02678/91001)

This refers to the safety inspection at the University of Cincinnati, conducted during the period of November 26 through December 27, 1990, of activities authorized by NRC Licenses No. 34-06903-05, 34-06903-09, 34-06903-11, 34-06903-13, SNM-490, and SUD-265. During the inspection, violations of NRC requirements were identified, and on January 25, 1991, an Enforcement Conference was held in the Region III office between you and members of your staff, and Mr. A. Bert Davis and members of the NRC staff. A copy of the Enforcement Conference report was mailed to you on February 13, 1991.

During the inspection, numerous violations, which are described in the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice), were identified and include the failure to: (a) monitor the amounts of licensed material possessed by the University of Cincinnati; (b) ensure that hourly burn limits for radioactive material incineration were not exceeded; (c) evaluate the gross quantity of licensed material discharged into the sanitary sewer system; (d) properly instruct the incinerator operator in incineration of radioactive materials and other ancillary staff members in the handling of radioactive materials; and (e) audit research laboratories at required intervals. The remaining violations concerned a broad spectrum of failures to properly implement license conditions and to follow NRC regulations. One apparent violation noted in the inspection report involved failure to perform thyroid bioassays, or other adequate evaluations, to determine the possible exposure of technologists who administered volatile iodine-131 to patients. Upon further consideration of the requirement to perform evaluations in 10 CFR 20.201(b),

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

the bioassay requirement in 10 CFR 35.315(c)(8), and the amount of iodine-131 involved, NRC is not issuing a citation in this matter.

Considered collectively, the violations described in the Notice represent a failure to completely correct a breakdown in the control of several significant aspects of the radiation safety program at the University of Cincinnati. These issues were part of a previous enforcement actior (EA 90-40, July 2, 1990). That enforcement action arose out of the violations identified in 1989. Therefore, in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy) 10 CFR Part 2, Appendix C (1990), the violations are classified in the aggregate as a Severity Level III problem. The root causes of the violations include senior management's failure to broadly focus corrective actions for previously identified problems, failure to promptly address all programmatic concerns, and failure to provide sufficient Radiation Safety Office staff.

In the NRC's July 2, 1990 enforcement action resulting from our 1989 inspection, we decided to support the initiatives of University management by not proposing a civil monetary penalty. While the University management has made progress since that time, it has not been fully effective in taking comprehensive, timely, and lasting corrective actions. This is evidenced by the fact that nine of the present violations also had been identifieo during the 1989 inspection, and by the numerous violations and ongoing programmatic weaknesses identified during the current 1990 NRC inspection. These programmatic weaknesses include: (a) continued problems in the inventory and accounting of radioactive materials, (b) an ineffective personnel dosimetry program, and (c) insufficient staffing of the Radiation Safety Office. It is essential that the University of Cincinnati implement effective corrective actions and program improvements to address not only the specific violations described in the enclosed Notice but also the degree of management control and attention necessary to assure overall adherence to NRC requirements and license conditions.

The University of Cincinnati responded to the Enforcement Conferenc Report by letter dated February 21, 1991. We considered that information du.ing our deliberations. However, to emphasize the need for strict adherence to NRC requirements and the implementation of timely, effective, and lasting corrective actions, 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 $8,750 for the Severity Level III problem.

The base value of a civil penalty for a Severity Level III problem is $2,500. The adjustment factors in the Enforcement Policy were considered and the amount of the base civil penalty was increased 250 percent. The amount of the base civil penalty was increased 50 percent because, although you were generally aware of deficiencies in your program, these had not all been corrected, and a significant number of the violations were identified by the NRC. The amount of the civil penalty was increased an additional 100 percent due to the past

poor performance of the University of Cincinnati in managing the NRC licensed program. Past poor performance is evidenced by the fact that NRC, in the July 2, 1990 enforcement action, issued a citation for a Severity Level II problem concerning a breakdown in management control over the University's radiation safety program. As already explained, many of the currently identified violations are repetitions of problems which resulted in that enforcement action. The amount of the civil penalty was further increased 100 percent due to the duration of the problem concerning lack of adequate control of licensed activities and because many of the specific violations, including the more safety significant violations associated with the inventory of radioactive materials, the disposal of radioactive wastes through the sanitary sewers, and personnel dosimetry, have existed for periods in excess of one year. This, coupled with the University of Cincinnati management's general awareness of these problems for a similar period, was considered in escalating for duration. The University of Cincinnati has initiated adequate corrective actions in response to the specific violations; however, we have determined that mitigation of the civil penalty for your corrective actions would be inappropriate considering that your long-term corrective actions are continuations of the corrective actions that were initiated in response to EA 90-40 but were not adequately implemented at the time of the recent inspection. The remaining factors in the Enforcement Policy were also considered and no further adjustment to the base civil penalty is considered appropriate.

During the Enforcement Conference, you described the actions you have taken to correct the specified violations. However, you are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. In addition, we request that you develop and submit with your response to the specific violations, a Radiation Safety Improvement Plan, suitable for incorporation into the terms and conditions of your license, that addresses those actions necessary to ensure timely and lasting improvement in the radiation safety program. The Plan should address the management and staffing of the program, and improvements needed in procedures and practices to achieve and maintain compliance with NRC requirements and license conditions. The Plan should also address any periodic internal or external audits you plan to implement to assess your program effectiveness. Finally, the Plan should include schedules for completion of all actions described therein. Interim milestones should be included for the more complex actions.

After reviewing your response to this letter and Notice, including your proposed corrective actions, the Radiation Safety Improvement Plan, 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:
DCD/DCB (RIDS)
State of Ohio
J. Lieberman, Director
Office of Enforcement

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

University of Cincinnati
Cincinnati, Ohio

Dockets Nos. 30-02764; 30-20526; and 40-02678
Licenses Nos. 34-06903-05; 34-06903-13; and SUD-265

EA 90-001

During an NRC inspection conducted on November 26 through December 27, 1990, 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 (1990), 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 No. 34-06903-05

1. License Condition No. 20 requires the licensee to conduct its program in accordance with the statements, representations, and procedures contained in a letter dated April 11, 1986.

   Item 6 of the letter states that "We continuously monitor amounts of radioactive material in possession of the University when we examine and total...the amounts of radioactivity released into the sewage, incinerated, and/or shipped in drums for disposal."

   Contrary to the above, the licensee did not continuously monitor amounts of licensed material possessed by the University, because as of December 27, 1990, authorized user inventory data was not complete and the licensee had incomplete sewer disposal information.

   This is a repeat violation.

2. License Condition No. 20 requires the licensee to conduct its program in accordance with the statements, representations, and procedures contained in an application dated August 13, 1984, including the attachment dated August 9, 1984.

   Item 14, of the August 9, 1984 attachment states that incinerator personnel have a list of isotopes and maximum quantities which they may incinerate and are given specific limits for each radionuclide which may be incinerated. The licensee's "incinerator burning limits"

list limits the hourly incinerator burn limits for I-125 and I-129 to 0.19 microcuries and 0.08 microcuries, respectively.

Contrary to the above, licensee incinerator personnel incinerated licensed materials in excess of hourly incinerator burn limits on several occasions in 1990. Specifically, an average of 3.3 microcuries of I-125 was burned per hour on January 2 and an average of 3.3 microcuries of I-125 was burned per hour on May 1, 1990. In addition, on February 16, 1990, an average of 0.63 microcuries of I-125 was burned per hour and on May 1, 1990, an average of 0.63 microcuries of I-129 was burned per hour.

3. 10 CFR 20.201(b) requires that each licensee make such surveys as may be necessary to comply with the requirements of Part 20 and which are reasonable under the circumstances to evaluate the extent of radiation hazards that may be present. As defined in 10 CFR 20.201(a), "survey" means an evaluation of the radiation hazards incident to the production, use, release, disposal, or presence of radioactive materials or other sources of radiation under a specific set of conditions.

   Contrary to the above, the licensee did not make surveys to assure compliance with 10 CFR 20.303, which limits the daily, monthly and annual quantity of licensed material which may be disposed of by release into a sanitary sewerage system. Specifically, as of December 27, 1990, the licensee did not make surveys necessary to comply with daily and monthly sanitary sewerage disposal limits since approximately 50% of 250 authorized users had not reported 1990 sanitary sewer disposal information to the Radiation Safety Office.

4. License Condition No. 20 requires the licensee to conduct its program in accordance with the statements, representations, and procedures contained in a letter dated April 11, 1986.

   Item 9(a) of the April 11, 1986 letter requires that laboratories be surveyed with a wipe test at least monthly when less than millicurie amounts of "unsealed" radionuclides are used and weekly when millicurie amounts are used.

   Contrary to the above, research laboratory surveys (wipe tests) have not, in all cases, been performed at the required frequencies, as evidenced by the following examples:

   a. Crosley Building Room No. 1406, where microcurie quantities of unsealed C-14 were used on at least a monthly basis from September 1989 to December 1990, was not wipe tested during that time.

   b. Crosley Building Rooms No. 300 and 309, where millicurie quantities of unsealed Tc-99 and Tc-99m were used on a weekly basis from March 1990 to December 1990, were not wipe tested weekly on at least ten occasions during this period.

c. Crosley Building Room No. 1307, where microcurie quantities of unsealed C-14 were used in June and October 1990, was not wipe tested during either of these two months of use.

d. Medical Sciences Building Room No. 6205, where millicurie quantities of unsealed S-35 were used on October 4 and 11, 1990, was not wipe tested during that month.

This is a repeat violation.

5. License Condition No. 20 requires the licensee to conduct its program in accordance with the statements, representations, and procedures contained in the letter dated April 11, 1986.

Item 9(d) of the April 11, 1986 letter requires that all nuclear medicine elution, preparation and routine injection areas be surveyed daily with an appropriate meter.

Contrary to the above, the licensee failed to survey the nuclear medicine preparation and injection areas at the Children's Hospital Medical Center (CHMC) between April 27, 1990 and May 15, 1990, and between July 26, 1990 and August 8, 1990, and on five other occasions between August 9, 1990 and December 14, 1990.

This is a repeat violation.

6. 10 CFR 20.201(b) requires that each licensee make such surveys as may be necessary to comply with all sections of Part 20. As defined in 10 CFR 20.201(a), "survey" means an evaluation of the radiation hazards incident to the production, use, release, disposal, or presence of radioactive materials or other sources of radiation under a specific set of conditions.

Contrary to the above, as of December 14, 1990, the licensee had not made evaluations (surveys) to assure compliance with 10 CFR 20.101(a), which limits the radiation exposure to the whole body and extremities. Specifically, radiation exposure evaluations were not made for the exposure period August 1-30, 1990 to evaluate the radiation exposure of at least 30 research laboratory workers who failed to submit their whole body and extremity personnel monitoring devices for vendor processing.

This is a repeat violation.

7. 10 CFR 19.12 requires, in part, that all individuals working in a restricted area be instructed in the precautions and procedures to minimize exposure to radioactive materials, in the purpose and functions of protective devices employed, and in the applicable provisions of the Commission's regulations and licenses.

Contrary to the above, individuals who were working in restricted areas, had not been nstructed in the precautions and procedures to minimize exposure, and the applicable provisions of the Commission's regulations and licenses. Specifically, as of December 4, 1990, two Central Pharmacy employees and nine Grounds and Transportation Department employees were not instructed in the health protection problems associated with exposure to radioactive materials or the precautions or procedures to minimize exposure; and the two Pharmacy employees worked in the radioactive material package receipt/storage area, a restricted area, and the nine Grounds employees routinely frequented restricted areas in the performance of their duties.

8. License Condition No. 20 requires the licensee to conduct its program in accordance with the statements, representations, and procedures contained in a letter dated April 11, 1986.

Item 8 of the April 11, 1986 letter requires that incinerator operators be instructed in the proper way to record amounts of radioactive material incinerated and be given specific limits for each radionuclide which may be incinerated, and that this training and retraining (if necessary) be available as required.

Contrary to the above, as of November 27, 1990, the individual who conducted incinerator operations in early 1990 was not adequately instructed to ensure that radioactive burn limits were not exceeded.

9. 10 CFR 71.5(a) requires, in part, that licensees who transport licensed material outside of the confines of their plant comply with the applicable requirements of the regulations appropriate to the mode of transport of the Department of Transportation (DOT) in 49 CFR Parts 170 through 189.

49 CFR 177.817(a) requires that a carrier not transport a hazardous material unless it is accompanied by a shipping paper that is prepared in accordance with Subsections 200 through 203 of 49 CFR Part 172. Pursuant to 49 CFR 172.101, radioactive material is classified as a hazardous material.

49 CFR 172.203(d) requires that the shipping paper for a shipment of radioactive material include the name of the radionuclide, a description of the physical and chemical form of the material and the activity contained in each package in terms of curies, millicuries, or microcuries.

Contrary to the above, on December 11, 1990, licensee personnel transported a package containing approximately 65 millicuries of Mo-99/Tc-99m via motor vehicle on a public roadway from the radiation safety office to a west campus laboratory and the package was not accompanied by a properly completed shipping paper. Specifically, the shipping paper did not include the activity contained in the package and the physical or chemical form of the material transported.

10. License Condition No. 20 requires that the licensee conduct its program in accordance with statements, representations, and procedures contained in a letter dated May 17, 1990.

    The May 17, 1990 letter, with enclosure, requires the Radiation Safety Officer, through the Radiation Safety Office staff, to conduct audits on a semi-annual schedule of each laboratory or area authorized for use of licensed material.

    Contrary to the above, from June 14, 1990 through December 31, 1990, the Radiation Safety Office staff did not audit approximately 50% of the 700 laboratories or areas where radioactive material is authorized for use.

11. License Condition No. 12.C requires, in part, that each source containing licensed material designed for the purpose of emitting alpha particles be leak tested at intervals not to exceed three months.

    Contrary to the above, sources containing licensed material designed for the purpose of emitting alpha particles have not been leak tested at intervals not to exceed 3 months. Specifically, eight americium-241 foil sources, each with a nominal activity of 20 microcuries, were not leak tested between November 29, 1989 and December 14, 1990. Additionally, a nominal 80 microcurie americium-241 foil source was not leak tested between March 29, 1990 and August 20, 1990.

    This is a repeat violation.

12. 10 CFR 35.50(b)(1) requires, in part, that the licensee check each dose calibrator for constancy with a dedicated check source at the beginning of each day of use and that the check be done on a frequently used setting.

    Contrary to the above, on at least 8 days of use between June 16 and November 24, 1990, the licensee did not check the dose calibrator for constancy at the Children's Hospital Medical Center.

    This is a repeat violation.

13. 10 CFR 19.13(c) requires, in part, that, at the request of a worker formerly engaged in licensed activities controlled by the licensee, the licensee furnish to the worker a report of the worker's exposure to radiation. The report shall be furnished within 30 days from the time the request is made, or within 30 days after the exposure of the individual has been determined by the licensee, whichever is later.

    Contrary to the above, as of December 14, 1990, the licensee failed to furnish, within 30 days from the time the request was made, or within 30 days after the exposure of the individual had been determined by the licensee, reports of workers' exposure to radiation for

six individuals who had requested these reports and who formerly engaged in licensed activities controlled by the licensee during the period 1989 and 1990.

14. License Condition No. 20 requires the licensee to conduct its program in accordance with the statements, representations, and procedures contained in an application dated August 13, 1984, including an attachment dated August 9, 1984.

Appendix D of the August 9, 1984 attachment, entitled "General Laboratory Rules and Procedures," prohibits eating, drinking, smoking, use of cosmetics, and the storage of edibles in labs where radioactive materials are used or stored.

Contrary to the above, on November 29, 1990, there was evidence of drinking in Medical Sciences Building Room No. 5256, a laboratory where radioactive materials are used and stored. Additionally, on at least three occasions between June 1990 and October 1990, individuals were drinking in radioactive material use areas. Further, on November 29, 1990, food and beverages were stored in Medical Sciences Building Room No. 2058, a designated radioactive material cold storage room.

15. 10 CFR 35.406(b) requires that a licensee make a record of brachytherapy source use, including: (1) the names of the individuals permitted to handle the sources; (2) the number and activity of sources removed from storage, the patient's name and room number, the time and date they were removed from storage, the number and activity of the sources in storage after the removal, and the initials of the individuals who removed the sources from storage; (3) the number and activity of sources returned to storage, the patient's name and room number, the time and date they were returned to storage, the number and activity of sources in storage after the return, and the initials of the individual who returned the sources to storage.

Contrary to the above, as of December 14, 1990, the licensee's records of brachytherapy source use did not include all required information, as evidenced by the following examples:

a. The brachytherapy source use records for a cesium-137 implant which began on September 17, 1990 did not include: (1) the number and activity of the sources in storage after the removal, and (2) the number and activity of sources in storage after the return.

b. The brachytherapy source use records for an iodine-125 seed implant which began on August 29, 1990 did not include: (1) the number and activity of sources removed from storage, (2) the patient's room number, (3) the time and date they were removed from storage, (4) the number and activity of the sources in storage after the removal, and (5) the initials of the individual who removed the sources from storage.

c. The brachytherapy source use records for an iodine-125 seed implant which began on August 15, 1990 did not include the patient's room number. In addition, the source use record inaccurately identified the number of sources in storage after the removal.

16. 10 CFR 35.60(a) requires that the licensee keep syringes that contain byproduct material to be administered in a radiation shield.

Contrary to the above, on November 30, 1990, a syringe at Children's Hospital Medical Center that contained byproduct material to be administered was not kept in a radiation shield.

This is a repeat violation.

17. 10 CFR 35.205(d) requires, in part, that the licensee post the calculated time and safety measures to be instituted in case of a spill of radioactive gas at the area of use.

Contrary to the above, on November 30, 1990, the Xenon gas clearance time and safety measures to be instituted in case of a spill were not posted in the diagnostic imaging room, the area of use at University Hospital.

18. License Condition No. 20 requires the licensee to conduct its program in accordance with the statements, representations, and procedures contained in an application dated August 13, 1984, including an attachment dated August 9, 1984.

Item 14, "Solid Waste Incineration," of the August 9, 1984 attachment to the application requires that materials brought to the incinerator be clearly labeled as to contents.

Contrary to the above, on September 25, 1990, several bags of unspecified radioactive wastes were delivered to the incinerator for incineration and were not labeled as to contents.

This is a repeat violation.

19. 10 CFR 20.203(f) requires, in part, that, except as provided by 10 CFR 20.203(f)(3), each container of licensed material bear a durable, clearly visible label identifying the radioactive contents.

Contrary to the above, on November 29, 1990, a 55-gallon drum containing I-125 contaminated waste, a licensed material, located in Room G562 of the Medical Science Building, did not bear any label identifying the radioactive contents, and the container was not excepted from such labeling.

This is a repeat violation.

D. License No. 34-06903-13

10 CFR 20.105(b) requires that, except as authorized by the Commission, 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. As defined in 10 CFR 20.3(a)(17), an unrestricted area is any area access to which is not controlled by the licensee for purposes of protection of individuals from exposure to radiation and radioactive materials.

Contrary to the above, on December 11, 1990, the licensee allowed the creation of radiation levels in an unrestricted area such that if an individual were continuously present in the area, he could have received a dose in excess of 2 millirems in any one hour or 100 millirems in any seven consecutive days, and such levels had not been authorized by the Commission. Specifically, radiation levels of approximately 50 millirems per hour existed in unrestricted accessible areas near the source shutter region of the veterinary teletherapy unit located in the Medical Science Building Room E 357. This area was unrestricted because the door to the room was open and unlocked, licensee personnel were not in attendance, and access to the room was not controlled by the licensee.

C. License No. SUD-265

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 a survey to assure compliance with 10 CFR 20.303, which limits the disposal of licensed material by release into a sanitary sewer system. Specifically, on several occasions between January 1987 and December 1989, the licensee failed to evaluate water moderator used in the subcritical assembly prior to the disposal of the moderator via the sanitary sewer system.

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

Cumulative Civil Penalty - $8,750 (assessed equally among the 21 violations)

Pursuant to the provisions of 10 CFR 2.201, the University of Cincinnati (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 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 187 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 (1990), should be addressed. Any written answer in accordance with 10 CFR 2.205 should be set forth separately from the statement or explanation in reply pursuant to 10 CFR 2.201, but may incorporate parts of the 10 CFR 2.201 reply by specific reference (e.g., citing page and paragraph numbers) to avoid repetition. The attention of the Licensee is directed to the other provisions of 10 CFR 2.205, regarding the procedure for imposing a civil penalty.

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

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

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

FOR THE NUCLEAR REGULATORY COMMISSION

A. Bert Davis
Regional Administrator

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

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

SEP 20 1991

Dockets No. 30-02764; 30-20526;
and 40-02678
Licenses No. 34-06903-05; 34-06903-13;
and SUD-265
EA 91-001

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: ORDER IMPOSING CIVIL MONETARY PENALTY - $8,750

This refers to your letter dated May 17, 1991, in response to the Notice of Violation and Proposed Imposition of Civil Penalty (Notice) sent to you by our letter dated March 22, 1991. Our letter and Notice described 21 violations which were identified during an NRC routine safety inspection, conducted November 26 through December 27, 1990.

To emphasize the need for strict adherence to NRC requirements and the implementation of timely, effective, and lasting corrective actions, a civil penalty of $8,750 was proposed.

In your responses ("Answer to a Notice of Violation" and "Reply to a Notice of Violation"), you denied in whole 7 of the 21 violations (Violations No. A.1, A.2, A.3, A.6, A.8, A.18 and B), denied in part 3 violations (Violations No. A.4, A.7, and A.10), and admitted the remaining 11 violations. Additionally, you disagreed with the NRC position (set forth in the March 22, 1991, letter transmitting the Notice) on escalating the amount of the base civil penalty for identification and reporting (50%), past performance (100%) and duration (100%), and requested that the civil penalty be remitted in its entirety or mitigated substantially. 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

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

violations did occur (Violation A.2 is amended and example A.4.b is being withdrawn), and that an adequate basis was not provided for mitigation of the civil penalty. Accordingly, we hereby serve the enclosed Order Imposing Civil Monetary Penalty on the University of Cincinnati imposing a civil monetary penalty in the amount of $8,750. 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

Dated at Rockville, Maryland
this 24th day September 1991

Enclosures: As stated
cc w/enclosures:
DCD/DCB(RIDS)
State of Ohio

UNITED STATES
NUCLEAR REGULATORY COMMISSION

| | | |
|---|---|---|
| In the Matter of | ) | Dockets No. 30-02764; 30-20526 and 40-02678 |
| The University of Cincinnati<br>Cincinnati, Ohio | ) | Licenses No. 34-06903-05; 34-06903-13; and SUD-265 |
| | ) | EA 91-001 |

ORDER IMPOSING CIVIL MONETARY PENALTY

I

The University of Cincinnati (Licensee) is the holder of six licenses issued by the Nuclear Regulatory Commission (NRC or Commission), including:

A. License No. 34-06903-05 was first issued on June 11, 1979, was renewed on May 21, 1986, and was last amended (Amendment No. 6?) on August 3, 1990. License No. 34-06903-05 authorizes possession of: (1) radiopharmaceuticals and brachytherapy sources in quantities as needed for medical diagnosis and therapy, for use at several medical centers and hospitals affiliated with the University; (2) curie quantities of any byproduct material (with atomic numbers 3 to 83, inclusive) in any form for medical research, research and development (R&D) pursuant to 10 CFR 30.4, and student instruction, animal studies, and calibration of instruments; (3) other miscellaneous licensed material for instrument calibration and leak test analysis services for other licenses; and (4) a portable gauge for the measurement of

soil moisture, in accordance with the conditions specified therein.

B. License No. 34-06903-13 was first issued on December 6, 1983, was renewed on April 13, 1989, and was last amended (Amendment No. 9) on November 20, 1990. License No. 34-06903-13 authorizes the possession and use of cobalt-60 sealed source(s) in a teletherapy unit, in accordance with the conditions specified therein.

C. License No. SUD-265 was first issued on May 26, 1961, was renewed on September 15, 1987, and was last amended (Amendment No. 6) on June 14, 1990. License No. SUD-265 authorizes the possession and use of natural uranium in the form of cylindrical slugs in a light water moderated subcritical assembly, in accordance with the conditions specified therein.

II

An inspection of the Licensee's activities was conducted during the period of November 26 through December 27, 1990. The results of the inspection indicated that the Licensee had not conducted its activities in full compliance with NRC requirements. A written Notice of Violation and Proposed Imposition of Civil Penalty (Notice) was served upon the Licensee by letter dated

March 22, 1991. The Notice states the nature of the violations, the provisions of the NRC's requirements that the Licensee had violated, and the amount of the civil penalty proposed for the violations. The Licensee responded to the Notice by two letters dated May 17, 1991. In its responses, the Licensee denied in whole 7 of the 21 violations (Violations No. A.1, A.2, A.3, A.6, A.8, A.18 and B), denied in part 3 violations (Violations No. A.4, A.7, and A.10), and admitted the remaining 11 violations. Additionally, the licensee disagreed with the NRC position (set forth in the March 22, 1991, letter transmitting the Notice) on escalating the amount of the base civil penalty for identification and reporting (50%), past performance (100%) and duration (100%).

III

After consideration of the Licensee's responses and the statements of fact, explanation, and argument for mitigation contained therein, the NRC staff has determined, as set forth in the Appendix to this Order, that the violations did occur (Violation A.2 is amended and example A.4.b is being withdrawn) and that the $8,750 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 A t 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 $8,750 within 30 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.

V

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

If a hearing is requested, the Commission will issue an Order designating the time and place of the hearing. If the Licensee fails to request a hearing within 30 days of the date of this Order, the provisions of this Order shall be effective without

further proceedings. If payment has not been made by that time, the matter may be referred to the Attorney General for collection.

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

(A) whether the Licensee was in violation of the Commission's requirements as set forth in Violations A.1, A.2, A.3, A.4.a, c, and d, A.6, A.7, A.8, A.10, A.18, and B. in the Notice, as amended, referenced in Section II above, and

(B) whether, on the basis of such violations, and the additional violations set forth in the Notice that the Licensee admitted, this Order should be sustained.

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

Dated at Rockville, Maryland
this 20th day of September 1991

APPENDIX
EVALUATION AND CONCLUSIONS

On March 22, 1991, a Notice of Violation and Proposed Imposition of Civil Penalty (Notice) was issued for the violations identified during an NRC inspection. The University of Cincinnati responded to the Notice by letter dated May 17, 1991. In its responses, the licensee denied in whole 7 of the 21 violations (Violations No. A.1, A.2, A.3, A.6, A.8, A.18 and B), denied in part 3 violations (Violations No. A.4, A.7, and A.10), and admitted the remaining 11 violations. Additionally, the licensee disagreed with the NRC position (set forth in the March 22, 1991, letter transmitting the Notice) on escalating the amount of the base civil penalty for identification and reporting (50%), past performance (100%) and duration (100%) and requested that the civil penalty be remitted in its entirety or substantially mitigated. The NRC's evaluation and conclusion regarding the licensee's request are as follow:

I. Violations Denied in Total

Restatement of Violation A.1

License Condition No. 20 requires the licensee to conduct its program in accordance with the statements, representations, and procedures contained in a letter dated April 11, 1986.

Item 6 of the letter states that "We continuously monitor amounts of radioactive material in possession of the University when we examine and total . . . the amounts of radioactivity released into the sewage, incinerated, and/or shipped in drums for disposal."

Contrary to the above, the licensee did not continuously monitor amounts of licensed material possessed by the University, because as of December 27, 1990, authorized user inventory data was not complete and the licensee had incomplete sewer disposal information.

This is a repeat violation.

Summary of Licensee's Response to Violation A.1

The licensee denies this violation and states that Item 6 of the referenced letter dated April 11, 1986 does not promise that the University will compile cumulative inventory and sewer disposal data for each day in a year. The licensee contends that although monitoring is continuous, cumulative data is only compiled on a quarterly basis. According to the licensee, inventory data compiled on January 15, 1991, confirmed that license possession limits were met. The licensee also contends that its system has been in effect and accepted by the NRC during numerous prior inspections.

NRC Evaluation of Licensee's Response to Violation A.1

Item 6 of the referenced letter dated April 11, 1986, quoted without ellipsis, states: "We continuously monitor amounts of radioactive material in possession of the University when we examine and total (as required by NRC regulations) the amounts of radioactivity released into the sewage, incinerated, and/or shipped in drums for disposal." [Emphasis added.] Thus the frequency of the monitoring is tied to the requirements of the NRC regulations.

Among the NRC regulations relevant here, 10 CFR 20.201(b) requires that each licensee make or cause to be made such surveys as (1) may be necessary for the licensee to comply with the regulations in this part, and (2) are reasonable under the circumstances to evaluate the extent of radiation hazards that may be present. 10 CFR 20.303 requires that no licensee discharge licensed material into a sanitary sewerage system unless the quantity of licensed material released into the system in any one day and any one month does not exceed specified limits. A quarterly compilation does not fulfill the requirement of the NRC regulations for surveys (e.g., compilations) to assure that daily and monthly disposal limits are met. Since the license condition at issue here includes the frequency schedule specified by the regulations, a quarterly compilation also does not fulfill the requirement of the license condition.

As described in Section 9(a) of Inspection Report No. 030-02764/90001(DRSS), the licensee's inventory system is conceptually inadequate because it is incapable of yielding cumulative institutional quantities of licensed material possessed at any given time (i.e., continuously). This is because the system employed by the licensee provides an inventory snapshot of licensed material possessed on only one day of a given calendar quarter (i.e., the day the quarterly compilation is performed).

Furthermore, about 50% of the authorized users failed to provide timely radioactive material disposal data to the radiation safety office for 1990. Consequently, not only is the licensee's material inventory and accountability system incapable of monitoring amounts of radioactive material disposed via the sewer system on a daily or monthly basis as required by 10 CFR 20.303, but also the quarterly data compilation system was not adequately implemented because necessary disposal data from individual authorized users was incomplete. Without the necessary information, the licensee is not capable of monitoring its annual discharges, much less compiling quarterly totals of licensed material possessed by the University.

Contrary to the licensee's assertion, the licensee did have prior notice that NRC found its inventory system unacceptable. As described in Inspection Report No. 030-02764/89002(DRSS), the licensee and its consultant performed an audit of the University's NRC-licensed program in 1989. The audit revealed that the University did not adequately determine quantities of licensed material possessed. The methods employed by the licensee were inadequate in that (1) accurate inventory/disposal records were not maintained by individual researchers and (2) researchers routinely forwarded disposal records to the radiation safety office long after (up to 2 years) the disposals were actually made. Field audits conducted by a licensee consultant identified that 23% of the 677 labs audited did not maintain running inventories. As a result of these 1989 audit findings, NRC concluded the licensee violated License Condition No. 20, which references the letter dated April 11, 1986. NRC incorporated this violation into a Notice issued July 2, 1990 (EA 90-40).

Restatement of Violation A.2

License Condition No. 20 requires the licensee to conduct its program in accordance with the statements, representations, and procedures contained in an application dated August 13, 1984, including the attachment dated August 9, 1984.

Item 14, of the August 9, 1984, attachment states that incinerator personnel have a list of isotopes and maximum quantities which they may incinerate and are given specific limits for each radionuclide which may be incinerated. The licensee's "incinerator burning limits" list limits the hourly incinerator burn limits for I-125 and I-129 to 0.19 microcuries and 0.08 microcuries, respectively.

Contrary to the above, licensee incinerator personnel incinerated licensed materials in excess of hourly incinerator burn limits on several occasions in 1990. Specifically, an average of 3.3 microcuries of I-125 was burned per hour on January 2 and an average of 3.3 microcuries of I-125 was burned per hour on May 1, 1990. In addition, on February 16, 1990, an average of 0.63 microcuries of I-125 was burned per hour and on May 1, 1990, an average of 0.63 microcuries of I-129 was burned per hour.

Summary of Licensee's Response to Violation A.2

The licensee denies this violation and states that its NRC license does not limit the incineration of radioactive materials to an hourly value. License Condition 19 states

that the University is "authorized to dispose of isotopes specified in item 14 of application dated August 9, 1984 by incineration, provided gaseous effluents from incineration do not exceed the limits specified for air in Appendix B, Table II, 10 CFR 20." The licensee points out that no reference is made in 10 CFR 20 requiring hourly averaging of concentrations.

The licensee also contends that Item 14 of the August 9, 1984 attachment to the application dated August 23, 1984 was incompletely stated in the violation. According to the licensee, the balance of the Item 14 statement makes clear that the hourly burn limit is a guideline to ensure that license limits are not exceeded.

NRC Evaluation of Licensee's Response to Violation A.2

The NRC agrees that License Condition No. 19 authorizes the licensee to dispose of isotopes specified in Item 14 of application dated August 9, 1984, by incineration provided the gaseous effluents from incineration do not exceed the limits specified for air in Appendix B, Table II, 10 CFR Part 20. The NRC also agrees that hourly averaging of effluent concentrations is not required by 10 CFR Part 20 and that 10 CFR 20.106(a) allows effluent concentrations to be averaged over a period not greater than 1 year. However, License Condition No. 20 requires the licensee to conduct its program in accordance with the statements, representations, and procedures contained in an application dated August 13, 1984, including the attachment dated August 9, 1984, and the letter dated April 11, 1986. License Condition No. 20 also clearly states, "The Nuclear Regulatory Commission's regulations shall govern unless the statements, representations and procedures in the licensee's application and correspondence are more restrictive than the regulations." [Emphasis added.]

Item 14 of the August 9, 1984 attachment to the August 23, 1984 application states, in part, that incinerator personnel have a list of isotopes and maximum quantities which they may incinerate. The letter dated April 11, 1986 states that incinerator operators are given specific limits for each radionuclide which may be incinerated. Neither passage specifies or suggests that the list of isotopes and maximum quantities which incinerator personnel may incinerate are guidelines and need not to be met.

As restated below, Violation A.2. is corrected to clarify that the licensee's April 11, 1986 letter is the origin of the requirement regarding specific limits for each radionuclide which may be incinerated.

License Condition No. 20 requires the licensee to conduct its program in accordance with the statements, representations, and procedures contained in an application dated August 13, 1984, including the attachment dated August 9, 1984, and a letter dated April 11, 1986.

Item 14, of the August 9, 1984, attachment states that incinerator personnel have a list of isotopes and maximum quantities which they may incinerate. The letter dated April 11, 1986 states that incinerator operators are given specific limits for each radionuclide which may be incinerated. The licensee's "incinerator burning limits" list limits the hourly incinerator burn limits for I-125 and I-129 to 0.19 microcuries and 0.08 microcuries, respectively.

Contrary to the above, licensee incinerator personnel incinerated licensed materials in excess of hourly incinerator burn limits on several occasions in 1990. Specifically, an average of 3.3 microcuries of I-125 was burned per hour on January 2 and an average of 3.3 microcuries of I-125 was burned per hour on May 1, 1990. In addition, on February 16, 1990, an average of 0.83 microcuries of I-125 was burned per hour and on May 1, 1990, an average of 0.63 microcuries of I-129 was burned per hour.

Restatement of Violation A.1

10 CFR 20.201(b) requires that each licensee make such surveys as may be necessary to comply with the requirements of Part 20 and which are reasonable under the circumstances to evaluate the extent of radiation hazards that may be present. As defined in 10 CFR 20.201(a), "survey" means an evaluation of the radiation hazards incident to the production, use, release, disposal, or presence of radioactive materials or other sources of radiation under a specific set of conditions.

Contrary to the above, the licensee did not make surveys to assure compliance with 10 CFR 20.303, which limits the daily, monthly and annual quantity of licensed material which may be disposed of by release into a sanitary sewerage system. Specifically, as of December 27, 1990, the licensee did not make surveys necessary to comply with daily and monthly sanitary sewerage disposal limits since approximately 50% of 250 authorized users had not reported 1990 sanitary sewer disposal information to the Radiation Safety Office.

Summary of Licensee's Response to Violation A.3

The licensee denies this violation and states that due to the large volume of sewage released daily by the University, it is impossible for the licensee to exceed the daily or monthly concentration limits in Part 20. The licensee implies that this obviates the need for the survey since 10 CFR 20.201 only requires such surveys as may be necessary to comply with the requirements of Part 20. The licensee's response specifies the daily sewage volume released by the University and the quantity (activity) of various isotopes it could dispose into the sewage system and satisfy 10 CFR 20.303 concentration limits. The licensee states, "the fact that 50% of 250 authorized users had not reported sewer disposal as of December 27, 1990 is irrelevant."

NRC Evaluation of Licensee's Response to Violation A.3

10 CFR 20.201(b) requires surveys (evaluations) as may be necessary to comply with the requirements of Part 20. As of the last day of the NRC site inspection, December 27, 1990, the licensee had not performed an evaluation to demonstrate compliance with 10 CFR 20.303, which limits the daily, monthly, and annual quantity of licensed material which may be disposed of by release into the sanitary sewerage system. The violation was issued because the evaluation had not been performed. The fact that the licensee subsequently performed the evaluation and demonstrated that it had been in compliance with the release limits does not change the fact that the violation occurred.

Further, 10 CFR 20.303(d) limits the gross quantity of all licensed material released into the sanitary sewerage system to one curie per year (excluding tritium and carbon-14 which cannot exceed five curies and one curie per year, respectively) regardless of the sewage release rate. Thus, the licensee's very large sewage release rate is not the controlling factor and does not obviate the need for the evaluation.

The licensee contends that it is irrelevant that 50% of authorized users had not reported sewer disposal information as of December 27, 1990. However, complete and timely authorized user disposal data is necessary to evaluate the annual gross quantity of licensed material discharged into the sanitary sewerage system to ensure compliance with 10 CFR 20.303(d). Absent timely and continual monitoring of authorized user sewer disposal data, the licensee would be unaware of its 10 CFR 20.303(d) compliance status until the data was summed at the end of the year. As a result, sewer disposal limits could be unknowingly exceeded sometime during a given year. The licensee should be well aware of

this problem since, as reported in Inspection Report No. 030-02764/89002(DRSS), this actually did occur in 1986.

Restatement of Violation A.6

10 CFR 20.201(b) requires that each licensee make such surveys as may be necessary to comply with all sections of Part 20. As defined in 10 CFR 20.201(a), "survey" means an evaluation of the radiation hazards incident to the production, use, release, disposal, or presence of radioactive materials or other sources of radiation under a specific set of conditions.

Contrary to the above, as of December 14, 1990, the licensee had not made evaluations (surveys) to assure compliance with 10 CFR 20.101(a), which limits the radiation exposure to the whole body and extremities. Specifically, radiation exposure evaluations were not made for the exposure period August 1-30, 1990, to evaluate the radiation exposure of at least 30 research laboratory workers who failed to submit their whole body and extremity personnel monitoring devices for vendor processing.

This is a repeat violation.

Summary of Licensee's Response to Violation A.6

The licensee denies the violation and contends that its experience from documented radiation exposure reports confirms that exposure to research laboratory personnel is minimal and, therefore, these individuals are not required to wear personnel dosimetry devices pursuant to 10 CFR 20.202. Thus, the licensee contends that deficiencies in evaluating personnel dosimetry devices for research personnel are irrelevant.

NRC Evaluation of Licensee's Response to Violation A.6

In effect, the licensee claims that it has very low radiation exposure reports from the previous film badges worn by the researchers in question, and that these reports constitute the licensee's survey or evaluation to show that personnel monitoring equipment is not required for these individuals pursuant to with 10 CFR 20.202(a)(1). This would be acceptable if the licensee, at that time, had had assurance, by way of administrative controls or by means of evaluations, that the licensed activities performed by the individuals in question had not changed during the period in which they failed to submit their dosimetry devices for processing. However, licensee personnel informed the inspector at the time of the inspection that this was not the case, and the licensee has provided no new information

to show that such administrative controls or evaluations were in fact in place at that time.

Restatement of Violation A.8

License Condition No. 20 requires the licensee to conduct its program in accordance with the statements, representations, and procedures contained in a letter dated April 11, 1986.

Item 8 of the April 11, 1986 letter requires that incinerator operators be instructed in the proper way to record amounts of radioactive material incinerated and be given specific limits for each radionuclide which may be incinerated, and that this training and retraining (if necessary) be available as required.

Contrary to the above, as of November 27, 1990, the individual who conducted incinerator operations in early 1990 was not adequately instructed to ensure that radioactive burn limits were not exceeded.

Summary of Licensee's Response to Violation A.8

The licensee denies the violation and states that the incinerator operator was adequately instructed in his responsibilities. The licensee states that it provided initial training and that the radiation safety office reviewed the incinerator operator's procedures during 1990.

NRC Evaluation of Licensee's Response to Violation A.8

Section 6 of Inspection Report No. 030-02764/90001(DRSS), states: "The incinerator operator stated during inspector interviews that he was confused and unsure of his responsibilities for radioactive material incineration." Had the operator been adequately instructed, and had the necessary retraining been provided, he would not have been confused and would not have incinerated amounts of radioactive material in excess of specific limits provided to him.

Restatement of Violation A.18

License Condition No. 20 requires the licensee to conduct its program in accordance with the statements, representations, and procedures contained in an application dated August 13, 1984, including an attachment dated August 9, 1984.

Item 14, "Solid Waste Incineration," of the August 9, 1984 attachment to the application requires that materials

brought to the incinerator be clearly labeled as to contents.

Contrary to the above, on September 25, 1990, several bags of unspecified radioactive wastes were delivered to the incinerator for incineration and were not labeled as to contents.

This is a repeat violation.

Summary of Licensee's Response to Violation A.18

The licensee denies the violation and states that the bags were believed to be correctly labeled when placed into the freezer and the labels fell off during storage.

NRC Evaluation of Licensee's Response to Violation A.18

Item 14 of the August 9, 1984 attachment to the application requires that materials brought to the incinerator, not the freezer, be clearly labeled as to contents. If the labels fell off during storage, it was the licensee's responsibility to ensure that the bags were properly relabeled.

Restatement of Violation B

10 CFR 20.105(b) requires that, except as authorized by the Commission, 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. As defined in 10 CFR 20.3(a)(17), an unrestricted area is any area access to which is not controlled by the licensee for purposes of protection of individuals from exposure to radiation and radioactive materials.

Contrary to the above, on December 11, 1990, the licensee allowed the creation of radiation levels in an unrestricted area such that if an individual were continuously present in the area, he could have received a dose in excess of 2 millirems in any one hour or 100 millirems in any seven consecutive days, and such levels had not been authorized by the Commission. Specifically, radiation levels of approximately 50 millirems per hour existed in unrestricted accessible areas near the source shutter region of the veterinary teletherapy unit located in the Medical Science Building Room E 357. This area was unrestricted because the door to the room was open and unlocked, licensee personnel were not in attendance, and access to the room was not controlled by the licensee.

Summary of Licensee's Response to Violation B

The licensee denies the violation. The licensee contends that Medical Science Building Room E357 is a restricted area because the door to the room is labeled "Caution Radiation Area" and the door to the outer area is labeled "Authorized Personnel Only". The licensee also contends that NRC staff previously indicated that a "Caution Radiation Area" sign was sufficient for designating a restricted area.

NRC Evaluation of Licensee's Response to Violation B

As defined in 10 CFR 20.3(a)(14), a restricted area is any area access to which is controlled by the licensee for purposes of protection of individuals from exposure to radiation and radioactive materials. Conversely, as defined in 10 CFR 20.3(a)(17), an unrestricted area is any area access to which is not controlled by the licensee for purposes of protection of individuals from exposure to radiation and radioactive materials. While a "Caution Radiation Area" sign fulfills the requirement of 10 CFR 20.203(b), the mere posting of precautionary signs on a door does not ensure that individuals will not enter the area and therefore does not define an area as either restricted or unrestricted. Positive access control can only be achieved by mechanical means such as locking the area or by the presence of licensee personnel who have been instructed to control access.

As stated in Section 23 of Inspection Report No. 030-02764/90001(DRSS), the inspectors observed the outer area door ajar and the door to the teletherapy unit irradiation area also ajar with the key to the treatment room door in the door lock. Both areas were unattended. Furthermore, the key to operate the teletherapy unit and expose the source was on the key ring attached to the room key. In this instance, in the absence of positive access control, the area in question was, at that time, an unrestricted area.

II. Violations Denied in Part

Restatement of Violation A.4

License Condition No. 20 requires the licensee to conduct its program in accordance with the statements, representations, and procedures contained in a letter dated April 11, 1986.

Item 9(a) of the April 11, 1986 letter requires that laboratories be surveyed with a wipe test at least monthly when less than millicurie amounts of "unsealed"

radionuclides are used and weekly when millicurie amounts are used.

Contrary to the above, research laboratory survey (wipe tests) have not, in all cases, been performed at the required frequencies, as evidenced by the following examples:

a. Crosley Building Room No. 1406, where microcurie quantities of unsealed C-14 were used on at least a monthly basis from September 1989 to December 1990, was not wipe tested during that time.

b. Crosley Building Rooms No. 300 and 309, where millicurie quantities of unsealed Tc-99 and Tc-99m were used on a weekly basis from March 1990 to December 1990, were not wipe tested weekly on at least ten occasions during this period.

c. Crosley Building Room No. 1307, where microcurie quantities of unsealed C-14 were used in June and October 1990, was not wipe tested during either of these two months of use.

d. Medical Sciences Building Room No. 6205, where millicurie quantities of unsealed S-35 were used on October 4 and 11, 1990, was not wipe tested during that month.

This is a repeat violation.

Summary of Licensee's Response to Violation A.4

The licensee denies example (a) in part and example (b) in whole and admits examples (c) and (d). In response to example (a), the licensee acknowledges that required surveys were not conducted in September and October 1990 and claims that its records show that surveys were conducted in November and December 1990 for the indicated laboratory. However, the licensee makes no response regarding the missing surveys between September 1989 and August 1990 and does not provide documentation of the claimed November and December 1990 surveys. With regard to example (b), the licensee contends that all surveys were performed as required and that the "missed" surveys were during periods of no use.

NRC Evaluation of Licensee's Response to Violation A.4

With regard to example (a), the licensee provided no documentation to support its contention that surveys were conducted in two of the months cited; therefore NRC does not

intend to amend the example at this time. In any event, example (a) is still a valid example because the licensee does not dispute that surveys were not conducted during the remaining 14 months specified in the example.

With regard to example (b), NRC is withdrawing that example based on the licensee's explanation that the "missed" surveys were during periods of no use. Violation A.4 remains a violation, however, since examples (a), (c), and (d) remain valid examples; and because the licensee admits that the wipe tests were not in all cases performed at the required frequencies.

Restatement of Violation A.7

10 CFR 19.12 requires, in part, that all individuals working in a restricted area be instructed in the precautions and procedures to minimize exposure to radioactive materials, in the purpose and functions of protective devices employed, and in the applicable provisions of the Commission's regulations and licenses.

Contrary to the above, individuals who were working in restricted areas had not been instructed in the precautions and procedures to minimize exposure, and the applicable provisions of the Commission's regulations and licenses. Specifically, as of December 4, 1990, two Central Pharmacy employees and nine Grounds and Transportation Department employees were not instructed in the health protection problems associated with exposure to radioactive materials or the precautions or procedures to minimize exposure; and the two Pharmacy employees worked in the radioactive material package receipt/storage area, a restricted area, and the nine Grounds employees routinely frequented restricted areas in the performance of their duties.

Summary of Licensee's Response to Violation A.7

The licensee denies the violation in part. Specifically, the licensee denies that one of the two Central Pharmacy employees in question was not instructed as required. The licensee admits that the nine Grounds and Transportation Department employees were not instructed as required.

NRC Evaluation of Licensee's Response to Violation A.7

As stated in Section 6.d. of Inspection Report No. 030-02764/90001(DRSS), the NRC conclusion about the two Central Pharmacy employees is based on inspector interviews. The licensee has provided no further explanation or documentation to support its position; therefore, NRC does not intend to amend the citation at this time. In any

event, Violation A.7 remains a violation since the licensee admits that at least ten of the eleven individuals specified in the violation had not been instructed as required.

Restatement of Violation A.10

License Condition No. 20 requires the licensee to conduct its program in accordance with the statements, representations, and procedures contained in a letter dated May 17, 1990.

The May 17, 1990 letter, with enclosure, requires the Radiation Safety Officer, through the Radiation Safety Office staff, to conduct audits on a semi-annual schedule of each laboratory or area authorized for use of licensed material.

Contrary to the above, from June 14, 1990 through December 31, 1990, the Radiation Safety Office staff did not audit approximately 50% of the 700 laboratories or areas where radioactive material is authorized for use.

Summary of Licensee's Response to Violation A.10

The licensee admits the violation in part but states that all areas were surveyed for radiation and that certain elements of an audit were performed during the radiation surveys. The licensee states that it was unaware that the audit requirement was incorporated into its NRC license.

NRC Evaluation of Licensee's Response to Violation A.10

Although the licensee states that some elements of an audit were performed during laboratory radiation surveys, it admits that audits were not completed as required. NRC expects the licensee to be cognizant of applicable regulatory requirements and commitments incorporated by reference into its license.

III. Licensee's Request for Mitigation of Civil Penalty

Restatement of Licensee's Request for Reconsideration Regarding Escalation Based on Identification and Reporting

The licensee argues that it reported twelve of the alleged violations, identified six of the violations that the University either admits or admits in part, and corrected many violations prior to the time that NRC conducted its inspection in 1990. (Regarding this latter point, the licensee gives as examples A.4, A.5, A.7, A.12, A.13, and A.15.) Under these circumstances, the licensee contends that escalation of the base civil penalty by 50% under

Section V.B.1. of the Enforcement Policy is an abuse of discretion. With respect to the violations that the licensee admits, but did not identify, the licensee believes that NRC has not provided any basis which demonstrates that the licensee should have reasonably discovered the violation before the NRC identified it.

NRC Evaluation of Licensee's Request for Reconsideration Regarding Escalation Based on Identification and Reporting

The licensee was well aware of many of the violations, since nine of them were identified during a 1989 inspection and were found again during the 1990 inspection. In addition, the licensee was aware of deficiencies in key program areas and had not corrected these weaknesses. This indicates that the licensee, while aware of the existence of some of the violations, had not taken immediate effective action in 1989 to correct the problems. The NRC Enforcement Policy provides in Paragraph V.B.1, ". . . No consideration will be given to a reduction in penalty if the licensee does not take immediate action to correct the problem upon discovery. . ." Moreover, although the licensee identified some violations, 13 of the 21 violations (more than 50%) were identified solely by the NRC, and those violations could have been identified earlier by the licensee through increased management attention and an effective self-audit program.

Restatement of Licensee's Request for Reconsideration Regarding Escalation Based on Past Performance

The licensee recognizes that the basis for escalating the base civil penalty by 100% due to past poor performance is the fact that the NRC, in an enforcement action dated July 2, 1990, issued a citation for a Severity Level II problem with regard to the University Radiation Safety Program. As the licensee notes, NRC found that many of the currently identified violations are repetitions of problems which resulted in the prior enforcement action. The licensee contends that NRC has ignored the fact that the 1990 inspection period followed the July 1990 enforcement action by a little more than four months. While some of the alleged violations are characterized by the NRC as repeat violations, the University views these alleged violations as examples of continuing problems for which the four month time period between July and November 1990 was not sufficient for corrective actions to be fully implemented and perfected.

NRC Evaluation of Licensee's Request for Reconsideration Regarding Escalation Based on Past Performance

The NRC acknowledges that the enforcement action for the 1989 NRC inspection (EA 90-040) was forwarded to the licensee by letter dated July 2, 1990. However, the enforcement action resulted from problems identified during an inspection conducted on August 25, 1989 and during the period September 19, 1989 through October 6, 1989. Findings from this inspection were initially conveyed to licensee representatives at the conclusion of the site inspection on October 6, 1989.

Although EA 90-040 was issued on July 2, 1990, the University was provided with detailed NRC inspection and consultant audit findings, including description of specific problems and program weaknesses, on several occasions between October 6, 1989 and February 16, 1990. Since the subsequent inspection of the NRC licensed program was conducted during the period November 26, 1990 through December 27, 1990, the licensee had approximately twelve months to correct known problems. Therefore, ample time was available to the licensee to fully implement lasting and effective corrective actions for 1989 inspection findings.

As pointed out by the licensee, the NRC acknowledged the initiatives taken by licensee management in 1989 to identify and correct problems. These initiatives resulted in the NRC's decision not to issue a civil penalty for the Severity Level II problem identified in the Notice of Violation dated July 2, 1990 (EA 90-040).

Many of the currently identified violations are repetitions or continuations of problems which resulted in EA 90-040. The NRC Enforcement Policy provides in paragraph V.B.3., that in weighing past performance, consideration is given to the effectiveness of previous corrective actions for similar problems and prior performance in the area of concern. Failure to implement effective and lasting corrective action for prior similar problems, warrants an increase in the civil penalty.

Restatement of Licensee's Request for Reconsideration Regarding Escalation Based on Duration

The licensee correctly notes that NRC further increased the base civil penalty by 100% due to the duration of the problem concerning the lack of adequate control of licensed activities because many of the specific violations, including the more safety significant violations associated with inventory of radioactive materials, disposal of radioactive waste through the sanitary sewers, and personal

dosimetry, existed for periods in excess of one year. The licensee denies the alleged violations regarding inventory of radioactive materials, disposal of radioactive waste through the sanitary sewers and personal dosimetry, all of which the NRC claims are the more safety significant violations (A.1, A.3 and A.6). Moreover, the licensee asserts that, at the present time, it is in full compliance with respect to all of the alleged 21 violations.

NRC Evaluation of Licensee's Request for Reconsideration Regarding Escalation Based on Duration

The NRC Enforcement Policy provides in paragraph V.B.6. that a greater civil penalty may be imposed if violations continue. For example, if the licensee is aware of a condition which results in ongoing violations and fails to initiate effective corrective actions, it may be considered for additional civil penalties. Although licensee senior management became aware of many of the programmatic weaknesses in 1989 and some corrective actions were initiated, these actions were not properly focused to achieve adequate regulatory compliance. As a result, many of the problems still existed at the time of the November 26 - December 27, 1990 inspection.

The licensee contends that many of the citations were not valid, including those deemed by the NRC as more safety significant. Moreover, the licensee states it is in full compliance at this time. However, as explained above, the NRC has found no basis for withdrawing any of the violations (example A.4.b is being withdrawn) identified in the Notice of Violation and Proposed Imposition of Civil Penalty. Furthermore, full compliance is expected of all NRC licensees. The fact that the licensee is now in full compliance has no bearing on the assessment of the civil penalty, which is for the failure to completely correct a breakdown in the control of several significant aspects of the licensee's radiation safety program, a problem that existed at the time of the 1990 inspection.

IV. NRC Conclusion

Based on the information presented by the licensee and evaluated by the NRC, NRC concludes that the violations did occur and that the licensee has not provided an adequate basis for mitigation of the civil penalty. Consequently, the proposed civil penalty in the amount of $8,750 should be imposed.

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

October 29, 1991

Docket No. 50-186
License No. R-103
EA 91-113

University of Missouri - Columbia
ATTN: Dr. James J. Rhyne, Director
Research Reactor Facility
Research Park
Columbia, MO 65201

Dear Dr. Rhy.

SUBJECT: MISSOURI UNIVERSITY RESEARCH REACTOR FACILITY NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY - $1,875
(NRC INSPECTION REPORT NO. 50-186/91004)

This refers to the inspection conducted on August 21, 1991, of the events surrounding the September 4, 1990, and August 5, 1991, inadvertent switching of samples in your hot cell, which resulted in incorrect shipments of byproduct material. The report documenting this inspection was sent to you by a letter dated September 10, 1991. During this inspection violations of NRC requirements were identified. Although neither event was reportable, the August 5, 1991 event was voluntarily reported to the NRC Office of Nuclear Reactor Regulation by telephone, on August 7, 1991, and to NRC Region III by telephone on August 9, 1991. A written report was submitted to the NRC by letter dated September 4, 1991. An Enforcement Conference was held on September 18, 1991, at the NRC Region III Office to discuss the violations, their causes, and your corrective actions. The report summarizing this conference was sent to you by letter dated September 23, 1991.

On August 5, 1991, when irradiated cans were removed from the reactor pool to the hot cell, one can contained cosmic dust (quartz grains) which had been irradiated for NASA/Johnson Space Center. The primary activity was 16 millicuries of sodium-24. Another can contained capsules, one of which contained 11 curies of rhenium-186 produced for Mallinckrodt Medical. In the hot cell each sample was to be placed into its respective lead pig (identified with the respective can number and customer). The shipping technician inadvertently placed the Mallinckrodt sample in the NASA pig and vice versa. Each lead pig was placed in a Type A package, dose rate readings on contact and at one meter were taken, and an appropriate transport index was assigned for each package. The package bound for NASA was given a Yellow II label and marked as containing 16 millicuries of sodium-24, when it actually contained 11 curies of rhenium-186. The package bound for Mallinckrodt was given a Yellow III label and marked as containing 11 curies of rhenium-186, when it actually

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

contained 16 millicuries of sodium-24. The shipping papers and radioactive label for each package had the wrong radionuclide name and activity specified. Further, NASA was not authorized to receive 11 curies of rhenium. On August 6, 1991, a researcher at NASA opened the package and immediately recognized that it was the wrong material. NASA estimated that the researcher received 750 millirem to the hand.

During the NRC inspection, you also described a similar event which occurred in September 1990, when you inadvertently shipped 35 curies of palladium-103,-109 to Mallinckrodt Medical instead of 6.19 curies of rhenium-186. However, you discovered the error internally and notified Mallinckrodt before they opened the package.

Four violations were identified regarding the September 1990 and August 1991 events as described in the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice). Violation I.A involves three instances of failure to place the correct radionuclide name and activity on the shipping papers and radioactive labels for three byproduct material shipments. Violation I.B involves one transfer of byproduct material to an unauthorized person. These violations were caused by personnel errors (inattention to detail) when the shipping technician incorrectly read markings, resulting in the technician placing byproduct materials into the wrong lead pig while working in the hot cell.

The safety consequences of these events were potentially significant. In cases where the item distributed is different from that stated on the radioactive label, serious health physics consequences can result during package opening and initial handling. Recipients who are not authorized to possess certain nuclides, quantities, or forms may not have the facilities or properly trained personnel to recognize and deal with the contents of such inadvertent shipments. In addition, proper labeling and shipping papers allow civil authorities, in case of an accident during transport, to properly identify the type, quantity, and form of material; allow the carrier and recipient to exercise adequate controls; and minimize the potential for overexposure, contamination, and improper transfer of material.

The events described above involve significant failure to control licensed material intended for distribution, failure to control access to licensed material as required pursuant to 10 CFR 30.41, and noncompliance with labeling and shipping paper requirements. 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 associated violations are classified in the aggregate as a Severity Level III problem.

We recognize that you took immediate corrective actions upon identification of the September 1990 and August 1991 events including notification of Mallinckrodt Medical, retrieval of shipments, procedure reviews and revisions, and personnel actions. In regard to your long term corrective actions, we acknowledge that you have undertaken further procedure reviews and revisions including implementation of double verification and increasing the staffing and qualification level of personnel working in the shipping area, and that you intend to

implement a refresher and update training program. Additionally, we acknowledge that you are evaluating a sodium iodide detector system as a possible enhancement to the shipping program, and funding is being sought for new hot cells which may improve the safety, accuracy, and efficiency of your shipping process. With regard to the September 1990 event, your corrective actions appear to have been narrowly focused on identification markings on the small aluminum cans (capsules) used in that operation. We expect your corrective actions for future problems to be more comprehensive.

To emphasize the importance the NRC places on attention to detail while preparing byproduct material for distribution, and on ensuring that byproduct material is properly shipped in accordance with NRC and Department of Transportation (DOT) requirements, I have been authorized, after consultation with the Director, Office of Enforcement, and the Deputy Executive Director for Nuclear Reactor Regulation, to issue the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice) in the amount of $1,875 for the Severity Level III problem.

NRC views this as a plant operations problem as opposed to a transportation problem because all of the violations were inevitable once the containers were switched as they came from the reactor pool. In accordance with Table 1A of the Enforcement Policy, the base civil penalty for a plant operations problem at a research reactor is $2,500. The escalation and mitigation factors in the Enforcement Policy were considered. Mitigation of the base civil penalty by 25 percent was warranted to encourage voluntary reporting, which occurred in this case. Full 50 percent mitigation for identification and reporting was not warranted in that the August 1991 event was identified by NASA. No mitigation of the base civil penalty was warranted for the corrective action factor. Although your corrective actions following the August 1991 event appear adequate, your corrective actions following your identification of the September 1990 event were not sufficiently comprehensive. No escalation or mitigation of the base civil penalty was warranted for the past performance factor. Although your overall performance is considered good, there have been other recent violations involving shipping and receiving. The other adjustment factors in the Policy were considered and no further adjustment to the base civil penalty is considered appropriate. Therefore, based on the above, the base civil penalty has been decreased by 25 percent.

An additional violation not assessed a civil penalty was identified regarding inadequate documentation of Type A package design and testing 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 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,

Carl J Paperiello for

A. Bert Davis
Regional Administrator

Enclosure:
Notice of Violation and
Proposed Imposition of Civil Penalty

cc w/enclosure:
DCD/DCB (RIDS)
OC/LFDCB
Dr. William Vernetson, Director
of Nuclear Facilities

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

University of Missouri
Missouri University Research Reactor

Docket No. 50-186
License No. R-103
EA 91-113

During an NRC inspection conducted on August 21, 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 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 Parts 170-189.

49 CFR 172.203(d)(1)(i) requires that the description for a shipment of radioactive material must include the name of each radionuclide in the radioactive material that is listed in 49 CFR 173.435.

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

49 CFR 172.403(a) and (g) require in part that the contents and activity of each package of radioactive material must be entered on the radioactive label, unless the package is excepted from labeling.

1. Contrary to the above, on August 5, 1991, the licensee delivered 11 curies of rhenium-186 to a carrier for transport to the NASA/Johnson Space Center with the description on the shipping papers and the radioactive label stating that the shipment contained 16 millicuries of sodium-24, and the package was not excepted from labeling.

2. Contrary to the above, on August 5, 1991, the licensee delivered 16 millicuries of sodium-24 to a carrier for transport to Mallinckrodt Medical with the description on the shipping papers and the radioactive label stating that the shipment contained 11 curies of rhenium-186, and the package was not excepted from labeling.

3. Contrary to the above, on September 4, 1990, the licensee delivered 17.9 curies of palladium-103, and 18 curies of palladium-109 to a carrier for transport to Mallinckrodt Medical with the description on the shipping papers and the radioactive label stating that the shipment contained 6.19 curies of rhenium-186, and the package was not excepted from labeling.

B. 10 CFR 30.41(a) and (b)(5) require, in part, that no licensee transfer byproduct material except to a person authorized to receive such byproduct material under the terms of a specific or general license issued by the Commission or Agreement State.

Contrary to the above, on August 5, 1991, the licensee transferred a source containing 11 curies of rhenium-186 to NASA/Johnson Space Center, a person who was not authorized to receive such byproduct material under the terms of a specific or general license issued by the Commission or Agreement State.

This is a Severity Level III problem (Supplements V and VI).

Civil Penalty - $1,875 (assessed equally among the four violations).

II. Violation Not Assessed a Civil Penalty

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 Parts 170-189.

49 CFR 173.415(a) requires, in part, that each shipper of a Specification 7A package must maintain on file a complete documentation of tests and an engineering evaluation or comparative data showing that the construction methods, packaging design, and materials of construction comply with that specification.

Specification 7A, 49 CFR 178.350, requires, in part, that each packaging must be so designed and constructed that it meets the standards for Type A packaging.

Contrary to the above, as of August 21, 1991, the video documentation for the licensee's Type A containers did not provide an engineering evaluation or comparative data showing that the construction methods, packaging design, and materials of construction comply with the specification 7A. Additionally, the video documentation of testing did not provide complete documentation of tests performed. Specifically, the licensee could not locate the completed checklists which document and certify that the Type A container testing acceptance criteria were met.

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

Pursuant to the provisions of 10 CFR 2.201, the University of Missouri (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, the Commission may issue an Order or 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 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 III, 799 Roosevelt Road, Glen Ellyn, Illinois 60137.

FOR THE NUCLEAR REGULATORY COMMISSION

Carl J Paperiello

A. Bert Davis
Regional Administrator

Dated at Glen Ellyn, Illinois
this 29th day of October 1991

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

November 4, 1991

Docket No. 030-10026
License No. 31-02755-05
EA 91-050

Veterans Administration Medical Center
ATTN: Fred Malphurs, Director
113 Holland Avenue
Albany, New York 12208

Gentlemen:

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY - $2,500
(NRC INSPECTION REPORT 90-001 AND OI INVESTIGATION REPORT 1-90-018)

This letter refers to the NRC inspection conducted on November 20 and 21, 1990, and to a subsequent investigation by the NRC Office of Investigations (OI) of activities authorized by NRC License No. 31-02755-05 at the Veterans Administration Medical Center, Albany, New York. The inspection report was sent to you on December 7, 1990. A copy of the synopsis of the OI investigation was sent to you on June 26, 1991. Numerous violations were identified during the inspection. A number of those violations were the subject of a Notice of Violation and Proposed Imposition of Civil Penalty (Notice) in the amount of $3,750 dated January 29, 1991 (EA 90-209); however, some apparent violations were held in abeyance pending the completion of the OI investigation.

The civil penalty proposed in January 1991 focused on lack of management attention to, and oversight of, the radiation safety program. As a separate and distinct issue, the violations described in the enclosed Notice focus on the maintenance of records to document the performance of sealed source inventories that, in fact, had not been completed. These violations were discussed at an enforcement conference held July 8, 1991. As discussed below, we have concluded that the root cause of these violations is careless disregard for meeting regulatory requirements on the part of licensee management. Pursuant to 10 CFR 30.9, NRC requires its licensees to maintain NRC-required records and provide information to NRC that is complete and accurate in all material respects. The ability to rely on the completeness and accuracy of NRC-required records and information provided to NRC is inherent in the issuance and continuation of an NRC license to conduct activities involving radioactive materials. In accordance with the Enforcement Policy, the violations listed in the enclosed Notice are of significant regulatory concern and warrant a separate civil penalty.

During the inspection in November 1990, the inspector reviewed the records of the January, April, July, and October 1990 quarterly sealed source inventories with the Radiation Safety Officer (RSO) designated on the license at that time

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

(hereinafter, "the RSO"). The inspector became concerned when the RSO could not explain the meaning of certain codes on the October 14, 1990 inventory record and the inspector asked if the inventory had, in fact, been done. The RSO answered that the inventory was done. The OI investigation substantiated that the sealed source inventory records dated April 10, 1990, July 10, 1990, and October 14, 1990 were inaccurate in that complete physical inventories were not actually performed. This matter is cause for significant concern because it involves failures both on the part of the licensee management and the RSO. (While the OI Report concluded that the January 10, 1990, sealed source inventory was also incomplete but signed by the RSO as complete, the RSO maintains that this inventory was properly conducted. NRC does not intend to pursue this matter.)

Concerning the April 10, 1990 inventory, the RSO created the record without performing an actual physical inventory by using the January 1990 inventory list and merely adding the new items received since that time to the list. He subsequently stated at the enforcement conference that he also "called a few labs" to verify that sources from those laboratories had not been lost. Concerning the July 10, 1990 and October 14, 1990 sealed source inventories, the RSO offered the explanation at the enforcement conference that on these two separate occasions, when he discovered a computer-generated list of sealed sources among the numerous papers on his desk, he presumed that they represented completed physical inventories performed by the individual who had been hired to assume the duties of RSO, and he signed the lists as representing completed inventories without any further review, discussion, or documentation.

The RSO maintains that the inaccurate April 1990 inventory record resulted in part from his confusion and lack of understanding concerning the inventory requirement. However, as the RSO, he should have made more of an effort to achieve a thorough understanding of how to satisfy NRC inventory requirements.

Notwithstanding the RSO's failures, the failures on the part of the licensee management created a situation in which the RSO did not clearly understand nor properly implement the RSO responsibilities under the terms of the NRC license and did not devote sufficient time to those responsibilities. In 1989, the licensee employed the RSO on a part time basis (7/8 full time) as the Physician-Director of the nuclear medicine department and yet assigned him the additional duties of the RSO position, as well as the duties of the Chairman of the RSC, without providing sufficient continuity, oversight, training, and resource support to assure that he adequately discharged these additional duties. Further, licensee management was aware that previously, the duties of the RSO required a full-time position to adequately oversee this broad NRC license. These facts demonstrate careless disregard for meeting regulatory requirements on the part of licensee management, which is the root cause of the violations in the enclosed Notice. Violations that involve careless disregard 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 (1990), the violations listed in the enclosed Notice are classified in the aggregate as a Severity Level III problem.

The NRC recognizes that the licensee has taken corrective actions relative to these matters. These actions include (1) retention of contract health physics support shortly after the inspection to assist the existing RSO in the daily implementation of the program until a full-time RSO is hired, trained, and added to the NRC license; (2) replacement of the RSO with another interim individual in January 1991; and (3) removal of the RSO as Chairman of the Radiation Safety Committee.

In addition, as noted earlier, a civil penalty was previously assessed for violations indicative of lack of management control. That lack of management control, which is also applicable to the two violations described in the enclosed Notice, constitutes careless disregard by licensee management for meeting regulatory requirements (which the NRC determined from review of the OI report and from the licensee presentation at the July 8, 1991 enforcement conference). As a result of this conclusion that licensee management actions constitute careless disregard, which is a form of wrongdoing under the NRC enforcement policy, an additional civil penalty is warranted for the separate violations. The civil penalty is intended to emphasize to licensee management that they have a fundamental responsibility in assuring that: (1) NRC requirements are met including the accuracy of required records; and (2) trained and qualified staff, as well as adequate resources, are essential to maintaining such assurance. Therefore, 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 in the amount of $2,500 for this Severity Level III problem.

The base civil penalty for a Severity Level III violation is $2,500. The escalation and mitigation factors set forth in the Enforcement Policy were considered and, on balance, no change to the base civil penalty was considered appropriate. While NRC identified these violations and you should have been aware of them sooner, escalation based on this factor was offset by mitigation for your corrective actions, which are described above.

You are required to respond to the enclosed Notice and, in preparing your response, you should document the specific actions taken and any additional actions you plan to prevent recurrence. You should include in your response a description of the actions (for example, orientation, training, and periodic refresher training) taken or planned to assure that, in the future, all individuals associated with NRC-licensed activities are trained and qualified for their positions and fulfill their responsibility to the Veterans Administration and the NRC to conduct those activities in accordance with NRC requirements, including the provisions of 10 CFR 30.9 pertaining to complete and accurate information.

After reviewing your response to this Notice, including your proposed corrective actions and the results of future inspections, the NRC will determine whether further NRC enforcement action is necessary to ensure compliance with NRC regulatory requirements.

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

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

Sincerely,

Thomas T. Martin
Regional Administrator

Enclosure: Notice of Violation
and Proposed Imposition of Civil Penalty

cc:
Public Document Room (PDR)
Nuclear Safety Information Center (NSIC)
State of New York

Director, Nuclear Medicine (115)
ATTN: Helen Malaskiewicz
Department of Veterans Affairs
810 Vermont Avenue, N.W.
Washington, D.C. 20420

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

Veterans Administration Medical Center
Albany, New York

Docket No. 030-10026
License No. 31-02755-05
EA 91-050

During an NRC inspection conducted on November 20-21, 1990 and subsequent investigation by the NRC Office of Investigations (OI), 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 (1990), 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:

A. 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 and shall retain each inventory record for five years.

Contrary to the above, the licensee did not complete a physical inventory of all sealed sources in its possession between April and December 1990, a period in excess of a calendar quarter. Specifically, during this period, a comprehensive determination of the location of all sealed sources and whether any such sources were missing was not performed.

B. 10 CFR 30.9(a) requires, in part, that information provided to the Commission by a licensee, or information required by the Commission's regulations to be maintained by the licensee, shall be complete and accurate in all material respects.

Contrary to the above, between April 1990 and November 21, 1990, the licensee maintained inaccurate written records dated April 10, 1990, July 10, 1990, and October 14, 1990, documenting three quarterly physical inventories of sealed sources; and, during an inspection conducted on November 20-21, 1990, these records were presented to an NRC inspector for review. The records were inaccurate in that the quarterly physical inventories that they documented had not, in fact, been completed. The inaccurate information was material in that it directly related to compliance with NRC requirements.

These violations have been categorized in the aggregate as a Severity Level III problem (Supplements VI and VII).

Cumulative Civil Penalty - $2,500 (assessed equally between the two violations).

Pursuant to the provisions of 10 CFR 2.201, the Veterans Administration 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 may be issued to show cause why the license should not be modified, suspended, or revoked or why such other action as may be proper should not be taken. Consideration may be given to extending the response time for good cause shown. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, this response shall be submitted under oath or affirmation.

Within the same time as provided for the response required above under 10 CFR 2.201, the Licensee may pay the civil penalty by letter addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, with a check, draft, money order, or electronic transfer payable to the Treasurer of the United States in the amount of the civil penalty proposed above, or may protest imposition of the civil penalty in whole or in part, by a written answer addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission. Should the Licensee fail to answer within the time specified, an order imposing the civil penalty will be issued. Should the Licensee elect to file an answer in accordance with 10 CFR 2.205 protesting the civil penalty, in whole or in part, such answer should be clearly marked as an "Answer to a Notice of Violation" and may: (1) deny the 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 (1990), 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.

FOR THE NUCLEAR REGULATORY COMMISSION

Thomas T. Martin
Regional Administrator

Dated at King of Prussia, Pennsylvania
this 4th day of November 1991

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

November 7, 1991

Docket No. 030-13891
License No. 48-18578-01
EA 91-138

Watertown Memorial Hospital
ATTN: Leo Bargielski
President
125 Hospital Drive
Post Office Box 290
Watertown, WI 53094-3384

Dear Mr. Bargielski:

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY - $6,250
(INSPECTION REPORT NO. 30-13891/91001)

This refers to the routine inspection at the Watertown Memorial Hospital, conducted on September 26, 1991, and authorized by NRC License No. 48-18578-01. The report documenting this inspection was sent to you on October 25, 1991. As a result of the inspection, violations of NRC requirements were identified, and on October 31, 1991, an enforcement conference was held in the Region III office between you and other members of your staff, and Mr. William L. Axelson, Deputy Director, Division of Radiation Safety and Safeguards and other members of the NRC staff.

The NRC has determined that a number of violations of NRC requirements occurred under the Byproduct Material License issued to Watertown Memorial Hospital. The violations, which are described in the enclosed Notice of Violation, include, but are not limited to, the periodic failure to: establish procedures for the receipt of radioactive materials during off-duty hours; perform the daily constancy and the quarterly linearity tests of the dose calibrator and record certain specified information pertaining to the tests; train personnel; survey areas where radioactive materials are used and stored; and perform annual reviews of the radiation safety program. These violations, taken collectively, represent a significant breakdown in the control of NRC licensed activities at Watertown Memorial Hospital. 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.

The root causes of the violations and the subsequent corrective action were discussed during the October 31, 1991, enforcement conference. The NRC recognizes that corrective actions have been initiated and acknowledges the additional information regarding corrective actions you telefaxed to us on November 6, 1991. The major factor contributing to the violations appeared to

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

be a lack of management support and oversight of the NRC licensed program and a lack of leadership by those responsible for overseeing the radiation safety program, including the Radiation Safety Committee and the Radiation Safety Officer.

The NRC license issued to Watertown Memorial Hospital entrusts responsibility for radiation safety to the management of the hospital; therefore, the NRC expects effective management and oversight of its licensed programs. Incumbent upon each NRC licensee is the responsibility to protect the public health and safety, including the health and safety of 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 have allowed these violations of NRC requirements to occur and go undetected and uncorrected demonstrates that ineffective and insufficient management oversight of the implementation of the radiation safety program exists at Watertown Memorial Hospital. While no single violation represents a significant health or safety concern, the number and scope of the violations indicate that a significant breakdown exists in the implementation of your radiation safety program. Had proper training been provided to the personnel responsible for implementing the day-to-day radiation safety program, and if routine, comprehensive program audits had been conducted, many of these violations may not have occurred.

To emphasize the need for effective management and oversight of NRC licensed activities, I am issuing the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice) in the amount of $6,250 for the Severity Level III problem.

The base value of a civil penalty for a Severity Level III problem is $2,500. The civil penalty adjustment factors in the Enforcement Policy were considered and the amount of the civil penalty was escalated 50 percent since the NRC identified the violations. The amount of the civil penalty was increased an additional 100 percent for the prior notice of similar events provided to Watertown Memorial Hospital by NRC Information Notice No. 90-71. That Information Notice discussed various failings in exercising management oversight and control of radiation safety programs, including case histories where annual reviews by the Radiation Safety Committee were not done and where the fundamental program deficiency was the lack of sufficient time and attention to the radiation safety program by the Radiation Safety Officer. In addition, the Information Notice indicated the NRC expected the licensee to distribute the Information Notice to hospital management and urged senior managers to carefully read the information contained in the Notice to consider actions to prevent problems from occurring at their facilities.

Your corrective actions were sufficient to return Watertown Memorial Hospital to compliance with NRC requirements with one exception: you did not propose or implement sufficient corrective action concerning the receipt of radiopharmaceuticals during off-hours. At the enforcement conference you proposed to continue to allow representatives of the nuclear pharmacy access to your radiation restricted area during off-hours without the presence of a hospital representative. The November 6, 1991, telefax appears to indicate that this problem has been corrected. Therefore, on balance, an adjustment to the

amount of the civil penalty for the licensee's corrective actions was not made. On the whole, the past regulatory performance of Watertown Memorial Hospital has been good with only one violation in each of the two previous inspections. However, the number and scope of the violations disclosed during the September 26, 1991, inspection indicates that your performance significantly deteriorated since the previous NRC inspection. Therefore, no adjustment to the amount of the base civil penalty was made for your past good performance. The remaining factors in the enforcement policy were also considered and no further adjustment to the base civil penalty is considered appropriate.

You are required to document your response to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. In your response, please ensure that you described the actions you have taken to strengthen the management and oversight of your NRC licensed program. 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 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 addition to the violations described in the enclosed Notice, two other apparent violations of NRC requirements were discussed at the enforcement conference. With the information you presented at the enforcement conference, or will obtain in the very near future, the two apparent violations have been withdrawn. Those apparent violations were:

- Contrary to the requirements of 49 CFR 173.475(i), it was believed that you did not examine the surfaces of shipping packages for contamination. At the enforcement conference, you presented information indicating that such examinations were performed.

- Contrary to the requirements of 10 CFR 35.70(f), you did not conduct weekly surveys for contamination so as to be able to detect contamination of each wipe sample of 2,000 disintegrations per minute, as the wipe test samples were analyzed with your nuclear medicine gamma camera. And, the camera was not sufficiently sensitive to detect 2,000 disintegrations were minute. At the enforcement conference, you stated that you believed the nuclear medicine gamma camera could detect 2,000 disintegrations per minute, and planned to perform tests within the next week to demonstrate that capability. Please forward the results of those tests for our review and evaluation to determine if further action by the NRC is required.

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,

Carl J. Paperiello for

A. Bert Davis
Regional Administrator

Enclosure:
Notice of Violation and Proposed
Imposition of Civil Penalty

cc w/enclosure:
DCD/DCB (RIDS)

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

Watertown Memorial Hospital
Watertown, Wisconsin

Docket No. 030-13891
License No. 48-18578-01
EA 91-138

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:

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 for receiving and opening packages of byproduct material are described in the licensee's letter dated February 16, 1989, and were approved by License Condition No. 14.

Item K of the letter dated February 16, 1989, states the licensee will establish and implement the model guidance for ordering and receiving radioactive materials published in Appendix K of Regulatory Guide 10.8, Revision 2.

Appendix K of Regulatory Guide 10.8, Revision 2, "Model Guidance for Ordering and Receiving Radioactive Material," requires the Radiation Safety Officer provide written procedures for receiving packages of radioactive material during off-duty hours.

Contrary to the above, as of September 26, 1991, the licensee, through its Radiation Safety Officer, failed to ensure that radiation safety activities were being performed in accordance with the above procedures. Specifically, the Radiation Safety Officer had not implemented written procedures for the receipt of packages containing radioactive material during off-duty hours.

B. 10 CFR 35.21(a) requires that the licensee, through the Radiation Safety Officer, ensure that radiation safety activities are being performed in accordance with approved procedures. The licensee's procedures for the training of employees in specified subjects are described in the licensee's letter dated February 16, 1989, and were approved by License Condition No. 14.

The letter dated February 16, 1989, states in Item A that the licensee will establish and implement the model training program published in Appendix A of Regulatory Guide 10.8, Revision 2.

Appendix A of Regulatory Guide 10.8, Revision 2, "Model Training Program," requires the licensee instruct personnel, including ancillary personnel, in specified subjects at the following intervals: during annual refresher training; or whenever there is a significant change in duties, regulations, or the terms of the license.

Contrary to the above, as of September 26, 1991, the licensee, through its Radiation Safety Officer, failed to ensure that radiation safety activities were being performed in accordance with the above procedures. Specifically, the Radiation Safety Officer: failed to provide annual refresher training from January 1, 1990, through September 26, 1991, to ancillary personnel working in the vicinity of the Nuclear Medicine Department; and failed to provide instruction to employees of the Nuclear Medicine Department when terms of the license were significantly changed upon the renewal of the license on May 31, 1989.

C. 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, on September 26, 1991, the licensee did not check the dose calibrator for constancy at the beginning of the day of use. Specifically, on September 26, 1991, the dose calibrator was used to measure t patient doses of radiopharmaceuticals on that day prior to performing the constancy check.

D. 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 the dose calibrator for linearity from March 14, 1991, through September 26, 1991, a period in excess of a calendar quarter.

E. 10 CFR 35.50(e) and 10 CFR 35.50(e)(3) require, in part, that a licensee retain records of quarterly dose calibrator linearity tests for three years unless directed otherwise, and that the records contain the calculated activities and the signature of the Radiation Safety Officer.

Contrary to the above, the licensee's record of the quarterly linearity test of its dose calibrator for the fourth quarter of 1990 and for the first quarter of 1991 did not include the calculated activities and did not contain the signature of the Radiation Safety Officer.

F. 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 31, 1989, through September 26, 1991, the licensee did not survey with a radiation detection instrument at the end of each day the image scanning area, an area where radiopharmaceuticals were routinely administered. In addition, no such surveys were performed of the hot lab, an area where radiopharmaceuticals are routinely prepared for use, on the following dates: July 15, 19, 26, and 27, 1991; August 22, 1991; and September 4 and 11, 1991.

G. 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 May 31, 1989 through September 26, 1991, the licensee did not survey for removable contamination in the radioactive waste storage area, an area where radiopharmaceuticals were routinely stored.

H. 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 May 31, 1989, through September 26, 1991, the Radiation Safety Committee did not review annually, with the assistance of the Radiation Safety Officer, the radiation safety program.

I. 10 CFR 35.92(b) requires, in part, that a licensee retain for three years a record of each disposal of byproduct material permitted under 10 CFR 35.92(a).

Contrary to the above, from May 31, 1989, through September 26, 1991, the licensee's did not retain records of disposal of byproduct material permitted under 10 CFR 35.92(a).

J. 10 CFR 35.120 and 10 CFR 35.220 require, in part, that a licensee authorized to use byproduct material for uptake, dilution or excretion measurements or for imaging and localization possess a portable radiation detection survey instrument capable of detecting dose rates over the range 0.1 millirem per hour to 100 millirem per hour.

Contrary to the above, as of September 23, 1991, the licensee did not possess a portable radiation detection survey instrument capable of detecting dose rates over the range 0.1 millirem per hour to 100 millirem per hour.

K. 10 CFR 19.11(a), and (b) require, in part, that the licensee post current copies of 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, on September 26, 1991, the licensee did not post or have available for examination, in the Nuclear Medicine Department as indicated on the posted notice, a copy of NRC Regulatory Guide 10.8, Revision 2, August 1987, which is a document incorporated into the license by License Condition No. 14 and the licensee's letter dated February 16, 1989.

This is a Severity Level III problem (Supplement VI).
Cumulative Civil Penalty - $6,250 (assessed equally among the 11 violations).

Pursuant to the provisions of 10 CFR 2.201, the Watertown Memorial Hospital (Licensee) is hereby required to submit a written statement of explanation to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, within 30 days of the date of this Notice of Violation and Proposed Imposition of Civil Penalty (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each alleged violation: (1) admission or denial of the alleged violation, (2) the reasons for the violation if admitted, and if denied, the reasons why, (3) the corrective steps that have been taken and the results achieved, (4) the corrective steps that will be taken to avoid further 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 violations listed in this Notice in whole or in part, (2) demonstrate extenuating circumstances, (3) show error in this Notice, or (4) show other reasons why the penalty should not be imposed. In addition to protesting the civil penalty in whole or in part, such answer may request remission or mitigation of the penalty.

In requesting mitigation of the proposed penalty, the factors addressed in Section V.B of 10 CFR Part 2, Appendix C (1991), should be addressed. Any written answer in accordance with 10 CFR 2.205 should be set forth separately from the statement or explanation in reply pursuant to 10 CFR 2.201, but may incorporate parts of the 10 CFR 2.201 reply by specific reference (e.g., citing page and paragraph numbers) to avoid repetition. The attention of the Licensee is directed to the other provisions of 10 CFR 2.205, regarding the procedure for imposing a civil penalty

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

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

FOR THE NUCLEAR REGULATORY COMMISSION

Carl J Paperiello for

A. Bert Davis
Regional Administrator

Dated at Glen Ellyn, Illinois
this 7th day of November 1991

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

NOV 14 1991

Docket No. 030-19888
License No. 32-21183-01
EA 91-140

Westinghouse Environmental &
Geotechnical Services, Inc.
ATTN: Mr. L. Matthews
District Manager
3109 Spring Forest Road
Raleigh, North Carolina 27658

Gentlemen:

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY - $1,750 (NCR INSPECTION REPORT NO. 32-21183-01/91-02)

This refers to the Nuclear Regulatory Commission (NRC) inspection conducted by Mr. H. Bermudez on September 26 and October 8, 1991, at Westinghouse Environmental and Geotechnical Services, Inc. located at 2800 East Parham Road, Richmond, Virginia. The inspection included a review of the radiation safety program, organization, use of licensed materials, and transportation of radioactive material. The report documenting this inspection was sent to you by letter dated October 29, 1991. As a result of this inspection, violations of NRC requirements were identified. An enforcement conference was held on November 5, 1991, in the NRC Region II office to discuss the violations, their cause, and your corrective actions to preclude recurrence. In addition, on October 7, 1991, during a telephone conversation between Mr. C. Hosey of the Region II staff and Mr. I. Frost, Manager of Environmental Sciences, Westinghouse Environmental and Geotechnical Services, Inc., there was an agreement that you would take action to preclude any further use of radioactive material at the Richmond, Virginia facility until the use of such material was authorized by a specific license issued by the NRC. That action was documented in a Confirmation of Action letter sent to you on October 7, 1991.

The violations, which are described in Part I of the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice), involved the possession and use of NRC licensed material at a location not authorized in the license. In addition, other violations include the failure to: (1) evaluate radiation doses to employees, (2) maintain records indicating receipt of byproduct material, (3) properly store shipping papers during the transport of radioactive material, (4) provide complete information on shipping papers, (5) maintain documentation establishing specifications of shipping packages, (6) conduct leak tests at the required frequency, and (7) maintain personnel dosimetry records. These violations, when considered collectively, indicate a serious lack of management attention to licensing requirements and conditions as well as inadequate management oversight of radiation safety program requirements. 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.

The NRC is concerned with several aspects of this problem which indicate a breakdown in the management of the radiation safety program. First and foremost is the fact that licensed byproduct material was used and stored at your facility in Richmond, Virginia, even though the use and storage of such materials at this site was not authorized by your NRC license. The license limited the possession and use of byproduct materials to a permanent location in Cincinnati, Ohio, and temporary job sites anywhere in the United States where the NRC has jurisdiction. Nevertheless, the Richmond facility had been in continuous operation as a permanent facility since 1988. Also of significant concern is the failure of the Radiation Safety Officer to ensure compliance with all terms and conditions of the NRC license, a responsibility inherent in that position. This failure was a contributing factor to the additional violations which relate to routine operational activities such as leak test requirements, personnel dosimetry, transportation compliance and evaluation of radiation doses.

The staff recognizes that once you understood the scope of the problem, corrective action was initiated and included the preparation of correspondence to obtain proper licensing for the Richmond facility, training a new Radiation Safety Officer at the Richmond facility, instituting a more reliable and accurate record keeping program, and development of written operating procedures regarding the use of byproduct material.

To emphasize the importance of adequate program oversight and compliance with regulatory requirements and license conditions, I have been authorized to issue the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice) in the amount of $1,750 for the Severity Level III problem.

The base value of a civil penalty for a Severity Level III problem is $500. The escalation and mitigation factors in the Enforcement Policy were considered. The base civil penalty has been increased by 50 percent because the violations were identified by the NRC. Neither escalation nor mitigation was warranted for corrective action to prevent recurrence because mitigation for the immediate actions was offset by your lack of specific long-term plans to ensure adequate management attention and oversight of the program. Escalation of 50 percent was warranted for prior notice of similar events because a State of North Carolina inspection conducted in June 1988 at your Raleigh, North Carolina facility, then licensed under the name S&ME, Inc., identified similar violations. In addition, a June 1991 NRC inspection at your Cincinnati, Ohio facility also identified a violation related to the requirement for leak testing. Also, the cover letters which transmitted the two most recent license amendments requested that the information contained in the license be verified. Escalation of 50 percent was warranted for multiple occurrences related to Violation B in the enclosed Notice because an evaluation of radiation dose was not conducted on at least eight occasions for 13 individual dosimetry badges when notification was received that dosimetry badges were unreadable. In addition, there were eight examples of failure to perform leak tests at the

required frequency. Escalation of 100 percent was warranted for duration because of the length of time the facility operated as a permanent facility in violation of license requirements. None of the other factors warranted further adjustment of the base civil penalty. Therefore, based on the above, the base civil penalty has been increased by 250 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,

James L. Milhoan for
Stewart D. Ebneter
Regional Administrator

Enclosure:
Notice of Violation and Proposed
Imposition of Civil Penalty

cc w/encl:
State of North Carolina

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

Westinghouse Environmental and
Geotechnical Services, Inc.
Raleigh, North Carolina

Docket No. 030-19888
License No. 32-21183-01
EA 91-140

During an NRC inspection conducted on September 26 and October 8, 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 30.34(c) requires, in part, that each licensee confine his possession and use of byproduct materials to the locations and purposes authorized by the license. Condition 10 of License Number 32-21183-01 limits the use of licensed materials to Suite 100, 11785 Highway Drive, Cincinnati, Ohio, and at temporary job sites of the licensee anywhere in the United States where the NRC maintains jurisdiction for regulating the use of licensed material.

Contrary to the above, between 1988 and September 26, 1991, the licensee possessed and used licensed materials at a permanent place of business at 2800 East Parham Road, Richmond, Virginia, a location not authorized by the license.

B. 10 CFR 20.201(b) requires that the licensee make or cause to be made such surveys as may be necessary to comply with the requirements of Part 20 and which are reasonable under the circumstances to evaluate the extent of radiation hazards that may be present. As defined in 10 CFR 20.201(a), "survey" means an evaluation of the radiation hazards incident to the production, use, release, disposal, or presence of radioactive materials or other sources of radiation under a specific set of conditions.

10 CFR 20.101(a) requires that the licensee limit the whole body radiation dose of an individual in a restricted area to one and one quarter rems per calendar quarter, except as provided by 10 CFR 20.101(b).

Contrary to the above, between 1988 and September 26, 1991, an evaluation of radiation dose was not conducted in order to demonstrate compliance with 10 CFR 20.101(a) on at least eight occasions for thirteen individual badges when the licensee's personnel at the Richmond, Virginia facility were notified by their dosimetry processor that dosimetry badges were unreadable.

C. 10 CFR 30.51(a) requires that each licensee keep records showing the receipt, transfer, export, and disposal of byproduct material.

Contrary to the above, as of September 26, 1991, the licensee did not keep records indicating receipt of byproduct material at the Richmond, Virginia facility.

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

1. 49 CFR 177.817(e) requires, in part, that shipping papers be stored as follows: When the driver is at the vehicle 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. When the driver is not at the vehicle 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, between 1988 and September 26, 1991, licensee personnel at the Richmond, Virginia facility stored the shipping papers inside the radioactive materials package while transporting the radioactive materials in motor vehicles and not as specified in 49 CFR 177.817(e).

2. 49 CFR 172.203(d) requires, in part, that the description for a shipment of radioactive material include the transport index assigned to each package in the shipment bearing RADIOACTIVE YELLOW-II or RADIOACTIVE YELLOW-III labels.

   Contrary to the above, on January 29, 1991, licensee personnel at the Richmond, Virginia facility made a shipment of radioactive materials labeled RADIOACTIVE YELLOW-II without the transport index included in the description of the radioactive material.

3. 49 CFR 173.415(a) requires, in part, that each shipper of a Specification 7A package must maintain on file for at least one year after the latest shipment, a complete documentation of tests and engineering evaluation or comparative data showing that the construction methods, packaging design, and materials of construction comply with that specification.

Contrary to the above, between May 1991 and September 26, 1991, licensee personnel at the Richmond, Virginia facility made shipments of licensed materials contained in two Campbell Pacific Nuclear Gauges, Model MC-1, a specification 7A package, without maintaining on file a complete documentation of test and engineering evaluation or comparative data showing that the construction methods, packaging design and materials of construction complied with the specification.

E. Condition 12 of License Number 32-21183-01 requires, in part, that sealed sources used by the licensee be tested for leakage and/or contamination at intervals not to exceed six months.

Contrary to the abuve, on at least eight instances between 1988 and September 26, 1991, leak tests were conducted at intervals greater than six months at the Richmond, Virginia facility.

This is a Severity Level III problem (Supplements IV, V and VI).

Cumulative Civil Penalty - $1750 (assessed equally among the seven violations).

II. Violation Not Assessed A Civil Penalty

10 CFR 30.41(c) requires that, prior to transferring byproduct material, the licensee verify that the transferee's license authorizes the receipt of the type, form, and quantity of byproduct material to be transferred. 10 CFR 30.41(d) specifies acceptable methods for this verification.

Contrary to the above, on January 29, 1991, the licensee transferred approximately eight millicuries of cesium 137 and 40 millicuries of americium 241 to Troxler Electronic laboratories, Inc. and, prior to the transfer, the licensee did not verify by an acceptable method that the transferee's license authorized receipt of this material.

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

Pursuant to the provisions of 10 CFR 2.201, Westinghouse Environmental and Geotechnical 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 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 14th day of November 1991

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

October 16, 1991

Docket No. 030-10966
License No. 13-16404-01
EA 91-124

Winona Memorial Hospital
ATTN: Mr. Rod Tank
Chief Operating Officer
3231 North Meridian Street
Indianapolis, IN 46208

Dear Mr. Tank:

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY - $1,250
(NRC INSPECTION REPORT NO. 030-10966/91001)

This refers to the routine inspection at the Winona Memorial Hospital, conducted on September 5, 1991, and authorized by NRC License No. 13-16404-01. During the inspection, violations of NRC requirements were identified, and on October 1, 1991, an enforcement conference was held in the Region III office between you and other members of your staff, and Mr. Charles E. Norelius, Director, Division of Radiation Safety and Safeguards and other members of the NRC staff.

The violations, which are described in the enclosed Notice of Violation, include the periodic failure to: (a) perform the quarterly linearity and the annual accuracy tests of the dose calibrator; (b) conduct semiannual leak tests of a sealed source; (c) survey at the end of each day the areas where radiopharmaceuticals are used; (d) check the operation of the radioactive gas collection system and measure the ventilation rates in areas where radioactive gasses are used; (e) hold quarterly meetings of the Medical Isotopes Committee (Radiation Safety Committee) or to have the Radiation Safety Officer in attendance at such meetings; (f) post certain required documents; and (g) retain certain required documents. These violations, taken collectively, represent a significant breakdown in the control of NRC licensed activities at Winona Hospital. 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.

The root causes of the violations and the subsequent corrective action were discussed during the October 1, 1991, enforcement conference. The NRC recognizes that corrective actions have been initiated and appear acceptable. The major factor contributing to the violations appeared to be a lack of management support and oversight of the NRC licensed program and a lack of leadership by those responsible for overseeing the radiation safety program, including the Radiation Safety Committee and the Radiation Safety Officer.

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

The NRC license issued to Winona Hospital entrusts responsibility for radiation safety to the management of the hospital. Incumbent upon each NRC licensee is the responsibility to protect the public health and safety, including the health and safety of the employees, by assuring that all requirements of the NRC license are met and any potential violation of NRC requirements is identified and expeditiously corrected. The fact that in April 1991 you retained the services of an independent consultant to audit your radiation safety program is commendable. However, the consultant identified a number of violations of NRC requirements that remained uncorrected at the time of a July 1991 follow-up visit by your consultant, some of which were still not corrected as of the day of the NRC inspection, September 5, 1991. To have allowed these violations of NRC requirements to occur and go undetected for an extended period and uncorrected for several months demonstrates that ineffective and or insufficient management oversight of the implementation of the radiation safety program existed at Winona Hospital.

To emphasize the need for effective management and oversight of NRC licensed activities, I am issuing the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice) in the amount of $1,250 for the Severity Level III problem.

The base value of a civil penalty for a Severity Level III problem is $2,500. The civil penalty adjustment factors in the Enforcement Policy were considered and the amount of the civil penalty was mitigated 50 percent for your corrective actions. In addition to correcting the individual violations, your more noteworthy, long term, corrective actions included the use of two separate computer systems to track regulatory requirements and your personal participation in future meetings of the Radiation Safety Committee. In evaluating the civil penalty adjustment factor of identification and reporting, the NRC recognized that your consultant identified the majority of the violations of NRC requirements. However, your actions to correct the violations were not prompt. Therefore, on balance an adjustment to the amount of the civil penalty was not made for your identification of the majority of the violations. The remaining factors in the enforcement policy were also considered and no further adjustment to the basic civil penalty is considered appropriate.

You are required to document your response to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. In your response, please ensure that you describe the actions you have taken to strengthen the management and oversight of your NRC licensed program.

After reviewing your response to this Notice, including your proposed corrective actions and the results of future inspections, the NRC will determine whether further NRC enforcement action is necessary to ensure compliance with NRC regulatory requirements.

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

Carl J Paperiello for

A. Bert Davis
Regional Administrator

Enclosure:
Notice of Violation and Proposed
Imposition of Civil Penalty

cc w/enclosure:
DCD/DCB (RIDS)

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

Winona Memorial Hospital
Indianapolis, Indiana

Docket No. 030-10965
License No. 13-16404-01
EA 91-124

During an NRC inspection conducted on September 5, 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 35.50(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 the dose calibrator for instrument linearity from February 23, 1990 until July 13, 1990 and from December 12, 1990 until April 19, 1991, periods in excess of a calendar quarter.

B. 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 conduct an annual test of the dose calibrator for instrument accuracy from November 2, 1987 until August 22, 1991.

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 232 microcuries of cesium-137 for leakage from March 27, 1989 to September 5, 1991, an interval which exceeded six months, and no other interval was approved by the Commission or an Agreement State.

D. 10 CFR 35.22(a)(2), requires that the Radiation Safety Committee meet at least quarterly.

Contrary to the above, from April 5, 1989 to September 5, 1991, the licensee's Radiation Safety Committee (Medical Isotopes Committee) did not meet during the third calendar quarter 1989, the second calendar quarter 1990, or the second calendar quarter 1991.

E. 10 CFR 35.22(a)(3) requires that to establish a quorum and conduct business, at least one half of the Radiation Safety Committee's membership must be present, including the Radiation Safety Officer and the management's representative.

Contrary to the above, on April 5, 1989, the licensee's Radiation Safety Committee (Medical Isotopes Committee) met and conducted business and the Radiation Safety Officer was not present.

. License Condition No. 18, which was in effect from September 3, 1985, until superseded by 10 CFR 35.205(e) on January 27, 1991, required that licensed material be possessed and used in accordance with statements, representations and procedures contained in an application dated March 26, 1980.

Item 21 of the March 26, 1980 application, required that the collection system (gas trap) be checked after every fifth xenon-133 ventilation study and that velometer measurements be made at least every six months to ensure that all airflow rates are maintained.

10 CFR 35.205(e), in effect since the license was renewed in its entirety on January 28, 1991, requires that a licensee check each month the operation of reusable collection systems for radioactive gases. 10 CFR 35.205(e) also requires that a licensee each six months measure the ventilation rates available in areas of use of radioactive gas.

Contrary to the above, the licensee did not check the operation of the reusable collection system (gas trap) for xenon-133 after every fifth xenon-133 ventilation study from March 27, 1989 to January 28, 1991, and from January 28, 1991, until July 1991, the licensee did not check the reusable collection system once each month. Also, the licensee did not make velometer (ventilation rate) measurements at least every six months to ensure that all ventilation rates were maintained, for the periods May 20, 1988 until February 14, 1990; February 15, 1990 until August 17, 1990; and August 17, 1990 until August 7, 1991, intervals exceeding six months.

G. 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 March 7, 1991, until May 10, 1991, the licensee did not survey with a radiation detection instrument at the end of each day, the hot lab and imaging room, areas where radiopharmaceuticals were routinely prepared for use and administered. Specifically, no such survey was performed at the end of each day of use on March 7, 1991, April 18 and 19, 1991, May 6, 7, 8, 9 and 10, 1991.

H. 10 CFR 35.50(e), 10 CFR 35.50(e)(2), and 10 CFR 35.50(e)(3) require, in part, that a licensee retain a record of the annual accuracy test of dose calibrators, retain a record of the quarterly linearity test of the dose calibrator and that the record contain the signature of the Radiation Safety Officer.

Contrary to the above, the record of annual accuracy test of the dose calibrator conducted on August 22, 1991, and the record of eight quarterly dose calibrator linearity tests conducted between April 1989 and July 1991 did not contain the signature of the Radiation Safety Officer.

I. 10 CFR 35.205(d) requires, in part, that a licensee post the safety measures to be instituted in case of a spill of a radioactive gas at the area of use and the calculated time needed after a spill to reduce the concentration to the occupational limit listed in 10 CFR Part 20, Appendix B.

Contrary to the above, from March 17, 1989 to September 5, 1991, the licensee used and stored radioactive xenon-133 gas in the hot lab and imaging room and the licensee did not post thereat the safety measures to be instituted in case of a spill of xenon-133 gas and the calculated time to reduce the concentration in the room to the limit listed in 10 CFR Part 20, Appendix B.

J. 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 and retain for five years records of its quarterly physical inventories.

Contrary to the above, for the period August 17, 1990, to March 19, 1991, the licensee did not maintain any record of the quarterly physical inventories of the one sealed source in its possession.

This is a Severity Level III problem (Supplement VI).
Cumulative Civil Penalty - $1,250 (assessed equally among the 10 violations).

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

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

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

In requesting mitigation of the proposed penalty, the factors addressed in Section V.B of 10 CFR Part 2, Appendix C (1991) should be addressed. Any written answer in accordance with 10 CFR 2.205 should be set forth separately from the statement or explanation in reply pursuant to 10 CFR 2.201, but may incorporate parts of the 10 CFR 2.201 reply by specific reference (e.g., citing page and paragraph numbers) to avoid repetition. The attention of the Licensee is directed to the other provisions of 10 CFR 2.205, regarding the procedure for imposing a civil penalty.

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

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

FOR THE NUCLEAR REGULATORY COMMISSION

Carl J Paperiello for

A. Bert Davis
Regional Administrator

Dated at Glen Ellyn, Illinois
this 16 day of October 1991

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

FEB 2 [illegible] 1990

Docket No. 9999004
License No. General License
EA 87-223

Wrangler Laboratories,
Larsen Laboratories,
Orion Chemical Company, and
Mr. John P. Larsen
3853 North Sherwood Drive
Provo, Utah 84604

Dear Mr. Larsen:

Subject: Order Suspending Licenses (Effective Immediately)

Enclosed is an Order, effective immediately, suspending the general licenses applicable to you and your three firms pending the results of NRC's investigation.

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.

The response directed by this letter and accompanying Order are not subject to the clearance procedures of the Office of Management and Budget, as required by the Paperwork Reduction Act of 1980, PL 96-511.

Sincerely,

James M. Taylor, Deputy Executive Director
for Regional Operations

Enclosure: As stated

cc: Wyoming Radiation Control Program Director
Utah Radiation Control Program Director

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

UNITED STATES
NUCLEAR REGULATORY COMMISSION

| | | |
|---|---|---|
| In the Matter of<br>Wrangler Laboratories,<br>Larsen Laboratories,<br>Orion Chemical Company, and<br>John P. Larsen<br>3853 North Sherwood Road<br>Provo, Utah 84604 | )<br>)<br>)<br>)<br>)<br>)<br>) | Docket No. 9999004<br>License No. General License<br>EA 87-223 |

ORDER SUSPENDING LICENSES (EFFECTIVE IMMEDIATELY)

I

Wrangler Laboratories, Larsen Laboratories, and Orion Chemical Company (the licensees) are firms using source material under general licenses granted by the Nuclear Regulatory Commission (the Commission/NRC) pursuant to 10 CFR 40.22. The general license granted by 10 CFR 40.22 authorizes the use or transfer of not more than 15 pounds of source material at one time and the receipt of not more than 150 pounds of source material in any one calendar year.

Larsen Laboratories is also a holder of a specific Radioactive Material License UT 2500183 issued by the State of Utah. The specific license, which authorizes possession of up to 150 kilograms of depleted uranium (DU) at one time, is currently suspended by the State of Utah.

Mr. Larsen has been doing business as (dba) Wrangler Laboratories, Larsen Laboratories, and Orion Chemical Company and is the owner and sole proprietor of these firms. Mr. Larsen's companies are all involved in the chemical processing of DU. The licensees receive slugs of DU, dissolve the material in boiling nitric acid, precipitate uranyl acetyl acetate (UAA) using 2,4 pentanedione, dissolve the UAA precipitate in benzene to produce recrystallized UAA, and subsequently dry, grind, filter, package and ship the pure UAA product. The UAA product is ultimately used as a catalyst in the production of Department of Defense munitions.

II

On August 23, 1982, an inspection was conducted at Orion Chemical Company. During the inspection NRC determined that the licensee was in violation of several regulatory requirements. These violations included possession of source material at one time in excess of the 15 pound limitation on such material, refusal to make records available to NRC, unauthorized disposal of DU, and failure to maintain complete records. Subsequently, on September 3, 1982, the NRC issued an Order to Show Cause and Order Temporarily Suspending License (Effective Immediately). On October 25, 1982, the NRC issued an Order Rescinding Order to Show Cause and Order Temporarily Suspending License. This action was taken following the licensee's corrective measures, to bring the operations into compliance. On December 15, 1982, the NRC issued a Notice of Violation (NOV) and Proposed Imposition of Civil Penalty for the above violations. The amount of the Civil Penalty was $500. On March 16, 1983, the licensee responded to the NOV and paid the Civil Penalty.

A specific license (SUB-1436) was issued by the NRC in December 1983 to Larsen Laboratories of Provo, Utah. The responsibility for overseeing this specific license was transferred to the State of Utah upon its becoming an Agreement State. On May 13, 1985, Utah reissued the specific license to Larsen Laboratories.

On April 15, 1986, NRC received an allegation of improper activities being conducted by Larsen Laboratories. The allegation was transferred to the State

of Utah which performed inspections and found numerous violations. In all, the State of Utah found 5 contaminated facilities that Mr. Larsen had abandoned.

At one of these facilities, contaminated liquids were leaking from drums that had been stored on a truck for approximately 2 years. On November 5, 1986, the State of Utah issued an Order Suspending License (Effective Immediately) and Order Imposing Civil Monetary Penalties in the amount of $13,000. The Order, which is still in effect, required, among other specified actions, that the licensee (1) not receive or use source material except to secure or transfer such source material in its possession, (2) dispose of radioactive wastes, (3) decontaminate 2 facilities in the Oren area, (4) move to production facilities that have been approved through license amendment procedures, and (5) obtain a qualified Radiation Protection Officer. On January 15, 1987, a Settlement Agreement between the State of Utah and Larsen Laboratories was signed. The Agreement required that the specified activities in the Order be completed by April 15, 1987, and that $8,000 of the civil penalties would be suspended. The licensee paid the remaining $5,000 civil penalties but has not complied with items (4) and (5) of the Order.

On October 28, 1987, the State of Wyoming informed the NRC of an allegation that it had received concerning improper activities at Wrangler Laboratories in Evanston, Wyoming. On November 4-5, 1987, NRC inspected Wrangler Laboratories and found that Mr. Larsen, doing business as Wrangler Laboratories, was conducting chemical operations in a temporary facility and appeared to have exceeded uranium possession limits. As a result of NRC concerns, NRC Region IV staff discussed with Mr. Larsen, the potentially hazardous conditions at his

Evanston facility and obtained an agreement for certain corrective measures. Those actions were specified in Confirmation of Action Letters (CAL) issued on November 12, 1987, December 8, 1987, and December 31, 1987.

An enforcement conference was held with Mr. Larsen on December 2, 1987, in Salt Lake City. During the course of the enforcement conference a number of matters of regulatory concern arose:

1. Mr. Larsen stated that he had previously conducted chemical processing of DU operations in the State of California (Fountain Valley, Huntington Beach area) about 10 to 11 years ago and in the State of Nevada (in the back of a pickup truck in the Henderson area) between November 1986 and March 1987. These statements were contradictory to those he gave to the NRC inspector during the November 4-5, 1987 inspection. During the NRC inspection, Mr. Larsen was specifically asked whether he conducted operations with source material at any place outside of the States of Utah and Wyoming. Mr. Larsen responded that he hadn't.

2. In the November 12, 1987 CAL, the licensee committed to having employees submit urine samples for uranium analyses before resuming and following the completion of the processing of the licensed material on hand at the Evanston, Wyoming, facility. During the enforcement conference, Mr. Larsen provided a November 25, 1987, letter that gave the results of such sampling. The licensee deviated from the commitment described in the November CAL in that baseline analyses were not conducted and, instead, only post-cleanup analyses were obtained on one of two individuals in these activities. The indicated post-cleanup analyses were slightly in excess of NRC action levels

for uranium bioassays. Mr. Larsen stated the reason for the elevated uranium concentrations was the use of laboratory glassware that might have been contaminated with uranium. On about November 19, 1987, four samples were taken with pharmaceutically clean glassware. Two of these four samples showed higher than baseline concentrations and none of the specimens were controlled or independently verified. Another deviation from the November 12, 1987 CAL was a failure by the licensee to require individuals who were to perform the processing of licensed material on hand to wear lapel air samplers.

3. Mr. Larsen stated that his companies were the only ones supplying UAA for Department of Defense (DOD). The NRC has determined that, contrary to this assertion, DOD purchases UAA from others.

4. Prior to and during the enforcement conference, Mr. Larsen told the NRC that UAA shipments from Wrangler Laboratories were made from Provo, Utah. Mr. Larsen provided NRC with records to support his statements. These statements, however, were contrary to statements given previously to the State of Utah authorities, who were told that all Wrangler Laboratory shipments were from Evanston, Wyoming. In addition, the records provided by Mr. Larsen also show that, notwithstanding the 15 pound possession limit, a shipment sent to the UAA buyer on August 7, 1987 from Provo, Utah, contained 16.768 pounds of source material.

5. Mr. Larsen was asked whether he or any of his companies had purchased DU from any supplier other than Nuclear Metals, Inc. Mr. Larsen responded that they hadn't. Contrary to that statement, the NRC obtained records from

Aerojet Heavy Metals Company that show that they had made DU shipments to Larsen Laboratories on more than one occasion.

In late December 1987, the NRC learned from Mr. Larsen that urine samples analyzed pursuant to the commitments in the December 8, 1987 CAL had indicated some uranium intake by persons involved in cleanup of the Evanston facility. On December 31, 1987, another CAL was issued confirming termination of activities at the Evanston facility involving uranium until further notice from the NRC and the performance of further bioassays. In deviation from a commitment specified in the December 31st CAL, the licensee failed to have two individuals submit urine samples for uranium analyses until January 10, 1988, nine days after the agreed upon date. As a result, the uranium intakes for these individuals could not be estimated.

III

The NRC is currently conducting an investigation of Mr. Larsen's NRC-licensed activities. Based on the information to date, Mr. Larsen has failed to fulfill commitments made on behalf of his firms to the NRC, has made contradictory statements to NRC and the State of Utah authorities, and his firms have processed uranium in an unsafe manner with inadequate controls and resulting contamination. These actions demonstrate an unwillingness to comply with NRC regulatory requirements and safe work practices which cannot be tolerated. Therefore, I lack the requisite reasonable assurance that Mr. Larsen, individually, and the companies, which he is the owner of and/or principal of, will

comply with Commission requirements in the future. Therefore, I have determined, pursuant to 10 CFR 2.201(c) and 2.202(f), that the public health, safety, and interest require that pending the results of the investigation and further order of the NRC, the general license authorization for Mr. Larsen, as well as the named licensees, to receive and use NRC licensed material under their respective general licenses should be suspended subject to conditions, as described below, effective immediately, and that no prior notice is required.

IV

Accordingly, in view of the foregoing and pursuant to Sections 62, 63, 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 Parts 2 and 40, IT IS HEREBY ORDERED, EFFECTIVE IMMEDIATELY, THAT:

A. The general license authority of 10 CFR 40.22 with respect to Wrangler Laboratories, Larsen Laboratories, Orion Chemical Company, and Mr. Larsen is suspended and the foregoing licensees and Mr. Larsen shall not receive or use source material, except as permitted in Condition B below.

B. 1. Mr. Larsen, dba Wrangler Laboratories, shall decontaminate all surfaces and equipment within the Evanston, Wyoming, facility to or below the following levels:

Average* fixed - 5,000 dpm alpha per 100 $cm^2$

Maximum fixed - 15,000 dpm alpha per 100 $cm^2$

Removable - 1,000 dpm alpha per 100 $cm^2$

*Average over an area not greater than 1 square meter.

2. Mr. Larsen, dba Wrangler Laboratories, shall dispose of licensed material (DU) remaining in the Evanston, Wyoming, facility. Material in process, but not recovered as UAA to date, must be disposed of as radioactive waste in accordance with NRC requirements.

3. Mr. Larsen, dba Wrangler Laboratories, shall complete the disposal and decontamination work required by Items B.1 and B.2 within 30 days of the date of this Order.

4. Mr. Larsen shall notify the Region IV office that the decontamination and disposal has been in accordance with this Order before vacating the Evanston Wyoming facility. Upon vacating the facility, Mr. Larsen, dba Wrangler Laboratories, shall remove all items belonging to the licensee.

C. Within 30 days of the date of this Order, Mr. Larsen, dba the licensees, any other company, or himself shall provide, in writing, to the Region IV office the address, if available, or a description of all locations at which DU in any form or quantity has at any time been received, processed, or shipped by Mr. John P. Larsen or by any other person or firm on Mr. Larsen's behalf.

D. Mr. Larsen, dba the licensees, shall submit a report of the results of all urine sample uranium analyses which were committed to NRC on and since December 4, 1987, to NRC Region IV within 30 days of the date of this Order.

The Regional Administrator, Region IV may, in writing, relax or rescind any of the above provisions in Section IV for good cause.

V

Pursuant to 10 CFR 2.202(b), the licensees and Mr. Larsen, may show cause why this Order should not have been issued by filing a written answer under oath or affirmation within 20 days of the date of issuance of this Order, setting forth the matters of fact and law on which the licensees and Mr. Larsen rely. The licensees and Mr. Larsen, may answer this Order, as provided in 10 CFR 2.202(d), by consenting to the provisions specified in Section IV above. Upon consent of Mr. Larsen or the licensees, to the provisions set forth in Section IV of this Order, or upon their failure to file an answer within the specified time, the provisions specified in Section IV above shall be final without further Order.

VI

Pursuant to 10 CFR 2.202(b), Mr. Larsen and the licensees, or any other person adversely affected by this Order may request a hearing within 20 days of this Order. Any answer to this Order or request for hearing shall be

submitted to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555. Copies also shall be sent to the Assistant General Counsel for Enforcement, Office of General Counsel at the same address and to the Regional Administrator, NRC Region IV, 611 Ryan Plaza Drive, Suite 1000, Arlington, Texas 76011. If a person other than Mr. Larsen, dba the licensees requests a hearing, that person shall set forth with particularity the manner in which the petitioner's interest is adversely affected by this Order and should address the criteria set forth in 10 CFR 2.714(d). AN ANSWER TO THIS ORDER OR A REQUEST FOR HEARING SHALL NOT STAY THE IMMEDIATE EFFECTIVENESS OF THIS ORDER.

If a hearing is requested, 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

James M. Taylor, Deputy Executive Director
for Regional Operations

Dated at Bethesda, Maryland,
this 25th day of February 1988

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

AUG 15 1988

Docket No. 9999004
License No. General License
EA 87-223

Wrangler Laboratories,
Larsen Laboratories,
Orion Chemical Company, and
Mr. John P. Larsen
3853 North Sherwood Drive
Provo, Utah 84604

Dear Mr. Larsen:

Subject: Order Revoking Licenses

Enclosed is an Order revoking, as applicable to you and your three firms, the general licenses which authorize the use and transfer of source material under the provisions of 10 CFR 40.22.

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.

The response directed by this letter and accompanying Order are not subject to the clearance procedures of the Office of Management and Budget, as required by the Paperwork Reduction Act of 1980, PL 96-511.

Sincerely,

James M. Taylor, Deputy Executive Director
for Regional Operations

Enclosure: As stated

cc w/enclosure:
Wyoming Radiation Control Program Director
Utah Radiation Control Program Director
Nevada Radiation Control Program Director

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

UNITED STATES
NUCLEAR REGULATORY COMMISSION

| | | |
|---|---|---|
| In the Matter of<br>WRANGLER LABORATORIES,<br>LARSEN LABORATORIES,<br>ORION CHEMICAL COMPANY, and<br>JOHN P. LARSEN<br>Provo, Utah | ) | Docket No.: 9999004<br>License No.: General License<br>EA 87-223 |

ORDER REVOKING LICENSES

I

Wrangler Laboratories, Larsen Laboratories, and Orion Chemical Company (the licensees) are firms using source material under general licenses granted by the Nuclear Regulatory Commission (the Commission/NRC) pursuant to 10 CFR 40.22. The general license granted by 10 CFR 40.22 authorizes the use or transfer of not more than 15 pounds of source material at one time and the receipt of not more than 150 pounds of source material in any one calendar year.

II

Mr. John P. Larsen has been doing business as (dba) Wrangler Laboratories, Larsen Laboratories, and Orion Chemical Company and is the owner and sole proprietor of these firms. Mr. Larsen's companies are all involved in the chemical processing of depleted uranium (DU). The licensees receive slugs of DU, dissolve the material in boiling nitric acid, precipitate uranyl acetyl acetate (UAA) using 2,4 pentanedione, dissolve the UAA precipitate in benzene to produce recrystallized UAA, and subsequently dry, grind, filter, package and ship the pure UAA product. The UAA product is ultimately used as a catalyst in the production of Department of Defense munitions.

On August 23, 1982, an inspection was conducted at Orion Chemical Company. During the inspection, NRC determined that the licensee was in violation of several regulatory requirements. These violations included possession of source material at one time in excess of the 15-pound limitation on such material, refusal to make records available to NRC, unauthorized disposal of DU, and failure to maintain complete records. Subsequently, on September 3, 1982, the NRC issued an Order to Show Cause and Order Temporarily Suspending License (Effective Immediately). On October 25, 1982, the NRC issued an Order Rescinding Order to Show Cause and Order Temporarily Suspending License. This action was taken following the licensee's corrective measures to bring the operations into compliance. On December 15, 1982, the NRC issued a Notice of Violation (NOV) and Proposed Imposition of Civil Penalty for the above violations. The amount of the Civil Penalty was $500. On March 16, 1983, the licensee responded to the NOV and paid the Civil Penalty.

As a result of the August 1982 inspection, the NRC determined that Mr. Larsen's chemical processing activity should be conducted under a specific license, due to the potential for contamination of workers and the environment. A specific license (SUB-1436) was issued by the NRC in December 1983 to Larsen Laboratories of Provo, Utah. The responsibility for overseeing this specific license was transferred to the State of Utah upon its becoming an Agreement State. On May 13, 1985, Utah reissued to Larsen Laboratories specific Radioactive Material License UT2500183, which authorizes possession of up to 150 kilograms of DU at one time.

On April 15, 1986, NRC received an allegation of improper activities being conducted by Larsen Laboratories. The allegation was transferred to the State of Utah, which performed inspections and found numerous violations. In all, the State of Utah found five contaminated facilities in which Mr. Larsen had conducted activities.

At one of these facilities, contaminated liquids were leaking from drums that had been stored on a truck for approximately 2 years. On November 5, 1986, the State of Utah issued an Order Suspending License (Effective Immediately) and Order Imposing Civil Monetary Penalties in the amount of $13,000. The Order, which is still in effect, required, among other specified actions, that the licensee: (1) not receive or use source material except to secure or transfer such source material in its possession, (2) dispose of radioactive wastes, (3) decontaminate two facilities in the Orem area, (4) move to production facilities that have been approved through license amendment procedures, and (5) obtain a qualified Radiation Protection Officer. On January 15, 1987, a Settlement Agreement between the State of Utah and Larsen Laboratories was signed. The Agreement required that the specified activities in the Order be completed by April 15, 1987, and that $8,000 of the Civil Penalties would be suspended. The licensee paid the remaining $5,000 Civil Penalties but has not complied with items (4) and (5) of the Order.

On October 28, 1987, the State of Wyoming informed the NRC of an allegation that it had received concerning improper activities at Wrangler Laboratories in Evanston, Wyoming. On November 4-5, 1987, NRC inspected Wrangler Laboratories and found that Mr. Larsen, dba Wrangler Laboratories, was conducting chemical

operations in a temporary facility and appeared to have exceeded uranium possession limits. As a result of NRC concerns, an enforcement conference was held with Mr. Larsen on December 2, 1987, in Salt Lake City. Subsequent to the November 4-5, 1987, inspection of the Evanston, Wyoming, facility, NRC Region IV also obtained agreements with Mr. Larsen for certain corrective measures intended (1) to terminate licensed activities at the Evanston facility, which was considered inadequately equipped for the chemical processing of depleted uranium, (2) to provide followup monitoring for certain individuals who had previously shown elevated uranium in their urine, and (3) to safely remove all licensed material, waste, and contamination from the facility so that it could be returned to unrestricted use. These actions were specified in Confirmation of Action Letters (CALs) issued on November 12, December 8 and 31, 1987 and March 18 and April 1, 1988.

NRC Region IV also began an investigation of Mr. Larsen's NRC licensed activities. This action was taken in response to questions raised during the NRC inspection and the enforcement conference concerning Mr. Larsen's previous activities in acquiring, processing, and transferring DU, and questions surrounding bioassay samples and Mr. Larsen's compliance with the CALs. The results of the investigation have not been issued as of the date of this Order. However, the investigative results available substantiate the NRC staff's concerns that Mr. Larsen's activities under the general license were conducted with a significant disregard for the safety of himself and his employees, and for the public health and safety. This was indicated by the uranium levels in the employee bioassay samples.

Due to the questions surrounding Mr. Larsen's activities, the apparent use of inadequate controls that resulted in contamination exceeding NRC guidelines, evidence of internal contamination of workers, and Mr. Larsen's apparent inability to strictly comply with Confirmation of Action Letters, an NRC Order dated February 25, 1988, issued to Mr. Larsen and the companies he represents suspended the general licenses. The Order also allowed the licensees and Mr. Larsen to show cause why the Order should not have been issued by filing a written answer under oath or affirmation setting forth the matters of fact and law on which the licensees and Mr. Larsen rely. Mr. Larsen's response to the Order, which was not under oath or affirmation, was sent by letter dated March 18, 1988. That response is addressed below and in the Appendix to this Order.

Mr. Larsen's March 18, 1988, reply to the NRC Order confirmed the following information:

(1) That he exceeded the 15-pound limit for transfer of source material under a general license issued pursuant to 10 CFR 40.22 by originating shipments from Wyoming of 16.7 and 16.3 pounds of DU on June 1 and December 20, 1987, respectively. He also confirmed that he transferred DU from his Utah facility to his customer on five dates (December 9, 1986; February 2, 9, and 17, and March 3, 1987) that were well after the State of Utah's November 3, 1986 Order suspending his specific license and requiring, among other things, that he immediately place all source material in his possession in locked storage or transfer such material to an authorized recipient.

(2) That he exceeded the annual limit of 150 pounds for receipt of source material under a general license at his Evanston, Wyoming, facility. The amount received was at least 155.8 pounds in 1987.

(3) That, in deviation from Item 1 of the CAL dated November 12, 1987, Mr. Larsen failed to obtain baseline urine samples from two individuals who worked in the final processing and cleanup of the Evanston, Wyoming, facility. According to Mr. Larsen, "their baseline levels were assumed to be zero," and he "was trying to keep expenses down."

(4) That, in deviation from Item 2 of the CAL dated December 31, 1987, Mr. Larsen failed to submit with the workers' urine samples a background sample. The employee samples that were submitted showed high uranium values that Mr. Larsen later attributed to contamination within the sample containers and/or the fact that the samples were damaged in transit to the laboratory.

(5) That, in deviation from Item 3 of the CAL dated December 31, 1987, Mr. Larsen stopped collecting urine samples from two individuals every 3 days, as committed to, before he had received confirmation that results from two consecutive samples were less than 30 micrograms per liter.

(6) That, in deviation from Item 4 of the CAL dated December 31, 1987, the results of certain urine bioassay results that showed a high uranium concentration were not submitted to the Region IV office when they were received by Mr. Larsen. In his letter of March 18, 1988, Mr. Larsen claims the results were not sent to Region IV because "the samples were questionable."

In addition to the above, the NRC had determined by inspection or by other information provided by Mr. Larsen that his activities in Wyoming involved the following:

- Mr. Larsen stated in the March 18, 1988 reply to the Order Suspending License that when he moved his operation from Utah to Wyoming he started with "a new understanding and resolve for absolute confinement of source material and waste materials," and "on the whole, we were much improved in our work operation." Despite this claim, the NRC found that Mr. Larsen's Wyoming facility was inadequate for the purpose it was being used. For example, prudent engineering controls such as those that Mr. Larsen was committed to under the terms of his Utah license for the same activity -- ventilation and air filtration units or filtered fume hoods -- were not in place in Larsen's Wyoming facility. There was no plumbing in the facility, and few contamination surveys or air samples had been documented by Mr. Larsen.

- The personnel bioassay samples obtained by Mr. Larsen have shown unacceptably high uranium concentrations. Since February 1987, samples have been submitted on a total of four individuals who have worked at the Evanston facility. All four have, on at least one occasion, exceeded levels at which action is recommended by NRC. Of all the sample results reported, 50 percent exceeded the action level (30 ug/l). Mr. Larsen has suggested reasons for the high values, including contaminated sample containers, samples damaged and found leaking in transport, the consumption of food in his facility which may have been contaminated, and questionable analytical results by the contractor laboratory. Many, if not all, of

these reasons could have been confirmed or ruled out if Mr. Larsen had complied with the CALs by collecting samples in containers known to be free of contamination, by submitting baseline and background samples, and by collecting samples according to the committed schedule.

III

Aside from Mr. Larsen's enforcement history and previous noncompliance under his specific licenses in Utah, the activities conducted in Wyoming under an NRC general license have raised serious concerns within the NRC. The activities have taken place in a facility which was inadequate, with no assurance that similar activities in the future would be conducted in a more suitable facility. The activities, which have involved the chemical processing of significant amounts of source material, are of such a nature that the radiation safety, chemical safety, and waste disposal aspects of the operation should not be conducted under a general license. Moreover, activities of this nature were not anticipated by the AEC at the time of 10 CFR 40.22 rulemaking. The exemption in 10 CFR 40.22(b) from the requirements of 10 CFR Parts 19 and 20 clearly indicates that activities under the general license were seen as not involving an occupational radiation hazard. Finally, the specific conduct of Mr. Larsen's Wyoming operation with respect to compliance with source material possession limits and Confirmation of Action Letters has established a record of performance unacceptable to the NRC.

In consideration of the collective conclusions stated above, I lack the requisite reasonable assurance that Mr. Larsen, individually, and his companies

will comply with Commission requirements in the future. Therefore, I have determined that the public health, safety, and interest require that the general license authorization for Mr. Larsen, as well as the named licensees, to receive and use NRC licensed material, under their respective general licenses, should be revoked.

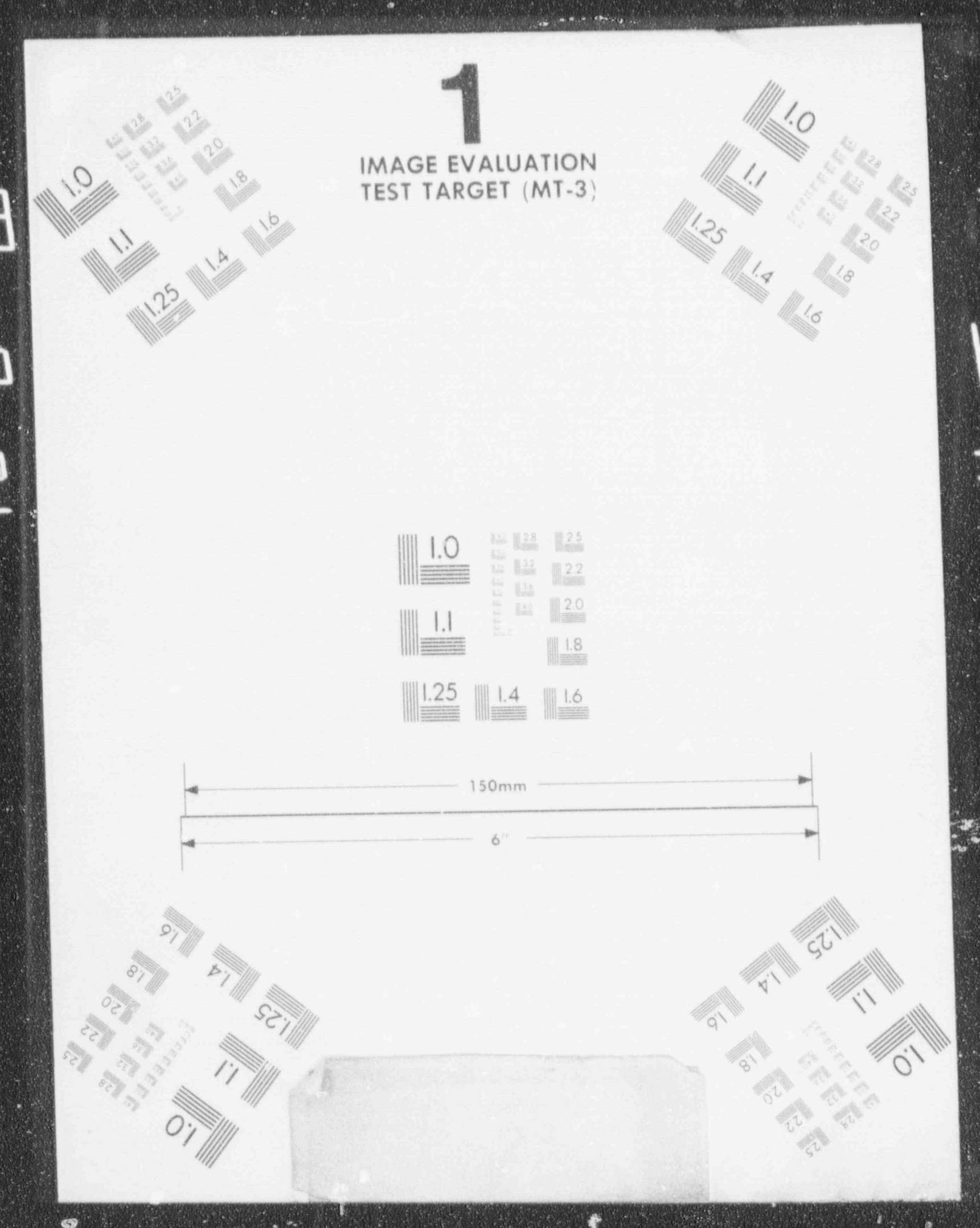
IV

Accordingly, in view of the foregoing and pursuant to Sections 62, 63, 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 Parts 2 and 40, IT IS HEREBY ORDERED THAT:

The general license authority of 10 CFR 40.22 with respect to Wrangler Laboratories, Larsen Laboratories, Orion Chemical Company, and Mr. John P. Larsen is revoked and the foregoing licensees and Mr. Larsen shall not receive or use source material under the auspices of a general license in locations under NRC jurisdiction.

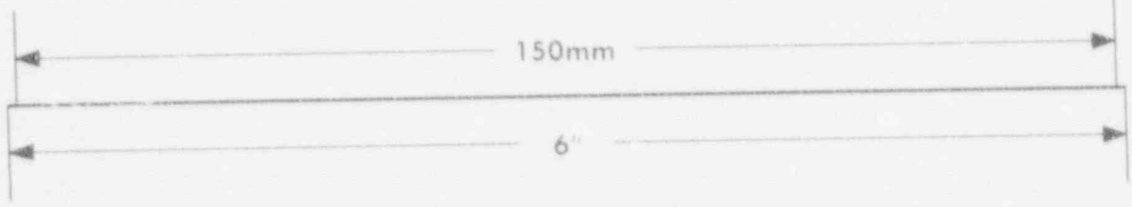
V

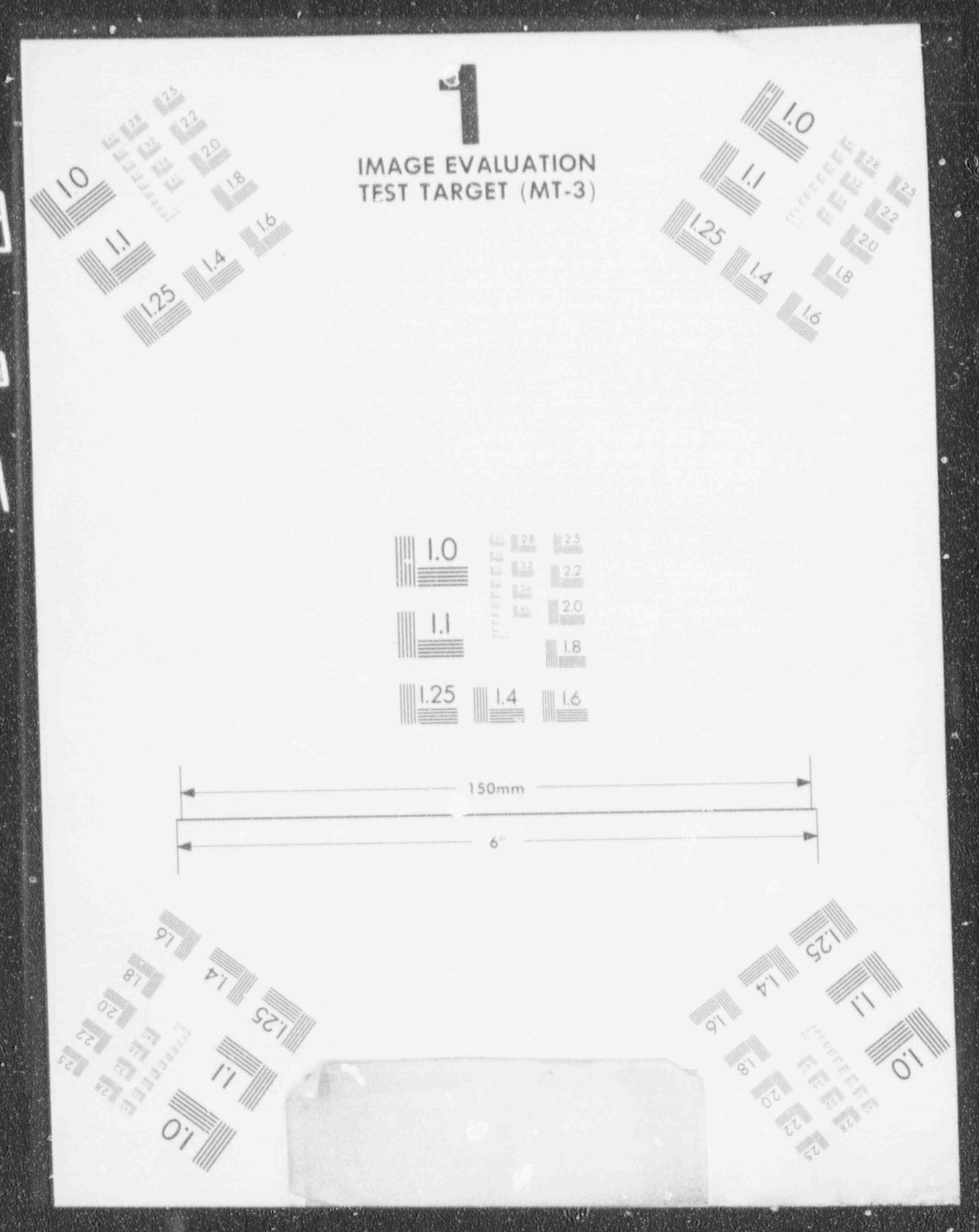
Upon consent of Mr. Larsen or the licensees to the provisions set forth in Section IV of this Order, the provisions specified in Section IV above shall be final without further Order.


1
IMAGE EVALUATION
TEST TARGET (MT-3)
1.0
1.1
1.25
1.4
1.6
1.8
2.0
2.2
2.5
2.8
3.2
3.6
4.0
150mm
6"

# 1

## IMAGE EVALUATION TEST TARGET (MT-3)


1
IMAGE EVALUATION
TEST TARGET (MT-3)
1.0
1.1
1.25
1.4
1.6
1.8
2.0
2.2
2.5
2.8
3.2
3.6
4.0
150mm
6"

VI

Pursuant to 10 CFR 2.202(b), Mr. Larsen, either one or more of the licensees, or any other person adversely affected by this Order, may request a hearing within 20 days of this Order. Any request for hearing shall be submitted to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555. Copies also shall be sent to the Assistant General Counsel for Enforcement, Office of the General Counsel at the same address and to the Regional Administrator, NRC Region IV, 611 Ryan Plaza Drive, Suite 1000, Arlington, Texas 76011. If a person other than Mr. Larsen dba the licensees, requests a hearing, that person shall set forth, with particularity, the manner in which the petitioner's interest is adversely affected by this Order and should address the criteria set forth in 10 CFR 2.714(d). Upon the failure of the licensee to request a hearing within the specified time, this Order shall be final without further proceedings.

If a hearing is requested, 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

James M. Taylor, Deputy Executive Director
for Regional Operations

Dated at Rockville, Maryland,
this 15th day of August 1988

APPENDIX

Supplemental Evaluation Of Mr. Larsen's March 18, 1988, Reply To The February 25, 1988, Order

Some aspects of Mr. Larsen's March 18, 1988, letter are addressed in the body of this Order. The remaining aspects are addressed in this supplement. The page references are to Mr. Larsen's letter.

Page 1 - Mr. Larsen expre a valid concern about not having received the findings and recommended decontamination plan following the January 19-20, 1988, survey by Oak Ridge Associated Universities. Coincidentally, that information was mailed to Mr. Larsen on March 18, 1988.

Page 1 - Mr. Larsen expressed concern about the connotation of the word "abandoned," as used in the February 25, 1988, Order. The Order published in the March 8, 1988, Federal Register states, "In all, the State of Utah found 5 contaminated facilities that Mr. Larsen had abandoned." As we understand it, the Utah Bureau of Radiation Control found uranium contamination at every facility that Mr. Larsen had vacated or, as we chose to state it, "had abandoned." To our knowledge this is a truthful statement. The remainder of the paragraph is fact.

Page 2 - Mr. Larsen expressed concern about the accuracy of the state that "On October 28, 1987, the state of Wyoming informed the NRC of an allegation that it had received concerning improper activities at Wrangler Laboratories in Evanston, Wyoming." That statement describes accurately how NRC Region IV first learned of Mr. Larsen's activities in Evanston.

Page 2 - Mr. Larsen implied that he had been candid regarding the locations where he had processed depleted uranium. We concede that Mr. Larsen might not have understood the period of interest to the inspector. However, we also note that Mr. Larsen was not immediately candid in answering a similar question during the December 2, 1987, enforcement conference.

Page 3 - Mr. Larsen contested the statement that he had deviated from a November 12, 1987, CAL commitment to conduct baseline urinalyses. But Mr. Larsen in his March 18, 1988 reply to the NRC Order dated February 25, 1988 admitted that baseline urine samples from two individuals were not obtained because their baseline levels were assumed to be zero and he was trying to keep expenses down.

Page 3 - During the enforcement conference on December 2, 1987, Mr. Larsen stated that he did not have results of lapel air sampler measurements required by the November 12, 1987, CAL. Subsequently, the NRC determined that a lapel sampler probably had been worn by one person (but not by all involved persons) during work performed November 10-13, 1987, thus partly satisfying the November 12 CAL.

Page 3 - Regarding Mr. Larsen's claim to being the sole supplier of UAA to the Department of Defense, as stated in the Order, NRC has determined that DOD purchases UAA from others.

Page 4 - As stated in the Order, State of Utah authorities had been told that UAA was being shipped from Evanston, Wyoming, not from Utah.

Page 4 - Mr. Larsen notes that the purchase of DU from Aerojet Heavy Metals had occurred several years ago. This fact is unimportant. The Order simply states the discrepancy between Mr. Larsen's statement and a supplier's records without regard to time.

Page 4 - Mr. Larsen stated that he tried to comply with the December 31, 1987 CAL. Specifically, the CAL called for two individuals, who had previously shown elevated uranium concentrations in their urine, to submit additional urine sarples starting no later than January 1, 1988, and continuing once every three days until such time that the results of two consecutive samples for each individual showed less than 30 micrograms per liter. The reason for the action, as explained to Mr. Larsen during the telephone conversation of December 31, 1988, was concern for the individuals, and the uncertainty surrounding the cause of the previous high values. At that time the best method of validating the bioassay results and estimating potential intake was to immediately begin tracking the concentration over time before the remainder of any internally deposited uranium was excreted.

As NRC learned later, Mr. Larsen did obtain samples from the two individuals during the period from December 28, 1987 to January 3, 1988. One individual submitted two samples, the other three, with a sample frequency of three days. After January 3, 1988, no other samples were obtained until January 10, 1988, despite the fact that the results of the December 28, 1987 through January 3, 1988 samples would not be known by Mr. Larsen until the samples were assayed on January 8, 1988. The assayed samples once again showed high uranium concentrations, all well above 30 micrograms per liter. In deviation from the CAL, there were no subsequent three day samples following January 3, 1988, and the opportunity to track the bioassays over time until they were below the action level had been lost. Recognizing that the results were above the stated action levels, Mr. Larsen reinitiated the sampling on January 10 and 13, 1988. These samples, which were assayed on January 21, 1988, were less than 30 micrograms per liter and were, in fact, background levels.

The December 31, 1988 CAL also called for Mr. Larsen to submit copies of the results of the urine sample measurements to the Region IV office as he received them. Noting that Region IV had not received copies of the results in the time frame expected, the NRC inspector called Mr. Larsen on February 4, 1988. Mr. Larsen stated that he had just received the results and was forwarding them. The results he forwarded were those from January 10-13, 1988 samples.

The December 28, 1987 through January 3, 1988 samples that Mr. Larsen learned from his contractor laboratory on January 8, 1988, contained high uranium concentrations, were not reported to Region IV. Noting that the sample dates of the results reported to Region IV did not coincide with those specified in the CAL, the NRC inspector again called Mr. Larsen on February 9, 1988 to inquire into the discrepancy. Only then did Mr. Larsen reveal that the earlier samples had been taken and showed high values. Mr. Larsen stated that these results were not reported to the NRC because he believed they were erroneous.

II.B. MATERIALS LICENSEES, SEVERITY LEVEL III VIOLATION,
NO CIVIL PENALTY

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

November 25, 1991

Docket No. 030-17800
License No. 29-19503-01
EA 91-150

Lippincott Engineering Associates
ATTN: Moustafa A. Gouda
Principal
One Pavillion Avenue
Riverside, New Jersey 08075

Dear Mr. Gouda:

Subject: NOTICE OF VIOLATION
(NRC Inspection Report No. 030-17800/91-001)

This letter refers to the NRC inspection conducted on October 30-31, 1991, at your facility in Riverside, New Jersey, and at a temporary field (construction) site in Willow Grove, Pennsylvania, of activities authorized by NRC License No. 29-19503-01. The inspection report was sent to you on November 8, 1991. During the inspection, eight apparent violations of NRC requirements were identified. On November 20, 1991, an enforcement conference was conducted with you and a member of your staff to discuss the apparent violations, their causes and your corrective actions. A copy of the Enforcement Conference Report is enclosed.

The most significant violations identified during the inspection involved the failure to maintain proper security of licensed radioactive material located at the field site in Willow Grove. Specifically, on October 30, 1991, a United States OSHA inspector observed a Troxler moisture/density gauge (which contained 8 millicuries of cesium-137 and 40 millicuries of americium-241) unattended within the perimeter of the fence of the field site. This constituted a violation of NRC requirements since the gauge, while unattended in this unrestricted area, was not secured from removal. In addition, when NRC inspectors arrived a short time later, they determined that the gauge, while unattended, did not have a lock, or an outer container that was locked, so as to prevent unauthorized or accidental removal of the sealed source from its shielded position. This failure constitutes a second violation of NRC requirements.

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

These two violations are of particular concern to the NRC because they could have resulted in the loss or theft of the radioactive material, as well as unnecessary exposure of individuals to radiation, since the entrance to the site, which was located in a residential area, could have allowed easy access to the gauge by members of the public. The second violation made this occurrence particularly significant because not only could the gauge be lost or stolen, but the sealed source, which was also easily accessible, could have been easily operated to an exposed position or removed, which could have resulted in significant radiological consequences. These two violations are described in Section I of the enclosed Notice.

With respect to the other six violations, five are described in Section II of the enclosed Notice, and consisted of: (1) failure by a technician to wear a film badge when operating the portable nuclear gauge; (2) failure to perform a leak test of the sealed sources within the gauge within the required time interval; (3) transporting the gauge in the passenger compartment of a privately owned vehicle; (4) failure to properly block and brace the gauge while in transport; and (5) failure to maintain a shipping paper in an accessible and recognizable location when transporting the gauge. These violations are described in Section II of the enclosed Notice. With respect to the sixth violation, involving the failure to have appropriate records of physical inventories, the NRC has decided to exercise enforcement discretion and not issue a citation for this violation, for the reasons described in the enclosed enforcement conference report.

The two violations set forth in Section I of the enclosed Notice are classified 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) (1991), because of the loss of control of the radioactive material, and the potential hazards associated with that condition. The five violations set forth in Section II of the Notice are individually classified at Severity Level IV.

The NRC recognizes that subsequent to the inspection, prompt and extensive actions were initiated to correct the violations and effect improvements in the control of these gauges. These actions, which were described at the enforcement conference, included: (1) counselling of the individual involved; (2) promptly summoning all technicians from the field sites to your main office so as to inform them of the need to abide by regulatory requirements; (3) prompt issuance of a memorandum by the Radiation Safety Officer on October 31, 199[illegible], regarding the importance of following procedures, and noting in that memorandum that individuals will be held accountable for such adherence; (4) placement of the memorandum in the personnel file of each of the technicians, with a requirement that they read and initial it; (5) purchase of chains and handle locks for each of the gauges for use by the technicians while the gauges are used at field sites; (6) planned creation of additional checklists, both for the technicians, as well as the Radiation Safety Officer, to assist them in ensuring adherence

to requirements during the performance of their duties; (7) quarantining out-of-service gauges under the RSO's control; and (8) reinstatement of the technician's film badge prior to continued use of the gauges.

Normally, a civil penalty is issued for violations of the type set forth in Section I of the enclosed Notice in order to emphasize the importance of implementing long-lasting corrective actions to ensure that licensed activities are conducted safely and in accordance with requirements. However, after consideration of the escalating and mitigating factors in this case, I have been authorized to issue the enclosed Notice of Violation without a civil penalty in view of your prompt and comprehensive corrective actions, as well as your past good history. The NRC emphasizes, however, that any similar violations in the future may result in escalated enforcement action.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice of Violation when preparing your response. In your response, you should document the specific actions taken and any additional actions you plan to prevent recurrence. After reviewing your response to this Notice, including your proposed corrective actions, and the results of future inspections, the NRC will determine whether further 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 Enclosure 1 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

NOTICE OF VIOLATION

Lippincott Engineering Associates
Riverside, New Jersey 08075

Docket No. 030-17800
License No. 29-19503-01
EA 91-150

During an NRC inspection conducted on October 30-31, 1991, violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR 2, Appendix C (1991), the violations are set forth below:

I. VIOLATIONS OF SECURITY REQUIREMENTS

A. 10 CFR 20.207(a) requires that licensed materials stored in an unrestricted area be secured against unauthorized removal from the place of storage. 10 CFR 20.207(b) requires that licensed materials in an unrestricted area and not in storage be tended under constant surveillance and immediate control of the licensee. As defined in 10 CFR 20.3(a)(17), an unrestricted area is any area access to which is not controlled by the licensee for purposes of protection of individuals from exposure to radiation and radioactive materials.

Contrary to the above, between approximately 9:50 a.m. and 10:30 a.m. on October 30, 1991, licensed material (consisting of 8 millicuries of cesium-137 and 40 millicuries of americium-241 contained in a Troxler portable moisture/density gauge, Model 3440), located in a field construction site at 307 Davisville Road, Willow Grove, Pennsylvania, an unrestricted area, was not secured against unauthorized removal, nor was it under the constant surveillance and immediate control of the licensee's technician who had left the area where the gauge was stored.

B. Licensee Condition 16 of License No. 29-19503-01 requires that each portable nuclear gauge shall have a lock or outer locked container designed to prevent unauthorized or accidental removal of the sealed source from its shielded position. The gauge or its container shall be locked when in transport or when not under the direct surveillance of an authorized user.

Contrary to the above, between approximately 9:50 a.m. and 10:30 a.m. on October 30, 1991, a Troxler portable moisture/density gauge, Model 3440, containing 8 millicuries of cesium-137 and 40 millicuries of americium-241, did not have a lock or outer locked container designed to prevent unauthorized or accidental removal of the sealed source from its shielded position when it was not under the direct surveillance of an authorized user at the field construction site located at 307 Davisville Road, Willow Grove, Pennsylvania.

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

II. VIOLATIONS OF OTHER REQUIREMENTS

A. License Condition 18 of License No. 29-19503-01 requires, in part, that the licensee conduct its program in accordance with the statements, representations, and procedures contained in an application dated July 24, 1980.

Item 12.A of the application, dated July 24, 1980, requires that a film badge be worn when operating Troxler Electronic Laboratories, Incorporated, portable moisture/density gauges.

Contrary to the above, on October 30, 1991, a technician operated a Troxler Electronic Laboratories, Incorporated, portable moisture/density gauge, Model 3440, containing 8 millicuries of cesium-137 and 40 millicuries of americium-241, at a field construction site located at 307 Davisville Road, Willow Grove, Pennsylvania, and at the time, the technician did not wear a film badge.

B. License Condition 13.A of License No. 29-19503-01 requires that sealed sources be tested for leakage and/or contamination at intervals not to exceed 6 months, or at such other intervals specified by the certificate of registration (but not exceeding 3 years).

Contrary to the above, as of October 31, 1991, a Troxler Electronic Laboratories, Incorporated, portable moisture/density gauge, Model 3440, containing 8 millicuries of cesium-137 and 40 millicuries of americium-241, had not been leak tested since April 4, 1991, a time interval greater than 6 months, and no other such interval was specified in the certificate of registration.

C. 10 CFR 71.5(a) requires that a licensee who transports licensed material outside of the confines of its plant or other place of use, or who delivers licensed material to a carrier for transport, comply with the applicable requirements of the regulations appropriate to the mode of transportation of the Department of Transportation in 49 CFR Parts 170 through 189.

1. 49 CFR 177.817(e) requires that a driver of a motor vehicle containing hazardous material, and each carrier using such a vehicle, shall ensure that the shipping paper required by this section is readily available to, and recognizable by, authorities in the event of an accident or inspection.

   Contrary to the above, on October 30, 1991, a motor vehicle was used to transport hazardous material (namely, a Troxler moisture/density gauge containing 8 millicuries of cesium-137 and 40 millicuries of americium-241) from Riverside, New Jersey to the field construction site in Willow Grove, Pennsylvania, and, at the time, the required shipping paper would not have been readily available to, and recognizable by, authorities in the event of accident or inspection, in that the driver stored the shipping paper in the locked gauge transportation container among miscellaneous documents.

2. 49 CFR 177.842(d) requires that packages must be so blocked and braced so that they cannot change position during conditions normally incident to transportation.

   Contrary to the above, on October 30, 1991, a transportation container within which was located a Troxler Electronic Laboratories, Incorporated, moisture/density gauge, Model 3440, was not properly blocked and braced while it had been transported to a field construction site located at 307 Davisville Road, Willow Grove, Pennsylvania, so that it could not change position during conditions normally incident to transportation. Specifically, the gauge was placed on the back passenger seat of a station wagon, and only a briefcase and the front passenger seat were available to secure the container in place. As a result, the package could have changed position during conditions normally incident to transportation.

3. 49 CFR 173.448(c) requires that packages bearing labels prescribed in 49 CFR Part 172.403, may not be carried in compartments occupied by passengers, except in those compartments exclusively reserved for couriers accompanying those packages.

   Contrary to the above, on October 30, 1991, a package labeled "Radioactive - Yellow II" in accordance with 49 CFR 172.403, containing 8 millicuries of cesium-137 and 40 millicuries of americium-241, was carried in the passenger compartment of a privately owned

car which was driven to a field construction site located at 307 Davisville Road, Willow Grove, Pennsylvania, from Riverside, New Jersey. Such transportation did not involve a compartment exclusively reserved for a courier.

These are Severity Level IV violations (Supplements IV, V and VI).

Pursuant to the provisions of 10 CFR 2.201, Lippincott Engineering Associates (Licensee) is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555, with a copy to the Regional Administrator, Region I, within 30 days of the date of the letter transmitting this Notice of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each alleged violation: (1) the reasons for the violation, or if contested, the basis for disputing the violation, (2) the corrective steps that have been taken and the results achieved, and (3) the corrective steps that will be taken to avoid further violations, and (4) the date when full compliance will be achieved. If an adequate reply is not received within the time specified in this Notice, an order 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.

Dated at King of Prussia, Pennsylvania
this 25th day of November 1991

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. 10, No. 4

2. TITLE AND SUBTITLE

Enforcement Actions: Significant Actions Resolved
Quarterly Progress Report
October - December 1991

3. DATE REPORT PUBLISHED

MONTH: March
YEAR: 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, D.C. 20555

9. SPONSORING ORGANIZATION – NAME AND ADDRESS (If NRC, type "Same as above"; if contractor, provide NRC Division, Office or Region, U.S. Nuclear Regulatory Commission, and mailing address.)

Same as above

10. SUPPLEMENTARY NOTES

11. ABSTRACT (200 words or less)

This compilation summarizes significant enforcement actions that have been resolved during one quarterly period (October - December 1991) 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

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

OFFICIAL BUSINESS
PENALTY FOR PRIVATE USE, $300

FIRST CLASS MAIL
POSTAGE & FEES PAID
USNRC

PERMIT No. G-67