

NUREG-0940
Vol. 10, No. 1

Enforcement Actions: Significant Actions Resolved

Quarterly Progress Report
January-March 1991

U.S. Nuclear Regulatory Commission

Office of Enforcement



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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 (January - March 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

	<u>Page</u>
ABSTRACT	iii
INTRODUCTION.....	1
SUMMARIES.....	3
I. REACTOR LICENSEES	
A. Civil Penalties and Orders	
Baltimore Gas and Electric Company, Baltimore, Maryland (Calvert Cliffs Nuclear Power Plant) EA 90-185.....	I.A-1
Commonwealth Edison Company, Downers Grove, Illinois (Braidwood Nuclear Power Station, Unit 1) EA 90-208.....	I.A-7
Commonwealth Edison Company, Downers Grove, Illinois (Quad Cities Nuclear Power Station, Unit 2) EA 90-203.....	I.A-15
Consolidated Edison Company of New York, Inc., Buchanan, New York (Indian Point, Unit 2) EA 90-114.....	I.A-22
Entergy Operations, Inc., Russellville, Arkansas (Arkansas Nuclear One) EA 90-175.....	I.A-32
Georgia Power Company, Birmingham, Alabama (Vogtle Electric Generating Plant) EA 90-188.....	I.A-40
Northeast Nuclear Energy Company, Hartford, Connecticut (Millstone Nuclear Power Station, Unit 2) EA 90-219.....	I.A-47
Portland General Electric, Portland, Oregon (Trojan Nuclear Plant) EA 91-005.....	I.A-54
Southern California Edison Company, Irvine, California (San Onofre Nuclear Generating Station, Units 2 and 3) EA 90-201.....	I.A-60
Tennessee Valley Authority, Chattanooga, Tennessee (Sequoyah Nuclear Plant) EA 90-200.....	I.A-67

CONTENTS (Continued)

REACTOR LICENSEES (Continued)	<u>Page</u>
Virginia Electric and Power Company, Glen Allen, Virginia (Surry Power Station) EA 90-215.....	I.A-75
Wolf Creek Nuclear Operating Corporation, Burlington, Kansas (Wolf Creek Generating Station) EA 91-003.....	I.A-83
B. Severity Level III Violation, No Civil Penalty	
Rochester Gas and Electric Company, Rochester, New York (R. E. Ginna Nuclear Power Plant) EA 91-002.....	I.B-1
II. MATERIALS LICENSEES	
A. Civil Penalties and Orders	
C & R Laboratories, Pearl City, Hawaii EA 89-101.....	II.A.1
McCallum Testing Laboratories, Inc., Chesapeake, Virginia EA 90-183.....	II.A-11
Muskogee Regional Medical Center, Muskogee, Oklahoma EA 90-212.....	II.A-17
Newman Memorial Hospital, Shattuck, Oklahoma EA 90-106.....	II.A-23
Process Technology North Jersey, Rockaway, New Jersey EA 89-80.....	II.A-50
Radiology-Ultrasound-Nuclear Consultants, PA, Freehold, New Jersey EA 90-061.....	II.A-62
Sequoyah Fuels Corporation, Gore, Oklahoma EA 90-162.....	II.A-84
Tumbleweed X-Ray Company, Greenwood, Arkansas EA 90-210.....	II.A-92
University of Wisconsin - Madison, Madison, Wisconsin EA 90-098.....	II.A-98
Veterans Administration Medical Center, Albany, New York EA 90-209.....	II.A-116

B. Severity Level III Violation, No Civil Penalty

Stuart Circle Hospital, Richmond, Virginia
EA 91-010.....II.B-1

Union Carbide Chemicals and Plastics Company, Inc.,
Sisterville, West Virginia
EA 91-013.....II.B-7

ENFORCEMENT ACTIONS: SIGNIFICANT ACTIONS RESOLVED

January - March 1991

INTRODUCTION

This issue of NUREG-0940 is being published to inform NRC licensees about significant enforcement actions and their resolution for the first 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, and the Regional Administrator (DEDR). 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 first 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 copies of Notices of Violation that has been issued to material licensees, but for which no civil penalties were assessed.

SUMMARIES

I. REACTOR LICENSEES

A. Civil Penalties and Orders

Baltimore Gas and Electric Company, Baltimore, Maryland
(Calvert Cliffs Nuclear Power Plant) Supplement III, EA 90-186

A Notice of Violation and Proposed Imposition of Civil Penalty in the amount of \$12,500 was issued December 5, 1990 to emphasize the importance of maintaining alarm systems in proper working order and of ensuring that security staffs are aware of their responsibilities. The action was based on a security shift supervisor suspending metal detector searches because of malfunctioning equipment and allowing employees to enter the protected area during a 15 minute period without either pat-down or hand-held metal detector searches. While the penalty was escalated 25% for corrective action, this was offset by 100% mitigation for good past performance in the area of security. The licensee responded and paid the civil penalty on January 3, 1991.

Commonwealth Edison Company, Downers Grove, Illinois
(Braidwood Nuclear Power Station, Unit 1) Supplement I, EA 90-208

A Notice of Violation and Proposed Imposition of Civil Penalty in the amount of \$87,500 was issued January 30, 1991 to emphasize the need for management control and oversight of safety-related activities regarding surveillance testing and the conduct of operations. The action was based on violations involving the failure of the control room operation staff and technical staff engineer to adhere to various administrative and surveillance procedures during the performance of multiple residual heat removal system tests on October 4, 1990. The violations resulted in an unexpected loss of reactor coolant from the primary system and the contamination of several operators. The civil penalty was mitigated by only 25% for identification and reporting as this was considered a self-disclosing event. The civil penalty was escalated by 100% due to poor past performance in that the licensee had experienced similar problems with regard to how licensed responsibilities were discharged in the control room during non-routine evolutions. The licensee responded and paid the civil penalty March 1, 1991.

Commonwealth Edison Company, Downers Grove, Illinois
(Quad Cities Nuclear Power Station, Unit 2) Supplement I, EA 90-203

A Notice of Violation and Proposed Imposition of Civil Penalty in the amount of \$50,000 was issued January 30, 1991 to emphasize the importance of adherence to procedures, effective communication between operating crew members, turnover of information between operating crews, and management oversight and direction of operating crews. The action was based on deficiencies in the performance of the operating crew and management that resulted in a series of procedural violations during the conduct of a special turbine torsional

test which led to a reactor scram on October 27, 1990. No mitigation was applied for licensee identification and reporting as the reactor scram was a self-identifying event that was required to be reported under 10 CFR 50.72. Additionally, no mitigation was applied for the licensee's corrective action because it was not sufficiently directed toward management of control room operations during special tests or evolutions. The licensee responded and paid the civil penalty on March 1, 1991.

Consolidated Edison Company of New York, Inc., Buchanan, New York
(Indian Point, Unit 2) Supplement I, EA 90-114

A Notice of Violation and Proposed Imposition of Civil Penalty in the amount of \$62,500 and a Demand for Information were issued February 11, 1991 to emphasize the need to ensure that the licensee's employees understand the importance of following procedures and of clearly and accurately completing all documentation of such activities. The action was based on violations involving the failure to follow procedures and the falsification of a record. The base civil penalty was escalated by 50% for the licensee's failure to identify the issue and was mitigated by 25% for the licensee's corrective action. The licensee responded and paid the civil penalty on March 8, 1991.

Entergy Operations, Inc., Russellville, Arkansas
(Arkansas Nuclear One) Supplement I, EA 90-175

A Notice of Violation and Proposed Imposition of Civil Penalty in the amount of \$50,000 was issued December 17, 1990 to emphasize the need for effective management and engineering controls to ensure that information related to potential safety-system problems is adequately reviewed and accurately reported to the NRC and that appropriate corrective action is taken. The action was based on (1) the failure to identify and correct a deficiency with the air-operated control room isolation dampers and (2) providing inaccurate information to the NRC in response to Generic Letter 88-14, Instrument Air Supply System Problems Affecting Safety-Related Equipment. These violations were categorized as a single Severity Level III problem. The base civil penalty was escalated 50% for NRC identification, however, a 50% mitigation was applied because once put on notice of the problem, the licensee's corrective actions were extensive. The licensee responded and paid the civil penalty on January 16, 1991.

Georgia Power Company, Birmingham, Alabama
(Vogtle Electric Generating Plant) Supplement III, EA 90-188

A Notice of Violation and Proposed Imposition of Civil Penalty in the amount of \$50,000 was issued February 5, 1991 to emphasize the importance of protecting safeguards information and ensuring that such information is not inadvertently compromised. The action was based on five examples of failure to protect sensitive unclassified safeguards information. The base civil penalty was mitigated by 100% because the licensee identified and corrected the violations, but was escalated by 100% due to the licensee's continued poor performance in that area. The licensee responded and paid the civil penalty February 28, 1991.

Northeast Nuclear Energy Company, Hartford, Connecticut
(Millstone Nuclear Power Station, Unit 2) Supplement I, EA 90-219

A Notice of Violation and Proposed Imposition of Civil Penalty in the amount of \$50,000 was issued February 11, 1991 to emphasize the importance of (1) proper control of equipment at the facility to assure that the reactor is operated and maintained safely and in accordance with the technical specifications in shutdown conditions as well as during power operations, and (2) performing adequate root cause evaluations when deficiencies occur. The action was based on two violations of containment integrity requirements during refueling operations. The licensee responded and paid the civil penalty on March 13, 1991.

Portland General Electric, Portland, Oregon
(Trojan Nuclear Plant) Supplement I, EA 91-005

A Notice of Violation and Proposed Imposition of Civil Penalty in the amount of \$50,000 was issued February 25, 1991 to emphasize the importance of ensuring that all licensed operators are medically qualified, that such determinations are timely and properly documented, and that any discrepancies are aggressively and thoroughly pursued. This action was based on (1) inaccurate certification of licensed operator medical examinations, (2) failure to notify the NRC of a licensed operator's potentially incapacitating medical condition, and (3) incomplete documentation of medical histories and qualifications data. The licensee responded and paid the civil penalty on March 28, 1991.

Southern California Edison Company, Irvine, California
(San Onofre Nuclear Generating Station, Units 2 and 3)
Supplement I, EA 90-210

A Notice of Violation and Proposed Imposition of Civil Penalties in the amount of \$150,000 was issued January 4, 1991 to emphasize the importance the NRC attaches to thorough assessment of indicated problems and to an operating environment which fosters operator attentiveness to plant conditions. The action was based on two violations of plant Technical Specifications. The first violation involved the inoperability for a period of 55 days of the Unit 2 steam driven auxiliary feedwater pump because of a valve misalignment. The second violation involved inoperability of one train of the safety injection and containment spray systems due to the undetected inadvertent opening of a Unit 3 containment emergency sump outlet isolation valve. The base civil penalty for each violation was escalated a total of 50%. The licensee responded and paid the civil penalties on February 3, 1991.

Tennessee Valley Authority, Chattanooga, Tennessee
(Sequoyah Nuclear Plant) Supplement I, EA 90-200

A Notice of Violation and Proposed Imposition of Civil Penalty in the amount of \$30,000 was issued December 28, 1990 to emphasize the importance of management controls and ensuring the implementation

of effective corrective action. The action was based on the licensee's repeated failure to control overtime for personnel performing safety-related activities. The base civil penalty for a Severity Level IV violation was escalated 100% after assessing escalation for past performance and multiple occurrences. The licensee responded and paid the civil penalty on January 28, 1991.

Virginia Electric and Power Company, Glen Allen, Virginia
(Surry Power Station) Supplement I, EA 90-215

A Notice of Violation and Proposed Imposition of Civil Penalty in the amount of \$50,000 was issued February 12, 1991 to emphasize the importance of ensuring operability of equipment important to safety. The action was based on the licensee's failure to maintain the recirculation spray heat exchangers operable. The licensee responded and paid the civil penalty on March 14, 1991.

Wolf Creek Nuclear Operating Corporation, Burlington, Kansas
(Wolf Creek Generating Station) Supplement I, EA 91-003

A Notice of Violation and Proposed Imposition of Civil Penalty in the amount of \$25,000 was issued February 28, 1991 to emphasize the importance of the necessary design, administrative, and procedural controls to ensure the operability of safety systems. The action was based on the licensee's failure to ensure the operability of the safety injection pumps due to the freezing of the common recirculation line to the refueling water storage tank. The licensee responded and paid the civil penalty on March 28, 1991.

B. Severity Level III Violation, No Civil Penalty

Rochester Gas and Electric Corporation, Rochester, New York
(R. E. Ginna Nuclear Power Plant) Supplement I, EA 91-002

A Notice of Violation was issued February 8, 1991 involving violations resulting from an event which occurred on December 12, 1990 involving the disabling of safeguards logic instrumentation for approximately 20 minutes. The event involved the disabling of a portion of both trains of the engineered safety feature actuation system instrumentation channels. The instrumentation was disabled during implementation of a maintenance procedure. The procedure was deficient since it allowed the DC breakers to be opened in any operating mode, even though opening of those breakers should only be permitted in the Cold Shutdown mode. A civil penalty was not issued because the event and violations were promptly identified as a result of the questioning attitude and vigorous actions of the oncoming shift supervisor and, when identified, were promptly reported to the NRC. The licensee's corrective actions were considered prompt and comprehensive. The licensee's past performance was good as evidenced by no related violations of this nature in the past two years.

II. MATERIALS LICENSEES

C & R Laboratories, Pearl City, Hawaii
Supplements V and VII, EA 89-101

A Notice of Violation and Proposed Imposition of Civil Penalty in the amount of \$1500 was issued November 28, 1990 to emphasize the importance of making proper surveys, creation of accurate records, and proper supervision of part-time and temporary employees. The action was based on failure of a former part-time employee to conduct required radiation surveys of an exposure device on removal of the device from and return to storage, willful creation of false records to make it appear that the required radiation surveys had been performed, and failure to properly post the van that was being used for storage. In addition, an Order Modifying License was issued formalizing the licensee's commitment not to utilize the offending radiographer without providing notice to the NRC. The licensee responded and paid the civil penalty on December 20, 1990.

McCallum Testing Laboratories, Inc., Chesapeake, Virginia
Supplement VI, EA 90-183

A Notice of Violation and Proposed Imposition of Civil Penalty in the amount of \$800 was issued December 10, 1990 to emphasize the importance of complying with regulatory requirements associated with license conditions. The action was based on failure to prevent loss of control of a moisture density gauge that was unsecured and in a truck that was loaned to a non-employee who left it unattended and running. Subsequently, the truck and the gauge were stolen. The licensee responded and paid the civil penalty on January 4, 1991.

Muskogee Regional Medical Center, Muskogee, Oklahoma
Supplement VI, EA 90-212

A Notice of Violation and Proposed Imposition of Civil Penalty in the amount of \$1,250 was issued December 20, 1990 to emphasize the importance of strict adherence to procedures related to radiation safety, the importance of effective oversight and the importance of lasting corrective actions for these weaknesses. The action was based on violations that contributed to the occurrence of a therapeutic misadministration, in that radiation therapy treatments were administered to the wrong side of a patient's neck. The violations that formed the basis for the civil penalty involved: (1) a failure on the part of MRMC to require its staff to follow procedures promulgated by the supervising physician; and (2) a failure on the part of the radiation safety officer to ensure that approved procedures and regulatory requirements were being met in the daily operation of the radiation therapy department. The base civil penalty was mitigated by 50% because the licensee's corrective actions were prompt and comprehensive. The licensee responded and paid the civil penalty on January 15, 1991.

Newman Memorial Hospital, Shattuck, Oklahoma
Supplements IV and VI, EA 90-106

A Notice of Violation and Proposed Imposition of Civil Penalty in the amount of \$5,000 was issued July 25, 1990 to emphasize the importance of radiation safety program management and compliance with radiation safety requirements. The action was based on 10 violations demonstrating a lack of attention to NRC requirements by the radiation safety officer and a lack of management oversight by the Radiation Safety Committee. These related to: (1) responsibilities of the RSO and RSC, (2) personnel dosimetry and ALARA, (3) ensuring proper operation of the hospital's dose calibrator, (4) radiation surveys and (5) labeling and use of radiopharmaceuticals. The base civil penalty was escalated 100% because of NRC identification of the violations and a lack of prompt and comprehensive corrective actions subsequent to the initial NRC inspection in January 1990. The licensee responded in letters dated August 21, 1990 and after considering the responses, an Order Imposing Civil Monetary Penalty was issued December 20, 1990. The licensee paid the civil penalty on January 18, 1991.

Process Technology North Jersey, Rockaway, New Jersey
Supplements IV, VI and VII, EA 89-80

A Notice of Violation and Proposed Imposition of Civil Penalties in the amount of \$13,000 was issued January 31, 1991 to emphasize the importance of ensuring that (1) licensed activities are conducted safely and in accordance with the conditions of the license; (2) deficiencies, when they exist, are promptly identified and corrected; and (3) all information communicated to the NRC is both complete and accurate. The action was based on a violation involving inaccurate and incomplete statements by current and former members of the licensee's staff and a number of violations which represent a significant lack of attention to and carelessness for licensed responsibilities by supervisors and managers at the licensee's facility. Only the base civil penalties were proposed because the licensee's performance was good subsequent to the violations; the violations were identified and/or occurred shortly after a new President and CEO had been appointed, and he had minimal opportunity to reorient the licensee's operations; and, for the most part, managers involved in the violations had been removed. The licensee responded and paid the civil penalties February 26, 1991.

Radiology-Ultrasound-Nuclear Consultants, PA, Freehold, New Jersey
Supplement VI, EA 90-061

A Notice of Violation and Proposed Imposition of Civil Penalty in the amount of \$1,000 was issued June 13, 1990 to emphasize the need for increased and improved attention to the licensee's radiation safety program to ensure that activities are conducted safely and in accordance with the terms of the license. The action was based on violations involving, but not limited to, failures: (1) to perform certain checks and calibrations of equipment, including required checks of the teletherapy room radiation monitor; (2) to perform

dose calibrator linearity tests at required frequency or plot results when performed; and (3) of the RSO to wear required personnel dosimetry when handling licensed materials and to retain or fully complete required records. The base civil penalty was escalated 100% based on NRC identification of the violations and because the licensee's corrective actions were neither prompt nor comprehensive. The licensee responded in a letter dated June 21 to July 10, 1990. After consideration of the licensee's response, an Order Imposing Civil Monetary Penalty was issued February 22, 1991. The licensee paid the civil penalty on March 15, 1991.

Sequoyah Fuels Corporation, Gore, Oklahoma
EA 90-162

An Order Modifying License was issued September 20, 1990 requiring that the licensee characterize the site, take actions to prevent further releases of contaminated water, and conduct appropriate monitoring of ground water. The Order was based on concerns that uranium contaminated water seeping from underneath the main process building may contaminate ground water and the environment in the plant's unrestricted area.

Tumbleweed X-Ray Company, Greenwood, Arkansas
EA 90-210

An Order Modifying License was issued December 4, 1990 to prohibit a radiographer and an assistant radiographer from engaging in any NRC-licensed activities on behalf of the licensee, pending further authorization by the NRC. The action was based on an incident that occurred on November 12, 1990 in which the assistant radiographer apparently received a serious overexposure to his right hand and was hospitalized. Preliminary results from an inspection indicated that the assistant radiographer failed to perform a radiation survey to confirm that the source had returned to the shielded position before approaching the source and the radiographer failed to supervise the assistant radiographer.

University of Wisconsin - Madison, Madison, Wisconsin
Supplements IV and VI, EA 90-098

A Notice of Violation and Proposed Imposition of Civil Penalties in the amount of \$7,500 was issued July 25, 1990 to emphasize the need for compliance with NRC regulatory requirements and the licensee's radiological safety procedures. The action was based on failures: to have trained operators present on two occasions while treating patients with the high dose-rate afterloader, to verify treatment time calculations on 35 occasions (one of which led to a therapy misadministration), and to have a second person verify 35 treatment plans (one of which led to a therapy misadministration). One of the civil penalties was escalated 100% because NRC identified the associated violations and because there were multiple examples. The licensee responded in a letter dated September 24, 1990 requesting mitigation of one of the penalties and denying one of the violations. After

consideration of the response, it was concluded that the licensee did not provide sufficient justification to withdraw the contested violation or mitigate the civil penalty. The licensee paid the civil penalties on January 23, 1991.

Veterans Administration Medical Center, Albany, New York
Supplements IV and VI, EA 90-209

A Notice of Violation and Proposed Imposition of Civil Penalty in the amount of \$3,750 was issued January 29, 1991 to emphasize the importance of adequate management attention to and oversight of the radiation safety program, including proper oversight of the Radiation Safety Officer. The action was based on violations which included the failure to: 1) secure certain licensed material from unauthorized removal, 2) perform leak tests of sealed sources, 3) perform the required annual review of the radiation safety program, 4) provide training to personnel in radiological safety, and 5) maintain adequate records of certain required activities, including records of the constancy, linearity, and geometry tests of the dose calibrator. The licensee responded and paid the civil penalty on February 26, 1991.

B. Severity Level III Violation, No Civil Penalty

Stuart Circle Hospital, Richmond, Virginia
Supplements IV and VI, EA 91-010

A Notice of Violation was issued March 1, 1991 based on violations involving the improper transfer of NRC licensed material to an unauthorized individual on September 29, 1990. The incident, which was identified and reported by the licensee, involved the alleged theft of a lixiscope device from the facility. A civil penalty was not issued because the licensee identified and reported the incident and because of the licensee's good past performance.

Union Carbide Chemicals and Plastics Company, Inc., Sistrerville,
West Virginia
Supplements IV and VI, EA 91-013

A Notice of Violation was issued March 1, 1991 based on a violation involving the misalignment of a 37 millicurie cesium-137 sealed source holder with an open shutter that had been rotated away from the condenser tank where it was intended to monitor the tank content level. A civil penalty was not proposed because the licensee identified and reported the incident and because of the licensee's good past performance.

I.A. REACTOR LICENSEES, CIVIL PENALTIES AND ORDERS



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

December 5, 1990

Docket Nos. 50-317 and 50-318
License Nos. DPR-53 and DPR-69
EA 90-186

Baltimore Gas and Electric Company
ATTN: Mr. G. Dowell Schwartz, Jr.
Vice President
General Services Division
Post Office Box 1475
Baltimore, Maryland 21203

Gentlemen:

Subject: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY - \$12,500
(NRC Inspection Report Nos. 50-317/90-28 and 50-318/90-28)

This letter refers to the NRC inspection conducted on October 10-11, 1990 at the Calvert Cliffs Nuclear Power Plant to review the circumstances associated with a violation of NRC requirements, confirmed by your staff as a result of their followup of an allegation received by the NRC, and reported to the NRC in a letter dated October 2, 1990. The inspection report was sent to you on October 19, 1990. On November 2, 1990, an enforcement conference was conducted with you, Mr. C. Poindexter, and other members of the Baltimore Gas & Electric Company staff, to discuss the violation, its causes, and your corrective actions.

The violation, which is described in the enclosed Notice, involved the failure by the security force to conduct a firearms search of approximately 100 personnel who entered the protected area during a 15 minute interval on the morning of September 11, 1990. At the time, three of the four metal detectors were not operating satisfactorily in that they were in a constant alarm mode. The security shift supervisor directed suspension of the metal detector searches and let the employees process through the alarming detectors (on which the volume had been muted) without performing either hand-held metal detector or pat-down ("hands on") searches for firearms as required.

Although the responsible security shift supervisor informed the NRC inspector, as well as your staff, that he believed he was acting within the scope of his authority, the NRC is concerned that the security shift supervisor, at a minimum, exercised extremely poor judgment in making this decision. In addition, at least four of the other security officers on duty at the time, who should have known that the supervisor made an improper decision, did not take action to prevent, correct or even report this obvious violation.

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

The NRC recognizes that all of the individuals who entered the protected area during this time were employees who were authorized access to the area. The NRC also recognizes that there does not appear that any threat was created by this condition (the personnel who passed through the detectors were unaware of the problems because the alarm volume had been muted). However, given the number of individuals involved, as well as the poor judgment exercised by the responsible security shift supervisor and the lack of response by the other security officers present, the NRC considers this violation significant. Therefore, the violation is classified at Severity Level III in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C (Enforcement Policy) (1990).

The NRC recognizes that subsequent to becoming aware of the event, corrective actions were initiated to improve control and implementation of the security program, and to prevent recurrence of this condition. These actions included: removal of the responsible security shift supervisor from the site and reassignment to the corporate offices in Baltimore; specific counseling of all nuclear security officers concerning the seriousness of the event and their responsibilities for communicating concerns to management; review and revision of plans, procedures, and post orders for clarity regarding the supervisor's scope of authority (the Post Orders stated that a Nuclear Security Supervisor may temporarily change Orders to conform to a current situation); and redevelopment of the initial supervisory training program. However, the NRC does not consider these actions thorough because you did not address any plans to include the "lessons learned" from this event in your initial and requalification training programs for security officers, to assure that over the long term, current and future security officers understand their responsibilities concerning prevention, correction, and reporting of security violations. In addition, as of the date of the enforcement conference, you appeared not to have appropriately considered the causes of, the corrective actions for, and the failure by the other security officers to prevent the violation.

To emphasize the importance of these matters, I have been authorized, after consultation with the Director, Office of Enforcement, and the Deputy Executive Director for Nuclear Reactor Regulation, Regional Operations and Research, to issue the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice) in the amount of \$12,500 for the Severity Level III violation set forth in the enclosed Notice. The base civil penalty amount for the Severity Level III violation is \$50,000.

The escalation and mitigation factors set forth in the enforcement policy were considered as follows: (1) since the violation was identified as a result of NRC referring an allegation to the licensee, no adjustment of the base civil penalty on this factor is warranted; (2) your corrective actions did not include applying the lessons learned from this event in the initial and requalification training programs for security officers, and therefore, 25% escalation of the base civil penalty on this factor is warranted; (3) your past performance in the security area has been good, as evidenced by only one level IV security violation during the three security inspections in the past two years, as well as

Category I ratings in the security area during the last six SALP periods, and therefore, 100% mitigation of the civil penalty on this factor is warranted; and (4) this case did not involve prior notice, duration, or multiple occurrences (although multiple individuals were allowed to enter the protected area without searches, this was caused by the single poor decision by the then security shift supervisor, and the failure by the other security officers involved to take preventive action), and, therefore, no adjustment on these factors is warranted. Therefore, based on the above, the base civil penalty has been decreased by 75%.

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/encl:

R. McLean, Administrator, Nuclear Evaluations
J. Walter, Engineering Division, Public Service Commission of Maryland
G. Adams, Licensing (CCNPP)
K. Burger, Esquire, Maryland People's Counsel
P. Birnie, Maryland Safe Energy Coalition
Public Document Room (PDR)
Local Public Document Room (LPDR)
Nuclear Safety Information Center (NSIC)
NRC Resident Inspector
State of Maryland (2)

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

Baltimore Gas & Electric Company
Calvert Cliffs Nuclear Power Plant
Units 1 & 2

Docket Nos. 50-317 and 50-318
License Nos. DPR-53 and DPR-69
EA 50-186

During an NRC inspection conducted on October 10-11, 1990, an NRC inspector reviewed the circumstances associated with a violation of NRC requirements identified as a result of an allegation received by the NRC on September 13, 1990. The allegation was substantiated by the licensee and the violation was reported to the NRC in a letter dated October 2, 1990. 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 violation and the associated civil penalty are set forth below:

10 CFR 73.55(d)(1) requires, in part, that the licensee control all points of personnel and vehicle access into a protected area. Identification and search of individuals must be checked at these points. The search function for detection of firearms, explosives and incendiary devices must be accomplished through the use of both firearms and explosives detection equipment capable of detecting those devices. Whenever firearms or explosives detection equipment at a portal is out of service or not operating satisfactorily, the licensee shall conduct a physical pat-down search of all persons who would otherwise have been subject to equipment searches.

Amendments Nos. 132 and 113 of the Facility Operating Licenses Nos. DPR-53 and DPR-69, Paragraphs 2.C.(4) and 2.D respectively, require the licensee to implement fully and maintain all provisions of the NRC-Approved Physical Security Plan (Plan).

The Calvert Cliffs Nuclear Power Plant, Units 1 and 2, NRC-approved Security Plan states, in Section 5.3.1.a, that all personnel entering the protected area through the Security Processing Building are searched with acceptable metal and explosives detectors. Whenever all metal or explosives detection equipment is out of service or not operating satisfactorily, a physical "hands-on" search will be conducted on all persons who would have otherwise been subject to equipment search.

Contrary to the above, on September 11, 1990, from approximately 6:15 a.m. until 6:30 a.m., while three of the four metal detectors were not operating satisfactorily, approximately 100 personnel (all on the list of individuals authorized access to the protected area) entered the protected area through the Security Processing Building without being searched either with an acceptable metal detector, or being the subject of a physical pat-down ("hands-on") search.

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

Pursuant to the provisions of 10 CFR 2.201, Baltimore Gas and Electric Company is hereby required to submit a written statement or explanation to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, within 30 days of the date of the Notice. The reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each alleged violation: (1) admission or denial of the alleged violation, (2) the reasons for the violation if admitted, (3) the corrective steps that have been taken and the results achieved, (4) the corrective steps that will be taken to avoid further violations, and (5) the date when full compliance will be achieved. If an adequate reply is not received within the time specified in this Notice, an order may be issued to show cause why the license should not be modified, suspended, or revoked or why such other action as may be proper should not be taken. Consideration may be given to extending the response time for good cause shown. Under the authority of Section 182 of the 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 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, 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. 2282(c).

The responses to the Director, Office of Enforcement, noted above (Reply to a Notice of Violation, letter with payment of civil penalty, and Answer to a Notice of Violation) should be addressed to: Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, 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 Senior Resident Inspector, Calvert Cliffs.

FOR THE NUCLEAR REGULATORY COMMISSION



Thomas T. Martin
Regional Administrator

Dated at King of Prussia, Pennsylvania
this 5 day of December 1990



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

January 30, 1991

Docket No. 50-456
License No. NPF-72
EA 90-208

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

Gentlemen:

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY - \$87,500
(NRC INSPECTION REPORT NO. 50-456/90023 AND AUGMENTED INSPECTION TEAM
REPORT NO. 50-456/90020)

This refers to the NRC Augmented Inspection Team (AIT) review conducted on October 4-6, 1990 and special followup inspection conducted on November 19-23, 1990 of events that led to a loss of reactor coolant and personnel contamination on October 4, 1990 at the Braidwood Nuclear Power Station, Unit 1. The reports documenting these inspections were sent to you by letters dated October 23, 1990 and December 3, 1990, respectively. During these inspections, violations of NRC requirements were identified. An Enforcement Conference was held on December 11, 1990 at the Braidwood facility to discuss the violations, their cause, and your corrective actions. The report summarizing this conference was sent to you by letter dated December 19, 1990.

The violations involved the failure of the control room operations staff (licensed operators and senior operators) and Technical Staff Engineers (TSE) to adhere to various administrative and surveillance procedures during the performance of multiple Residual Heat Removal (RH) system tests on October 4, 1990. The most significant aspect of this event was the failure of the licensed operators to maintain positive control over plant evolutions and system configuration. Contributing programmatic deficiencies included (1) coordination problems between the Work Planning Department, the Operations Department and the Technical staff, including poor intra and inter-shift communications, (2) weaknesses in the shift turnover process regarding in-progress testing, (3) the lack of rigorous guidance for controlling multiple surveillance evolutions and (4) excessive overtime for personnel performing complex safety-related work. Senior plant management appears to have failed to ensure that management expectations regarding control of plant evolutions were appropriately implemented, particularly those that are infrequent or unusual.

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

A March 18, 1990 Unit 2 loss of reactor coolant event highlighted problems with control room communications and system configuration control for abnormal lineups during plant shutdown conditions. Your "Heightened Level of Awareness" special operating order (HLA) developed in response to this event was viewed as a good start toward correcting those deficiencies. Though the shift preceding the October event implemented the HLA, the following shift did not. Senior plant management failed to ensure that corrective actions and expectations associated with the March event were effectively communicated and implemented. Had this program been rigorously followed, this event may not have happened.

Fatigue appears to have contributed to the October event because the technical staff engineers involved had worked excessive hours (18 to 20 hours). Though provisions were in place to have a relief crew available, there were no controls in place to require management approval prior to cancelling the relief crew work assignment. The engineers involved had a major responsibility to ensure that surveillance activities are conducted in a manner to minimize unnecessary challenges to the plant. The reduction in awareness demonstrated by the engineers may have been due to excessive work hours.

While the out of sequence performance of a surveillance test step initiated the event, the root cause was a significant failure in the control room command and control function. The violations represent a recurring breakdown in the control of licensed activities and a significant lack of attention toward licensed responsibilities. It is clearly not acceptable for the control room to not be cognizant of significant plant activities. 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 related to the control of operations have been classified in the aggregate at a Severity Level III. The violation related to inadequate overtime controls for the technical staff engineer has been classified at a Severity Level IV.

Following the October event, you instituted a number of additional corrective actions that included development of a program to review operational performance through periodic audits, crew evaluations and performance feedback. Various procedures were clarified and senior management met with each shift crew to emphasize their responsibilities and authorities. Additionally, guidance has been provided for Technical Staff performed surveillances and overtime and the Operation Shift Advisor has been assigned to assist the SCRE in supervising surveillance activities.

To emphasize the need for management control and oversight of safety-related activities regarding surveillance testing and the conduct of operations, I have been authorized, after consultation with the Director, Office of Enforcement, and the Deputy Executive Director for Nuclear Reactor Regulation, Regional Operations and Research, to issue the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice) in the amount of \$87,500 for the Severity Level III problem. The base value of a civil penalty for a Severity Level III violation or problem is \$50,000. The escalation and mitigation factors in the Enforcement Policy were considered.

January 30, 1991

The base civil penalty was mitigated by 25% for identification and reporting. However, the full amount allowed under the Policy was not applied because of the self-disclosing nature of this event. The base civil penalty was neither escalated nor mitigated because your corrective actions did not adequately address the long term resolution of management overview of plant activities.

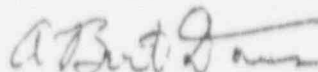
In this regard the NRC takes specific exception to the views expressed in your Confirmatory Action Letter response of November 5, 1990, that the "reduction of awareness that occurred during the event is believed to be unique to the individuals involved and does not represent a normal characteristic..." or that "the deficiencies that led to the March 18 event were not evident in this case...and our investigation concluded that a loss of command and control did not occur." The cover letter transmitting Inspection Report No. 50-457/90012, dated April 18, 1990, noted the deficiency in communication practices between supervisors and operators during non-routine evolutions such as occurred on March 18, 1990. That event was similar to the October event with regard to how licensed responsibilities were discharged in the control room during non-routine evolutions. Had adequate corrective action been implemented for that event, this current problem likely would not have occurred. Therefore, as a result of such poor past performance, the base civil penalty is being escalated by 100%. The other factors were considered and no further adjustment of the civil penalty was deemed appropriate. Therefore, a \$87,500 civil penalty is assessed for these violations.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. In your response, you should document the specific actions taken and any additional actions you plan to prevent recurrence. In light of another enforcement action pending against your Quad Cities facility (EA 90-203) involving plant operations where management did not assure sufficient oversight and training, you should discuss how you intend to apply the corrective actions adopted for the Braidwood incident to your other licensed facilities. After reviewing your response to this Notice, including your proposed corrective actions and the results of future inspections, the NRC will determine whether further NRC enforcement action is necessary to ensure compliance with NRC regulatory requirements.

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

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

Sincerely,



A. Bert Davis
Regional Administrator

Enclosure: Notice of Violation and
Proposed Imposition of Civil Penalty

See Attached Distribution

January 30, 1991

Distribution

cc w/enclosure:

M. Wallace, Vice President,
PWR Operations
T. Kovach, Nuclear
Licensing Manager
A. Checca, Nuclear
Licensing Administrator
K. Kofron, Station Manager
D. Miller, Regulatory
Assurance Supervisor
DCD/DCB (RIDS)
OC/LFDCB
Resident Inspectors, Byron,
Braidwood, Zion
D. W. Cassel, Jr., Esq.
Richard Hubbard
J. W. McCaffrey, Chief, Public
Utilities Division
Stephen P. Sands, LPM, NRR
Robert Newmann, Office of Public
Counsel, State of Illinois Center

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

Commonwealth Edison Company
Braidwood Nuclear Station Unit 1

Docket No. 50-456
License No. NPF-72
EA 90-208

During an NRC inspection conducted on November 19-23, 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, 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

Technical Specification 6.8.1.a requires that written procedures be established, implemented, and maintained for activities listed in Appendix A of Regulatory Guide 1.33, Revision 2, February 1978. Listed activities include administrative procedures and surveillance testing.

1. Surveillance procedure BwVS 4.6.2.2-1, Steps 2.21 through 2.24, requires, in part, the closure of Residual Heat Removal Hot Leg Suction Vent Valve (RH028B), and removal of the hose from the vent connection on RH028B, prior to restoring the Residual Heat Removal system to the original as found condition.

Contrary to the above, on October 4, 1990, the Technical Staff Engineer directing the performance of surveillance procedure BwVS 4.6.2.2-1, failed to follow steps 2.21 through 2.24 by not closing vent valve RH028B before opening isolation valve RHB702B, a step in restoring the Residual Heat Removal system to its original as found configuration.

2. Braidwood administrative procedure BwAP 335-1, Operating Shift Turnover and Relief, sections C.3.d (Shift Engineer), C.4.d (Station Control Room Engineer - SCRE), and C.5.e (Shift Supervisor), requires, in part, that the off-going Shift Engineer, SCRE and Shift Supervisor document on the turnover sheet surveillances in progress at turnover.

Contrary to the above, on October 3, 1990, the off-going Shift Engineer, SCRE, and Shift Supervisor failed to document on their respective turnover sheets that surveillance BwVS 0.5-2.RH.2-1 was then in progress on the Unit 1 Residual Heat Removal system.

3. Braidwood administrative procedure BwAP 300-1, Conduct of Operations, Section C.3.n.(3), requires, in part, that the individual who is to perform the activity is responsible to adequately review the procedure, to fully understand what he (she) is doing, and to be cognizant of all the limitations, precautions, and requirements.

Contrary to the above, on October 4, 1990, the extra Nuclear Station Operator assigned to perform the residual heat removal system surveillance activities failed to adequately review surveillance procedure BwVS 4.6.2.2-1, to fully understand the activities and was not cognizant of all limitations, precautions, and requirements when opening isolation valve RH8702B prior to closing vent valve RH028B.

4. Braidwood administrative procedure BwAP 300-1, Conduct of Operations, Section C.3.n.(2), requires, in part, that briefings shall be conducted by the Shift Engineer or designee for individuals involved in an evolution that is to be performed.

Contrary to the above, on October 3, 1990, the Shift 1 Shift Engineer or designee failed to conduct an adequate briefing with the individuals assigned to perform the residual heat removal system surveillance tests.

5. Braidwood administrative procedure BwAP 390-1, Operating Department Surveillance Program, Section E.3, requires, in part, that when the Station Control Room Engineer (SCRE) assigns a surveillance to the appropriate nuclear station operator (NSO), the SCRE shall inform the NSO of any effects on total plant operations, limiting conditions, or any other significant information concerning the performance of a surveillance.

Contrary to the above, on October 3, 1990, the Station Control Room Engineer failed to inform the appropriate NSO assigned to perform the surveillances, of effects on plant operation, limiting conditions or any other significant information concerning the performance of surveillances BwVS 4.6.2.2-1 and BwVS 0.5-2.RH.2-1 on the Unit 1 Residual Heat Removal system.

6. Braidwood administrative procedure BwAP 390-1, Operating Department Surveillance Program, Section E.5, requires, in part, the Station Control Room Engineer record in the comments section of the applicable surveillance data package cover sheet the reason for non-scheduled or extra surveillances being performed if the surveillance is not listed on the current schedule.

Contrary to the above, on October 3, 1990, the Shift 3 Station Control Room Engineer failed to record on the data package cover sheet the reason for performing surveillance BwVS 0.5-2.RH.2-1, a non-scheduled or extra surveillance that was not listed on the current schedule.

7. Braidwood administrative procedure BwAP 390-1, Operating Department Surveillance Program, Section E.4, requires, in part, that the Unit Nuclear Station Operator shall ensure that the surveillance is performed in accordance with the applicable station procedures.

Contrary to the above, on October 4, 1990, the Unit 1 Nuclear Station Operator failed to ensure that activities associated with Residual Heat Removal system surveillances, BwVS 4.6.2.2-1 and BwVS 0.5-2.RH.2-1, were conducted in accordance with the surveillance procedures in that isolation valve RHB702B was opened prior to closing vent valve RH028B.

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

Cumulative Civil Penalty - \$87,500 (assessed equally among the 7 violations).

II. Violation Not Assessed a Civil Penalty

Technical Specification 6.2.2.e requires, in part, that administrative procedures be developed and implemented to limit the working hours of unit staff who perform safety-related function; e.g., licensed Senior Operator, licensed Operator, health physics personnel, equipment operators, and key maintenance personnel.

Contrary to the above, as of October 4, 1990, the licensee failed to develop adequate administrative procedures to limit the working hours of unit staff who perform safety-related functions. Specifically, BWAP 100-7, Revision 2, Overtime Guidance for Personnel that Perform Safety-Related Functions, the administrative procedure implementing Technical Specification 6.2.2.e was deficient in that it did not address all unit staff groups responsible for performing safety-related functions such as Technical Staff Engineers who direct the performance of surveillance testing.

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

Pursuant to the provisions of 10 CFR 2.201, the Commonwealth Edison Company (licensee) is hereby required to submit a written statement or explanation to the 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. 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.

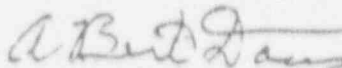
Within the same time as provided for the response required above under 10 CFR 2.201, the Licensee may pay the civil penalty by letter addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, with a check, draft, money order, or electronic transfer payable to the Treasurer of the United States in the cumulative amount of the civil penalty or may protest imposition of the civil penalty in whole or in part, by a written answer addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission. Should the Licensee fail to answer within the time specified, an order imposing the civil penalty will be issued. Should the Licensee elect to file an answer in accordance with 10 CFR 2.205 protesting the civil penalty, in whole or in part, such answer should be clearly marked as an "Answer to a Notice of Violation" and may: (1) deny the violations listed in this Notice in whole or in part, (2) demonstrate extenuating circumstances, (3) show error in this Notice, or (4) show other reasons why the penalties 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. 2232c.

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

FOR THE NUCLEAR REGULATORY COMMISSION



A. Bert Davis
Regional Administrator

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



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
785 ROOSEVELT ROAD
GLEN ELLYN, ILLINOIS 60137
January 30, 1991

Docket No. 50-265
License No. DPR-30
EA 90-203

Commonwealth Edison Company
ATTN: Mr. Cordell Reed
Senior Vice President
Opus West III
1400 Opus Place - Suite 300
Downers Grove, Illinois 60515

Gentlemen:

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY - \$50,000
QUAD CITIES NUCLEAR POWER STATION, UNIT 2 (NRC INSPECTION REPORT
NO. 50-265/90020)

This refers to the special safety inspection conducted from October 30 through November 9, 1990 at the Quad Cities Nuclear Power Station, Unit 2. The inspection included an examination of the available facts and circumstances related to the performance of control room activities, following the attempted performance of a special turbine torsional test, which led to a reactor scram on October 27, 1990. The report documenting this inspection was mailed to you on November 21, 1990. As a result of the inspection, a significant failure to comply with NRC regulatory requirements was identified, and accordingly, the NRC discussed its concerns relative to the inspection findings with members of your staff in an Enforcement Conference held on December 7, 1990. The licensed individuals involved in the October 27, 1990, event also attended the Enforcement Conference.

To summarize the events leading to the scram, on October 27, 1990, the Nuclear Station Operator (NSO) at Quad Cities, Unit 2, at the direction of the Shift Control Room Engineer (SCRE) attempted to control reactor pressure at 800 psig in the hot standby condition and with the turbine bypass valves closed in order to allow the removal of test equipment from the turbine control valve electro-hydraulic control (EHC) circuit. Throughout this evolution, the NSO did not follow appropriate procedures and was inattentive to his nuclear instruments. The procedure to be followed called for the reactor to be taken subcritical by a determined amount. However, the NSO focused his attention on reactor pressure and, as a consequence, did not adequately monitor status of the reactor with respect to criticality. Because he did not adequately monitor reactor power, he inserted more control rods than were needed to maintain the desired pressure and when reactor pressure reached 776 psig he began to withdraw control rods. A rod block was experienced since the Intermediate Range Monitors (IRM) were on Range 1 and the Source Range Monitors (SRM) were indicating less than 100 counts. The insertion of the SRMs cleared the rod block and allowed the operator to initiate control rod withdrawal. The operator continued with control rod withdrawal but

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

because he failed to monitor nuclear instrumentation, he failed to detect a rapid power increase which resulted in a reactor scram.

Many factors contributed to this event. First, the NSO narrowly focused his attention on reactor pressure, which distracted his attention from the addition of reactivity, and the NSO was not following any specific procedure at the time of the event. Second, the SCRE was not aware that the NSO was not following an appropriate procedure and had taken the reactor significantly subcritical. Third, Quad Cities management did not ensure managers and supervisors involved in off-normal events or special tests clearly understood their roles in such evolutions. For example, the Quad Cities Station Assistant Superintendent for Operations did not communicate to the Test Directors involved in the turbine test what their responsibilities were and in turn they did not adequately brief or supervise the personnel performing the evolutions. Specifically, the Shift Engineer assigned to the third shift on October 27, 1990, did not conduct a briefing for third shift personnel regarding the evolutions in progress or expected to occur during the shift. Fourth, communications were poor between operating shifts and within the third shift operating crew. Fifth, the control room operators were not adequately trained regarding special precautions and the actions required when the plant was in a hot standby condition. Finally, station management failed to assure that control room operators and their supervisors utilized and adhered to appropriate procedures to assure that procedural inadequacies identified during the course of the turbine torsional test were evaluated for significance and corrected.

As discussed above, the NRC is concerned with the performance of station management and Operations Department personnel during both the event and the planning for the special test. The failure of plant management to communicate to the operating crew management guidance and requirements delineated in plant procedures regarding the control of plant evolutions, particularly those which are unusual or occur infrequently is a significant failure. It is our view that the lack of sufficient involvement by plant senior management in the turbine torsional test was the major contributor of the poor turnover of information between shifts and the general lack of awareness and alertness to plant conditions on the part of the October 27, 1990, third shift operating crew.

The NRC recognizes that the event had minor safety significance on the reactor core; however, the event is considered significant due to the lack of management oversight, poor shift communications, lack of training and procedural problems associated with reactivity during the evolution. The deficiencies in the performance of the operating crew and management are of significant concern because a series of procedural violations were made that resulted in the Technical Specification violations described in the enclosed Notice of Violation (Notice). These violations taken collectively represent a programmatic deficiency in the management of control room activities. Therefore, in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy) 10 CFR Part 2, Appendix C (1990), these violations are categorized in the aggregate as a Severity Level III problem.

The corrective actions taken after the October 27, 1990, event included: discussion of the event between the shift operating crew and station management,

January 30, 1991

training of the shift operating crew for operating the unit in a hot standby mode, assignment of the NSO to a remedial training program, and assignment of nuclear engineers to operating shifts whenever control rods will be manipulated when the unit is below 15 percent power. The NRC recognizes that corrective actions in addition to the ones described above were also taken; however, all of the corrective actions taken to date or proposed for the future were largely limited to operating personnel. None of the corrective actions, either taken or proposed, were sufficiently directed towards the management of control room operations during special tests or evolutions.

To emphasize the importance of adherence to procedures, effective communication between operating crew members, turnover of information between operating crews, and management oversight and direction of operating crews, 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. Mitigation for the civil penalty adjustment factor of identification and reporting was considered but found inappropriate in this case because the reactor scram was easily identified and the report of the event was required by 10 CFR 50.72. Your corrective actions were also considered as a basis for mitigation of the base civil penalty but such mitigation was not applied as your corrective actions were limited to the operating personnel. Had the corrective actions been broad, and encompassed the managerial and supervisory contributions to the October 27, 1990, event, then mitigation of the base civil penalty for broad corrective action may have been appropriate. The remaining factors in the Enforcement Policy were also considered and overall no adjustment to the base civil penalty is considered appropriate.

The NRC is also concerned with the apparent lack of a comprehensive procedure that would have addressed expected primary and secondary plant evolutions. Such a comprehensive procedure would describe the specific steps from the time power was reduced to establish plant conditions for test equipment, through the entire test sequence, and conclude with instructions for power escalation for the resumption of normal plant operations. This lack of a comprehensive test procedure, combined with a failure to communicate the identification of an unusual primary condition approaching that of a "hot notch rod," were indicators of management's lack of oversight of the October 27, 1990 plant scram.

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.

January 30, 1991

The inspection report (No. 50-265/900020) concerning the October 27, 1990, event identified three other issues which were identified in that report as potential violations of NRC requirements. Those issues were inadequacy of the test procedure for the turbine torsional test; inadequate corrective action taken between the identification of a deficiency in the hot standby operations procedure on the first shift on October 27, 1990, and the attempt by the third shift on October 27, 1990, to perform the procedure; and, two separate examples of failing to follow a procedure when an Operations Engineer did not contact a Nuclear Engineer and the failure to make an operating log entry reading the discovery of a "hot notch" control rod. After further consideration of the information you presented at the December 7, 1990, Enforcement Conference, the NRC staff has decided not to taken enforcement action on those issues. While the NRC is not taking enforcement action on those issues, we are concerned that they may have contributed to the overall problem and we request that you discuss them and their impact on the October 27, 1990, event in your response to the enclosed Notice.

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
Regional Administrator

Enclosure:
Notice of Violation and Proposed
Imposition of Civil Penalty

cc w/enclosure:
D. Galle, Vice President - BWR Operations
T. Kovach, Nuclear Licensing Manager
R. L. Bax, Station Manager
DCD/DCB (RIDS)
OC/LFDCB
Resident Inspectors LaSalle
Dresden, Quad Cities
Richard Hubbard
J. W. McCaffrey, Chief, Public
Utilities Division
L. Olshan, NRR LPM
Robert Newmann, Office of Public
Counsel, State of Illinois Center

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

Commonwealth Edison Company
Quad Cities Nuclear Power Station, Unit 2

Docket No. 50-265
License No. DPR-30
EA 90-203

During an NRC inspection conducted from October 30, 1990, through November 9, 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:

Quad Cities Nuclear Station Technical Specification Section 6.2.A.1 requires in part, that detailed written procedures covering start-up, operation, and shutdown of the reactor, and other systems and components involving nuclear safety of the facility shall be prepared and adhered to.

1. Temporary Procedure (TP) 6303, "Shutdown from Power Operations to a Standby Hot Pressurized Condition," stipulated the procedures for taking the unit from a power generation mode to a hot standby condition following a turbine torsional test.

Contrary to the above, on October 27, 1990, following an attempted turbine torsional test the Nuclear Station Operator (NSO) failed to utilize the procedures specified in TP 6303 for taking the unit from a power generation mode to a hot standby condition.

2. Quad Cities Station Administrative Procedure (QAP), "Conduct of Shift Operations," QAP 300-2, Section C.13.j, requires that briefings be conducted by cognizant personnel for individuals involved in an evolution that is to be performed and Section C.28.c of procedure QAP 300-2 requires the Shift Control Room Engineer (SCRE) to be responsible for control room activities to assure safe plant operation.

Contrary to the above, on October 27, 1990, an inadequate shift briefing was conducted by the test director and shift engineer for the third shift activities in that shift personnel were not briefed on the status of TP 6303 and the SCRE failed to supervise control room activities by maintaining cognizant of the status of Unit 2 reactor operation in that he was unaware that the Nuclear Station Operator (NSO) had made the reactor subcritical in the source range by control rod insertion.

3. QAP 300-1, "Operations Department Organization," Section C.10.q.5, requires in part that the NSO initiate "holds" during plant evolutions to ensure that an evolution does not threaten the stability of the unit. QAP 300-1, Section C.10.p also requires the NSO be alert and capable of performing his assigned duties in a professional manner at all times.

Contrary to the above, on October 27, 1990, the NSO failed to initiate a hold required to ensure unit stability associated with the Electro Hydraulic Control system restoration when reactor power was subcritical in the source range (100 cps). A hold was required to facilitate a controlled approach to criticality. Additionally, the NSO failed to remain alert to control panel indications by failing to adequately monitor nuclear instrumentation during control rod withdrawal which resulted in rapidly increasing power and a subsequent reactor scram.

4. Quad Cities Operations Procedure (QOP) 700-1, "Source Range Monitor Operation," Section F.2.a, requires that the source range monitor (SRM) detectors be inserted as "range 4" is approached on the Intermediate Range Monitors (IRM).

Contrary to the above, on October 27, 1990, the NSO failed to insert the SRMs as "range 4" was approached on the IRMs but waited until "range 1" of the IRMs was reached.

5. QOP 700-2, "Intermediate Range Monitor Operation," Section F.3.g, requires the NSO to decrease the IRM ranges as necessary to maintain between 20/125 and 50/125 of full scale.

Contrary to the above, on October 27, 1990, the NSO failed to decrease the IRM ranges as necessary to maintain 20/125 and 50/125 of full scale.

This is a Severity Level III problem (Supplement 1).
Cumulative Civil Penalty - \$50,000 (assessed equally among the five violations).

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

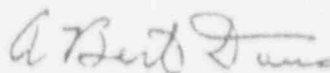
Within the same time as provided for the response required under 10 CFR 2.201, the Licensee may pay the civil penalty by letter addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, with a check, draft, money order, or electronic transfer payable to the Treasurer of the 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 (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 Notice of Violation) should be addressed to: Director, Office of Enforcement, Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555 with a copy to the Regional Administrator, U.S. Nuclear Regulatory Commission, Region III, 799 Roosevelt Road, Glen Ellyn, Illinois 60137, and a copy to the NRC Resident Inspector at the Quad Cities Nuclear Station.

FOR THE NUCLEAR REGULATORY COMMISSION



A. Bert Davis
Regional Administrator

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



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

FEB 11 1991

Docket No. 50-247
License No. DPR-26
EA 90-114

Consolidated Edison Company of New York, Inc.
ATTN: Mr. Stephen Bram, Vice President
Nuclear Power
Indian Point Station
Broadway and Bleakley Avenues
Buchanan, New York 10511

Gentlemen:

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY - \$62,500,
AND DEMAND FOR INFORMATION (NRC OFFICE OF INVESTIGATIONS REPORT
NO. 1-89-005)

This refers to the findings of an investigation conducted by the NRC Office of Investigations (OI) to determine whether licensee employees willfully falsified test documents for the installation of a solenoid operated valve (SOV) at your Indian Point 2 facility. The synopsis of the OI investigation was forwarded to you on July 24, 1990. As a result of the investigation, violations of NRC requirements were identified involving the failure to adhere to a Corrective Maintenance Procedure (CMP) utilized during the installation of an SOV in the Waste Gas System and the deliberate falsification of the associated record to indicate that the procedure had been accomplished appropriately. On August 7, 1990, an enforcement conference was held with you and members of your staff to discuss the violation, its causes, and your corrective actions.

On March 17-18, 1989, during the installation of a gas unloader valve (SOV 1035) in the No. 21 Waste Gas Compressor (WGC), your staff failed to meggar test the new SOV as required by the CMP. A Quality Control (QC) Inspector, who was responsible for verifying installation of the valve, refused to sign off on the CMP step when the SOV was initially installed, because he had not witnessed a meggar test. Subsequently, some time after March 18, 1989, the valve installer signed off the meggar test step and dated his signature as March 18, 1989, even though he had not performed the meggar test. In addition, some time after the valve installer signed this step, a General Maintenance Supervisor (GMS) annotated the specific step in the procedure with a note to indicate that he had performed an electrical test on the valve on March 17, 1989, but that a QC inspector was not present. While the note may not have been false in and of itself, it, or similar statements made by the GMS misled an Associate Quality Assurance (QA) Examiner to believe that the valve had been meggar tested. Therefore, as a result, even though the QC Inspector refused to sign off on the CMP step, the Associate QA Examiner inappropriately signed the CMP step on April 20, 1989, in the erroneous belief that a meggar test had been performed. In addition,

several other procedural steps that could not be performed as stated were signed off as complete. Finally, the GMS inappropriately signed the final step in the procedure on April 20, 1989, indicating that the procedure was complete and that all data were correct, when, in fact, the required meggar test and other procedural steps had not been performed as prescribed.

This event occurred, in part, because your employees were not sufficiently sensitive to (1) the need for strict adherence to the procedural requirements for the valve installation, (2) the expected significance of their signatures for the completion of procedure steps, and (3) the need to utilize established mechanisms (Open Item Reports (OIRs)) to correct procedure completion deficiencies when they discovered that the meggar test had not been performed. This event is a reflection of the inadequacies in your maintenance and quality assurance programs. In addition, this issue was complicated by the fact that the new CMP had not been properly validated prior to its use, as evidenced by several of the procedural steps being wholly inapplicable to the installation.

In accordance with the "General Statement of Policy and Procedures for NRC Enforcement Actions," (Enforcement Policy) 10 CFR Part 2, Appendix C (1990) (Supplement VII), the violations could be categorized at Severity Level I because two of the individuals involved could be considered licensee officials (first-line supervisors and above are considered licensee officials). However, the NRC recognizes that the individuals that could be considered licensee officials were either first or second level supervisors of craft personnel, rather than senior managers, and that the technical safety significance of the underlying event was minimal. Specifically, the SOV was new and had been meggar tested by the manufacturer, the WGC was satisfactorily checked for operability during a post-maintenance test, and the SOV has since been meggar tested successfully. Nevertheless, the NRC considers this a very significant regulatory concern because the failures to accurately follow procedures and document work relating to the performance of licensed activities were deliberate and reflect your failure to sufficiently educate your employees with respect to your expectations for the activities involved. After considering all the circumstances of this case, the violations are classified in the aggregate as a Severity Level III problem.

To emphasize the need to ensure that your employees understand the importance of following procedures and of clearly and accurately completing all documentation of such activities, I have decided, after consultation with the Region I Regional Administrator, the Deputy Director, Office of Enforcement, and the Commission, to issue the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice) in the amount of \$62,500 for the Severity Level III problem. The base value of a Severity Level III problem is \$50,000. The escalation and mitigation factors in the Enforcement Policy were considered.

Since you did not identify this issue (it was discovered as a result of an allegation), the base civil penalty was escalated by 50% based on the identification factor. After this issue was identified, your corrective actions, (that included remedial action against the individuals involved) were considered appropriate given the significance and serious nature of the individuals' actions. In addition, the staff recognizes that you have expended substantial efforts to improve your maintenance program (including the development of a Maintenance Quality Improvement Program emphasizing, among other things, the need for strict adherence to procedures), subsequent to the identification of programmatic

deficiencies during the NRC maintenance team inspection conducted in April - May 1989. However, the NRC needs assurance that implementation of the corrective actions will be effective. Therefore, only 25% mitigation of the base civil penalty was considered appropriate for your corrective actions. With respect to your past performance in the maintenance area, the staff considered (1) that you have not received any escalated enforcement action for the failure to follow procedures or for inaccurate records in the two years prior to this event, and (2) that your maintenance program had several significant programmatic weaknesses prior to and during the period the violations occurred, as indicated in the June 1990 SALP report. Therefore, on balance, no additional adjustment of the base civil penalty on the basis of this factor is warranted. The other escalation and mitigation factors were considered and no further adjustment is appropriate since this case did not involve prior notice, multiple examples, or duration considerations.

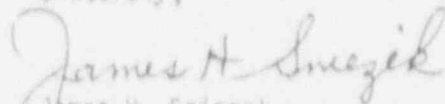
You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. In your response, you should document the specific actions taken and any additional actions you plan to prevent recurrence. After reviewing your response to this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

The NRC recognizes that a recent NRC team inspection conducted in January 1991 confirmed that you have made substantial efforts in improving your maintenance program. However, the problems discussed above may have been symptomatic of a larger, more widespread problem of employees not understanding the importance of strictly following procedures, the expected significance of signatures attesting to the completion of procedure steps, the use of OIR's to resolve procedural performance deficiencies, and inadequacies in your maintenance and quality assurance programs. Therefore, notwithstanding the corrective actions taken to date, the NRC needs assurance that those actions will be effective during periods of peak maintenance activity, such as the upcoming outage. Accordingly, you are required to respond to the enclosed Demand for Information.

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

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

Sincerely,



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

Enclosures: Notice of Violation and
Proposed Imposition of Civil Penalty
and Demand for Information

Consolidated Edison Company
of New York, Inc.

cc w/encls:

C. Jackson, Manager,
Regulatory Affairs
B. Brandenburg, Assistant
General Counsel
P. Kokolakis, Director,
Nuclear Licensing Department of
Public Service,
State of New York
State of New York, Department of Law
W. Stein, Secretary - NFSC
Public Document Room (PDR)
Local Public Document Room (LPDR)
Nuclear Safety Information Center (NSIC)
NRC Resident Inspector
State of New York,
SLO Designee

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

Consolidated Edison Company
of New York, Inc.
Indian Point Unit 2

Docket No. 50-247
License No. DPR-26
EA 90-114

During an NRC investigation conducted by the NRC Office of Investigations to determine whether licensee employees willfully falsified test documents relating to the installation of a solenoid operated valve at Indian Point 2, 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. Technical Specification 6.8.1 (Procedures and Programs) requires that written procedures be established and implemented covering, among others, the requirements and recommendations of ANSI N18.7-1972. Section 5.3 of ANSI N18.7-1972 states that nuclear power plants shall be operated and tested in accordance with written procedures. Corrective Maintenance Procedure (CMP) for ASCO Solenoid Valves (SOV) CM-16.66, Revision 2, describes the procedures to be followed when replacing ASCO Solenoid Valves. Section 5.5.16 of this procedure requires that the new SOV coil be checked for open circuits, short circuits, and grounds using a resistance meter and a megger.

Contrary to the above, on March 17-18, 1989, the new SOV coil installed on SOV 1035 located on Waste Gas Compressor No. 2, was not checked with a megger.

- B. 10 CFR Section 50.9 requires, in part, that information required to be maintained by the licensee shall be complete and accurate in all material respects.

Contrary to the above, CMP Number CM-16.66, Revision 2, was not accurate in that (1) step 5.5.16 of this procedure was signed by the valve installer some time after March 18, 1989, to indicate satisfactory completion of the step on March 18, 1989, when, in fact, the required megger test had not been performed; (2) step 5.5.16 of this procedure was signed by an Associate QA Examiner on April 20, 1989, also indicating the satisfactory completion of the step; and, (3) step 7.1 of this procedure was signed by a General Maintenance Supervisor on April 20, 1989 to indicate that the procedure was complete and that all data were correct and included when, in fact, the procedure was not complete (i.e., the megger test and other procedural steps were not performed as prescribed). These inaccuracies were material in that they relate directly to the requirement to follow an approved procedure.

This is a Severity Level III problem (Supplement I and VII).

Cumulative Civil Penalty - \$62,500 (assessed equally between the two violations).

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

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

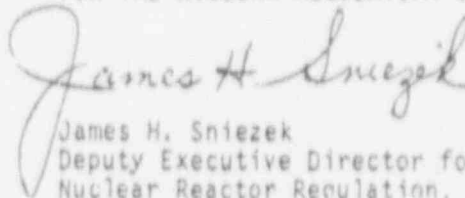
Upon failure to pay any civil penalty due which subsequently has been determined in accordance with the applicable provisions of 10 CFR 2.205, this matter may be referred to the Attorney General, and the penalty, unless compromised, remitted, or mitigated, may be collected by civil action pursuant to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

Notice of Violation

- 3 -

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: Deputy Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555 with a copy to the Regional Administrator, U.S. Nuclear Regulatory Commission, Region I, and a copy to the NRC Resident Inspector at the facility which is the subject of this Notice.

FOR THE NUCLEAR REGULATORY COMMISSION



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

Dated at Rockville, Maryland
this 23rd day of February 1991

UNITED STATES
NUCLEAR REGULATORY COMMISSION

In the matter of
CONSOLIDATED EDISON COMPANY
OF NEW YORK, INC.
Indian Point Nuclear Generating
Unit No. 2

}
Docket No. 50-247
License No. DPR-26
EA 90-114
}

DEMAND FOR INFORMATION

I

Consolidated Edison Company of New York, Inc. (Con Ed or Licensee) is the holder of Facility Operating License No. DPR-26, issued by the Nuclear Regulatory Commission (NRC or Commission) pursuant to 10 CFR Part 50. The license authorizes the operating of the Indian Point Nuclear Generating Unit No. 2 (IP 2) in accordance with conditions specified therein. The facility is located on the Licensee's site in Buchanan, New York.

II

On April 28, 1989, the NRC Office of Investigations (OI) initiated an investigation to determine if Con Ed employees at IP 2 falsified test documents related to installation of Solenoid Operating Valve (SOV) No. 1035 on March 17 - 18, 1989, using Corrective Maintenance Procedure (CMP) No. CM-16.66, Revision 2. Based on its investigation, OI concluded that three Con Ed employees deliberately falsified CMP No. CM-16.66 (Sections 5.5.16 and 7.1) by completing and signing it and thereby making it appear that a meggar check on the SOV had been completed as required by the procedure, when such a check had not been performed. A Notice of Violation and Proposed Imposition of Civil Penalty (Notice) in the amount of \$62,500 has been issued on the same date as this Demand for Information. In addition, based on the findings of this investigation and an NRC maintenance team inspection conducted April through May 1989, the NRC believes that the instance of inaccurate maintenance records was symptomatic of a larger, more

widespread problem of employees not understanding the importance of strictly following procedures or the significance of their signatures attesting to completion of the procedure steps, the need to utilize Open Item Reports to resolve identified procedure performance deficiencies, and additional inadequacies in your maintenance and quality assurance programs.

III

Accordingly, despite the significant improvements in the maintenance program noted during a January 10-18, 1991 team inspection, further information is needed to determine whether the actions taken by the Licensee to correct the problems discussed above were effective and provide the Commission with reasonable assurance that the Licensee will maintain complete and accurate records of licensed activities and otherwise conduct its activities in accordance with the Commission's requirements.

IV

Therefore, to determine whether the license should be modified, suspended, or revoked, or other enforcement action taken to ensure compliance with NRC regulatory requirements, the Licensee is required to submit to the Deputy Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, the following information, in writing and under oath or affirmation, pursuant to Sections 161c, 161o, 182, and 186 of the Atomic Energy Act of 1954, as amended, and 10 CFR 50.54(f):

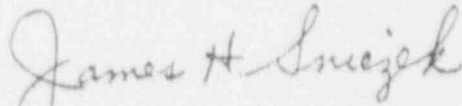
Within 30 days of the completion of the next refueling outage, currently scheduled to begin February 1991, provide an assessment of:

1. the effectiveness of QA/QC controls for ensuring that maintenance procedures are properly implemented, records are accurately completed, and concerns, when they exist, are surfaced to appropriate management for resolution; and
2. the effectiveness of your corrective actions for the violations set forth in the Notice.

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 your response, the NRC will determine whether further action is necessary to ensure compliance with regulatory requirements.

FOR THE NUCLEAR REGULATORY COMMISSION



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

Dated at Rockville, Maryland
this 17th day of February 1991.



UNITED STATES
NUCLEAR REGULATORY COMMISSION

REGION IV
611 RYAN PLAZA DRIVE, SUITE 1000
ARLINGTON, TEXAS 76011

DEC 17 1990

Docket Nos. 50-313 and 50-368
License Nos. DPR-51 and NPF-6
EA 90-175

Entergy Operations, Inc.
ATTN: Mr. N. S. Carns, Vice President
Operations, Arkansas Nuclear One
Route 3, Box 137G
Russellville, Arkansas 72801

Gentlemen:

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY - \$50,000
(NRC INSPECTION REPORT NO. 50-313 & 50-368/90-38)

This refers to the special NRC inspection conducted on October 1-5, 1990, at the Arkansas Nuclear One (ANO) facility operated by Entergy Operations, Inc. (Entergy Operations), to follow up on previously identified NRC concerns relating to operability of the control room emergency ventilation system (CREVS). The results of this inspection were provided to you in an NRC inspection report dated October 16, 1990, and were discussed with you and other Entergy Operations representatives at an Enforcement Conference on October 30, 1990.

The inspection focused on the ability of the control room ventilation dampers to function in the event of the loss of normal instrument air. This issue was initially identified by the NRC during an Operational Safety Team Inspection (OSTI) conducted September 10-21, 1990. In addition to the system operability concern, an issue regarding the accuracy of ANO's response to NRC Generic Letter (GL) 88-14, "Instrument Air Supply System Problems Affecting Safety-Related Equipment," was identified.

Subsequent investigation by your staff indicated that the CREVS may not have been able to perform its intended safety function since the time when damper air accumulators were installed in 1978. Post-modification testing failed to identify the system performance deficiency when normal instrument air (IA) is unavailable. Of equal concern from a regulatory perspective is the fact that on August 8, 1988, GL 88-14 informed all NRC reactor licensees of a generic problem with regard to safety systems reliant on instrument air. The GL requested all licensees to perform a design and operability verification of the instrument air system, including verification by test that air-operated safety-related components would perform as expected under normal conditions and upon loss of the normal IA system. A written response confirming that the above verifications were conducted was required to be submitted under oath or affirmation.

Arkansas Power & Light Company (AP&L), the predecessor licensee to Entergy Operations, provided inaccurate information to the NRC in its March 7, 1989 response to GL 88-14. Specifically, AP&L stated that each safety-related component encompassed by the generic letter "has an associated surveillance test which is conducted on a regular basis to verify the operability of that component" and that the "current surveillances conducted at ANO on "Q" components, we believe, adequately verifies the operability of air-operated IAS components and simulates a complete loss of instrument air for the components being tested." These statements were not accurate in the case of the reserve air accumulators. AP&L failed to recognize that the safety-related air reserve accumulators for the control room isolation dampers were not subject to any periodic testing requirements and had never been tested. This failure was due in part to an inadequate engineering evaluation, coupled with the lack of a clearly documented plant design basis. This is a significant regulatory concern because the inadequate evaluation of the GL 88-14 concerns resulted in the facility operating for an additional two years with the control room isolation function degraded.

To emphasize the need for effective management and engineering controls to ensure that information related to potential safety-system problems is adequately reviewed and accurately reported to the NRC, and that appropriate corrective action is taken, 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 described in the enclosed Notice. 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 by 50% because the NRC identified the control room isolation damper problem instead of AP&L, the predecessor licensee, which should have identified it two years earlier. However, 50% mitigation was applied for the prompt and comprehensive corrective action taken by Entergy Operations, the successor licensee, once the problem was identified. Those actions included modification of the control room isolation system, testing, enhancement of procedural guidance to ensure complete and accurate responses when communicating with the NRC, and initiation of a review of prior NRC submittals (1988 and 1989) for possible errors. Also, a number of significant licensee programs have previously been initiated to document the plant design configuration and design basis and upgrade surveillance testing. These actions were initiated to address the root causes of past problems that were the subject of escalated enforcement action (EA 80-284). In recognition of those actions your recent initiatives to improve engineering and technical support, as well as your improved operating philosophy, which collectively are viewed as positive changes that should prevent similar problems from occurring in the future, we have decided not to further escalate the civil penalty based on past performance and duration.

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,



Robert D. Martz
Regional Administrator

Enclosure:
Notice of Violation

cc w/encl:
Entergy Operations, Inc.
ATTN: Donald C. Hintz, Executive Vice
President & Chief Operating Officer
P.O. Box 31995
Jackson, Mississippi 39286

Entergy Operations, Inc.
ATTN: Gerald W. Muench, Vice President
Operations Support
P.O. Box 31995
Jackson, Mississippi 39286

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

Arkansas Nuclear One
ATTN: General Manager
Technical Support and Assessment
Route 3, Box 137G
Russellville, Arkansas 72801

Entergy Operations, Inc.

-4-

Arkansas Nuclear One
ATTN: Jerry Yelverton, Director
Nuclear Operations
Route 3, Box 137G
Russellville, Arkansas 72801

Arkansas Nuclear One
ATTN: Mr. Tom W. Nickels
Route 3, Box 137G
Russellville, Arkansas 72801

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

Honorable Joe W. Phillips
County Judge of Pope County
Pope County Courthouse
Russellville, Arkansas 72801

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

Arkansas Department of Health
ATTN: Ms. Greta Dicus, Director
Division of Environmental Health
Protection
4815 West Markam Street
Little Rock, Arkansas 72201

Babcock & Wilcox
Nuclear Power Generation Division
ATTN: Mr. Robert B. Borsum
1700 Rockville Pike, Suite 525
Rockville, Maryland 20852

Admiral Kinnaird R. McKee, USN (Ret)
P.O. Box 41
Oxford, Maryland 21654

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

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

Docket Nos. 80-413 and 50-368
License Nos. DPL-51 and NPF-6
EA 9-175

During an NRC inspection on October 1-5, 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 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 Section 50.9 requires, in part, that information provided to the Commission by a licensee shall be complete and accurate in all material respects.

NRC Generic Letter 88-14, "Instrument Air Supply System Problems Affecting Safety-Related Equipment", issued on August 8, 1988, requested licensees to perform a design and operations verification of the entire instrument air system, including verification by test that air-operated safety-related components will perform as expected in accordance with all design-basis events, including a loss of the normal instrument air system. In accordance with 10 CFR 50.54(f), a response confirming that the above verification was performed, including identification of any components that cannot accomplish their safety-related function, and stating the corrective actions taken or to be taken, was required to be submitted under oath or affirmation within 180 days of the letter.

Contrary to the above, Arkansas Power & Light Company (AP&L), Arkansas Nuclear One's then licensee of record, provided information to the Commission that was not accurate in all material respects. AP&L stated in its March 7, 1989, response to Generic Letter 88-14 that "Each 'Q' component has an associated surveillance test which is conducted on a regular basis to verify the operability of that component," and that "The current surveillances conducted at ANO on 'Q' components, we believe, adequately verifies [sic] the operability of air-operated IAS components and simulates a complete loss of instrument air for the component being tested." In fact, AP&L had never tested certain "Q" components, specifically the safety-related reserve air accumulators and associated check valves (IA-43A, IA-43B, IA-44A and IA-44B), to ensure that these components were functional under normal conditions or upon a complete loss of instrument air. Tests performed on September 21, 1990, by the successor licensee, Entergy Operations, Inc. (Entergy) revealed that the safety-related reserve air accumulators would not have performed as expected in the event of a loss of the normal air supply due to air leakage past system check valves, and

thus that the air-operated isolation dampers to the Control Room Emergency Ventilation System (CREVS) may not have been able to perform their intended safety function of isolating the control room in the event of design basis accident. The inaccurate information was material because had the NRC known of the air-operated isolation damper problem, the issue would have been reviewed for further regulatory action.

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

NRC Generic Letter 88-14, "Instrument Air Supply System Problems Affecting Safety-Related Equipment", issued on August 8, 1988, requested licensees to perform a design and operations verification of the entire instrument air system, including verification by test that air-operated safety-related components will perform as expected in accordance with all design-basis events, including a loss of the normal instrument air system. In accordance with 10 CFR 50.54(f), a response confirming that the above verification was performed, including identification of any components that cannot accomplish their safety-related function, and stating the corrective actions taken or to be taken, was required to be submitted under oath or affirmation within 180 days of the letter.

Contrary to the above, as of March 7, 1989, when AP&L responded to Generic Letter 88-14, and continuing until September 21, 1990, both AP&L and Entergy Operations had failed to identify or to correct a significant condition adverse to quality concerning the air-operated components of the CREVS. Specifically, safety-related reserve air accumulators might not have performed as expected in the event of a loss of the normal air supply because of air leakage past system check valves. AP&L failed to identify this significant condition adverse to quality in preparing its response to GL 88-14, which requested that the licensee perform a design and operations verification of the instrument air system. As a consequence, the CREVS air-operated dampers may not have been able to isolate the control room in the event of certain design basis accidents.

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

Civil Penalty - \$50,000 (assessed equally between the two violations).

Pursuant to the provisions of 10 CFR 2.201, Entergy Operations, Inc. (Licensee) is hereby required to submit a written statement of explanation to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, within 30 days of the date of this Notice of Violation and Proposed Imposition of Civil 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 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 (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.

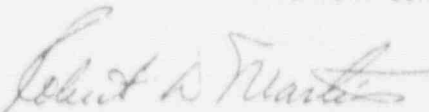
The response noted above (Reply to Notice of Violation, letter with payment of civil and Answer to a Notice of Violation) should be addressed to: Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, ATTN: Document

Notice of Violation

-4-

Control Desk, Washington, D.C. 20555 with a copy to the Regional Administrator, U.S. Nuclear Regulatory Commission, Region IV, 611 Ryan Plaza Drive, Suite 1000, Arlington, Texas 76011, and a copy to the NRC Resident Inspector at Arkansas Nuclear One.

FOR THE NUCLEAR REGULATORY COMMISSION


Robert D. Martin
Regional Administrator

Dated at Arlington, Texas
this 17th day of December 1990



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

FEB 05 1991

Docket Nos. 50-424 and 50-425
License Nos. NPF-68 and NPF-81
EA 90-188

Georgia Power Company
ATTN: Mr. W. G. Hairston, III
Senior Vice President -
Nuclear Operations
Post Office Box 1295
Birmingham, Alabama 35201

Gentlemen:

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY - \$50,000
(NRC INSPECTION REPORT NOS. 50-424/90-27 AND 50-425/90-27)

This refers to the Nuclear Regulatory Commission (NRC) inspection conducted by A. Tillman on October 16 - 17, 1990, at the Vogtle Electric Generating Plant (VEGP). This special announced inspection was conducted in the area of physical protection of sensitive unclassified Safeguards Information (SGI) in response to a licensee identified and reported safeguards event which occurred on October 11, 1990, and which involved the discovery of unsecured SGI in the VEGP Security Training Office located within the licensee's protected area. The report documenting this inspection was sent to you by letter dated October 29, 1990. As a result of this inspection, significant failures to comply with NRC regulatory requirements were identified. An Enforcement Conference was held on November 13, 1990, in the Region II office to discuss the violations, their cause, and your corrective actions to preclude their recurrence. The letter summarizing this conference was sent to you by letter dated November 20, 1990.

The violation described in the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice) includes five instances where SGI was unsecured, unprotected, or unattended at either VEGP or the Vogtle Project Engineering Office in Birmingham, Alabama, since August 29, 1990. On October 11 and October 19, 1990, SGI was found unsecured and unattended in the VEGP Security Training Office. On August 29 and October 16, 1990, SGI was found unsecured and unattended in the Vogtle Project Engineering Office in Birmingham, Alabama. On November 9, 1990, aperture cards containing SGI were discovered unsecured in Document Control at VEGP.

In addition to the above, on November 9, 1990 SGI was found unsecured and unattended in the Southern Company Services (SCS) Bechtel Office in Birmingham, Alabama. This event is not being cited as a violation because it was identified as part of corrective action for a previously identified violation.

Problems were identified relative to the marking of documents believed to contain Safeguards Information. Although overmarking is not considered a violation, a document marked as containing SGI must be protected. Overmarking of SGI may contribute to poor attention being paid to information

FEB 05 1991

protection procedures by guard force members if they learn over time that at least some of the documents marked as SGI in fact do not contain such information, thereby putting the protection of legitimately-marked documents at risk.

Some of the examples of the violation may have been of minor significance relative to the possible compromise of SGI. However, collectively they represent the continuation of a recurring problem involving the protection of SGI which you have not yet brought under adequate control. In February 1990, Georgia Power Company was assessed a civil penalty (EA 89-227, \$7,500) for similar Severity Level IV violations. In June 1990, the licensee was assessed a civil penalty (EA 90-090, \$50,000) for a similar violation which was categorized at a Severity Level III. Therefore, in view of the breakdown in management oversight of the protection of SGI and in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy) 10 CFR Part 2, Appendix C (1990), the violation has been classified as a Severity Level III violation.

To emphasize the importance of protecting SGI and ensuring that such information is not inadvertently compromised, I have been authorized, after consultation with the Director, Office of Enforcement, and the Deputy Executive Director for Nuclear Reactor Regulation, Regional Operations and Research, to issue the enclosed Notice of Violation and Proposed Imposition of Civil Penalty in the amount of \$50,000 for the Severity Level III problem. 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.

Mitigation of this civil penalty by 50% is warranted because of your identification and reporting of the violations and by 50% due to the corrective actions which you have instituted, including the formation of a Task Force described in your November 20, 1990 letter to examine the causes of these violations and recommend appropriate long-term solutions. However, escalation of the penalty by 100% is appropriate due to your continued poor performance in this area. The remaining factors of multiple occurrences and duration were used to categorize these violations as a Severity Level III problem and, therefore, will not be used as escalating factors.

The continued poor performance by Georgia Power Company with respect to the protection of sensitive unclassified Safeguards Information is of great concern to the NRC. Consideration was given to issuance of a more significant enforcement action; however, because Georgia Power Company identified all of the current violations and has demonstrated a heightened sensitivity to the problem in its formation of a Task Force, this civil penalty was considered adequate to appropriately emphasize the need for effective and lasting corrective action.

As noted above, previous violations relating to the failure to adequately protect SGI have resulted in two other civil penalties within the past year. In the most recent case, the staff had reduced the penalty based on the expected effectiveness of the corrective actions. However, the past corrective actions for these violations apparently have been insufficient in depth or breadth to reach the root causes of the violations. Therefore, Georgia Power Company is expected to consider whether the Task Force that is being formed to address

FEB 05 1991

these continuing problems would benefit from the involvement of individuals whose experience derives from sources outside of the Georgia Power Company corporate structure in general and Vogtle in particular. It is important that the Task Force identify the root causes of this problem, whether it is procedures, distribution of responsibilities, training, management oversight, or response to identified problems.

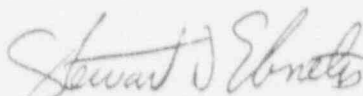
You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. In your response, you should document the specific actions taken and any additional actions you plan to prevent recurrence. Specifically, you should respond to the issues raised in the preceding paragraph. In addition, we expect you to provide the NRC with a detailed scope and schedule for completing your Task Force review by February 15, 1991 as provided in your November 20, 1990 letter. If that date or other dates described in your November 20, 1990 submittal are revised, please provide us written notification. Please also forward a copy of the Task Force's report upon completion of the project. 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 that regard, we recognize that you may find additional examples of improper control of SGI. Note that the staff may exercise enforcement discretion for these additional findings provided your review is being aggressively performed and your corrective actions are timely and comprehensive.

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. Ebnetter
Regional Administrator

Enclosure:
Notice of Violation and Proposed
Imposition of Civil Penalty

cc w/encl: See Next Page

Georgia Power Company

- 4 -

FEB 05 1991

cc w/encl:
R. P. McDonald
Executive Vice President-Nuclear
Operations
Georgia Power Company
P. O. Box 1295
Birmingham, AL 35201

C. K. McCoy
Vice President-Nuclear
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P. O. Box 1295
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W. B. Shipman
General Manager, Nuclear Operations
Georgia Power Company
P. O. 1600
Waynesboro, GA 30830

J. A. Bailey
Manager-Licensing
Georgia Power Company
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Lonice Barrett, Commissioner
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State of Georgia

FEB 05 1991

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

Georgia Power Company
Vogtle Electric Generating Plant
Units 1 and 2

Docket Nos. 50-424 and 50-425
NPF-68 and NPF-81

During an NRC inspection conducted on October 1-17, 1990, 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 (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 violation and associated civil penalty are set forth below:

10 CFR 73.21(a) requires, in part, that Safeguards Information (SGI) be protected against unauthorized disclosure, and that licensees establish and maintain an information protection system that includes certain measures to protect SGI.

10 CFR 73.21(d)(2) requires, in part, that while unattended, SGI shall be stored in a locked security storage container.

Contrary to the above, the licensee failed to provide adequate protection for documents and materials containing Safeguards Information as evidenced by the following examples:

1. On August 29, 1990, an unlocked and unattended container used to store SGI was discovered by a Southern Company Services employee in the Vogtle Project Engineering Support Office document file room, located in Birmingham, Alabama.
2. On October 11, 1990, unsecured and unattended documents containing SGI relating to training tasks were found in the Security Training Office, Vogtle Electric Generating Plant.
- * 3. On October 17, 1990, two elementary drawings of the Vogtle security power supply containing SGI were found unsecured and unattended in the Vogtle Project Engineering Office, Birmingham, Alabama.
4. On October 19, 1990, four documents containing Safeguards Information were found unsecured and unattended in the Security Training Office, Vogtle Electric Generating Plant.
- * 5. On November 9, 1990, aperture cards containing SGI were discovered unmarked and unprotected as SGI in the Engineering Satellite Office on the third floor of the Service Building.

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

Civil Penalty - \$50,000.

- * Portions modified per Licensee response to correct facts.

FEB 07 1990

Pursuant to the provisions of 10 CFR 2.201, Georgia 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.

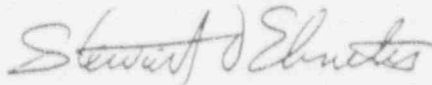
In requesting mitigation of the proposed penalty, the factors addressed in Section V.B of 10 CFR Part 2, Appendix C (1990), should be addressed. Any written answer in accordance with 10 CFR 2.205 should be set forth separately from the statement or explanation in reply pursuant to 10 CFR 2.201, but may 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.

FEB 05 1991

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 if applicable, a copy to the NRC Resident Inspector at the facility which is the subject of this Notice.

FOR THE NUCLEAR REGULATORY COMMISSION



Stewart D. Ebnetter
Regional Administrator

Dated at Atlanta, Georgia
this 5th day of February 1991



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

February 11, 1991

Docket No. 50-336
License No. DPR-65
EA 90-219

Northeast Nuclear Energy Company
ATTN: Mr. E.J. Mroczka
Senior Vice President - Nuclear
Engineering and Operations
Post Office Box 270
Hartford, Connecticut 06141-0270

Gentlemen:

Subject: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY - \$50,000
(NRC Inspection Report No. 50-336/90-22)

This letter refers to the NRC inspection conducted between October 2 and December 13, 1990 at Millstone Nuclear Power Station, Unit 2, Waterford, Connecticut. The inspection report was sent to you on December 28, 1990. During the inspection, the inspectors reviewed the circumstances associated with two violations of NRC containment integrity requirements which were identified by your staff and reported to the NRC. In both cases, the violations involved the existence of a direct access path from the containment atmosphere to the outside atmosphere while the reactor was in the refueling mode and core alterations were occurring. On January 15, 1991, an enforcement conference was conducted with Mr. W. Romberg and other members of your staff to discuss both violations, their causes, and your corrective actions.

In the first case, the direct access path from the containment to the outside atmosphere was through a steam generator atmospheric dump valve which was improperly opened (at a time when a steam generator manway was also open) to support a drain down of the steam generator. The condition existed for a little over an hour. The NRC is particularly concerned that the supervisory control room operator (SCO), a licensed Senior Reactor Operator, on duty at the time did not adequately evaluate the existing plant conditions and did not properly respond to precautions in the drain down procedure concerning the need to assure that opening of the atmospheric dump valve would not violate containment integrity. Moreover, the SCO followed the drain down procedure despite an explicit instruction on the tagging order for the valve (which stated that the valve had to remain closed for containment boundary protection). In doing so, he apparently proceeded without properly focusing on the fact that the opening of the valve would violate containment integrity and procedure OP 2316A under the existing conditions. With respect to this violation, the NRC is also concerned that when the valve was opened, a reactor operator in the control room also had an opportunity

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

to question this condition via the valve position indication in the control room, but did not do so, and the condition existed until identified by the Outage Coordinator (a Senior Reactor Operator) approximately one hour later.

In the second instance, which occurred four days after the first, the direct access path existed through the containment purge lines for more than three days. The path existed because the inlet valve on the supply line and the outlet valve on the exhaust line were open and not capable of being automatically closed, as required. (The actuation cabinet associated with these valves had been deenergized for a maintenance activity.) The NRC is concerned that when the actuator cabinet was removed for troubleshooting, the plant operations staff did not identify that a technical specification consideration was created because of the loss of the automatic isolation capability. The problem on the exhaust line was of additional concern because that line's inlet valve was removed for maintenance. The NRC is also concerned that the SCO, who was the same SCO involved in the first instance, apparently did not recognize the significance of opening the purge valves, given their status at the time. As a result, he opened the valves so as to relieve the uncomfortable temperature and humidity condition that existed in the containment and created the second problem. Furthermore, after the violation of containment integrity occurred, the condition was not recognized by your staff until an actual ESF actuation occurred more than three days later (when a containment gaseous radiation monitor failed high due to a loose wire), at which time prompt action was taken to manually close the outlet valves on the purge lines.

The NRC recognizes that the safety consequences of the violations were minimal. In the first instance, the condition existed for a short period, and the conditions were bounded by those assumed in the Final Safety Analysis Report (FSAR). In the second case, although the condition existed for more than three days, the valves were manually closed by the operators, as required by the abnormal operating procedure, within 48 seconds of their actuation. Nonetheless, the NRC has a significant regulatory concern with the personnel errors, inattention to detail, and inadequate assessments by the operations staff prior to manipulating plant equipment that resulted in these violations. Therefore, the above concerns, as well as the fact that the facility was, at times, not maintained in accordance with the technical specifications during refueling activities, has led to the classification of these violations in the aggregate as a Severity Level III problem in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions" (Enforcement Policy) 10 CFR Part 2, Appendix C.

The NRC recognizes that subsequent to the inspection, actions were initiated to correct these violations and prevent recurrence. These corrective actions, which were described at the enforcement conference, included counseling of operators, revision of procedures, plans for development of preoutage refresher training of operators, and planned development of status board improvements to assist in maintaining configuration control. However, the corrective actions were narrowly focused in that they were not based upon an adequate root cause analysis of these events. In spite of the recurrence of the loss of containment

integrity over a short interval of time and the involvement of the same SCO in both events, your staff's investigative activities did not include interviews with all individuals knowledgeable of the matters leading to and associated with the events. In addition, based on your presentation at the enforcement conference, the interviews that were performed did not appear to be comprehensive. Further, the corrective action did not include an evaluation of the adequacy of the training provided to the individuals most responsible for causing these events.

Therefore, to emphasize the importance of (1) proper control of equipment at the facility to assure that the reactor is operated and maintained safely and in accordance with the technical specifications in shutdown conditions as well as during power operations, and (2) performing adequate root cause evaluations when deficiencies occur, 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 set forth in the enclosed Notice.

The base civil penalty amount for a Severity Level III problem is \$50,000. The escalation and mitigation factors set forth in the enforcement policy were considered, as described below, and on balance, no adjustment of the civil penalty is warranted. Both violations were identified by your staff and reported to the NRC. Therefore, 25% mitigation of the base civil penalty on this factor is warranted. Full 50% mitigation on this factor is not warranted because the second violation was identified as the result of a self-disclosing event and your written licensee event report (LER) of that violation did not clearly describe the violation with respect to its duration, actual safety significance and potential consequences as required by 10 CFR 50.73. Although long-term corrective actions for both violations were taken or initiated, as described herein, the actions did not include an adequate evaluation of training deficiencies reflecting an incomplete root cause analysis of the events. Therefore, 25% escalation of the base civil penalty is warranted. Your past performance in the operation and outage planning areas has been good, as evidenced by Category I ratings in these 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 because three violations were identified by your staff in the past two years involving inadequate control of containment system operability. (Reference: LER 89-009, LER 90-002, and the Severity Level IV violation in IR 50-334/88-22.) Because the second violation existed for more than three days, with opportunities including shift turnovers, to identify and correct the violation sooner, 50% escalation of the penalty is warranted based on its duration. Full 100% escalation on this factor is not warranted since the other violation existed for a short period of time and both violations resulted in minimal safety consequences. This case did not involve prior notice, and therefore, no adjustment of the civil penalty on this factor is warranted. Although the case did involve two violations, the factor of

multiple examples was a consideration in classifying this as a Severity Level III problem, and therefore, the NRC has decided that further escalation based on this factor 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. Based on discussions at the enforcement conference, we understand that you are taking steps to address NRC concerns with your narrowly focused corrective actions and incomplete licensee event report. Please include in your response a description of what actions you are taking to provide assurance that in the future your corrective actions and LERs will be complete. 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, Station Director, Millstone
D. O. Nordquist, Director of Quality Services
R. M. Kacich, Manager, Generation Facilities Licensing
J. P. Stetz, Station Director, Haddam Neck
Gerald Garfield, Esquire
Public Document Room (PDR)
Local Public Document Room (LPDR)
Nuclear Safety Information Center (NSIC)
NRC Resident Inspector
State of Connecticut

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

Northeast Nuclear Energy Company
Waterford, Connecticut

Docket No. 50-336
License No. DPR-65
EA 90-219

During an NRC inspection conducted between September 18 and December 13, 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 the associated civil penalty are set forth below:

Technical Specification Limiting Condition for Operation (LCO) 3.9.4, Containment Penetrations, requires, in part, that, during core alterations, each penetration providing direct access from the containment atmosphere to the outside atmosphere shall be either closed by an isolation valve, blind flange, manual valve, or special device, or be capable of being closed by an automatic containment purge valve. Technical Specification LCO Action Statement 3.9.4 specifies that, when this specification is not satisfied, all operations involving core alterations are to be immediately suspended.

Technical Specification Limiting Condition for Operation (LCO) 3.9.10, Containment Purge Valve Isolation System (CPVIS), requires that the CPVIS be operable whenever the reactor is in the refueling mode of operation (Mode 6). Technical Specification LCO Action Statement 3.9.10 requires when the CPVIS is inoperable, the licensee must either close each of the penetrations providing direct access from the containment atmosphere to the outside atmosphere or suspend all operations involving core alterations or fuel movement within the containment building.

Contrary to the above,

1. Between 6:45 p.m. and 8:00 p.m. on October 2, 1990, while core alterations were taking place, a direct access path from the containment atmosphere to the outside atmosphere existed through the No. 1 steam generator atmospheric dump valve, which would not automatically close, and an open steam generator manway; and
2. Between 4:25 a.m. on October 6, 1990 and 2:55 p.m. on October 9, 1990, while core alterations were being performed, a direct access path from the containment to the outside atmosphere existed through both the supply and exhaust lines of the containment purge system, and at the time, both the isolation valves in the exhaust line and one isolation valve in the supply line were not capable of being automatically

closed. Specifically, the inlet valve (Valve 2-AC-6) on the exhaust line had been physically removed for maintenance, prior to 4:25 a.m. on October 6, 1990, and the outlet valve (Valve 2-AC-7) on the exhaust line and the inlet valve (Valve 2-AC-4) on the supply line were opened at 4:25 a.m. on that date even though their automatic closing function was disabled prior to that time when the associated actuation cabinet was deenergized for troubleshooting.

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

Pursuant to the provision of 10 CFR 2.201, Northeast Nuclear Energy Company 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). 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 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, 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. 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 I, 475 Allendale Road, King of Prussia, Pennsylvania 19406 and a copy to the Senior Resident Inspector, Millstone, Unit 2.

FOR THE NUCLEAR REGULATORY COMMISSION



Thomas T. Martin
Regional Administrator

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



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

FEB 25 1991

Docket No. 50-344
License No. NPF-1
EA 91-005

Portland General Electric
ATTN: Mr. James E. Cross
Vice President, Nuclear
121 S.W. Salmon Street
Portland, Oregon 97204

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY - \$50,000
(INSPECTION REPORT NO. 50-344/90-40)

This letter refers to the inspection conducted on December 10, 1990, through January 3, 1991, at the Trojan Nuclear Plant. The purpose of this inspection was to determine whether the facility's licensed operator medical examinations met the requirements established by ANSI/ANS-3.4-1983, "Medical Certification and Monitoring of Personnel Requiring Operator Licenses for Nuclear Power Plants," and by applicable portions of 10 CFR Parts 50 and 55. This inspection identified three apparent violations of these requirements. A report on this inspection was issued on January 11, 1991, and a report on the January 17, 1991, enforcement conference was sent to you on February 1, 1991.

The violations, which are described in the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice), involved: (1) inaccurate certification to the NRC that candidates for operator licenses had received complete medical examinations; (2) failure to notify the NRC regarding a licensed operator who had developed a potentially incapacitating medical condition; and (3) incomplete documentation of medical histories and qualifications data. These violations occurred from July 29, 1987 until identification by the NRC on January 3, 1991. The root cause of the violations appears to have been a breakdown in your program to ensure compliance with these requirements.

The violations have safety significance in that one licensed operator had a medical condition for an extended period which may have prevented him from safely performing his licensed duties. That violation combined with the repeated incomplete and incorrectly certified medical examinations of licensed operators collectively represent a breakdown in the control of licensed activities, which indicates a potentially significant lack of attention toward licensee responsibilities. 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 have been classified in the aggregate as a Severity Level III problem.

CERTIFIED MAIL
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The NRC staff recognizes that, subsequent to the event, you defined and implemented a revised medical records program which should ensure your licensed operators' medical examinations meet the requirements of ANSI/ANS-3.4-1983. In addition, the prompt corrective actions you took, after this problem was identified by the NRC, ensured that all licensed operators received a complete medical examination prior to going on shift. Finally, we understand that you have broadened your corrective action to include a review of other medical records areas, and that you are sponsoring a utility conference to share lessons learned from this event with other Region V licensees.

To emphasize the importance of ensuring that all licensed operators are medically qualified, that such determinations are timely and properly documented, and that any discrepancies are aggressively and thoroughly pursued, I have been authorized, after consultation with the Director, Office of Enforcement, and the Deputy Executive Director for Nuclear Reactor Regulation, Regional Operations, and Research, to issue the enclosed Notice of Violation and Proposed Imposition of Civil Penalty in the amount of \$50,000 for the Severity Level III problem. This is the base value of a civil penalty for a Severity Level III problem. The escalation and mitigation factors in the Enforcement Policy were considered as discussed below.

While you had identified prior to the inspection the need for significant revision to your medical records program, no revision nor any licensee investigation into the possible problems arising from this condition had been initiated prior to the NRC inspection. Further, each one of several events that could have triggered an investigation by the licensee into this area, such as approving an In-House Position adopting ANSI/ANS-3.4-1983, failed to produce an effective evaluation of the medical records program. Therefore, escalation of the civil penalty by 50% of the base amount is warranted for identification and reporting.

However, based on your prompt, aggressive and very extensive corrective actions after the violations were identified, mitigation of the civil penalty by 50% of the base amount is warranted for effective corrective actions.

The other adjustment factors in the Policy were considered and no further adjustment to the base civil penalty is considered appropriate. On balance, no adjustment of the base civil penalty has been deemed appropriate.

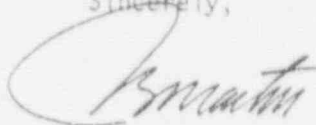
You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. In your response, you should document the specific actions taken and any additional actions you plan to prevent recurrence of the violations and to ensure complete,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

Portland General Electric

- 3 -

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 procedure of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, Pub. L. No. 96-511.

Sincerely,



John B. Martin
Regional Administrator

Enclosure: Notice of Violation
and Proposed Imposition of Civil Penalty

cc w/enclosure:

- S. Bauer, Regulation Branch Manager, PGE
- T. D. Walt, General Manager of Technical Functions, PGE
- W. Robinson, General Manager (Trojan Nuclear Plant)
- L. A. Girard, Vice President and General Counsel (Trojan Nuclear Plant)

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

Portland General Electric Company
Trojan Nuclear Plant

Docket No. 50-344
License No. NPF-1
EA 91-005

During an NRC inspection conducted on December 10, 1990, through January 3, 1991, three violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C (1990) (Enforcement Policy), 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 55.23 requires an authorized representative of the facility licensee to certify, to the NRC, the medical fitness of an operator license applicant by completing and signing Form NRC-396, "Certification of Medical Examination by Facility Licensee." Form NRC-396 is a certification that a medical examination has been conducted in accordance with ANSI/ANS 3.4 - 1983 or ANSI/ANS 15.4 - 1977 (N380).

Contrary to the above, on October 6, 1987, December 17, 1987, April 18, 1989, March 21, 1988, November 29, 1988, and June 21, 1990, an authorized facility representative certified on Form NRC-396 that operator licensing medical examinations were performed in accordance with the guidance contained in ANSI/ANS 3.4 - 1983 or ANSI/ANS 15.4 - 1977 (N380) when, in fact, they were not for twelve applicants.

- B. 10 CFR 55.25 requires the facility licensee to notify the NRC within 30 days if, during the term of a licensed operator's license, the facility licensee learns that the operator has developed a physical or mental condition that causes the operator to fail to meet the requirements of 10 CFR 55.21.

Contrary to the above, the facility licensee failed to notify the NRC within 30 days of the diagnosis of a licensed operator's medical condition, of which the facility licensee was aware, and which caused the respective operator to fail to meet the requirements of 10 CFR 55.33(a)(1). Specifically, on November 2, 1989 and January 13, 1988, a licensed operator disclosed to the facility licensee during his medical examination a condition which may cause sudden incapacitation (severe migraine headaches). He also disclosed to the facility that he controlled these headaches by routinely taking prescription medications for migraine headaches in such dosages that they could be expected to incapacitate him, and that delays in taking these medications could also be expected to incapacitate him.

- C. 10 CFR 55.27 requires the facility licensee to document and maintain the results of medical qualifications data, test results, and each operator's or senior operator's medical history for the current license period.

Contrary to the above, the facility licensee failed to completely document the results of each operator's or senior operator's medical history and medical qualifications data. Specifically, numerous data blocks were left blank on 19 licensed operators' medical examination records, including blocks for physician's summary and elaboration of medical history, heart, vascular, pupils, ears, weight, and cross visual field.

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

Cumulative Civil Penalty - \$50,000 (assessed equally among the three violations.)

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

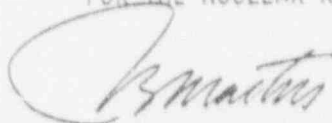
Within the same time as provided for the response required above under 10 CFR 2.201, the Licensee may pay the civil penalty by letter addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, with a check, draft, money order, or electronic transfer payable to the Treasurer 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 copies to the Regional Administrator, U.S. Nuclear Regulatory Commission, Region V, and to the NRC Resident Inspector at the Trojan Nuclear Plant.

FOR THE NUCLEAR REGULATORY COMMISSION



John B. Martin
Regional Administrator

Dated at Walnut Creek, California
the 25th day of February 1991



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION V

1460 MARIA LANE, SUITE 210
WALNUT CREEK, CALIFORNIA 94596-5368

JAN 04 1991

Docket Nos. 50-361 and 50-362
License Nos. NPF-10 and NPF-15
EA 90-201

Southern California Edison Company
Irvine Operations Center
ATTN: Mr. Harold B. Ray
Senior Vice President, Nuclear
23 Parker Street
Irvine, California 92718

Gentlemen:

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTIES -
\$150,000
(NRC INSPECTION REPORT NOS. 50-361/90-37 AND 50-362/90-37)

This refers to the special inspection conducted on October 1 through November 15, 1990 at the San Onofre Nuclear Generating Station, Units 2 and 3. The results of this inspection were documented in the referenced NRC inspection report, sent to you on December 5, 1990. The inspection report addresses two Technical Specifications violations, resulting from misaligned valves, which you identified and reported to our Resident Inspector. You also reported one event pursuant to 10 CFR 50.72 and discussed the events in Licensee Event Reports (LERs) 50-362/90-10 and 50-361/90-12, pursuant to the requirements of 10 CFR 50.73. These issues were discussed with you during an enforcement conference held in the Region V Office on December 11, 1990. Our discussion during the enforcement conference was summarized in Meeting Report Nos. 50-361/90-42 and 50-362/90-42, transmitted to you on December 20, 1990.

The first violation involved inoperability of the steam-driven auxiliary feedwater (AFW) pump in Unit 2 as a result of a misaligned steam drain trap which permitted condensate to accumulate in the steam supply line, and subsequently caused the AFW pump to trip on overspeed. This condition resulted from inadequate procedures for controlling plant evolutions, and remained undetected for a period of approximately 55 days (with the Unit operating in Mode 1) before the facility staff identified and corrected the misalignment. The failure to more promptly identify this violation appears to have resulted from (1) a failure to properly evaluate and respond to the discovery of another misaligned valve associated with the AFW system, (2) failure to properly diagnose the cause of overspeed trips which occurred on October 6 and 16, 1990, (3) poor and informal communication between the Technical and Operations divisions of your staff, and (4) insufficient operator awareness of plant conditions.

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

JAN 04 1991

The second violation involved inadvertent opening of the Unit 3 Train B containment emergency sump outlet isolation valve (3HV-9302), apparently caused by inadequate work control measures. This violation was exacerbated by the failure of Plant Operations personnel to recognize and correct the misalignment for almost four days, including 12 shift changes, (with the Unit operating in Mode 1), even though clear visual indication of the valve's position was provided on the control panel. Insufficient time available to operators for routine monitoring of plant conditions appears to have contributed to this failure. As noted during our inspection of this issue, we are concerned about the level of surveillance, work control, and other activities routinely assigned to Operations personnel, and the impact of these activities on their ability to properly monitor plant conditions. During the period while this valve was open, the Train B high pressure safety injection (HPSI), low pressure safety injection (LPSI), and containment spray (CS) pumps were inoperable, and Unit 3 containment integrity was compromised.

Analyses in your LERs concluded (based on realistic assumptions, and assuming no other equipment failures) that these violations would not have yielded consequences more severe than those determined from previous analyses. However, each of these violations involved undetected inoperability of important safety equipment for an extended period of time, when available indications should have provided for earlier detection of the misalignments. Moreover, the violations resulted in a significant reduction of the overall margin needed to assure safe operation of the plant. Each of these violations is considered a significant regulatory concern because of the safety importance of the affected components, the clear operability requirements provided in your Technical Specifications, and the missed opportunities to identify and correct the violations. Therefore, in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions" (Enforcement Policy), 10 CFR Part 2, Appendix C (1990), each of these violations has been categorized as Severity Level III.

The staff recognizes that immediate corrective action was taken when each of the violations was identified. Moreover, we found your response to these violations to be self-critical and aggressive.

However, to emphasize the importance the NRC attaches to thorough assessment of indicated problems and to an operating environment which fosters operator attentiveness to plant conditions, I have been authorized, after consultation with the Director, Office of Enforcement, and the Deputy Executive Director for Nuclear Reactor Regulation, Regional Operations, and Research, to issue the enclosed Notice of Violation and Proposed Imposition of Civil Penalties in the amount of \$150,000. 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 as discussed below.

Your staff identified and reported both of the cited violations. However, it is our judgment that both violations should have been identified much sooner than they were. You had opportunities to discover that the steam driven AFW pump was inoperable when your facility staff had indications, such as the improper drain

April 04 1991

lineup on the opposite steam line, of a potential problem. You also had an opportunity to identify the containment sump isolation valve was improperly opened if there had been adequate communications between control room personnel and the involved worker immediately after its occurrence, or had the available valve position indication been checked. Therefore, on balance, we conclude that no mitigation for identification and reporting is appropriate.

As noted above, your staff's response to these violations has been aggressive. The Nuclear Oversight organization and Operations Division showed an objective and self-critical attitude in investigating both events. You initiated immediate corrective actions, including procedure revisions, plant modifications, and operational training. Other longer term improvement efforts such as annunciator and work control enhancements have been identified. Moreover, at the enforcement conference, you acknowledged the weaknesses in work control and operator activity level and committed to address these areas comprehensively. Therefore, 50% mitigation is warranted for the corrective actions taken for each violation.

With regard to the duration of the cited violations, each is considered to have existed for an excessive period. As discussed above, your staff had indications of potential problems with the steam driven AFW pump. In addition to the previously discussed valve misalignment, the facility staff should have been alerted to the problem by the pump overspeed trips that occurred on October 6 and 16, 1990. In the case of the containment sump isolation valve, during the 95 hours it was improperly in the open position 12 shift changes occurred which provided the licensed operators numerous opportunities to discover the problem by recognizing the clear visual indication on the control panel that showed the valve was in the wrong position. Notwithstanding the absence of the indicator on a check list, the operators should have recognized the indicator during their observation of the control panels. We consider the duration of both violations to be significant because you should have known the systems were inoperable. Had your staff been more attentive and performed adequate investigations, these systems would not have been inoperable for an extended period. Therefore, escalation of the civil penalty by 100% of the base amount is warranted for each violation.

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

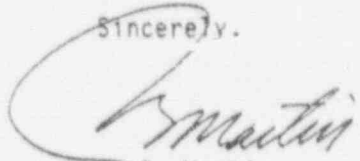
You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. In your response, you should document the specific actions taken and any additional actions you plan to prevent recurrence. After reviewing your response to this 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(a), a copy of this letter, the enclosure, and your response will be placed in the NRC Public Document Room.

JAN 0 4 1991

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

Sincerely,



J. B. Martin
Regional Administrator

Enclosure:
Notice of Violation and Proposed Imposition
of Civil Penalties

cc w/enclosure:
H. E. Morgan, Vice President and Site Manager
R. L. Krieger, Station Manager
State of California

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTIES

Southern California Edison Company
San Onofre Unit #2 and 3

Docket Nos. 50-361 and 50-362
License Nos. NPF-10 and NPF-15
EA 90-201

During an NRC inspection conducted on October 1 through November 15, 1990, violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions" (Enforcement Policy), 10 CFR Part 2, Appendix C (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:

- A. Technical Specification (TS) 3.7.1.2, "Auxiliary Feedwater System," requires that at least three independent steam generator auxiliary feedwater pumps and associated flow paths shall be operable in Modes 1, 2, and 3. The Action statement for this TS requires that with one auxiliary feedwater pump inoperable, the auxiliary feedwater pump shall be made operable within 72 hours or the reactor shall be placed in Hot Standby within the next 6 hours and in Hot Shutdown in the following 6 hours.

Section 1.17 of the TS states that "A...component or device shall be OPERABLE...when it is capable of performing its specified function(s) and when all necessary attendant instrumentation, controls...or other auxiliary equipment that are required for the...component or device to perform its function(s) are also capable of performing their related support function(s)."

Contrary to the above, a steam trap on a steam line to the turbine which drives auxiliary feedwater pump 2P-140 was isolated from 4:25 a.m. on August 31, 1990 to 2:00 p.m. on October 21, 1990, rendering auxiliary feedwater pump 2P-140 inoperable for Unit 2. The pump was inoperable because isolation of the trap allowed moisture to accumulate in the steam supply line to the turbine, causing the turbine to trip on overspeed when started; therefore, the automatic function of the pump was not available. Table 3.3-5 of the TS shows a response time of 42.7 seconds for actuation of the pump. Also, Section 10.4.9 of the FSAR states that the system automatically supplies feedwater to the steam generators during emergency conditions. The reactor was operated in Mode 1 during the entire period that the trap was isolated.

This item has been categorized as a Severity Level III violation (Supplement I), applicable to Unit 2.

Civil Penalty - \$75,000

- B. Technical Specification (TS) 3.5.2, "ECCS Subsystems - T-AVG Greater Than Or Equal to 350 Degree F," requires in Modes 1, 2, and 3 that two independent Emergency Core Cooling System (ECCS) subsystems be operable, with each subsystem including one operable high-pressure safety injection (HPSI) pump and one operable low-pressure safety injection (LPSI) pump. Subsection a.

of the Action Statement for TS 3.5.2 requires that, with one ECCS subsystem inoperable, the inoperable subsystem shall be restored to operable status within 72 hours or the Unit shall be placed in Hot Standby within the next 6 hours and in Hot Shutdown in the following 6 hours.

TS 3.6.2.1, "Containment Depressurization and Cooling System," requires that two independent containment spray systems shall be operable in Modes 1, 2, and 3 with each spray system capable of taking suction from the refueling water storage tank (RWST) on a Containment Spray Actuation Signal. The Action statement for TS 3.6.2.1 requires that with one containment spray system inoperable, the inoperable spray system shall be restored to operable status within 72 hours or the Unit shall be placed in Hot Standby within the next 6 hours.

TS 3.6.1.1, "Containment Integrity," requires that primary containment integrity be maintained in Modes 1, 2, 3, and 4. The Action statement for TS 3.6.1.1 requires that without primary containment integrity, containment integrity shall be restored within one hour or the Unit shall be in at least Hot Standby within the next 6 hours and in Cold Shutdown within the following 30 hours.

Contrary to the above, with Unit 3 operating in Mode 1, containment emergency sump outlet valve 3HV-9302 was open from 10:52 a.m. on September 24, 1990 to 9:00 a.m. on September 28, 1990, which rendered Train B HPSI, LPSI, and containment spray subsystems inoperable for lack of net positive suction head and resulted in containment integrity not being maintained by the creation of a flow path out of containment through the refueling water storage tank.

This item has been categorized as a Severity Level III violation (Supplement I), applicable to Unit 3.

Civil Penalty - \$75,000.

Pursuant to the provisions of 10 CFR 2.201, Southern California Edison Company 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. This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each violation (1) admission or denial of the 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 which 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.

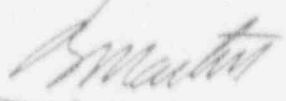
Within the same time as provided for the response required above under 10 CFR 2.201, the licensee may pay the civil penalties by letter addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, with a check, draft or money order payable to the Treasurer of the United States 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, (4) show other reasons why the penalties should not be imposed. In addition to protesting the civil penalties, such answer may request remission or mitigation of the penalties.

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

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

The responses to the Director, Office of Enforcement, noted above (Reply to a 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, Region V and a copy to the NRC Resident Inspector, San Onofre Nuclear Generating Station.

FOR THE NUCLEAR REGULATORY COMMISSION



John B. Martin
Regional Administrator

Dated at Walnut Creek, California
this 4 day of January 1991



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

DEC 28 1990

Docket Nos. 50-327 and 50-328
License Nos. DPR-77 and DPR-79
EA 90-200

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

Dear Mr. Kingsley:

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY -
\$30,000 (NRC INSPECTION REPORT NOS. 50-327/90-34 AND 50-328/90-34)

This refers to the Nuclear Regulatory Commission (NRC) inspection conducted by P. Harmon on October 6 - November 5, 1990, at the Sequoyah Nuclear Plant (SNP). The inspection included a review of SNP Quality Assurance (QA) surveillance and monitoring schedules prepared by your staff, specifically QA Monitoring Report OSQ-R-90-729, Overtime, which detailed the monitoring of compliance with plant overtime requirements during the current SNP Unit 2 Cycle 4 refueling outage. That report concluded that overtime requirements were being violated and that management control of overtime was inadequate. The NRC report documenting this inspection was sent to you by letter dated November 16, 1990. As a result of this inspection which included a review of various licensee records documenting hours worked, a potential failure to comply with NRC regulatory requirements was identified. An Enforcement Conference was held on November 27, 1990, in the Region II office to discuss the potential violation, its cause, and your corrective actions to preclude recurrence. The letter summarizing this conference was sent to you by letter dated December 10, 1990.

The violation described in the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice) involved a failure to comply with plant overtime requirements during the Unit 2 Cycle 4 refueling outage. The QA Monitoring Report referred to above and dated October 17, 1990, was initiated "...to evaluate the effectiveness of the corrective actions for NRC Notice of Violation 50-327, 328/90-22-01...and compliance with the NRC overtime limits at the Sequoyah Nuclear Plant." The report found that the implementation of Site Standard Practice (SSP) 32.53, Administration of Overtime, was inadequate and that increased management attention was required to ensure compliance with NRC mandated overtime limits. NRC Inspection Report Nos. 50-327/90-22 and 50-328/90-22, dated July 26, 1990, contained a Severity Level IV violation for exceeding overtime limits imposed by plant administrative procedures and cautioned that the violation was similar to a violation issued on March 14, 1988. The July 26, 1990, NRC Inspection Report also noted that recurring violations were of particular concern because the NRC expects licensees to learn from their past failures and to take effective corrective action. The latest violation continues to raise concerns relative to your management

DEC 28 1990

process to implement effective corrective actions. There is also concern relative to the effectiveness of administrative controls and management oversight of overtime requirements which failed to prevent this violation. The mandating of requirements to control overtime, particularly in safety-related work, reflects a legitimate regulatory and industry concern that excessive and uncontrolled overtime could lead to safety-related, human-factor failures. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy) 10 CFR Part 2, Appendix C (1990), this violation has been categorized at Severity Level IV.

To emphasize the importance of management controls and ensuring the implementation of effective corrective action, 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 \$30,000 for the Severity Level IV violation. Normally, civil penalties are not proposed for Severity Level IV violations. However, the Enforcement Policy states that civil penalties may be imposed for Severity Level IV violations that are similar to previous violations for which the licensee did not take effective corrective action, as is true of the present case.

The base value of a civil penalty for a Severity Level IV violation is \$15,000. The escalation and mitigation factors in the Enforcement Policy were considered. Mitigation of 50 percent was warranted for your QA staff's follow-up activities and subsequent identification and appropriate characterization of the problem. Mitigation of 50 percent was appropriate for corrective action to prevent recurrence based on actions by senior management to address the problem and the subsequent focusing of a high level of attention to get this issue under control. Consideration was also given to your development of a long-term Integrated Corrective Action Plan to address the administrative control and use of overtime, particularly in view of the senior management oversight that will be placed on ensuring the plan is fully implemented. Escalation of 100 percent was appropriate for past performance in the area of concern because of the recurring nature of the overtime problems over a considerable period of time and the fact that previous corrective action plans that TVA submitted to the NRC staff failed to adequately address the problem. Additional escalation of 100 percent was appropriate for multiple occurrences in this case which involved numerous significant examples of inadequate control of overtime. The findings cited here are those identified by NRC after your QA organization raised the issue and do not include those identified by your organization. The other adjustment factors in the Policy were considered, and no further adjustment to the base civil penalty is considered appropriate. On balance, the base civil penalty has been escalated by 100 percent. It should be noted that while in this case 50 percent mitigation has been deemed appropriate for your extensive corrective actions, your proposed corrective actions for past violations were also thought to be extensive but were never adequately implemented. We expect that TVA now understands what needs to be done and will do it. Therefore, recurrence of violations in this area would likely result in stronger enforcement actions without mitigation for proposed corrective actions.

DEC 28 1990

Tennessee Valley Authority

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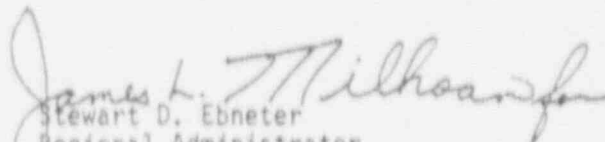
You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. In your response, you should document the specific actions taken and any additional actions you plan to prevent recurrence. After reviewing your response to this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

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

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

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

Sincerely,


Stewart D. Ebnetter
Regional Administrator

Enclosure:
Notice of Violation and Proposed
Imposition of Civil Penalty

cc w/encl:
M. Runyon, Chairman
Tennessee Valley Authority
ET 12A 7A
400 West Summit Hill Drive
Knoxville, TN 37902

J. B. Waters, Director
Tennessee Valley Authority
ET 12A 9A
400 West Summit Hill Drive
Knoxville, TN 37902

W. F. Willis
Chief Operating Officer
ET 12B 16B
400 West Summit Hill Drive
Knoxville, TN 37902

cc w/encl cont'd: (see page 4)

cc w/encl cont'd:
D. Nunn, Vice President
Nuclear Engineering
Tennessee Valley Authority
6N 38A Lookout Place
1101 Market Street
Chattanooga, TN 37402-2801

Dr. M. O. Medford
Vice President, Nuclear Assurance,
Licensing and Fuels
Tennessee Valley Authority
6N 38A Lookout Place
Chattanooga, TN 37402-2801

County Judge
Hamilton County Courthouse
Chattanooga, TN 37402

C. A. Vondra, Plant Manager
Sequoyah Nuclear Plant
Tennessee Valley Authority
P. O. Box 2000
Soddy-Daisy, TN 37379

E. G. Wallace, Manager
Nuclear Licensing and
Regulatory Affairs
Tennessee Valley Authority
5N 1575 Lookout Place
Chattanooga, TN 37402-2801

M. Cooper
Site Licensing Manager
Sequoyah Nuclear Plant
P. O. Box 2000
Soddy-Daisy, TN 37379

TVA Representative
Rockville Office
11921 Rockville Pike
Suite 402
Rockville, MD 20852

General Counsel
Tennessee Valley Authority
400 West Summit Hill Drive
ET 11B 33H
Knoxville, TN 37902

cc w/encl cont'd: (see page 5)

Tennessee Valley Authority

- 5 -

DEC 28 1990

cc w/encl cont'd:
Michael H. Mobley, Director
Division of Radiological Health
T.E.R.R.A. Building, 6th Floor
150 -9th Avenue North
Nashville, TN 37247-3201

Joseph Bynum, Acting Site Director
Sequoyah Nuclear Plant
Tennessee Valley Authority
P. O. Box 2000
Soddy-Daisy, TN 37379

State of Tennessee

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

Tennessee Valley Authority
Sequoyah Nuclear Plant
Units 1 and 2

Docket Nos. 50-327, 50-328
License Nos. DPR-77, DPR-79
EA 90-200

During an NRC inspection conducted on October 6 - November 5, 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 violation and associated civil penalty is set forth below:

10 CFR Part 50, Appendix B, Criterion V, requires in part that activities affecting quality shall be prescribed by procedures and accomplished in accordance with those procedures. Control of overtime for individuals performing safety-related tasks is an activity affecting quality. Site Standard Practice (SSP) 32.53, Administration of Overtime, is the procedure that implements the controls of overtime for individuals performing safety-related tasks.

SSP 32.53, Section 2.1.3, states that an employee performing safety-related work may work no more than 16 hours in any 24-hour period, 24 hours in any 48-hour period, or 72-hours in any 7-day period without the required documentation and without approval by the Plant Manager or Duty Plant Manager on the overtime limitation Exception Report. Section 2.1.3 further states that personnel affected by these controls include Senior Reactor Operators, Reactor Operators, Assistant Unit Operators, Health Physicists, Health Physics Technicians and key maintenance personnel (defined therein).

Contrary to the above, twenty-two operations department personnel performing safety-related work on Units 1 and 2 and covered by Section 2.1.3 of SSP 32.53 worked more than 72 hours during the week of October 8-14, 1990. For 21 employees, the approvals were signed without the required documentation, such as justification for exceeding overtime guidelines, on the Overtime Limitation Exception Report (Appendix A to SSP 32.53), and for one individual no documentation or approval was obtained.

This is a Severity Level IV violation (Supplement I).
Civil Penalty - \$30,000

Pursuant to the provisions of 10 CFR 2.201, Tennessee Valley Authority (Licensee) is hereby required to submit a written statement or explanation to the 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 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.

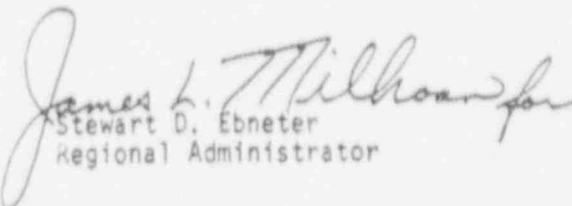
The response noted above (Reply to Notice of Violation, letter with payment of civil penalty, and Answer to a Notice of Violation) should be addressed to:

Notice of Violation

- 3 -

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 if applicable,
a copy to the NRC Resident Inspector at the Sequoyah Nuclear Plant.

FOR THE NUCLEAR REGULATORY COMMISSION


Stewart D. Ebnetter
Regional Administrator

Dated at Atlanta, Georgia
this 28th day of December, 1990



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION II
101 MARIETTA STREET, N.W.
ATLANTA, GEORGIA 30373

FEB 12 1991

Docket Nos. 50-280 and 50-281
License Nos. DPR-32 and DPR-37 EA 90-215

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
PENALTY - \$50,000 (NRC INSPECTION REPORT NOS. 50-280/90-36
AND 50-281/90-36)

This refers to the Nuclear Regulatory Commission (NRC) inspection conducted by W. E. Holland on October 28 - December 15, 1990, at the Surry Power Station (Surry). The inspection included a review of activities associated with the recent flow testing of the Unit 1 recirculation spray heat exchangers (RSHX) that revealed service water (SW) flow rates through the RSHXs were lower than the design flow rates because of macroscopic biological fouling (macrofouling) of the RSHXs. A licensee event report was submitted as required by 10 CFR 50.73. The report documenting this inspection was sent to you by letter dated December 21, 1990. As a result of this inspection, a significant failure to comply with NRC regulatory requirements was identified. An Enforcement Conference was held on January 8, 1991, in the Region II office to discuss the violation, its cause, and your corrective actions to preclude recurrence. The letter summarizing this conference was sent to you by letter dated January 15, 1991.

The violation described in the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice) was identified as a result of a special test of SW flow to the Unit 1 "B" and "C" RSHXs conducted during the period October 14-23, 1990. Evaluation of the test results indicated that adequate SW flow may not have been available to maintain RSHXs operable as required by Technical Specifications. On October 23, 1990, with Unit 1 in refueling shutdown and Unit 2 at 100 percent power, the Unit 1 and 2 RSHXs were declared inoperable and Unit 2 was brought to cold shutdown. The reduced SW flow to the RSHXs was caused by macrofouling in the form of 1) small pieces of coating which detached from the interior of the SW supply piping and 2) marine growth dislodged from SW supply piping when flow was initiated during the testing.

The Recirculation Spray system, in conjunction with the Containment Spray system, is designed to cool and depressurize the containment to subatmospheric pressure within 60 minutes following a design basis accident (DBA), and to maintain the subatmospheric pressure for 30 days. This violation is safety significant because the reduced SW flow to the RSHXs could delay or prevent

FEB 12 1991

the depressurization of containment to a subatmospheric condition which could result in increased containment leakage and radioactivity release during a DBA. The NRC is especially concerned in this case because (1) you failed to ensure that a system important to safety could perform its intended safety function and (2) you failed to take into account information that could impact the safe operation of your facility. First, instead of developing a test program to ensure RSHX operability, you chose to rely on RSHX design calculations and your understanding of the potential impact on SW flows at Surry due to macrofouling. Specifically, your estimation of macrofouling only considered the impact of debris being transported through the SW system and did not consider the additional impact of debris being dislodged from the SW piping and flushed through to the RSHXs. The NRC recognizes that even if you had performed preoperational testing after replacing the RSHXs during the 1988-89 outage, it may not have identified the macrofouling problem to the extent that it existed in October 1990 due to the excessive hydroid growth. However, preoperational testing would have established data baselining HX performance and may have identified not only SW flow problems as a result of macrofouling blockage of the RSHXs, but that the macrofouling was due to fouling dislodgement in addition to transported debris. The identification of macrofouling during this testing may have also prompted you to establish future periodic monitoring activities, such as the performance of SW system inspections during outage periods occurring during fuel cycles. Second, the NRC believes that problems associated with service water cooling systems and the effect of those problems on safety-related equipment have been known to the industry for a number of years. The NRC has raised this concern on several occasions through Bulletins and Information Notices, and most recently with Generic Letter 89-13. More specifically, excessive fouling was identified as a concern in the inspection report for the 1988 Safety System Functional Inspection (SSFI) on the SW system at Surry. Not only did the SSFI question the heat transfer capability of safety-related coolers in the SW system, it also identified that debris accumulated in front of the SW/RSHX isolation valves "would be flushed into the RSHXs when flow through the line is established." Licensees are ultimately responsible for ensuring, by whatever means, that equipment important to safety be maintained operable, and that information that may effect the operability of that equipment be appropriately considered. Therefore, in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy) 10 CFR Part 2, Appendix C (1990), this violation has been categorized at Severity Level III.

The staff recognizes that immediate corrective action was taken when the violation was identified which included placing Unit 2 in cold shutdown following the completion of the evaluation of test results for Unit 1 RSHXs.

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

FEB 12 1991

Regulation, Regional Operations and Research, to issue the enclosed Notice of Violation and Proposed Imposition of Civil Penalty in the amount of \$50,000 for the Severity Level III violation. The base value of a civil penalty for a Severity Level III violation is \$50,000. The escalation and mitigation factors in the Enforcement Policy were considered.

Although the NRC recognizes that you identified and reported the macrofouling's impact on RSHX operability as a result of performing SW flow tests, the NRC notes that (1) this testing was performed at the urging of NRC management and was not intended as part of your Generic Letter (GL) 89-13 program and (2) inspection alone, as you had planned, would not have identified the inoperability of the RSHXs. Therefore, neither mitigation nor escalation of the base civil penalty is appropriate for the identification and reporting factor. Mitigation of the base civil penalty by 50% is appropriate based on your prompt and extensive corrective action, including placing Unit 2 in cold shutdown, the inspection and cleaning of the SW systems for both units prior to restart, and the impending development of long term solutions for the macrofouling issue at Surry. Although Surry received a SALP 3 for the last two SALP rating periods for maintenance and surveillance, improvement has been noted in the current SALP assessment period. Therefore, neither escalation or mitigation of the base civil penalty is deemed appropriate for your past performance. While the NRC recognizes that the previous Information Notices and Bulletins would not have provided you with explicit notice regarding the impact of hydroid dislodgement on RSHX operability, you did have prior notice that you had a macrofouling problem at Surry as identified in the inspection report for the 1988 SSFI on the SW system. The inspection report, as previously referenced, also indicated that debris would be flushed into the RSHXs when flow was established in the SW line. This information coupled with your knowledge of the extensiveness of the hydroid growth problem as evidenced by your maintenance activities on the CCW Hxs and condenser water boxes, warrants 50% escalation of the base civil penalty for prior notice. The other adjustment factors in the Policy were considered and no further adjustment to the base civil penalty is considered appropriate. Therefore, on balance, the base civil penalty is proposed.

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


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

FEB 12 1991

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. Ebner
Regional Administrator

Enclosure:
Notice of Violation and
Proposed Imposition of
Civil Penalty

cc w/encl: (See Next Page)

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

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

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

M. L. Bowling, 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

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

Michael W. Maupin
Hunton and Williams
P. O. Box 1535
Richmond, VA 23212

C. M. G. Buttery, M.D., M.P.H.
Department of Health
109 Governor Street
Richmond, VA 23219

Attorney General
Supreme Court Building
101 North 8th Street
Richmond, VA 23219

Commonwealth of Virginia

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

Virginia Electric and Power Company
Surry Power Station
Units 1 and 2

Docket Nos. 50-280 and 50-281
License Nos. DPR-32 and DPR-37
EA 90-215

During an NRC inspection conducted on October 28 - December 15, 1990, 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 (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 violation and associated civil penalty are set forth below:

Technical Specification 3.4.A.2 requires that four Recirculation Spray Subsystems including coolers (heat exchangers) shall be operable whenever the unit's Reactor Coolant System temperature or pressure exceeds 350 degrees F or 450 psig, respectively.

Technical Specification 3.0.1 requires that, in the event a Limiting Condition for Operation cannot be satisfied because of circumstances in excess of those addressed in the specification, the unit shall be placed in at least hot shutdown within 6 hours and in at least cold shutdown within the following 30 hours.

Contrary to the above, prior to October 6, 1990 for Unit 1 and October 23, 1990 for Unit 2, all of the Unit 1 and 2 Recirculation Spray Heat Exchangers (eight total) were inoperable for a period greater than 6 hours without the units being placed in hot shutdown.

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 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 other negotiable 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 (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 II, and a copy to the NRC Resident Inspector at the facility which is the subject of this Notice.

FOR THE NUCLEAR REGULATORY COMMISSION


Stewart D. Ebnetter
Regional Administrator

Dated at Atlanta, Georgia
this 2nd day of February 1991



UNITED STATES
NUCLEAR REGULATORY COMMISSION

REGION IV
611 RYAN PLAZA DRIVE, SUITE 1000
ARLINGTON, TEXAS 76011

FEB 28 1991

Docket No. 50-482
License No. NPF-42
EA 91-003

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

Gentlemen:

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY - \$25,000
(NRC INSPECTION REPORT NO. 50-482/90-39)

This is in reference to the December 23, 1990 - January 7, 1991, inspection at the Wolf Creek Generating Station near Burlington, Kansas, and to the discussion of the inspection findings during an enforcement conference that you and other Wolf Creek Nuclear Operating Corporation (WCNOC) representatives attended on January 30, 1991, in NRC's office in Arlington, Texas. The results of the inspection were documented in a report issued by NRC on January 18, 1991.

NRC's inspection was conducted to review the circumstances and the significance of WCNOC's December 23, 1990, conclusion that both of the nuclear plant's safety injection pumps may have been prevented from performing their intended safety function, if called upon, due to the freezing of water in the pumps' common recirculation line. This condition, which existed for at least 12 hours prior to its discovery, would have caused pump damage and the inability of the pumps to add water to the reactor coolant system as designed under certain circumstances. WCNOC's analyses of the safety implications of this event indicate that adequate coolant inventory and core cooling could have been maintained by other emergency core cooling components.

However, there are significant aspects of this event: (1) the safety injection pumps, which are relied upon in many accident scenarios, clearly would have been disabled and been unavailable if needed under certain circumstances; and (2) WCNOC's program to establish and maintain a system to prevent freezing of this recirculation line broke down in several ways, resulting in missed opportunities to prevent this condition.

NRC's inspection found that both administrative and physical aspects of the freeze protection system at Wolf Creek, the system designed to prevent this very circumstance, broke down in the days leading up to this condition due to a combination of incomplete procedures, inadequate preventive maintenance and poor communications between elements of the plant staff.

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

NRC concludes that for at least 12 hours on December 23, 1990, the safety injection pumps were effectively inoperable, in that under certain, albeit limited, circumstances, the pumps would not have performed their intended function. This condition, which existed while the plant was operating at power, violated Technical Specification (TS) 3.5.2, in conjunction with TS 3.0.3. TS 3.5.2 requires two operable independent emergency core cooling system (ECCS) subsystems during plant operations, each consisting in part of one operable safety injection pump. TS 3.0.3 requires that the unit be placed in at least hot standby within 6 hours of the time a Limiting Condition for Operation cannot be met (in this case, the time when both SI pumps became inoperable). 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 violation has been classified at Severity Level III.

NRC's inspection found that WCNOG took prompt and effective action upon the discovery of this condition to ensure the safety of the plant and restore the pumps to a fully operable condition. These actions included placing the pump controls in pull-to-lock, declaring the pumps inoperable, promptly making the required notification to NRC, assigning an operator to start the pumps in the event that plant conditions warranted such, reducing plant power in accordance with the plant's Technical Specifications and eliminating the ice blockage from the recirculation line such that the pumps were quickly restored to an operable condition. NRC also recognizes that WCNOG has taken steps to enhance the freeze protection system to prevent a recurrence of this event and is considering additional measures to resolve the weaknesses revealed by this event.

To emphasize the importance of the necessary design, administrative, and procedural controls to ensure the operability of safety systems, I have been authorized, after consultation with the Director, Office of Enforcement, and the Deputy Executive Director for Nuclear Reactor Regulation, Regional Operations and Research, to issue the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice) in the amount of \$25,000 for this Severity Level III violation. The base value of a civil penalty for a Severity Level III violation is \$50,000. The escalation and mitigation factors in the Enforcement Policy were considered as discussed below.

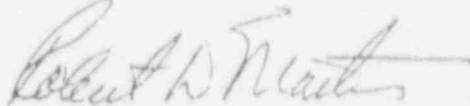
A 25-percent reduction was made to the base civil penalty because WCNOG promptly made the required report to NRC. Full mitigation under the identification and reporting factor (50 percent) was not made because this condition revealed itself when efforts to add water to the plant's Refueling Water Storage Tank were unsuccessful. Another 25-percent reduction was made because, as discussed earlier, WCNOG's short-term corrective actions were commendable and because WCNOG has taken steps to enhance the freeze protection system and prevent a recurrence of this event. Full mitigation under this factor (50 percent) was not made because WCNOG did not utilize the opportunity provided by this event to review other alarm response procedures to ensure that they do not have procedural inadequacies such as in this case, where following the procedure, in response to the annunciator, did not identify the actual deficiency. No adjustment to the penalty was made on the basis of the past performance factor after considering WCNOG's past regulatory performance in plant operations and related functional areas, as indicated by Systematic Assessment of Licensee Performance

(SALP) ratings. None of the remaining factors in Section V.B. of the Enforcement Policy were considered applicable. Therefore, the base penalty in this case has been reduced by a total of 50 percent.

WCNOC is required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing its response. In its response, WCNOC should document the specific actions taken and any additional actions planned to prevent recurrence. Your response should include action taken or to be taken to address the underlying weaknesses that resulted in the initial inoperability of a safety system, and the failure to promptly detect the loss of freeze protection. In addition, during the enforcement conference you indicated that you were considering several design enhancements. Your response should address your plan and schedule for implementing such enhancements, as well as the associated weaknesses in procedures, preventive maintenance and communications. After reviewing WCNOC's response to this Notice, including the 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:
Wolf Creek Nuclear Operating Corp.
ATTN: Gary Boyer, Plant Manager
P.O. Box 411
Burlington, Kansas 66839

Shaw, Pittman, Fotts & Trowbridge
ATTN: Jay Silberg, Esq.
1800 M Street, NW
Washington, D.C. 20036

Public Service Commission
ATTN: Chris R. Rogers, P.E.
Manager, Electric Department
P.O. Box 360
Jefferson City, Missouri 65102

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

Wolf Creek Nuclear Operating Corp.
ATTN: Otto Maynard, Manager
Regulatory Services
P.O. Box 411
Burlington, Kansas 66839

Kansas Corporation Commission
ATTN: Robert Elliot, Chief Engineer
Utilities Division
4th Floor - State Office Building
Topeka, Kansas 66612-1571

Office of the Governor
State of Kansas
Topeka, Kansas 66612

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

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

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

NOTICE OF VIOLATION
AND
IMPOSITION OF CIVIL PENALTY

Wolf Creek Nuclear Operating Corporation
Wolf Creek Generating Station

Docket No. STN 50-482
License No. NPF-42
EA 91-003

During an NRC inspection conducted on December 23, 1990, through January 7, 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 (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 violation and associated civil penalty is set forth below:

Wolf Creek Generating Station Technical Specification (TS) 3.5.2 requires that two independent emergency core cooling system (ECCS) subsystems be operable in Modes 1, 2, and 3 with each subsystem comprised, in part, of one operable safety injection (SI) pump.

TS 3.0.3 requires that when a Limiting Condition for Operation is not met, that action be initiated within 1 hour to place the unit in at least hot standby within 6 hours, at least hot shutdown within the following 6 hours, and at least cold shutdown within the subsequent 24 hours.

Contrary to the above, on December 23, 1990, between at least 12:07 a.m. and 12:30 p.m., the reactor was operated in Mode 1 with both SI pumps inoperable. Both SI pumps were rendered inoperable because they could not have performed their intended function for a limited range of loss of coolant accidents. This resulted when the common recirculation line between the SI pumps and the refueling water storage tank became blocked with ice after the freeze protection system failed. With both SI pumps inoperable during this period, the licensee failed to place the unit in at least hot standby within 6 hours.

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

Pursuant to the provisions of 10 CFR 2.201, Wolf Creek Nuclear Operating Corporation 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. 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.

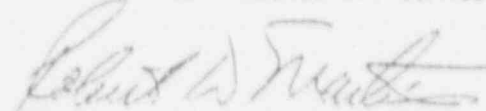
Within the same time as provided for the response required above under 10 CFR 2.201, the licensee may pay the civil penalty by letter addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, with a check, draft, money order, or electronic transfer payable to the Treasurer 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 (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 IV, and if applicable, a copy to the NRC Resident Inspector at the facility which is the subject of this Notice.

FOR THE NUCLEAR REGULATORY COMMISSION



Robert D. Martin
Regional Administrator

Dated at Arlington, Texas
this 28th day of February 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

February 8, 1991

Docket No. 50-244
License No. DPR-18
EA 91-002

Rochester Gas and Electric Corp.
ATTN: Mr. R. Smith
Senior Vice President
Production and Engineering
89 East Avenue
Rochester, New York 14649

Gentlemen:

Subject: NOTICE OF VIOLATION
(NRC Inspection Report No. 50-336/90-31)

This letter refers to the special NRC inspection conducted between December 13, 1990 and January 3, 1991, at the R. E. Ginna Nuclear Power Plant, Ontario, New York. The inspection report was sent to you on January 22, 1991. The inspection was conducted to review the circumstances associated with an event which occurred at the facility involving the disabling of safeguards logic instrumentation for approximately 20 minutes on December 12, 1990. The event, and the associated violations of NRC requirements, were identified by your staff and reported to the NRC. On January 29, 1991, an enforcement conference was conducted with you and other members of your staff to discuss the event, its related violations, their causes and your corrective actions.

The event (which occurred while the reactor was at three percent power) involved the disabling of a portion of both trains of the Engineered Safety Feature Actuation System (ESFAS) instrumentation channels. The instrumentation was disabled during implementation of a maintenance procedure. The specific procedure directed personnel to open certain "DC" breakers for safeguards logic instrumentation, which resulted in the disabling of the automatic actuation and manual (pushbutton) sequencing of the ESFAS. The procedure was deficient since it allowed the DC breakers to be opened in any operating mode, even though opening of those breakers should only be permitted in the Cold Shutdown mode.

The specific procedure had been changed in 1985 to require the disabling of the ESFAS during the procedure's implementation so as to prevent an inadvertent safety injection. The procedure specified at that time that this evolution could only be performed during Cold Shutdown. During a revision in early 1989, the procedure was changed to allow its performance during any mode of operation, and the step requiring the disabling of the ESFAS instrumentation was concurrently deleted. However, during the final review process in March 1989, a reviewer considered the deletion inadvertent, and it was restored to the procedure (without a restraint that this step should only be performed during cold shutdown).

The NRC is concerned that adequate review of the procedure was not accomplished prior to its approval and issue. Reviewers, especially the Plant Operation Review Committee (PORC), should have recognized that implementation of the procedure would disable automatic and manual single pushbutton initiation of both ESFAS trains and should have assured that such disabling was permitted only during Cold Shutdown. This failure to conduct an adequate safety review resulted in the issuance of a procedure that was technically incorrect and not in accordance with the requirements in 10 CFR Part 50, Appendix B. The violation is set forth in the enclosed Notice.

The NRC is also concerned that in addition to the deficient procedure, the maintenance planner and maintenance scheduler did not conduct an adequate review during development of the work order package that required implementation of the procedure. In addition, when the control room foreman (who was implementing the operational aspects of the procedure, after obtaining approval from the Shift Supervisor) came to the step which required opening of the switches, he questioned the Planner concerning implementation of the step. Further, given the existing plant condition, he verified that the procedure did in fact state that the procedure could be performed in any mode of operation. However, he lacked sufficient guidance (such as training and/or checklists) to assess the impact of the use of the procedure on plant operation. These failures to properly plan and implement the maintenance activity constitute another violation of NRC requirements that is also set forth in the enclosed Notice.

The NRC recognizes that the condition existed for only a short period, the equipment (various pumps and valves) was capable of manual operation from the control room, and the Emergency Operating Procedures required such operation in the event of a need for initiation of the equipment. The NRC also recognizes and strongly commends the actions of the oncoming Shift Supervisor who questioned and vigorously pursued the meaning of the alarm that was obtained when the switches were opened. Nonetheless, the violations resulted in the improper disabling of certain ESFAS components such that individual manual activation of the ESFAS components would have been required. Therefore, the violations are classified in the aggregate 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) (1990). The violations demonstrate the importance of (1) meticulous attention to detail during the performance of safety reviews at the facility to ensure procedures are properly reviewed, and implementation of the procedures will not have an adverse effect on safe plant operations; and (2) proper control of equipment at the facility to assure the reactor is operated and maintained safely and 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. These corrective actions, which were described either during the inspection or at the enforcement conference, included assignment of the operating crew to assist in event evaluation; establishment of a Human Performance

Enhancement System (HPES) evaluation to determine the underlying causes of this event; conduct of a senior management meeting with all operations and maintenance personnel, as well as PORC members, to emphasize the need for greater attention to detail and a more inquisitive attitude during the review of procedures and the planning of work activities; a quarantine of related procedures to preclude their use until a thorough review was conducted to ensure that similar deficiencies did not exist within those procedures; establishment of a requirement that a senior reactor operator (SRO) review all maintenance work packages; and changes to the process for reviewing procedures and developing work packages.

Although a civil penalty is normally issued for a Severity Level III violation, I have been authorized, after consultation with the Director, Office of Enforcement, and the Deputy Executive Director for Nuclear Reactor Regulation, Regional Operations and Research, to mitigate the penalty in its entirety and issue the enclosed Notice of Violation (Notice) for the 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 promptly identified as a result of the questioning attitude and vigorous actions of the oncoming shift supervisor and, when identified, were promptly reported to the NRC. Therefore, a 50% mitigation of the penalty on this factor is warranted. Your corrective actions, as described herein, were considered prompt and comprehensive, and therefore, 25% mitigation of the base civil penalty on this factor is warranted. Full 50% mitigation on this factor is not warranted because schedules for completion of long-term actions had not yet been established at the time of the enforcement conference. Your past performance has been good, as evidenced by no related violations of this nature in the past two years, and therefore, 50% mitigation on this factor is warranted. Full 100% mitigation on this factor is not recommended since the SALP ratings in the operations, maintenance, and safety assessment areas were Category 2 during the last SALP assessment. These violations did not involve prior notice, multiple examples or exist for an extended duration, and therefore, no adjustment of the civil penalty on these factors is warranted. Although the case did involve a maintenance procedural deficiency, the violation did not demonstrate a programmatic failure, and therefore, no adjustment on this factor is warranted.

You are required to respond to the enclosed Notice and, in preparing your response, 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.

Rochester Gas and Electric Corp. 4

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:

Robert C. Mecredy, Vice President - Nuclear Production
Harry H. Voigt, Esquire
Central Records (4 copies)
Director, Power Division
State of New York, Department of Law
Ginna Hearing Service List
Public Document Room (PDR)
Local Public Document Room (LPDR)
Nuclear Safety Information Center (NSIC)
NRC Resident Inspector
State of New York, SLO Designee

NOTICE OF VIOLATION

Rochester Gas & Electric Corp.
Ginna

Docket No. 50-244
License No. DPR-18
EA 91-002

During an NRC inspection conducted between December 13, 1990 and January 3, 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, (1990), the particular violations are set forth below:

- A. 10 CFR Part 50, Appendix B, Criterion VI, "Document Control," states in part, that measures shall be established to control the issuance of documents, such as procedures, including changes thereto, which prescribe all activities affecting quality. These measures shall assure that documents, including changes, are reviewed for adequacy.

Contrary to the above, in March 1989, a procedure affecting quality, namely, Procedure M-48.14, "Isolation of Bus 14 Undervoltage System for Maintenance, Troubleshooting, Rework and Testing," was changed without an adequate review being performed. The specific change involved inclusion of a step in the procedure which allowed the disabling of Engineered Safety Feature Actuation System (ESFAS) instrumentation while the reactor was in any mode of operation, including power. The licensee's organizational measures for review, approval, and issuance of this procedure change, including the review by the Plant Operations Review Committee, did not assure that the change was adequately reviewed in that it did not identify that implementation of the procedure change in a mode other than cold shutdown condition would place the plant in a condition that was prohibited by Technical Specification 3.5.2.

- B. Technical Specification 6.8.1 requires establishment of the applicable procedures recommended in Appendix "A" of Regulatory Guide 1.33, November 1972 (Safety Guide 33). Regulatory Guide 1.33, November 1972, Appendix A, Section I, specifies that maintenance which can affect the performance of safety-related equipment should be properly preplanned and performed in accordance with written procedures, documented instructions, or drawings appropriate to the circumstances.

Contrary to the above, on December 12, 1990, the licensee failed to adequately preplan and perform corrective maintenance on the A emergency diesel generator undervoltage circuit card. Specifically, maintenance procedure M-48.14, "Isolation of Bus 14 Undervoltage System for Maintenance, Troubleshooting, Rework and Testing," was used to perform the corrective maintenance while the reactor was at 3 percent power during startup. Step 5.5.1 directed personnel to open DC circuit breakers for the A and B safeguards logic trains which disabled the automatic and manual (push button) sequencing of safeguards equipment. This step was

both unnecessary to perform the required work and inappropriate for the circumstances as it disabled the safeguards sequencing function at a time prohibited by plant technical specifications. Additionally, use of M-48.14 proceeded despite indications that the procedure was inappropriate. Those indications included labels on the DC breaker panels warning of possible safety injection consequences and the initiation of alarm annunciator L-31, "Safeguards DC Bus Failure."

Violations A and B are classified in the aggregate at Severity Level III.
(Supplement 1)

Pursuant to the provisions of 10 CFR 2.201, Rochester Gas & Electric 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 after the letter transmitting this Notice of Violation. 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, (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.

FOR THE NUCLEAR REGULATORY COMMISSION



Thomas T. Martin
Regional Administrator

Dated at King of Prussia, Pennsylvania
this 5th day of February 1991

II.A. MATERIALS LICENSEES, CIVIL PENALTIES AND ORDERS



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

NOV 28 1990

Docket No. 030-17088
License No. 53-19179-01
EA 89-101

C & R Laboratories
ATTN: Mr. Roland Watson
President and Radiation Safety Officer
2248 Aumakua Street
Pearl City, Hawaii 96782

Dear Sir:

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY - \$1500
AND ORDER MODIFYING LICENSE (INVESTIGATION REPORT 5-89-005)

This refers to the investigation conducted by the Region V Office of Investigations (OI:PV) from April 3, 1989 to July 13, 1990 into your conduct of licensed activities on the island of Oahu, Hawaii, including your radiographic operations at the Honolulu Resource Recovery Venture, Hawaii. The investigation uncovered violations of NRC requirements. The preliminary findings of this investigation were discussed with you by Messrs. R. Thomas and A. Johnson of the NRC staff during an Enforcement Conference on May 12, 1989; a report on this Conference was mailed to you on July 7, 1989. The synopsis of the completed investigation (copy enclosed) was also discussed with you during a telephone conference on August 17, 1990.

The findings of the investigation indicate that certain of your activities are in violation of NRC requirements, as specified in the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice). The three violations identified, committed by a former part-time employee, include (a) the failure to conduct required radiation surveys of an exposure device on removal of the device from and return to the licensee's mobile laboratory, (b) the willful creation of false records to make it appear that these NRC-required radiation surveys had been performed, and (c) the failure to post "Caution, Radioactive Material" signs on your mobile laboratory van that was used for storing a radiographic exposure device. Although these violations could have been assessed at Severity Level III, in light of the relatively low safety significance of the surveys in question, the violations have been categorized in the aggregate as a Severity Level IV problem. Nevertheless, these violations demonstrate the need to assure proper supervision of part-time or temporary employees.

The staff recognizes that you took immediate corrective action when the NRC identified the violations to you, i.e., you terminated the employment of the responsible employee. However, because an inaccurate record was willfully created, and to emphasize the importance of making proper surveys, creation of accurate records, and proper supervision of part-time and temporary employees, I have been authorized, after consultation with the Commission, to issue the enclosed Notice of Violation and Proposed Imposition of Civil Penalty in the amount of \$1,500 for the Severity Level IV problem. The base value of a civil

penalty for a Severity Level IV problem is \$1,500. The escalation and mitigation factors in the Enforcement Policy were considered. Mitigation for your corrective action was offset by escalation for your prior poor performance based on a civil penalty assessed in 1988 for a survey violation (EA 88-256).

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. Your response should specifically address what actions will be taken to assure that part-time or temporary employees are properly supervised. After reviewing your response to this Notice, and the results of future inspections, the NRC will determine whether further NRC enforcement action is necessary to ensure compliance with NRC regulatory requirements.

In addition to the enclosed Notice, an Order modifying your license is also enclosed. The Order formalizes your commitment to us that you will not utilize Gary Wood in licensed activities without providing to this office prior, written, specific notice of your intent to do so.

In accordance with 10 CFR 2.790 of 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.

If you have any questions concerning this letter, Notice, and Order, please contact Robert J. Pate at (415) 943-3752.

Sincerely,



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

Enclosures:
Notice of Violation and Proposed
Imposition of Civil Penalty
Order Modifying License
OI:RV Investigation Synopsis

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

C & R Laboratories
Pearl City, Hawaii

Docket No. 030-17088
License No. 53-19179-01
EA 89-101

During an NRC investigation conducted on December 12, 1988, certain violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedures for NRC Enforcement Actions," 10 CFR Part 2, Appendix C (1990), the violations are listed below:

License Condition 16 requires, in part, that the licensee conduct its program in accordance with the statements, representations, and procedures contained in the letter dated April 29, 1985, with attachments, and the application dated June 13, 1988.

- A. Item 9 of the application dated June 13, 1988, requires in part, compliance with all of the safety and operations manuals under the C&R license, including all attached checklists, and survey and utilization logs. Sections 5.C. and 13.B. of the Operating and Emergency Procedures, and Form 2, "Radiation Survey Record and Utilization Log," attached to the letter dated April 29, 1985, as modified by the application dated June 13, 1988, require the licensee to conduct radiation surveys (a) to confirm that a source is properly stored when an exposure device is removed from or returned to a storage area before and after all radiographic operations, (b) to determine the Transport Index of containers of materials or components to be shipped, and (c) to confirm that radiation levels in the passenger compartments and outside surfaces of vehicles used to transport licensed materials are within required limits. Also, 10 CFR 34.43(c) requires a radiation survey of an exposure device when the device is placed into storage to assure that the sealed source is in its shielded position.
1. Contrary to the above requirements, on December 12, 1988, a radiographer employed by the Licensee failed to conduct a radiation survey of a radiographic exposure device upon removing the device from the licensee's mobile laboratory van storage facility in Pearl City, Hawaii.
 2. Contrary to the above, on December 12, 1988, a radiographer employed by the Licensee failed to conduct a survey of a Dodge Ram pickup truck, Hawaii license 378TDG, prior to transporting the exposure device in the Dodge pickup truck to the Honolulu Resource Recovery Venture job site.
 3. Contrary to the above, on December 12, 1988, radiation surveys were not conducted upon return of the exposure device to the mobile laboratory van storage facility following radiographic operations.
- B. Section 3 of the C&R Operating and Emergency Procedures, attached to the letter dated April 29, 1985, lists radiographers' duties, including the duty to record radiation survey results, as specified in the C&R "Form 2", "Radiation Survey Record and Utilization Log" (Log). The Log, as of April 25, 1985, required that the results of surveys of the radiographic exposure device upon removal from and return to storage be recorded; as

of June 13, 1988, the log required, in addition, that the results of a survey of the perimeter of any vehicle used to transport the device, and of the passenger compartment of such vehicle prior to transport be recorded. 10 CFR 30.9(a) provides in part that information provided to the Commission by a licensee, or information required by the Commission's regulations, orders, or license conditions to be maintained by the licensee, shall be complete and accurate in all material respects.

Contrary to the above requirement, between December 12, 1988 and March 9, 1989, the licensee employee cited in Violation A above created records showing the results of radiation surveys of the exposure device and vehicle noted above, when in fact no surveys were performed.

- C. Section 13.B. of the Operating and Emergency Procedures, attached to the letter dated April 29, 1985, requires the licensee to post "Caution, Radioactive Material" signs on all four sides of the mobile laboratory van used for temporary or permanent storage of radiographic exposure devices.

Contrary to the above requirement, the licensee's mobile laboratory van that was used for storing a radiographic exposure device on December 12, 1988, was not posted with any "Caution, Radioactive Material" signs.

This is a Severity Level IV problem (Supplements VI and VII). Cumulative Civil Penalty - \$1,500 (assessed equally among the five violations).

Pursuant to the provisions of 10 CFR 2.201, C & R Laboratories, 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. 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,

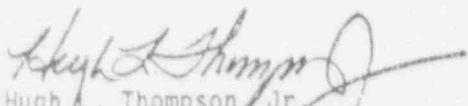
in whole or in part, such answer should be clearly marked as an "Answer to a Notice of Violation" and may: (1) deny the violations listed in this Notice in whole or in part, (2) demonstrate extenuating circumstances, (3) show error in this Notice, or (4) show other reasons why the penalty should not 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 V, 1450 Maria Lane, Suite 210, Walnut Creek, CA 94596.

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 28th day of November 1990

UNITED STATES
NUCLEAR REGULATORY COMMISSION

In the Matter of
C&R LABORATORIES, INC.
Pearl City, Hawaii

}
Docket No. 030-17088
License No. 53-19179-01
EA 89-101

ORDER MODIFYING LICENSE

I

C&R Laboratories, Inc. (C&R or Licensee) is the holder of NRC License No. 53-19179-01 issued by the Nuclear Regulatory Commission (NRC or Commission) pursuant to 10 CFR Part 34. The license authorizes the Licensee to receive, possess, and utilize sealed sources of Iridium 192 and Cobalt 60 in industrial radiographic exposure devices. The license was issued on March 21, 1980, was most recently renewed on July 8, 1986, and is due to expire on July 31, 1991.

II

Under C&R License Condition 16, and Sections 5.C. and 13.B. of the C&R Operating and Emergency Procedures, as set forth more fully in the Notice of Violation and Proposed Imposition of Civil Penalty attached to this Order, personnel performing licensed activities under C&R's license are required to conduct radiation surveys when exposure devices are removed from or returned to their storage areas, and to conduct such surveys to confirm that radiation levels in the passenger compartments and on the outside surfaces of vehicles used to transport licensed materials are within required limits.

On December 12, 1988, an NRC investigator observed a Licensee radiographer, Gary Wood, and another individual, remove a radiation exposure device from the Licensee's "mobile laboratory" vehicle located in front of the residence of Mr. Roland Watson, President of C&R Laboratories, Inc., place the device in the

back of a pickup truck, and drive to an industrial site to perform radiography. Later on the same day, Mr. Wood and the second individual returned to Mr. Watson's residence and returned the exposure device to the mobile laboratory. The investigator observed that at no time during the removal from and return to the mobile laboratory did Mr. Wood or the accompanying individual perform surveys of the radiation exposure device or of the mobile laboratory. When NRC personnel reviewed Licensee records on March 9, 1989, they found records signed by Mr. Wood purportedly documenting that the surveys had been performed as required on December 12, 1988. The investigator attempted to interview Mr. Wood to obtain his version of what occurred, but he refused to be interviewed. Under the circumstances, it is reasonable to conclude that the survey record was falsified. The investigator also observed that Mr. Wood failed to survey the vehicle into which the device was loaded.

On May 12, 1989, NRC representatives held an enforcement conference with the Licensee, at which time Mr. Watson informed the NRC that upon learning from the NRC of Mr. Wood's actions described above, C&R, on its own initiative, had terminated Mr. Wood's employment with C&R. On August 17, 1990, NRC representatives contacted Mr. Watson by telephone and discussed the findings of the investigation. During the discussion, Mr. Watson stated that the Licensee had not reemployed and does not intend to reemploy, Gary Wood to perform radiography. Mr. Watson also indicated that should C&R's intent in this regard change, the Licensee would provide NRC prior notice of any intention to employ Mr. Wood.

III

Considering the importance of compliance with all safety requirements in the conduct of radiography and the fact that radiographers work independently, the NRC must have confidence that each radiographer will comply with these requirements. I find the Licensee's commitments, as stated in the telephone discussion on August 17, 1990, and as modified below, acceptable and necessary in order to protect the public health and safety. In view of the foregoing, I have determined that it is appropriate that the Licensee's commitments concerning Mr. Wood, as modified, be formalized by this Order.

IV

Accordingly, pursuant to sections 81, 161b, 161c, 161i, 161o, 182 and 186 of the Atomic Energy Act of 1954, as amended, and the Commission's regulations in 10 CFR 2.204 and 10 CFR Part 34, IT IS HEREBY ORDERED THAT LICENSE NO. 53-19179-01 IS MODIFIED AS FOLLOWS:

C&R Laboratories, Inc. shall not utilize Mr. Gary Wood in licensed activities without providing written notice to the NRC two weeks in advance of the scheduled utilization. Such notice shall be provided to the Regional Administrator, Region V, and shall explain why the Licensee will have confidence that Mr. Wood will comply with the requirements of License No. 53-19179-01. This condition will expire five years from the date of this modification.

The Regional Administrator, Region V, may relax or rescind, in writing, the above conditions upon a showing of good cause by the Licensee.

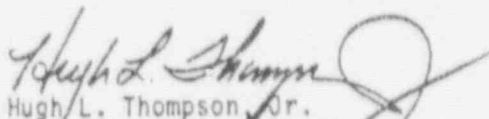
V

The Licensee, Mr. Gary Wood, or any other person adversely affected by this Order may submit an answer to this Order or request a hearing on this Order within 20 days of its issuance. The answer shall set forth the matters of fact and law on which the Licensee or other persons affected relies and the reasons as to why the Order should not have been issued. Any answer filed within 20 days of the date of this Order may include a request for a hearing. Any answer or request for a hearing shall be submitted to the 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, to the Regional Administrator, NRC Region V, 1450 Maria Lane, Suite 210, Walnut Creek, California 94596, and to the Licensee, if the answer or hearing request is by a person other than the Licensee. If a person other than the Licensee or Mr. Gary Wood requests a hearing, that person shall set forth with particularity the manner in which his interest is adversely affected by this Order and shall address the criteria set forth in 10 CFR 2.714(d).

If a hearing is requested by the Licensee or a person whose interest is adversely affected, the Commission will issue an Order designating the time and place of any hearing. If a hearing is held, the issue to be considered at the hearing shall be whether this Order should be sustained.

Upon the Licensee's consent to the provisions set forth in Section IV of this Order, or on failure of the Licensee or Mr. Gary Wood to file an answer within the specified time, and in the absence of any request for hearing, the provisions specified in Section IV above shall be final without further Order or proceedings.

FOR THE NUCLEAR REGULATORY COMMISSION


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

Dated at Rockville, Maryland
this 28th day of November 1990



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

DEC 10 1990

Docket No. 030-08916
License No. 45-15325-01
EA 90-183

McCallum Testing Laboratories, Inc.
ATTN: Mr. J. Pritchard, President
Post Office Box 13266
Chesapeake, Virginia 23325

Gentlemen:

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY - \$800
(NRC INSPECTION REPORT NO. 45-15325/01/90-01)

This refers to the Nuclear Regulatory Commission (NRC) special safety inspection conducted by D. J. Collins on October 12, 1990, at the McCallum Testing Laboratories facility in Chesapeake, Virginia. The inspection included an examination of the available facts and circumstances related to the theft and subsequent recovery of a Troxler portable density gauge containing licensed sources of cesium-137 and americium-241 in Virginia Beach, Virginia on October 4-5, 1990. The report documenting this inspection was sent to you by letter dated October 19, 1990. As a result of the inspection, a significant failure to comply with NRC regulatory requirements was identified, and accordingly, NRC concerns relative to the inspection findings were discussed in an Enforcement Conference held on November 5, 1990. The letter summarizing this Conference was sent to you on November 8, 1990. A Confirmation of Action Letter was also sent to you on October 17, 1990.

The violation described in Part I of the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice) involved the failure of a licensee technician to secure licensed material against unauthorized removal or to maintain continuous observation and control of licensed material in an unrestricted area. On October 4, 1990, the technician loaned his vehicle to another individual. The individual drove the vehicle to a construction office and while he went into the office he left the vehicle running and unattended and the gauge unsecured. The vehicle contained a Troxler Model 3440 moisture/density gauge. The technician stated that the gauge source operating rod was not locked, nor was the transport box locked. While the individual was in the construction office, someone stole the vehicle. The theft of the vehicle was reported to local law enforcement authorities and the vehicle and the gauge were subsequently recovered on the following day. Fortunately, there was no evidence to indicate that anyone had tampered with the gauge.

The NRC considers this event to be very significant because a qualified gauge operator, who had been trained and was fully aware of the requirements for and importance of controlling licensed material, created a potential hazard to the health and safety of the public. Although this violation would normally be categorized at Severity Level III, in accordance with the "General Statement of

DEC 10 1990

Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy) 10 CFR Part 2, Appendix C (1990), the violation has been categorized at Severity Level II, since the circumstances involved careless disregard of NRC requirements and public health and safety.

To emphasize the importance of complying with regulatory requirements associated with license conditions, I have been authorized, after consultation with the Director, Office of Enforcement, and the Deputy Executive Director for Nuclear Materials Safety, Safeguards, and Operations Support, to issue the enclosed Notice of Violation and Proposed Imposition of Civil Penalty in the amount of \$800.00 for the Severity Level II violation. The base value of a civil penalty for a Severity Level II violation is \$800.00. The escalation and mitigation factors in the Enforcement Policy were considered.

As to identification and reporting, we recognize that you identified and reported this self-disclosing event to the NRC and the local law enforcement authorities. However, the report was not made immediately and to the office specified in 10 CFR 20.402. Therefore, mitigation was not warranted. Neither escalation nor mitigation was warranted for corrective action. The staff recognizes that corrective action was taken in that licensee personnel were briefed on the event and instructed to ensure they comply with regulatory requirements. However, additional action should have been taken, such as additional physical reminders for your technicians and more frequent field audits that would help preclude recurrence. Mitigation of 50 percent was warranted for overall good past performance; however, full mitigation was not warranted because two violations were cited during each of the NRC inspections conducted in December 1987 and January 1984. Escalation of 50 percent was warranted for prior notice of similar events because at least four NRC Information Notices (INs) (INs 88-07, 88-02, 87-31, 86-67) sent to you related to the control of licensed material. Further escalation for this factor was not warranted because of your utilization of Information Notices to inform employees about potential problems described in those Notices. 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 neither increased nor decreased.

We considered an additional citation for failure to make a timely report of the loss or theft of licensed material. It is noted that an attempt was made to report the loss to our Headquarters office. However, that does not meet the requirements of 10 CFR 20.402. In the future, it is expected that the licensee will be familiar with the reporting requirements.

The violation described in Part II of the Notice involved the failure of your Radiation Safety Officer to ensure that personnel authorized to use gauges have completed the training required by license condition. We recognize your personnel did complete another training course subsequently determined to be equivalent to the manufacturer's and this has been included as an authorized course on your license in accordance with your October 17, 1990 request. Therefore, no further response is required from you on this matter.

DEC 10 1990

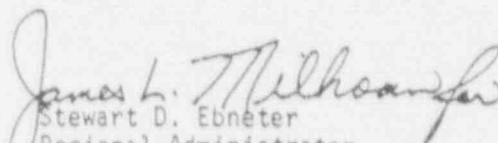
You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. In your response, you should document the specific actions taken and any additional actions you plan to prevent recurrence. After reviewing your response to this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

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

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

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

Sincerely,


Stewart D. Ebner
Regional Administrator

Enclosure:
Notice of Violation and Proposed
Imposition of Civil Penalty

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

McCallum Testing Laboratories, Inc.
Chesapeake, Virginia

Docket No. 030-08916
License No. 45-15325-01
EA 90-183

During an NRC inspection, conducted on October 12, 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 violation and associated civil penalty are set forth below:

I. Violation Assessed a Civil Penalty

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

Condition 16 of License No. 45-15325-01 requires the licensee to conduct its program in accordance with the statements and representations made in a letter dated March 17, 1988. Item 2.b of the letter dated March 17, 1988 states that licensed materials in devices will be stored in a locked enclosure such as a transport vehicle in a way that will prevent access by unauthorized personnel. Item 2.c (3) of that letter states that to prevent unauthorized access, use or removal of the gauge from temporary job sites, the gauge is never to be out of the operator's sight, and when not in use, it is locked up in a box and put in the vehicle.

Contrary to the above, on October 4, 1990, licensed materials consisting of two sealed sources (one 8 millicuries of Cs-137 and the other 44 millicuries of Am-241) contained in an unlocked Troxler 3440 moisture/density gauge located in the cargo area of an unlocked licensee vehicle parked on a public street, an unrestricted area, were not under constant surveillance and immediate control of the licensee.

This is a Severity Level II violation (Supplement VI),
Civil Penalty - \$800

II. Violation Not Assessed a Civil Penalty

Condition 11 of License No. 45-15325-01 requires that licensed materials be used by, or under the supervision and in the physical presence of, individuals who have completed the manufacturer's training, and are approved by the Radiation Protection Officer.

Contrary to the above, from July 16, 1990 through October 5, 1990, the Radiation Protection Officer permitted individuals to use licensed materials when those individuals neither had completed manufacturer's training nor were under the supervision and in the physical presence of individuals who had been trained by the manufacturer.

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

Pursuant to the provisions of 10 CFR 2.201, McCallum Testing Laboratories, 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 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.

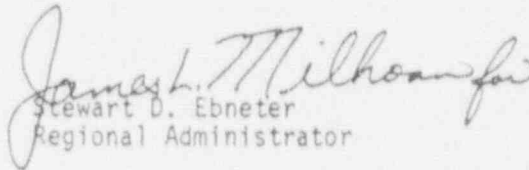
Within the same time as provided for the response required above under 10 CFR 2.201, the Licensee may pay the civil penalty by letter addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, with a check, draft, money order, or electronic transfer payable to the Treasurer 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 (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 11, 101 Marietta St, N.W., Atlanta, GA 30323.

FOR THE NUCLEAR REGULATORY COMMISSION


Stewart D. Ebnetter
Regional Administrator

Dated at Atlanta, Georgia
this ~~10th~~ day of December 1990



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION IV
611 RYAN PLAZA DRIVE, SUITE 1000
ARLINGTON, TEXAS 76011

DEC 20 1990

Docket No. 30-11571
License No. 35-13157-02
EA 90-212

Muskogee Regional Medical Center
ATTN: William Kennedy, CEO
300 Rockefeller Drive
Muskogee, Oklahoma 74401

Gentlemen:

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY - \$1,250
(NRC INSPECTION REPORT NO. 90-02)

This refers to NRC's inspection at Muskogee Regional Medical Center (MRMC) and its subsequent review of MRMC's own investigation report of a therapeutic misadministration which MRMC reported to NRC's Region IV office on September 19, 1990. NRC's inspection and review of this matter took place between October 3 and November 16, 1990. As a result of its inspection and reviews, which disclosed that violations of NRC requirements contributed to the occurrence of the therapeutic misadministration, an enforcement conference with MRMC representatives was conducted in NRC's Arlington, Texas office on December 13, 1990.

As described in some detail in NRC's November 30, 1990, inspection report, an error made during preparations for radiation treatment of a cancer patient led to the administration of radiation therapy to the wrong side of the patient's neck, which, according to NRC regulations, constituted a therapeutic misadministration required to be reported to NRC within 24 hours. Although the radiation therapy was administered in February and March 1990, MRMC staff did not discover this error until September 6, 1990, and did not recognize it as a potentially reportable matter until September 19, 1990, at which time the NRC was informed.

NRC's inspection and evaluation of this event disclosed three violations of requirements: 1) a failure by MRMC to require its staff to follow the instructions of the supervising physician, a violation of 10 CFR 35.25(a)(2); 2) a failure on the part of the MRMC, through its radiation safety officer (RSO), to ensure that radiation safety activities were being performed in accordance with approved procedures and regulatory requirements in the daily operations of its byproduct material program, a violation of 10 CFR 35.21(a); and 3) a failure on the part of MRMC to notify the NRC of the therapeutic misadministration within the time allotted by NRC regulations, a violation of 10 CFR 35.33(a).

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

On October 10, 1990, NRC issued a Confirmatory Action Letter (CAL) to MRMC to confirm MRMC's commitment to conduct a review of a sampling of other radiation therapy treatment records to determine whether other therapeutic misadministrations may have occurred and gone undetected. MRMC's November 5, 1990, letter in which it reported the results of its review of some 650 patient treatment charts, and the discussions during the enforcement conference indicate that the therapeutic misadministration reported on September 19 was an isolated occurrence. The disturbing result of MRMC's and NRC's review of this event, however, is the finding that procedures designed to guard against such errors being made were routinely not followed, due in part to a large number of patients in treatment and a heavy workload for MRMC staff, and in part to complacency among the staff.

We also find it significant that the RSO's involvement in radiation therapy activities was minimal, and view this as a factor that contributed to the complacency that had developed among MRMC staff and the procedural noncompliance that resulted.

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 involving the failure of MRMC staff to follow established procedures and the failure of the RSO to effectively oversee radiation therapy activities have been classified in the aggregate as a Severity Level III problem. The violation involving MRMC's failure to report the misadministration within the allowed time has been classified at Severity Level IV.

To emphasize the importance of strict adherence to procedures related to radiation safety, the importance of effective oversight and the importance of lasting corrective actions for these weaknesses, 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 Severity Level III problem described in the Notice.

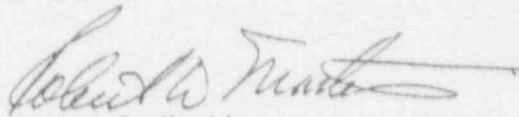
The base value of a civil penalty for a Severity Level III problem is \$2,500. The escalation and mitigation factors in the Enforcement Policy were considered and, on balance, this base penalty was reduced by 50 percent. NRC considered MRMC's corrective actions, which are summarized below, prompt and comprehensive and worthy of a 50-percent reduction in the base amount. NRC also considered MRMC's past regulatory performance as potentially worthy of some reduction in the penalty, but decided that no adjustment should be made because this therapeutic misadministration revealed that, in fact, MRMC staff had been routinely failing to follow procedures. In addition, although MRMC did identify and report this misadministration, no further reduction in the penalty was made because MRMC staff had many previous opportunities to identify this treatment error and did not, and because the report was not made within 24 hours as required.

During the enforcement conference, MRMC outlined a number of significant corrective actions taken and planned to preclude the possibility of such misadministrations recurring. These actions include, but are not limited to, increased staffing, attempts to better balance the staff's workload, the development of detailed sign-off forms to ensure that required checks are being performed, meetings with staff to emphasize the importance of procedural adherence, the purchase of new equipment to improve the quality of pre-treatment photographs, and a commitment that the RSC will conduct a review of relevant policies. NRC appreciates the candor and frankness with which MRMC representatives addressed NRC's concerns at the enforcement conference and considers the corrective actions outlined there to be a significant step toward eliminating the fundamental failures that led to this event.

MRMC is required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing its response. In its response, MRMC should document the specific actions taken and any additional actions it plans to prevent recurrence. In doing so, MRMC may make reference to previously submitted correspondence as necessary. After reviewing MRMC's response to this Notice, including its proposed corrective actions and the results of future inspections, the NRC will determine whether further NRC enforcement action is necessary to ensure compliance with NRC regulatory requirements.

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

Sincerely,



Robert D. Martin
Regional Administrator

Enclosure:
Notice of Violation and Proposed
Imposition of Civil Penalty

cc w/enclosure:
Oklahoma Radiation Control Program Director

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

Muskogee Regional Medical Center
Muskogee, Oklahoma

Docket No. 30-11571
License No. 35-13157-02
EA 90-212

During an NRC inspection conducted between October 3 and November 16, 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:

I. Violations Assessed a Civil Penalty

- A. 10 CFR 35.25(a) requires, in part, that a licensee that permits the use of byproduct material by an individual under the supervision of an authorized user shall require the supervised individual to follow the instructions of the supervising authorized user.

The licensee's Policy and Procedures for "Chart Checks," which constitute the instructions of the supervising authorized user, require, in part, that: (1) treatment technologists monitor the treatment chart daily to verify that the prescribed dose and actual given dose are identical and check all treatment chart parameters weekly when completing the patient daily log book; and (2) the radiation (teletherapy) physicist and dosimetrist check charts weekly for prescription, dose accuracy, and all other treatment parameters.

Contrary to the above, while participating in a teletherapy treatment administered in February and March 1990, the treatment technologists, teletherapy physicist, and dosimetrist, individuals under the supervision of the licensee's supervising authorized user, failed to conduct treatment chart checks as described in the supervising authorized user's instructions, and as a result did not detect an error in the treatment plan.

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

Contrary to the above, from January 1990 through October 3, 1990, the RSO was not ensuring that the radiation safety activities were being performed in accordance with approved procedures and

regulatory requirements in the daily operation of the licensee's byproduct material program. Specifically, licensee staff were not conducting all checks required by procedure, as described in Violation A above.

These violations are classified collectively as a Severity Level III problem (Supplement VI).

Cumulative Civil Penalty - \$1,250 (assessed equally between the two violations)

II. Violations Not Assessed a Civil Penalty

10 CFR 35.33(a) requires, in part, that when a misadministration involves any therapy procedure, the licensee shall notify by telephone the appropriate NRC Regional Office within 24 hours after the licensee discovers the misadministration.

Contrary to the above, the licensee failed to notify the appropriate NRC Regional Office within 24 hours of the discovery of a therapeutic misadministration on September 6, 1990. Such notification was not made until September 19, 1990.

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

Pursuant to the provisions of 10 CFR 2.201, Muskogee Regional 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 causes shown. Under the authority of Section 182 of the Act, 42 U.S.C. 223, this response shall be submitted under oath or affirmation.

Within the same time as provided for the response required above under 10 CFR 2.201, the Licensee may pay the civil penalty by letter addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, with a check, draft, money order, or electronic transfer payable to the Treasurer of the United States in the amount of the civil penalty proposed above, or the

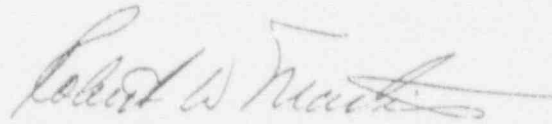
cumulative amount of the civil penalties if more than one civil penalty is proposed, or may protest imposition of the civil penalty, in whole or in part, by a written answer addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission. Should the Licensee fail to answer within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

In requesting mitigation of the proposed penalty, the factors addressed in Section V.B of 10 CFR Part 2, Appendix C (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 IV, 611 Ryan Plaza Drive, Suite 1000, Arlington, Texas.

FOR THE NUCLEAR REGULATORY COMMISSION



Robert D. Martin
Regional Administrator

Dated at Arlington, Texas
this 20th day of December 1990



UNITED STATES
NUCLEAR REGULATORY COMMISSION

REGION IV
611 RYAN PLAZA DRIVE, SUITE 1000
ARLINGTON, TEXAS 76011

JUL 25 1990

Docket No. 030-11681
License No. 35-16717-01
EA 90-106

Newman Memorial Hospital
ATTN: Walter Shain
Administrator
919 South Main Street
Shattuck, Oklahoma 73858

Gentlemen:

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY - \$5,000
(NRC INSPECTION REPORT 90-01)

This refers to NRC's inspections conducted on January 25-26, May 10, and June 14, 1990, of activities authorized by NRC License No. 35-16717-01 issued to Newman Memorial Hospital (NMH) and the enforcement conference held June 1, 1990 in our Arlington, Texas office, at which the results of the January 25-26, and May 10, 1990 inspections were discussed with you and Dr. Norman Naumoff. During the inspections, the NRC identified several violations of Commission requirements. The NRC's inspection findings were documented in a report issued on May 25, 1990, and a summary of the enforcement conference and program review was issued to you on July 10, 1990.

These violations, which are described in the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice), indicate a lack of attention to NRC requirements by the radiation safety officer (RSO) and a lack of management oversight by the radiation safety committee (RSC). In summary, NMH was found in violation of requirements related to: (1) responsibilities of the RSO and RSC, (2) personnel dosimetry and ALARA, (3) ensuring proper operation of the hospital's dose calibrator, (4) radiation surveys, and (5) labeling and use of radiopharmaceuticals.

NMH appears to have delegated its responsibility for management oversight of the radiation safety program to an RSO who relied on a technologist to perform most of the RSO's responsibilities, and to some degree, on the services of a consultant to verify that various tasks required by license commitments and NRC requirements had been performed. The RSO must have a thorough understanding of NRC requirements to provide competent management of the radiation safety program and adequate reviews of consultant activities. Additionally, the RSC must be actively involved in the oversight of all NRC licensed activities within your facility to ensure compliance.

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

The NRC has reviewed NMH's March 20, 1990, letter regarding corrective actions that were being implemented subsequent to the January 25-26, 1990 inspection and concludes that NMH is attempting to regain direct control of the radiation safety program. Some of the planned or implemented corrective actions are a restatement of commitments previously made in your license application dated January 29, 1987, and appear directed at improving program documentation. The NRC has also reviewed NMH's June 8, 1990, letter in response to our request at the enforcement conference and concludes that this response is directed at correcting management oversight concerns identified during the January 25-26, and May 10, 1990, inspections. NRC verified that the corrective actions stated in your March 20, and June 8, 1990, letters were implemented during our followup inspection on June 14, 1990, and we are satisfied that NMH has taken appropriate steps toward implementing an effective system of management control and oversight to ensure compliance with NRC requirements.

In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C (1990), (Enforcement Policy), these violations have been classified in the aggregate at Severity Level III because they indicate a breakdown in management control of licensed activities and a lack of attention to licensed responsibilities by the the RSO and RSC.

To emphasize the importance of radiation safety program management and compliance with radiation safety requirements, 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 \$5,000 for the violations described in the enclosed Notice.

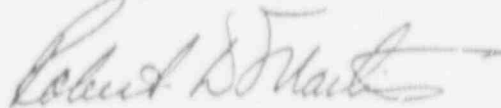
The base value of a civil penalty for a Severity Level III problem is \$2,500. The escalation and mitigation factors in the Enforcement Policy were considered and, on balance, the base value was increased by 100 percent. In arriving at that determination, a 50-percent escalation was warranted because the NRC identified the violations which should have been identified by NMH. Additionally a 50-percent escalation was warranted because the corrective actions that you took subsequent to our January inspection were neither prompt nor comprehensive and because the May inspection revealed that additional corrective action was needed. The other adjustment factors were considered and no further adjustment to the base civil penalty is considered appropriate.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. In your response, you should document the specific actions taken and any additional actions you plan to prevent recurrence. The NRC will review your response to this Notice, including your proposed corrective actions, and the results of future inspections, to 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:
Oklahoma Radiation Control Program Director
NRC Public Document Room

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

Newman Memorial Hospital
Shattuck, Oklahoma

Docket No. 030-11681
License No. 35-16717-01
EA 90-106

During NRC inspections conducted on January 25-26, and May 10, 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 (1980), 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 requires that 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. In addition, specific duties are prescribed in paragraph (b) of that section.

Contrary to the above, as of May 10, 1990, the RSO was not ensuring that the radiation safety activities were being performed in accordance with approved procedures and regulatory requirements, as evidenced by the violations cited in this Notice and the RSO's admission that, as of the May 10, 1990 inspection, he had not reviewed the regulations for which he was responsible and that he had not reviewed records that he had signed.

- B. 10 CFR 35.22(a)(3) requires that to establish a quorum and to conduct business, at least one-half of the Radiation Safety Committee's members must be present, including the Radiation Safety Officer (RSO) and the management's representative.

Contrary to the above, the RSO was not present during RSC meetings held to conduct business during August and November 1988 and February 1990.

- C. License Condition 15 specifies, in part, that the license is based on the licensee's statements and representations in the application dated January 29, 1987.

1. Item 9.4 of the application describes the licensee personnel external exposure monitoring program. Item 9.4.2 specifies, in part, that all individuals who are occupationally exposed to radiation on a regular basis will be issued film or TLD (thermoluminescent) whole body monitoring devices. Item 9.4.3 specifies, in part, that all individuals who handle radioactive material on a regular basis will be issued film or TLD (thermoluminescent) finger monitoring devices.

Contrary to the above, from October through December 1989, the licensee failed to issue whole body or finger monitoring devices to two individuals who were occupationally exposed to radiation and handled radioactive material on a regular basis during this period.

2. Item 10.4 of the application describes the licensee rules for safe use of radiopharmaceuticals. Item 10.4.7 specifies, in part, that personnel are to wear monitoring devices at all times while in areas where radioactive materials are used or stored.

Contrary to the above, on May 10, 1990, an inspector observed an individual working in an area where radioactive materials were in use and stored and who was not wearing a personal monitoring device.

3. Item 10.12 of the application specifies that the procedures described in Appendix N of Regulatory Guide 10.8, Revision 2, will be used to conduct area radiation surveys.

Appendix N, in part, requires that weekly surveys be performed to determine removable contamination levels in radiopharmaceutical elution, preparation, and administration areas. This method must be sufficiently sensitive to detect 2000 disintegrations per minute (dpm) per 100 square centimeters. Also, the records of the survey must contain a drawing of the areas surveyed, contamination action levels as established by the RSO, and measured contamination levels in dpm/100 square centimeters.

Contrary to the above: (1) from September 1989 through January 1990, the licensee had failed to conduct weekly surveys to determine removable contamination in radiopharmaceutical elution, preparation, and administration areas; (2) from 1987 through January 1990, the licensee failed to ensure that the method used to conduct contamination surveys was sufficiently sensitive to detect 2000 dpm/100 square centimeters; (3) from January 1988 through January 1990, records of contamination surveys did not include a drawing of the areas surveyed, and (4) from 1987 through May 10, 1990, did not include the measured contamination levels in dpm/100 square centimeters.

- D. 10 CFR 35.60(c) requires, in part, that a licensee require each individual who prepares a radiopharmaceutical kit to use a syringe radiation shield when preparing the kit.

Contrary to the above, as of May 10, 1990, the licensee's technologist who prepared radiopharmaceutical kits failed to always use a syringe radiation shield when preparing the kits during 1988 and 1989.

- E. 1. 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 August 20, 25, and 31; and November 2, 3, 9, 11, 26, and 28, 1989, the licensee did not check a dose calibrator for constancy with a dedicated check source and used the dose calibrator to measure patient doses on those days.

2. 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 complete a linearity test of the dose calibrator between November 1989 and May 10, 1990.

- F. 10 CFR 35.53(c) requires, in part, that a licensee retain a record of the measurements of radiopharmaceutical doses required by Section 35.53 for 3 years. To satisfy this requirement, the record must contain the:
(1) patient's name, and identification number if one has been assigned;
(2) date and time of the measurement; and (3) initials of the individual who made the record.

Contrary to the above, from 1988 through May 10, 1990, certain records of radiopharmaceutical dose measurements did not contain the patient name and identification number, the date and time of the measurement, and the initials of the individual who made the record.

- G. 10 CFR 35.60(b) requires a licensee to conspicuously label each syringe, or syringe radiation shield that contains a syringe with a radiopharmaceutical. The label must show the radiopharmaceutical name or its abbreviation, the clinical procedure to be performed, or the patient's name.

Contrary to the above, during 1988 and 1989 the licensee failed to label syringes or syringe radiation shields that contained syringes with radiopharmaceuticals.

- H. 10 CFR 35.14 requires, in part, that a licensee notify the Commission by letter within 30 days when an authorized user permanently discontinues performance of duties under the license.

Contrary to the above, as of May 10, 1990, the licensee had failed to provide the required notification for two authorized users who had permanently discontinued their performance of duties under this license in December 1989.

- I. 10 CFR 20.401(a) requires, in part, that each licensee maintain records showing the radiation exposures of all individuals for whom personnel monitoring is required under 10 CFR 20.202.

Contrary to the above, as of May 10, 1990, the licensee had failed to maintain records for three individuals of radiation exposures accrued during the period October through December 1989.

- J. 10 CFR 35.50(e) requires, in part, that a licensee retain a record of each check and test required by Section 35.50(b)(2), (3), and (4), and that the record include the signature of the Radiation Safety Officer (RSO).

Contrary to the above, from 1987 through January 1990, records of the checks and tests required under 10 CFR 35.50(b)(2), (3), and (4) did not include the signature of the RSO in every case.

These violations have been collectively classified as a Severity Level III problem (Supplements IV and VI).

Cumulative Civil Penalty - \$5,000 (assessed equally among the 10 violations)

Pursuant to the provisions of 10 CFR 2.201, Newman Memorial Hospital (Licensee) is hereby required to submit a written statement or explanation to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, within 30 days of the date of this Notice of Violation and Proposed Imposition of Civil Penalty (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each alleged violation: (1) admission or denial of the alleged violation, (2) the reasons for the violation if admitted, and if denied, the reasons why, (3) the corrective steps that have been taken and the results achieved, (4) the corrective steps that will be taken to avoid Notice of Violation 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 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 IV, 611 Ryan Plaza Drive, Suite 1000, Arlington, Texas 76011.

FOR THE NUCLEAR REGULATORY COMMISSION



Robert D. Martin
Regional Administrator

Dated at Arlington, Texas,
this 25th day of July 1990



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

DEC 20 1990

Docket No. 30-11681
License No. 35-16717-01
EA 90-106

Newman Memorial Hospital
ATTN: Gary Mitchell
Administrator
919 South Main Street
Shattuck, Oklahoma 73858

Gentlemen:

SUBJECT: ORDER IMPOSING CIVIL MONETARY PENALTY - \$5,000

This is in reference to Newman Memorial Hospital's (NMH) two letters dated August 21, 1990, in response to the Notice of Violation and Proposed Imposition of Civil Penalty (Notice) sent to you by NRC letter dated July 25, 1990. NRC's letter and Notice described numerous violations identified as a result of NRC inspections conducted on January 25-26 and May 10, 1990.

To emphasize the importance of effective management of radiation safety programs and compliance with all license requirements, a civil penalty of \$5,000 was proposed.

In response, NMH admitted nine violations, denied three violations in their entirety, and admitted in part and denied in part the remaining violation. In addition, the Licensee stated in regard to a number of the admitted violations that they had been identified by the Licensee's consulting physicist and were in the progress of being corrected or had been corrected prior to NRC's inspections, provided extenuating information in relation to several violations, and requested mitigation of the civil penalty.

While NRC acknowledges that some of the problems associated with the violations in the Notice had been identified by NMH's consulting physicist in 1989, prior to NRC's inspections in January and May 1990, NRC concludes that corrective actions based on the consulting physicist's findings were not prompt, had not been implemented, or were not effective in correcting the violations. In addition, in response to NMH's seeming inability during a June 1, 1990, enforcement conference to describe specific corrective actions and assure NRC that NMH was in compliance, a third inspection was conducted on June 14, 1990. Therefore, as discussed in detail in the Appendix attached to the enclosed Order Imposing Civil Monetary Penalty, NRC concludes that NMH's arguments in response to the Notice do not warrant mitigation of the civil penalty.

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

After consideration of NMH's responses, we have concluded for the reasons given in the Appendix attached to the enclosed Order Imposing Civil Monetary Penalty that the violations occurred as stated and that the proposed civil penalty should be imposed. Accordingly, the NRC hereby serves the enclosed Order on Newman Memorial Hospital imposing a civil monetary penalty in the amount of \$5,000. We will review the effectiveness of NMH's corrective actions during subsequent inspections.

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

Sincerely,



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

Enclosures: As Stated

UNITED STATES
NUCLEAR REGULATORY COMMISSION

In the Matter of
NEWMAN MEMORIAL HOSPITAL
Shattuck, Oklahoma

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Docket No. 30-11681
License No. 35-16717-01
EA 90-106

ORDER IMPOSING CIVIL MONETARY PENALTY

I

Newman Memorial Hospital (NMH) (Licensee) is the holder of NRC Materials License No. 35-16717-01 issued by the Nuclear Regulatory Commission (NRC or Commission) on May 23, 1989. The license authorizes the Licensee to use NRC-licensed radioactive materials in accordance with the conditions specified therein to conduct nuclear medicine activities.

II

Inspections of the Licensee's activities were conducted on January 25-26, and May 10, 1990. The results of these inspections 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 25, 1990. The Notice stated the nature of the violations, the provisions of the NRC's requirements that the Licensee had violated, and the amount of the civil penalty proposed for the violations. The Licensee responded to the Notice by two letters dated August 21, 1990. The Licensee admitted nine violations (Violations A, C.1, E.1, E.2, F, G, H, I and J), denied three violations in their entirety (Violations B, C.2, and D), and admitted in part and denied in part the remaining violation (Violation C.3). In addition, the Licensee stated in

regard to a number of the admitted violations that they had been identified by the Licensee's consulting physicist and were in the progress of being corrected or had been corrected prior to NRC's inspections, provided extenuating information in relation to several violations and requested mitigation of the civil penalty.

III

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

IV

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

The Licensee pay a civil penalty in the amount of \$5,000 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.

The Licensee may request a hearing within 30 days of the date of this Order. A request for a hearing should be clearly marked as a "Request for an Enforcement Hearing" and shall be addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555. Copies also shall be sent to the Assistant General Counsel for Hearings and Enforcement at the same address and to the Regional Administrator, NRC Region IV, 611 Ryan Plaza Drive, Suite 1000, Arlington, Texas 76011.

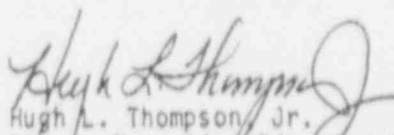
If a hearing is requested, the Commission will issue an Order designating the time and place of the hearing. If the Licensee fails to request a hearing within 30 days of the date of this Order, the provisions of this Order shall be effective without further proceedings. If payment has not been made by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

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

- (a) whether the Licensee was in violation of the Commission's requirements as set forth in Violations B, C.2, C.3 and D of the Notice referenced in Section II above, and

(b) whether, on the basis of such violations and the additional violations set forth in the Notice that the Licensee admitted, this Order should be sustained.

FOR THE NUCLEAR REGULATORY COMMISSION



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

Dated at Rockville, Maryland
this 20th day of December 1990

APPENDIX

EVALUATIONS AND CONCLUSIONS

Appendix to Order Imposing Civil Monetary Penalty

On July 25, 1990, a Notice of Violation and Proposed Imposition of Civil Penalty (Notice) was issued for violations identified during January 25-26, 1990 and May 10, 1990, NRC inspections. Newman Memorial Hospital (NMH) responded to the Notice in two letters dated August 21, 1990. The NRC's evaluations and conclusions regarding the licensee's response follow:

Restatement of Violations

- A. 10 CFR 35.21 requires that 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. In addition, specific duties are prescribed in paragraph (b) of that section.

Contrary to the above, as of May 10, 1990, the RSO was not ensuring that the radiation safety activities were being performed in accordance with approved procedures and regulatory requirements, as evidenced by the violations cited in this Notice and the RSO's admission that, as of the May 10, 1990 inspection, he had not reviewed the regulations for which he was responsible and that he had not reviewed records that he had signed.

- B. 10 CFR 35.22(a)(3) requires that to establish a quorum and to conduct business, at least one-half of the Radiation Safety Committee's members must be present, including the Radiation Safety Officer (RSO) and the management's representative.

Contrary to the above, the RSO was not present during RSC meetings held to conduct business during August and November 1988 and February 1990.

- C. License Condition 15 specifies, in part, that the license is based on the licensee's statements and representations in the application dated January 29, 1987.

1. Item 9.4 of the application describes the licensee personnel external exposure monitoring program. Item 9.4.2 specifies, in part, that all individuals who are occupationally exposed to radiation on a regular basis will be issued film or TLD (thermoluminescent) whole body monitoring devices. Item 9.4.3 specifies, in part, that all individuals who handle radioactive material on a regular basis will be issued film or TLD (thermoluminescent) finger monitoring devices.

Contrary to the above, from October through December 1989, the licensee failed to issue whole body or finger monitoring devices to

two individuals who were occupationally exposed to radiation and handled radioactive material on a regular basis during this period.

2. Item 10.4 of the application describes the licensee rules for safe use of radiopharmaceuticals. Item 10.4.7 specifies, in part, that personnel are to wear monitoring devices at all times while in areas where radioactive materials are used or stored.

Contrary to the above, on May 10, 1990, an inspector observed an individual working in an area where radioactive materials were in use and stored and who was not wearing a personal monitoring device.

3. Item 10.12 of the application specifies that the procedures described in Appendix N of Regulatory Guide 10.8, Revision 2, will be used to conduct area radiation surveys.

Appendix N, in part, requires that weekly surveys be performed to determine removable contamination levels in radiopharmaceutical elution, preparation, and administration areas. This method must be sufficiently sensitive to detect 2000 disintegrations per minute (dpm) per 100 square centimeters. Also, the records of the survey must contain a drawing of the areas surveyed, contamination action levels as established by the RSO, and measured contamination levels in dpm/100 square centimeters.

Contrary to the above: (1) from September 1989 through January 1990, the licensee had failed to conduct weekly surveys to determine removable contamination in radiopharmaceutical elution, preparation, and administration areas; (2) from 1987 through January 1990, the licensee failed to ensure that the method used to conduct contamination surveys was sufficiently sensitive to detect 2000 dpm/100 square centimeters; (3) from January 1988 through January 1990, records of contamination surveys did not include a drawing of the areas surveyed, and (4) from 1987 through May 10, 1990, did not include the measured contamination levels in dpm/100 square centimeters.

- D. 10 CFR 35.60(c) requires, in part, that a licensee require each individual who prepares a radiopharmaceutical kit to use a syringe radiation shield when preparing the kit.

Contrary to the above, as of May 10, 1990, the licensee's technologist who prepared radiopharmaceutical kits failed to always use a syringe radiation shield when preparing the kits during 1988 and 1989.

- E. 1. 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 August 20, 25, and 31; and November 2, 3, 9, 11, 26, and 28, 1989, the licensee did not check a dose calibrator for constancy with a dedicated check source and used the dose calibrator to measure patient doses on those days.

2. 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 complete a linearity test of the dose calibrator between November 1989 and May 10, 1990.

- F. 10 CFR 35.53(c) requires, in part, that a licensee retain a record of the measurements of radiopharmaceutical doses required by Section 35.53 for 3 years. To satisfy this requirement, the record must contain the:
 - (1) patient's name, and identification number if one has been assigned;
 - (2) date and time of the measurement; and (3) initials of the individual who made the record.

Contrary to the above, from 1988 through May 10, 1990, certain records of radiopharmaceutical dose measurements did not contain the patient name and identification number, the date and time of the measurement, and the initials of the individual who made the record.

- G. 10 CFR 35.60(b) requires a licensee to conspicuously label each syringe, or syringe radiation shield that contains a syringe with a radiopharmaceutical. The label must show the radiopharmaceutical name or its abbreviation, the clinical procedure to be performed, or the patient's name.

Contrary to the above, during 1988 and 1989 the licensee failed to label syringes or syringe radiation shields that contained syringes with radiopharmaceuticals.

- H. 10 CFR 35.14 requires, in part, that a licensee notify the Commission by letter within 30 days when an authorized user permanently discontinues performance of duties under the license.

Contrary to the above, as of May 10, 1990, the licensee had failed to provide the required notification for two authorized users who had permanently discontinued their performance of duties under this license in December 1989.

- I. 10 CFR 20.401(a) requires, in part, that each licensee maintain records showing the radiation exposures of all individuals for whom personnel monitoring is required under 10 CFR 20.202.

Contrary to the above, as of May 10, 1990, the licensee had failed to maintain records for three individuals of radiation exposures accrued during the period October through December 1989.

- J. 10 CFR 35.50(e) requires, in part, that a licensee retain a record of each check and test required by Section 35.50(b)(2), (3), and (4), and that the record include the signature of the Radiation Safety Officer (RSO).

Contrary to the above, from 1987 through January 1990, records of the checks and tests required under 10 CFR 35.50(b)(2), (3), and (4) did not include the signature of the RSO in every case.

These violations have been collectively classified as a Severity Level III problem (Supplements IV and VI).

Cumulative Civil Penalty - \$5,000 (assessed equally among the 10 violations)

Summary of Licensee's Response to Notice of Violation

(Note: Although the proposed civil penalty was assessed equally among 10 violations, A through J, Violations C and E had more than one part, such that if counted individually, the Notice could be viewed as containing 13 violations of NRC regulations and license conditions. For the purpose of summarizing and evaluating the Licensee's response, a total of 13 violations is used.)

The Licensee admitted 9 of the 13 violations (Violations A, C.1, E.1, E.2, F, G, H, I and J), denied 3 violations in their entirety (Violations B, C.2, and D), and admitted in part and denied in part the remaining violation (Violation C.3). In addition, the Licensee stated in regard to a number of the admitted violations that they had been identified by the Licensee's consulting physicist and were in the progress of being corrected or had been corrected prior to NRC's inspections, and provided extenuating information in relation to several violations.

For the purpose of this and the next section of this document, which are focused on determining whether the violations in the Notice did or did not occur, only those violations which the Licensee denied either in whole or in part are discussed. The Licensee's statements in regard to identification, corrective action, and extenuating circumstances are more appropriately addressed in the subsequent sections of this document in which the Licensee's arguments for mitigation of the proposed civil penalty are summarized and evaluated.

In denying Violations B, C.2 and D, and denying in part Violation C.3, the Licensee stated in general that it felt the conclusions reached by NRC's inspectors were incorrect and made the following arguments:

1. In response to Violation B, the Licensee stated that interim meetings of a portion of the radiation safety committee (RSC) had been held in August

and November 1988. These meetings included the administrative representative, nuclear medicine technologist, and the Licensee's consulting physicist, but not the RSO. The Licensee added that later, when the RSO could be present, the report of the consulting physicist and other matters were discussed with the RSO. The licensee stated that the RSO was on vacation and was not present during the February 1990 RSC meeting of the RSC, but that a meeting was held later with the RSO to discuss all matters, including the NRC inspection results.

2. In response to Violation C.2, the Licensee stated that the inspector arrived before the technologist, and that immediately upon the arrival of the technologist and before he could go to his office to get his film badge, the inspector requested entry to the hot lab area. The Licensee stated that the technologist complied with the inspector's request, letting the inspector into the Hot Lab where radioactive materials are kept, at which point the inspector informed the technologist that he was not wearing his badge. The Licensee stated that the technologist should have retrieved and worn his film badge, but that the approach on the part of the inspector was inappropriate and contributed to the error.
3. In response to Violation D, the Licensee stated that the inspectors could not have observed a failure of a technologist to use syringe shields to prepare kits because no patients "were done" during either the January or May 1990 inspections. The Licensee added that it had identified a need for "better" syringe shields in April 1989 and that the shields were in use by August 1989.
4. In response to Violation C.3 (part 3), the Licensee stated that it did have a pictorial diagram of the department and that it was available at the time of the inspection, and attached a copy of a daily survey record with the response. (This record documented ambient radiation surveys conducted during the period January 4-25, 1982).

NRC Evaluation of Licensee's Response to Notice of Violation

1. In regard to Violation B, the Licensee has indicated that meetings of the RSC may have been held without the RSO present, but that the matters discussed during the RSC meetings were discussed with the RSO when he became available. The Licensee has not, however, provided any information to suggest that the RSC was reconvened to discuss these matters with the RSO nor has the Licensee suggested that records of any such meetings of the RSC exist. Although the staff acknowledges the benefit of interim meetings of the RSC, whether or not a quorum is present, the requirement to gather specific responsible individuals quarterly, for the purpose of reviewing licensed activities, must be met. Additionally, minutes documenting the subjects discussed during these meetings must be maintained. The NRC staff concludes that the Licensee's explanation does not satisfy the requirements of 10 CFR 35.22(a)(3).

NRC concludes that the violation occurred as stated.

2. In regard to Violation C.2, the Licensee stated that the NRC inspectors reached an incorrect conclusion. The Licensee in its response admitted that the technologist did not wear a personal monitoring device while in a controlled area. The Licensee, in effect, requested that the violation be withdrawn based on the circumstances it described in its response. However, the staff does not fully agree with the Licensee's representation of the circumstances.

During the May 1990, inspection, the inspectors initially met with the hospital administrator who accompanied them to the nuclear medicine department. Prior to entering the Licensee's restricted area, the administrator introduced the inspectors to the RSO and several other individuals, including the subject technologist. The inspectors indicated that they wished to tour the nuclear medicine lab and waited with the Licensee's consulting physicist and the administrator while the technologist retrieved keys to the lab. Further, the inspectors indicated that the technologist should feel free to tend to any immediate patient concerns or other matters since the hospital staff was just beginning its workday.

During the enforcement conference conducted on June 1, 1990, the Licensee's representatives stated that they felt that the technologist had simply made an error. The Licensee representatives further stated that they believed the inspector's actions in this instance to have been inappropriate.

In NRC's view, the technologist was provided an opportunity to retrieve any required monitoring devices prior to accompanying the inspectors. The NRC does not agree with inferences in the licensee's position that NRC actions reasonably contributed to the violations. The inspectors did not notice that the individual was without the required film badge until after the inspectors had been taken into the hot lab. Once the inspectors noticed this error, it was promptly brought to the attention of the technologist and prior to requesting him to handle licensed material.

NRC is not in a position to know whether Licensee personnel have routinely met this requirement. In this instance, the violation is based on the observation of an inspector during an inspection. The NRC staff notes, however, that good radiation safety practices should be observed regardless of the presence of an NRC inspector and, in fact, that most individuals are more conscientious of items such as personal monitoring devices when in the presence of an inspector.

NRC concludes that the circumstances surrounding this violation do not provide a basis for withdrawing the violation and that the violation occurred as stated.

3. In regard to Violation D, the violation was based not on inspector observations, as the Licensee's response suggests, but on interviews with Licensee personnel. The violation cited events in 1988 and 1989. NRC staff acknowledges that syringe shields were available for use at the time of NRC's May 1990 inspection. However, the syringe shields that were available were not sized to accommodate all syringes used by the Licensee in preparing radiopharmaceuticals from reagent kits. This was discussed in detail during the inspection with Licensee personnel (technical staff) who indicated that when preparing radiopharmaceuticals requiring larger dilution volumes, necessitating the use of larger syringes, the kits had been prepared without the use of a syringe shield. The significance of the failure to use a syringe shield in these instances was compounded by the fact that the licensee had not implemented the use of a table-top "L-block" to provide additional shielding for its technical staff when reconstituting radiopharmaceuticals or drawing patient doses.

NRC concludes that the violation occurred as stated.

4. In regard to Violation C.3 (part 3), the NRC staff has reviewed the 1982 survey records provided with the licensee's response. While these records indicate that a pictorial diagram of the department was available at one time, and may indeed have been available at the time of the NRC's inspection, this has little to do with the actual violation. The violation involved a failure to have included a drawing of the area surveyed for contamination surveys performed from January 1988 through January 1990. The Licensee has provided no information to suggest that such records included drawings.

NRC concludes that the violation occurred as stated.

Summary of Licensee's Request for Mitigation

The Licensee made the following points in requesting mitigation of the proposed civil penalty:

1. The Licensee stated that six of the violations had been identified by its consulting physicist and that corrective actions had been initiated prior to NRC's January 1990 inspection. The violations that the Licensee stated it had identified prior to NRC's inspection are: Violations A, D, E.1, E.2, F, and G.
2. The Licensee stated that it was taking "decisive action to correct these problems" and that it "had corrected or were in various stages of correcting" the six violations noted above, without the threat of a civil penalty.
3. The Licensee attributed the most serious portion of its problems to the failure of a disgruntled employee to perform tasks assigned to him from August to November 1989 (this individual resigned his position in late

October 1989) and the concurrent failure of the RSO to properly supervise this individual and detect these deficiencies (this RSO is no longer employed at NMH). The Licensee stated that corrective actions to address these performance-related problems were promptly implemented, without the threat of a civil penalty, when hospital administration became aware of these problems in November 1989.

4. In response to violation C.1, the licensee stated that personal monitoring devices had been provided by another hospital where the two individuals identified in the violation were also employed during this period, and added that it believed this to be within the scope of good radiation safety practice as it would provide a cumulative radiation exposure record.
5. The Licensee stated that NRC's conclusions with respect to Violations B, C.2, C.3 (part 3) and D were incorrectly reached.

NRC Evaluation of Licensee's Request for Mitigation

1. The issue of licensee versus NRC identification of violations raises two policy matters relating to NRC's Enforcement Policy ("General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C): 1) Section V.G.1. of the Enforcement Policy provides that NRC may exercise discretion and not issue a Notice of Violation for licensee-identified Severity Level IV and V violations provided that specific criteria are met; and 2) Section V.B. provides that NRC may adjust a civil penalty (up to a 50% increase or decrease of the base civil penalty) depending on whether the licensee identified, promptly reported, and immediately corrected the violation or violations that led to the proposal of a civil penalty.

Inherent in the first case, however, are two factors of some relevance here. Specifically, NRC will apply this discretion only in cases of isolated Severity Level IV and V violations and not in cases of numerous Severity Level IV and V violations that suggest a more widespread problem with compliance, and NRC will apply this discretion only if the violations were or will be corrected (from the time the licensee identified them), including measures to prevent recurrence, within a reasonable time. In the case of NMH, NRC does not view the violations the Licensee claims to have identified and corrected as isolated Severity Level IV and V violations, but as a symptom of a more pervasive problem with compliance and a significant lack of attention to licensed responsibilities. As indicated in the July 25, 1990 letter accompanying the Notice, NRC viewed these violations in total as indicative of a lack of management oversight on the part of the Licensee's Radiation Safety Committee (RSC). In addition, NRC does not view the Licensee's corrective actions for the violations it claims to have identified and corrected to have included sufficient measures to prevent recurrence. Thus, NRC does not view this particular discretionary provision as applicable to this case.

Inherent in the second case, that of NRC's discretion to mitigate a proposed civil penalty based on licensee identification, is the immediacy

of a licensee's action to correct the problem upon discovery. NRC's Enforcement Policy states that no consideration will be given to a reduction in penalty if a licensee does not take immediate action to correct the problem upon discovery. Implicit in this factor is a presumption that a licensee's immediate corrective actions were successful in correcting the violation. In light of this factor, a discussion of each of the violations for which the Licensee cites self-identification is necessary.

- a. In regard to Violation A, the Licensee admitted that the RSO had failed to perform his incumbent duties, but stated that this problem was identified to hospital administration by the Licensee's consulting physicist in November 1989. The Licensee described actions taken to correct the situation which included verbal and written notification to the RSO. The Licensee attached a copy of its written notification to its response. The Licensee also stated that its approach to this problem was not successful and that the RSO's contract was not renewed, and further stated that this action had been taken prior to any indication from NRC that it was facing a civil penalty.

The NRC staff does not dispute the Licensee's contention that the hospital's consulting physicist and the hospital's administration had recognized the failure of the RSO to perform certain required tasks. However, the Licensee has, in NRC's view, provided little information to suggest that it had recognized the extent of the RSO's failures to ensure compliance with NRC requirements and has provided virtually no information to suggest that its corrective actions upon identification of this problem were effective. The "written notification" to which it referred amounted to a statement within an "Annual Report of the Radiation Safety Officer" which said, "[c]loser observation of activities in the department and closer inspection of records by Radiation Safety Officer will be implemented immediately." This report was completed by the consulting physicist and, although it provided a space for the RSO's signature, the RSO had not signed it. Based on the RSO's admission during the May 10, 1990 inspection that he had not reviewed the regulations for which he was responsible and that he had not reviewed the records that he had signed (see Violation A in the Notice), NRC does not accept the Licensee's conclusion that corrective actions had been taken and concludes that the Licensee had not recognized the extent of the problem with respect to the RSO and his responsibilities.

Further, the Licensee presented a renewal contract to this RSO after the June 1990 inspection. The administrator had reviewed the content of this contract with the inspector during the June inspection, indicating that he believed that this document would clearly define the RSO's responsibilities. This came after the enforcement conference, by which time the Licensee had been clearly

put on notice that the violations described in the inspection report could result in the assessment of a monetary civil penalty. NRC later learned that this RSO had resigned his duties with NMH of his own accord, and was designated as an authorized user at another facility in July 1990. NRC staff subsequently contacted the Licensee to confirm this fact, and this was acknowledged by the administrator during a telephone conversation on July 11, 1990.

In NRC's view, the Licensee failed to recognize the extent of the RSO's failures and, by its own admission, initiated corrective actions that were not successful in correcting the problem. In that the problem continued and was occurring at the time of NRC's inspections, NRC concludes that the Licensee's identification of this violation does not warrant mitigation of the proposed civil penalty within the framework of NRC's Enforcement Policy.

- b. In regard to Violation D, the Licensee stated that it had identified the need for better syringe shields in April 1988 and that these were in use by August 1989.

While the Licensee may indeed have identified the need for better syringe shields in April 1989, and may have been using these in August 1989, these facts have little to do with the specific violation. Violation D involves the Licensee's technologist admitting that he failed to use a syringe shield on certain occasions when preparing radiopharmaceutical kits in 1988 and 1989. The specific reason that this violation occurred was a failure to have syringe shields of a sufficient size to accommodate the larger syringes used with certain kits.

In that the Licensee had not identified the specific issue that was the subject of this violation, NRC concludes that there is no basis on which to mitigate the proposed civil penalty within the framework of NRC's Enforcement Policy.

- c. In regard to Violation E.1, the Licensee stated that the failure to perform daily constancy checks on the dose calibrator was identified by its consulting physicist on November 10, 1989 and was corrected shortly afterwards.

The NRC staff does not dispute the Licensee's assertion that the consulting physicist identified the failure to perform dose calibrator constancy checks on each day of use. However, the staff notes that the Licensee's corrective action was not prompt in that this requirement was violated on November 11, 26, and 28, 1989. Additionally, the Licensee's corrective actions did not include measures which would prevent recurrence of this problem should the same circumstances (new employee or temporary replacement) that contributed to this violation arise again.

In that the Licensee took no immediate corrective action upon discovering this problem, and in that the violation occurred on three separate occasions following the Licensee's identification of it, NRC concludes that the Licensee's identification of this violation does not warrant mitigation of the proposed civil penalty within the framework of NRC's Enforcement Policy.

- d. In regard to Violation E.2, the Licensee stated that the "potential" of this problem occurring was identified by the consulting physicist in February 1990, and that the technologist had attempted to conduct a dose calibrator linearity test in March 1990. The Licensee stated that a satisfactory test was not performed until the consulting physicist returned to the hospital in May 1990, at which time the unit was found to be performing correctly.

The NRC staff acknowledges the fact that the Licensee's consulting physicist brought this problem to the Licensee's attention in February 1990, and that the technologist attempted to conduct the required linearity test in March 1990, as described in the inspection report. However, at the time of the May 1990 inspection, the test had not yet been completed or evaluated. The NRC staff notes that the Licensee had ample time to conduct the required linearity test once it had been brought to its attention by the consultant.

In that this violation occurred despite the Licensee's consulting physicist identifying it as a potential problem, NRC concludes that the Licensee's identification of this violation does not warrant mitigation of the proposed civil penalty within the framework of NRC's Enforcement Policy.

- e. In regard to Violation F, the Licensee stated that the failure to include all required information in patient radiopharmaceutical dosage records had been identified in April and November 1989. The Licensee further stated that it believed that only one patient dose record was incomplete at the time of the May 10, 1990, inspection.

The NRC staff does not dispute the Licensee's statement that it had identified omissions in patient radiopharmaceutical dose records. However, this was a recurring problem and had not been corrected by the time of the January and May 1990 inspections. During the inspection conducted in May 1990, the inspectors determined that the Licensee's technical staff was not familiar with NRC requirements regarding patient dose records. Although the inspector noted in June 1990 that patient dose records showed considerable improvement, there were records which were not entirely complete for three of the five examinations conducted since the previous inspection. (These records were later completed by the technologist.)

In that this violation was recurring and was continuing at the time of NRC's inspections in January and May 1990, NRC concludes that the Licensee's identification of the violation does not warrant mitigation of the proposed civil penalty within the framework of NRC's Enforcement Policy.

- f. In regard to Violation j, the Licensee acknowledged the failure to label radiopharmaceutical syringes or syringe shields, but stated that this problem had been identified in April 1989, and that continued progress to correct the problem had been made.

The NRC staff does not dispute the Licensee's assertion that it identified the failure to label syringes in April 1989. However, the NRC staff notes that, as admitted by a Licensee employee, this was a recurring problem and continued well beyond the Licensee's identification of it.

In that this violation continued well past the Licensee's identification of it, NRC concludes that the Licensee's identification of the violation does not warrant mitigation of the proposed civil penalty within the framework of NRC's Enforcement Policy.

In summary, NRC does not consider the Licensee's arguments in regard to the identification of the violations as warranting mitigation of the civil penalty within the framework of NRC's Enforcement Policy. In NRC's view, the Licensee failed to recognize the extent of its compliance problems, failed to implement immediate corrective actions in response to the consulting physicist's identification of problems, or had failed to implement corrective actions that were successful in correcting a problem and preventing its continuation. In that the problems identified by NRC's inspections were of a continuing nature and were occurring at the time of the inspections, NRC concludes that, in relation to the identification issue, mitigation is not warranted, and that escalation of the base penalty by 50%, as proposed, is appropriate.

2. With regard to corrective actions, the issue here is whether mitigation of the proposed civil penalty is warranted based on the the Licensee's corrective actions taken after NRC's inspections. NRC acknowledges that the Licensee was taking some steps toward correcting the problems identified by NRC's inspections. However, the Licensee's responses referred primarily to actions it believes it had underway even before NRC's inspections took place. For the reasons already discussed, NRC finds those actions to have been lacking and insufficient to correct the problems. At the time of the June 1, 1990, enforcement conference, the Licensee was unable to describe corrective actions to address the scope of NRC's concerns regarding lack of sufficient management oversight to ensure compliance with regulatory requirements. In addition, because the Licensee was unable to describe corrective actions related to the specific violations in the Notice, NRC scheduled and conducted another inspection in June 1990 following the enforcement conference. As a result

of the June inspection, NRC concluded that the corrective actions the Licensee took following NRC's January and May 1990 inspections were neither prompt nor extensive, were narrowly focused on the individual violations, and failed to address the broader issue of management and control of licensed activities. */ The NRC expects full, complete, and long lasting corrective action, whether or not the licensee expects a civil penalty. In regard to the Licensee's resolution of personnel performance-related problems, NRC notes that the former RSO left Newman Memorial Hospital voluntarily and that this occurred after the Licensee was on notice that a civil penalty was possible. For these reasons, NRC concludes in relation to corrective actions that mitigation of the civil penalty is not warranted and that escalation of the base civil penalty by 50%, as proposed, was appropriate.

3. NRC acknowledges that several of the violations may be attributed to the failure of certain Licensee employees to complete required tasks. Nonetheless, as NRC's Enforcement Policy makes clear in Section V.A., licensees are responsible for the actions (or omissions) of their employees. It is a licensee's responsibility to ensure that all individuals participating in licensed activities are well trained and are conducting licensed activities in accordance with NRC regulations and license conditions. Thus, NRC concludes that the circumstances surrounding these particular violations do not warrant consideration of mitigation of the civil penalty.
4. In regard to violation C.1, although the NRC staff acknowledges that these individuals may have worn personal monitoring devices provided by another facility, this does not relieve the licensee of the requirement to provide these devices to employees in activities under this license. Separate devices would indicate in which facility an exposure occurred in order to correct problems and achieve exposures as low as reasonably achievable.
5. NRC's evaluation of the Licensee's arguments in denying three violations in their entirety and one violation in part are addressed in detail above. In that NRC concluded that each of the violations occurred as stated in the Notice, NRC concludes that the Licensee's arguments do not provide a basis for mitigating the civil penalty.

NRC Conclusion

Based on NRC's evaluation of the Licensee's responses, the NRC staff concludes that all violations occurred as stated and that Newman Memorial Hospital has provided no information to cause NRC to modify the proposed civil penalty. Accordingly, the NRC staff concludes that a civil penalty of \$5,000 should be imposed by order.

*/ As a result of a subsequent incident, the Licensee voluntarily suspended licensed activity pending completion of corrective action.



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PENNSYLVANIA 19406
January 31, 1991

Docket No. 030-07022
License No. 29-13613-02
EA 89-80

Process Technology North Jersey
ATTN: John Scandalios
President and Chief Executive
Officer
108 Lake Denmark Road
Rockaway, New Jersey 07866

Gentlemen:

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTIES - \$13,000
(NRC INSPECTION REPORT NO. 89-001 AND NRC INVESTIGATION REPORT
NOS. 1-89-006 and 1-89-0065)

This letter refers to the NRC safety inspection conducted on March 21 and 23, 1989, of activities authorized by NRC License No. 29-13613-02, and to the subsequent investigations conducted by the NRC Office of Investigations (OI). The report of the inspection was forwarded to you on April 17, 1989. The redacted versions of the OI investigation reports were forwarded to you on July 20, 1990. During the inspection and investigations, violations of NRC requirements were identified. On April 26, 1989 and August 14, 1990, enforcement conferences were held with you and members of your staff during which these violations, their causes and safety significance, and your corrective actions were discussed.

The violations are described in the enclosed Notice of Violation and Proposed Imposition of Civil Penalties (Notice). Violation I of the Notice involves inaccurate and incomplete statements by current and former members of your staff during the April 1989 enforcement conference and during the investigations. This violation contains four examples. Example (A) involves your former Plant Manager/Radiation Safety Officer (RSO) and your Vice President/Quality, both of whom during the April 1989 Enforcement Conference failed to acknowledge any keyless entries (climbing over the door) of the irradiator cell, when in fact, these individuals knew of two such entries. Not to have provided the NRC with this information was very significant because these entries bypassed interlocks designed to control access into an irradiator.

Example (B) involves your former RSO who, during the April 1989 enforcement conference, stated that the irradiator operating system computer records all entries into the cell (an assertion used to support that there were no keyless entries made into the cell) when, in fact, this was not true. Not to have

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provided accurate information was significant because the NRC was seeking information on whether the computer verified whether keyless entries occurred even if the source was in the "down" position.

Example (C) involves the former RSO who willfully misrepresented his prior knowledge of damage to the cell door knob. Example (C) also involves the failure of your former Vice President of Operations and Engineering (VP, Ops/Eng) and RSO to acknowledge during the enforcement conference that they were aware that the door to the irradiator cell had been forced open by a former Shift Supervisor/Irradiator Operator (Operator) prior to an audit conducted on February 13, 1989, without the use of a key. In addition the VP, Ops/Eng initially denied to an OI investigator having had knowledge prior to the enforcement conference that this had occurred, although in fact he had been told by the Operator prior to the enforcement conference that the door was forced open. This was significant because the NRC needed such information to understand the chronology of events involving the malfunctioning of the cell door knob and lockin mechanism.

Example (D) involves the former Operator who willfully misinformed the NRC of the manner in which the irradiator cell was improperly accessed by two other Operators. The failure to provide accurate information about how the irradiator was accessed significantly impacted the course of the NRC investigation.

With regard to Example (A) of this violation, your President and Chief Executive Officer (CEO) contends that he did not read the April 24, 1989 memoranda describing the climbing incidents, which he had been sent prior to the enforcement conference until after the enforcement conference and, therefore, was not aware of these occurrences. Your former Vice President of Operations and Engineering (VP, Ops/Eng) also contended he was not aware of these occurrences at the time of the enforcement conference, although your former RSO alleged that the VP, Ops/Eng was told. However, in our view, a CEO and the VP, Ops/Eng of an irradiator should have been aware of this information and the failure to be so informed is significant because of the fact that the failure of the lock mechanism on the Maze Access Door was one of the topics planned to be discussed at the April 26, 1989 enforcement conference, and operators gaining entry into an irradiator cell by climbing over the door is an extraordinary occurrence at an irradiator. Moreover, your Vice President of Quality demonstrated, at a minimum, poor judgment in not being more candid during the enforcement conference.

Violation I raises serious questions regarding the ability and willingness of Process Technology North Jersey to comply with NRC requirements, in particular, the specific NRC requirement that information provided to the NRC be complete and accurate in all material respects. Such concerns were of additional importance since false statements to the NRC, as well as other forms of wrongdoing by senior managers and employees of Radiation Technology, Incorporated (your predecessor company), had previously occurred between 1984 and 1986. Those previous violations resulted in orders suspending your license in March and June 1986, as well as the termination of employment, criminal prosecution and conviction of three former employees, and the incarceration of the former

President, who was also the Radiation Safety Officer in the 1984-1986 time period. While the more recent violations set forth in the enclosed Notice are not considered as egregious as those earlier violations, they are nonetheless disturbing, given the prior operating and enforcement history at this facility, and demonstrate the continuing need to emphasize complete and accurate communications.

A license to use radioactive material is a privilege that confers upon the licensee and 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 its dealings with the NRC, and ensure that any submittal of written or oral information to the NRC be complete and accurate. The number and nature of the violations with respect to the former RSO, including the submittal of inaccurate or incomplete information to NRC, is of particular concern to the NRC. If this individual had still been employed at your facility, the NRC would have considered issuance of an Order precluding him from the performance or supervision of licensed activities.

In addition to the violation set forth in Section I of the Notice, involving the submittal of inaccurate and incomplete information to the NRC, several other violations of NRC requirements were identified during the March 1989 inspection, or during the investigations. These violations are described in Section II of the enclosed Notice. These violations include, but are not limited to: (1) the failure by the plant superintendent, RSO, and VP/Quality to assure that the problem with the personnel access door lock was properly corrected when an operator notified the RSO in February 1989 that the lock was malfunctioning; (2) the deliberate bypassing of administrative procedures, safety interlock, and physical barriers by two operators who entered the irradiator cell by climbing over the irradiator cell access door, a method of entry not permitted by regulatory requirements; and (3) modification of the Irradiator Start-Up procedure by replacement of a certain key operated "time delay" safety switch, without first obtaining prior approval of the Commission. These violations are of particular concern as they represent a significant lack of attention to and carelessness for licensed responsibilities by supervisors and managers at your facility.

In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C (1989), the violation in Section I of the Notice has been classified at Severity Level II because it involves erroneous information on material matters given by supervisors and managers, and at least two examples of a licensee manager or supervisor deliberately providing inaccurate information to the NRC. The violations in Section II of the Notice have been classified in the aggregate at Severity Level III because they represent a significant breakdown in management attention and control of licensed responsibilities.

The NRC recognizes that your CEO had been employed in this capacity for only a short time prior to the March 1989 inspection. The NRC also acknowledges that your subsequent corrective actions, as described in your letter dated August 5, 1990, to the NRC and at the August 1990 enforcement conference, were extensive. These actions included: (1) procedural improvements; (2) increased training of your staff; (3) increased, improved, and expanded audits; and (4) the establishment and active involvement of the Radiation Safety Committee in all matters pertaining to the operation of the irradiator.

Nonetheless, to emphasize the importance of ensuring that (1) licensed activities are conducted safely and in accordance with the conditions of your license; (2) deficiencies, when they exist, are promptly identified and corrected; and (3) all information communicated to the NRC is both complete and accurate, I have been authorized, after consultation with the Commission to issue the enclosed Notice of Violation and Proposed Imposition of Civil Penalties in the amount of \$13,000 for the violations set forth in the enclosed Notice.

The base civil penalty amounts for Severity Level II and III matters are \$8,000 and \$5,000 respectively. Although a higher civil penalty is warranted based on the application of the adjustment factors in the Commission's Enforcement Policy for both the Severity Level II and III matters, after consultation with Commission only the base civil penalty provided under the Policy will be proposed for the violation in Section I and the violations in Section II of the Notice. We are exercising discretion in this case because your performance has been good subsequent to these violations, the violations were identified and/or occurred shortly after a new President and CEO had been appointed by the licensee and he had had minimal opportunity to re-orient the licensee's operations, and for the most part the managers involved in these violations have been removed.

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. This response should also provide your basis for concluding that each person involved in licensed activities understands his or her responsibilities and is committed to assuring that NRC requirements will be followed and 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 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 Penalties

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

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTIES

Process Technology North Jersey
Rockaway, New Jersey

Docket No. 030-07022
License No. 29-13613-02
EA 89-80

During an NRC inspection conducted on March 21 and 23, 1989 at the licensee's facility in Rockaway, New Jersey and subsequent investigations 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 (1989), 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, Pub. L. 96-295, and 10 CFR 2.205. The particular violations and the associated civil penalties are set forth below:

I. VIOLATION ASSOCIATED WITH INACCURATE AND INCOMPLETE STATEMENTS

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, the licensee provided incomplete or inaccurate information to the NRC during an investigation and enforcement conference involving keyless entries into an irradiator cell as evidenced by the following examples:

- A. During an Enforcement Conference with the NRC on April 26, 1989, in response to NRC's repeated questions, information provided by the licensee was incomplete. Specifically, in response to questions as to whether there were unauthorized, keyless entries into the licensee's irradiator cell, the licensee failed to provide information that unauthorized entries had occurred, when in fact, certain of the licensee representatives attending the conference did have knowledge of two such unauthorized entries involving climbing over the irradiator cell door. This omission was material because it directly related to violations of NRC requirements and could have affected the NRC review and investigation into the details of the violations.
- B. During an Enforcement Conference with the NRC on April 26, 1989, information provided by the licensee was inaccurate in that a licensee's representative stated, in response to questions concerning whether the facility's computer logged all entries into the irradiator cell, that the computer log showed all personnel entries through the irradiator cell door and that these logs showed no indication of keyless entries through the cell door.

These statements by the licensee's representative were not accurate, in that the computer log would not record all entries into the irradiator cell. Specifically, the computer would not record cell entries when the source was in the down position. These statements during the Enforcement Conference were material because they could have influenced the NRC review and investigation concerning whether the licensee had the capability of detecting all entries into the irradiator cell and whether there was the possibility that there had been keyless entries which had not been detected and recorded.

- C. During an Enforcement Conference with the NRC on April 26, 1989, information provided by the licensee was inaccurate in that a licensee representative, in response to questions regarding when he first became aware of possible damage to the irradiator cell door knob which led in part to the possibility of the door being forced open, stated that he was not aware of any damage to the cell door knob until an internal audit conducted on February 13, 1989. This statement was inaccurate in that the licensee representative subsequently admitted to an NRC investigator on June 22, 1989, that he was actually informed of the damage to the door knob during the week prior to February 13, 1989. Furthermore, the information provided by the licensee was inaccurate in that, in response to questions regarding whether the licensee was aware that the door to the irradiator cell had been forced open without the use of the key prior to the internal audit conducted on February 13, 1989, licensee representatives denied having such knowledge. This information was inaccurate in that one licensee representative subsequently admitted to the NRC investigator on June 22, 1989, that he had been informed by the licensee's former Shift Supervisor/Irradiator Operator (Operator) prior to the audit that the Operator had forced the door open and a second licensee representative, although initially denying having knowledge of such an entry, in interviews with the NRC investigator on June 21 and July 7, 1989, subsequently admitted on July 7, 1989, that he had in fact been told by the Operator prior to the Enforcement Conference that the Operator had been able to force the door open without a key prior to the February audit. These statements were material because they could have affected the NRC's review of the adequacy of management's response to existing deficiencies and problems.
- D. During an investigation interview with an NRC inspector and investigator on April 11, 1989, a former Shift Supervisor/Irradiator Operator (Operator) provided information that was not accurate in all material respects. The Operator volunteered information that he was aware that two Operators had entered the irradiator cell by forcing the loosened knob on the locked access door. This statement by the Operator was inaccurate in that the Operator subsequently admitted to the NRC investigator on June 8, 1989, that the Operators had actually entered the cell by climbing over the cell door rather than by forcing the door open. This statement was material because it directly

related to the violations of NRC requirements and would have affected the NRC review and investigation into the details of the specific violation.

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

II. VIOLATIONS OF OTHER REGULATORY REQUIREMENTS

- A. 10 CFR 20.203(c)(6)(i) and (vii) requires, in part, that each area in which there may exist radiation levels in excess of 500 rems in one hour at one meter from a sealed radioactive source must have each entrance or access point equipped with entry control devices which shall function automatically to prevent any individual from inadvertently entering the area when such radiation levels exist; and that no operations shall be conducted unless such entry control devices are functioning properly.

Contrary to the above, during the week of February 5, 1989, the personnel access door of the licensee's irradiator cell, an access control to an area in which there may exist radiation levels in excess of 500 rems in one hour at one meter from a sealed radioactive source, was malfunctioning such that inadvertent access to this area was possible; however, the licensee RSO continued operations and did not take sufficient corrective action to permanently repair the mechanism.

- B. Condition 26 of License No. 29-13613-02 requires that licensed material be possessed and used in accordance with statements, representations and procedures contained in the application dated June 3, 1987, and letters dated April 8, 1988, May 25, 1988, June 7, 1988, and September 8, 1988.

Procedure 9.100 B, enclosed in the letter dated May 25, 1988, entitled "Auto Run Mode Irradiator Start-Up," provides in Steps 7.6 through 7.24, directions for routine entries into the irradiator cell. The procedure states that "Deviation from this procedure is prohibited without the express written approval of the RSO or his alternate designated in the license."

Contrary to this requirement, two operators entered the irradiator cell on two separate occasions (some time in September 1988, and some time in either January or February 1989) by climbing over the locked irradiator cell access door, a method not authorized by the procedure, and such entry was not authorized or approved by the RSO or any designated alternate.

- C. Condition 26 of License No. 29-13613-02 requires that licensed material be possessed and used in accordance with statements, representations and procedures contained in the application dated June 3, 1987, and letters dated April 8, 1988, May 25, 1988, June 7, 1988, and September 8, 1988.

Condition 22 of License No. 29-13613-02 requires, in part, that all changes to procedures 9.100, 9.102 and 9.500 be approved, prior to implementation, by the U.S. Nuclear Regulatory Commission.

Procedure 9.100 B enclosed in the letter dated May 25, 1988, entitled "Auto Run Mode Irradiator Start-Up," requires in Step 7.13, activation with the machine key, of the 90-second start-up time delay.

Contrary to the above, on March 9-10, 1989, irradiator start-up did not require activation, with the machine key, of the 90-second start-up time delay. Specifically, the licensee removed the machine-key-operated 90-second start-up time delay switch and installed a toggle switch. In addition, the licensee did not obtain prior approval from the Commission to change this procedure.

- D. Condition 22 of License No. 29-13613-02 requires, in part, that the licensee follow the written instructions contained in procedure 9.500, "Preventative Maintenance." Procedure 9.500 describes various preventive maintenance procedures that must be conducted and their required frequency.

Item 8.0 of Procedure 9.500, Exhibits C and D, describe the parts of the irradiator system that must be checked for proper maintenance on a monthly and quarterly maintenance schedule.

Contrary to the above, between the commencement of operation of the 2102-B irradiator system in August 1988, and the NRC inspection on March 23, 1989, none of the specified quarterly (Exhibit D) maintenance procedures had been performed, and not all of the monthly preventive maintenance procedures (Exhibit C) were performed.

- E. 10 CFR 20.408(b) and 20.409(b), respectively, require the licensee to report to the Commission, and to the individual involved, the radiation exposure of each individual who has terminated employment and of each individual who is not employed by the licensee but has completed a work assignment in the licensee's facility. Such reports shall be furnished within 30 days after the exposure of the individual has been determined by the licensee, or 90 days after the date of termination of employment or work assignment, whichever is earlier.

Contrary to the above, from approximately December 21, 1988, and continuing through March 21, 1989, neither the individuals who had terminated their employment, or who had been reassigned, nor the Commission had been provided with a report of the individuals' radiation exposure within 30 days after their exposure was determined by the licensee, or 90 days after the date of termination of employment or work assignment.

- F. Condition 20.A of License No. 29-13613-02 requires that, within ten working days of the filing of each quarterly third-party audit report, the licensee shall provide to the Commission a written description of any corrective actions in response to the audit findings.

Contrary to the above, as of March 23, 1989, the licensee had not submitted to the Commission a description of corrective actions in response to deficiencies identified during the third-party audit conducted on December 21, 1988.

- G. Condition 15 of License No. 29-13613-02 requires that, after installation of additional cobalt-60 source(s) greater than the quantity for which a previous radiation survey has been conducted, and prior to initiation of the irradiation program, a radiation survey be conducted to determine maximum radiation levels in each area adjoining the irradiation room. A detailed report of the survey is to be sent to the Commission no later than 30 days following the installation of the source(s).

Contrary to the above, on August 15, and November 22 and 23, 1988, additional cobalt-60 source(s) were installed in the irradiator creating a quantity greater than the quantity for which a previous survey had been conducted, and a radiation survey was not conducted to determine the maximum radiation levels in each area adjoining the irradiation room, prior to the subsequent initiation of the irradiation program. Further, a report of a survey performed on September 12, 1988, subsequent to the August 15, 1988 installation, was not sent to the Commission until October 11, 1988 (57 days after installation of the source).

- H. Condition 26 of the License 29-13613-02 requires that the licensee shall conduct its program in accordance with statements, representations and procedures contained in an application dated June 3, 1987, and letters dated April 8, 1988, May 25, 1988, June 7, 1988, and September 8, 1988.

1. Item 4 of Section 9.1.H "Irradiator Control Alarms" contained in the letter dated April 8, 1988, requires that a radiation monitor (that would alarm if high radiation levels existed) mounted above the storage pool be audible in the control room and pool room.

Contrary to the above, on March 23, 1989, the audible alarm installed above the storage pool was only audible in the storage pool room, and was not audible in the control room.

2. Procedure 10.2.E.3. submitted in the letter dated June 7, 1988, requires that the radiation monitor on the water treatment system be checked for proper functioning monthly using a portable radiation survey instrument.

Contrary to the above, for at least the three months prior to March 1989, the monitor on the water treatment system had not been checked for proper functioning using a portable survey instrument.

These violations have been classified in the aggregate at Severity Level III (Supplements IV and VI).

Cumulative Civil Penalty - \$5,000 (assessed \$1,000 for Violation A, \$1,000 for Violation B, \$1,000 for Violation C, \$450 for Violation D, \$100 for Violation E, \$100 for Violation F, \$450 for Violation G, \$450 for Violation H.1, \$450 for Violation H.2.)

Pursuant to the provisions of 10 CFR 2.201, Process Technology North 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 Penalties (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 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 "Answer to a Notice of Violation" and may: (1) deny the violations(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, 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 (1989), should be addressed. Any written answer in accordance with 10 CFR 2.205 should be set forth separately from the statement or explanation in reply pursuant to 10 CFR 2.201, but may incorporate parts of the 10 CFR 2.201 reply by specific reference (e.g., citing page and paragraph numbers) to avoid repetition. The attention of the Licensee is directed to the other provisions of 10 CFR 2.205, regarding the procedure for imposing civil penalties.

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

The response noted above (Reply to Notice of Violation, letter with payment of civil penalties, and Answer to a Notice of Violation) should be addressed to: Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555 with a copy to the Regional Administrator, U.S. Nuclear Regulatory Commission, Region I, 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 3/5th day of January 1991



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

June 13, 1990

Docket Nos. 030-09761
030-12688
License Nos. 29-06760-07
29-06760-08

EA 90-061

Radiology-Ultrasound-Nuclear
Consultants, PA
Radiology-Oncology Clinic
ATTN: G. Anthony Doener, M.D.
303 West Main Street
Freehold, New Jersey 07728

Gentlemen:

Subject: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY - \$1000
(NRC Inspection No. 90-001)

This letter refers to the NRC inspection conducted on March 14, 1990, at your facility in Freehold, New Jersey, of activities authorized by NRC License Nos. 29-06760-07 and 29-06760-08. The inspection report was sent to you on April 6, 1990. During the inspection, violations of NRC requirements were identified. On April 19, 1990, an enforcement conference was conducted with you and one of your employees to discuss the violations, their causes, and your corrective actions.

The violations, which are described in the enclosed Notice of Violation and Proposed Imposition of Civil Penalty, include, but are not limited to: (1) failure to perform certain checks and calibrations of equipment used at your facility, including the required checks of the permanent radiation monitor installed in the teletherapy unit room prior to initiating patient treatments; (2) failure to perform the dose calibrator linearity tests at the required frequency, or to properly plot the results when performed; (3) failure by the Radiation Safety Officer to wear ring badges, as required, when handling licensed materials; and (4) failure to maintain certain required records of licensed activities.

These violations are of particular concern to the NRC not only because of the number of violations, but also because certain of the violations involve multiple examples. For example, the permanent radiation monitor installed in the teletherapy unit room was not checked on any day prior to use of the teletherapy unit (Violation A), and the dose calibrator was not tested for linearity once each quarter on more than one occasion prior to this inspection (Violation F). The NRC is also concerned that Violation F was identified during the two previous inspections at your facility in 1983 and 1986.

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Notwithstanding the issuance of a Notice of Violation for this matter on September 8, 1983 and again on September 4, 1986, adequate corrective action was not taken to prevent recurrence of this violation.

These violations collectively demonstrate the need for increased and improved attention to your radiation safety program to ensure that activities are conducted safely and in accordance with the terms of your licenses. To emphasize this need, I have been authorized, after consultation with the Director, Office of Enforcement, and the Deputy Executive Director for Nuclear Materials Safety, Safeguards and Operations Support, to issue the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice) in the amount of \$1000 for the violations described in the enclosed Notice. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C (1990) (Enforcement Policy), the violations set forth in the enclosed Notice have been classified in the aggregate as a Severity Level III problem to focus on our underlying concern, namely, a lack of management attention to licensed activities.

The base civil penalty for a Severity Level III violation is \$500. The escalation and mitigation factors set forth in Sections V.B.1 - V.B.6 of the enforcement policy were considered, and the base civil penalty has been escalated by 100% because: (1) the violations were identified by the NRC and should reasonably have been identified sooner if the licensee had provided adequate attention to, and oversight of, licensed activities, and, therefore, 50% escalation on this factor is warranted; and (2) your corrective actions were neither prompt nor comprehensive and, in fact, had not been initiated for some items at the time of the conference (such as performing dose calibrator linearity tests and possessing a dedicated check source for your survey meter) and, therefore, 50% escalation on this factor is warranted. Your past performance over the last two inspections included a total of seven violations, and, therefore, no adjustment on this factor is warranted. The other escalation and mitigation factors were considered and no further adjustment is warranted.

You are required to respond to this letter and the enclosed Notice, 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 take to prevent recurrence. Furthermore, you should describe the actions taken or planned to increase and improve management attention to your radiation safety program.

After reviewing your response to this Notice, including your proposed corrective actions and the results of future inspections, the NRC will determine whether further NRC enforcement action is needed to ensure compliance with regulatory requirements. We emphasize that any recurrence of these violations may result in more significant enforcement action.

Two of the apparent violations set forth in the inspection report, involving an apparent overexposure in 1986, as well as the failure to report it, are not being cited. Our decision not to cite these violations is based on your reasonable explanation that the apparent overexposure did not occur, as

documented in your letters dated March 21, April 4, and April 27, 1990, and as explained at the enforcement conference. Further, at the conference, the individual who was the recipient of the apparent overexposure indicated that she did not perform any activity involving NRC regulated material that would likely cause such an overexposure and she was certain that she did not receive the dose indicated on the film badge.

In accordance with Section 2.790 of the NRC's "Rules of Practice," Part 2, Title 10, Code of Federal Regulations, a copy of this letter and its 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 1990, Pub. L. No. 96-511.

Sincerely,



Thomas T. Martin
Regional Administrator

Enclosure:
Notice of Violation and Proposed
Imposition of Civil Penalty

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

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

Radiology-Ultrasound-Nuclear Consultants, PA
Freehold, New Jersey

Docket Nos. 030-09761
030-12688
License Nos. 29-06760-07
29-06760-08
EA 90-061

During an NRC inspection conducted on March 14, 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. 10 CFR 35.615(d)(3) requires that the permanent radiation monitor installed in each teletherapy room be checked with a dedicated check source for proper operation each day before the teletherapy unit is used for treatment of patients.

Contrary to the above, on those days prior to March 14, 1990 that the teletherapy unit was used for treatment of patients, the permanent radiation monitor in the teletherapy room was not checked with a dedicated check source for proper operation before the teletherapy unit was used for treatment.

- B. 10 CFR 35.634(f) requires, in part, that a licensee's retained record of each spot-check required by 10 CFR 35.634(a) and (d) must include, among other things, the difference between the anticipated output and the measured output of the teletherapy unit.

Contrary to the above, as of March 14, 1990, the licensee's retained spot check records did not include the difference between the anticipated output and the measured output of the teletherapy unit.

- C. 10 CFR 35.70(h) requires, in part, that a licensee retain for three years a record of each survey. 10 CFR 35.70 (a) requires, in part, that a licensee survey at the end of each day of use all areas where radiopharmaceuticals are routinely prepared for use or administered.

Contrary to the above, as of March 14, 1990, the licensee did not retain records of daily surveys of areas where radiopharmaceuticals were routinely prepared for use or administered.

- D. 10 CFR 35.632(a)(2)(i) requires that a licensee perform full calibration measurements on each teletherapy unit whenever the spot-check measurements indicate that the output differs by more than 5 percent from the output obtained at the last full calibration, corrected mathematically for radioactive decay.

Contrary to the above, the licensee did not perform full calibration measurements when spot check measurements performed by the licensee in November 1986, in January, February, March, May and June 1987, and in March 1988, indicated that the teletherapy unit output differed by more than 5 percent from the output obtained at the last full calibration.

- E. 10 CFR 35.21(a) requires that a licensee appoint a Radiation Safety Officer responsible for implementing the radiation safety program. The licensee through the Radiation Safety Officer, is required to ensure that radiation safety activities are performed in accordance with approved procedures. 10 CFR 35.21(b)(2) requires, in part, that the Radiation Safety Officer (RSO) establish and implement written policy and procedures for using byproduct material safely and performing checks of survey instruments and other safety equipment.

For using byproduct materials safely and performing checks of survey instruments and other safety equipment, the licensee's Radiation Safety Officer established the procedures in NRC Regulatory Guide 10.8, Revision 2, Appendix C and D, which are required by Condition 13 of License No. 20-06760-08 to be met.

Appendix C requires, in part that the measurements obtained during the dose calibrator linearity test be plotted and that the percent deviation be determined. Appendix D requires, in part, that all individuals who are occupationally exposed to ionizing photon radiation on a regular basis be issued a film or TLD whole body monitor and that individuals who, on a regular basis handle radioactive material that emits ionizing photon, be issued a film or TLD finger monitor to be processed on a monthly basis.

Contrary to the above:

1. between January 1987 and February 1988, the dose calibrator linearity test results did not include either a plot of the measurements or a determination of the percent deviation.
2. as of March 14, 1990, the RSO neither wore the issued whole body monitor while working with radioactive material on a regular basis, nor was he issued a finger monitor for use when handling radioactive material.

- F. 10 CFR 35.50(b)(3) requires, in part, that the licensee test the dose calibrator for linearity at least quarterly.

Contrary to the above, the licensee did not test the dose calibrator for linearity during the last three quarters of 1988, nor at any time during 1989.

This is a repeat violation

- G. 10 CFR 35.51(a)(3) and (c) require that a licensee conspicuously note on each survey instrument the apparent exposure rate from a dedicated check source as determined at the time and date of the calibration and check each survey instrument for proper operation with the dedicated check source each day of use.

Contrary to the above, as of March 14, 1990, the licensee did not conspicuously note on the survey instrument the apparent exposure rate from a dedicated check source as determined at the time and date of the calibration, and did not check each survey instrument for proper operation with a dedicated check source each day of use.

- H. 10 CFR 35.92(b) requires that a licensee retain a record of each disposal of byproduct material held for decay-in-storage as permitted under 10 CFR 35.92(e) for three years. The record must include, among other things, the date on which the byproduct material was placed in storage, the radionuclides disposed, and the background dose rate.

Contrary to the above, as of March 14, 1990, the licensee's retained records of disposal of byproduct material held for decay-in-storage did not include the date on which the byproduct material was placed in storage; the radionuclides disposed; or the background dose rate.

These violations have been classified in the aggregate as a Severity Level III problem. (Supplement VI)

Civil Penalty - \$1000 - (assessed equally among the 9 violations)

Pursuant to the provisions of 10 CFR 2.201, Radiology-Ultrasound-Nuclear Consultants, PA (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. 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 Atomic Energy Act, 42 U.S.C. 2232, this response shall be submitted under oath or affirmation.

Within the same time as provided for the response required above under 10 CFR 2.201, the Licensee may pay the civil penalty by letter to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, with a check, draft, 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, 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 Atomic Energy Act, 42 U.S.C. 2282c.

The responses to the Director, Office of Enforcement, noted above (Reply to a Notice of Violation, letter with payment of civil penalty, and Answer to a Notice of Violation) should be addressed to: Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 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 13th day of June 1990



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

FEB 22 1991

Docket Nos. 030-09761 and 030-12688
License Nos. 29-06760-07 and 29-06760-08
EA 90-061

Radiology-Ultrasound-Nuclear
Consultants, PA
Radiology-Oncology Clinic
ATTN: G. Anthony Doener, M.D.
303 West Main Street
Freehold, New Jersey 07728

Gentlemen:

SUBJECT: ORDER IMPOSING A CIVIL MONETARY PENALTY - \$1,000

This letter refers to your letter dated "June 21 to July 10, 1990," in response to the Notice of Violation and Proposed Imposition of Civil Penalty (Notice) sent to you by our letter dated June 13, 1990. Our letter and Notice described violations that were identified during an NRC inspection conducted on March 14, 1990. The violations involved the failure to perform certain licensed activities in accordance with regulatory requirements. To emphasize the need for increased and improved attention to your radiation safety program to ensure that activities are performed safely and in accordance with the terms of your licenses, a civil monetary penalty of \$1,000 was proposed.

In your response to the Notice, you have (1) admitted Violation D (but asserted it is irrelevant); (2) denied Violation A; and (3) denied Violation C, in that you contend that you have recorded daily wipe tests. Further, you have not explicitly admitted or denied Violations B, E.1, E.2, F, G, and H. You also requested cancellation of the proposed civil penalty. In addition, you discussed an issue involving a film badge record that our Notice did not raise, as well as the manner in which the Enforcement Conference was called. Because the film badge issue was not raised in our Notice, it is not the subject of the enclosed Order Imposing a Civil Penalty. The NRC staff considered the matter resolved by the Enforcement Conference. After consideration of your response, we have concluded, for the reasons given in the Appendix attached to the enclosed Order Imposing a Civil Monetary Penalty, that the violations did occur as stated in the Notice, with the exception of Violation E.2. The Licensee's response leaves no doubt that the Licensee violated the NRC requirements associated with Violation E.2 as stated in the Notice. Accordingly, the NRC staff has amended Violation E.2, as set forth in the Appendix to the enclosed Order, to clarify it. Because the Licensee's response demonstrates that Violation E.2, as amended, occurred, the NRC staff concludes that Violation E.2, as amended

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RETURN RECEIPT REQUESTED

for clarification, should replace Violation E.2 as stated in the Notice, and that the amendment of Violation E.2 should have no effect on the civil penalty. In addition, the NRC staff concludes, for reasons set forth in the Appendix to the enclosed Order, that mitigation of the civil penalty is inappropriate. Accordingly, we hereby serve the enclosed Order on Radiology Ultrasound - Nuclear Consultants, PA imposing a civil monetary penalty in the amount of \$1,000.

In your response to the Notice, you questioned the NRC's practices for conducting an enforcement conference, in particular suggesting that you had the right to be represented by an attorney at the conference in the same manner that a person accused of committing a crime has a right to legal counsel. While we have no objection to your bringing counsel to an enforcement conference and many licensees do so, the NRC's enforcement action in this case is a civil action, and not a criminal action. In a civil action, a person may obtain counsel as he or she sees fit, but the outcome of a civil action is valid irrespective of whether a person is represented by counsel. Note that an adjudicatory proceeding involving the violations identified in the Notice has not yet begun. It will begin only if you request a hearing on the enclosed Order. Moreover, the purpose of the enforcement conference was to (1) discuss the violations, their significance and causes, and your corrective actions, (2) determine whether there were any aggravating or mitigating circumstances, and (3) obtain other information to help determine the appropriate enforcement action. (See "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C (1990)). This enforcement conference was a preliminary step in the enforcement process designed to provide the licensee an opportunity to provide information to the NRC. In view of the above, the NRC staff concludes that the enforcement conference in this case was held in accordance with law and Commission policy.

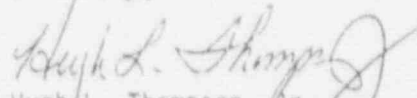
The NRC also notes that your response to the Notice did not provide information adequate to enable the NRC to assess the effectiveness of your corrective actions. Your response did not fulfill NRC's requirements set forth in 10 CFR 2.201(a) and the Notice to describe the corrective steps that have been taken and the results achieved, the corrective steps that will be taken to avoid further violations, and the date when full compliance will be achieved for each violation stated in the Notice. Specifically, you did not give any description of your corrective actions for Violations C, D, E, and F, and for Violations A, G, and H, you only stated the action you had taken to stop their immediate continuation. Additionally, for Violation B, the statement you made under the heading "Corrective Action" does not indicate that you took any action. Moreover, you did not describe any action you have taken to avoid further violations. Nevertheless, the NRC is giving you another opportunity to satisfy these NRC requirements. This information shall be submitted to the Regional Administrator, NRC Region I, 475 Allendale Road, King of Prussia, PA 19406, within 30 days of the date of this letter. Failure to provide such information could be considered a willful violation and may result in further escalated enforcement action, which could include further civil penalties or orders modifying, suspending, or revoking your license. We will review the effectiveness of your corrective actions during a subsequent inspection.

Radiology-Ultrasound-Nuclear
Consultants, PA

- 3 -

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

Sincerely,



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

Enclosures: As Stated

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

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 in the Notice, with the exception of Violation E.2, which needed clarification. The NRC staff, as set forth in the Appendix to this Order, has determined that: (1) the Licensee violated the NRC requirements associated with Violation E.2 as stated in the Notice; (2) Violation E.2 should be amended for clarification of the violation; and (3) the amendment of Violation E.2 should have no effect on the civil penalty. In addition, as set forth in the Appendix to this Order, the NRC staff has determined that cancellation of the civil penalty is not warranted 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 \$1,000 within 30 days of the date of this Order, by check, draft, money order, or electronic transfer, payable to the Treasurer of the United States and mailed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555.

The Licensee may request a hearing within 30 days of the date of this Order. A request for a hearing shall be clearly marked as a "Request for an Enforcement Hearing" and shall be addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, 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 described in Violations A, B, C, E.1, F, G, and H set forth in the Notice referenced in Section II above and Violation E.2, as amended and as set forth in the Appendix to this Order referenced in Section III above, which the Licensee either denied, or did not admit or deny, and

(b) whether, on the basis of the violations referred to in Section V.(a) above, and Violation D set forth in the Notice, which the Licensee admitted, this Order should be sustained.

FOR THE NUCLEAR REGULATORY COMMISSION



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

Dated at Rockville, Maryland
this 22nd day of February 1991

APPENDIX

EVALUATION AND CONCLUSION

On June 13, 1990, a Notice of Violation and Proposed Imposition of Civil Penalty (Notice) was issued for violations identified during an NRC inspection. Radiology-Ultrasound-Nuclear Consultants, PA (G. Anthony Doener, M.D.) (Licensee) responded to the Notice by letter dated June 21 - July 10, 1990. In its response, the Licensee: (1) admitted Violation D (but asserted Violation D is irrelevant); (2) denied Violations A and C; and (3) neither admitted nor denied Violations B, E.1, E.2, F, G, and H. The Licensee also requested cancellation of the civil penalty. The NRC's evaluation and conclusion regarding the Licensee's requests are as follows:

Restatement of the Violations

- A. 10 CFR 35.615(d)(3) requires that the permanent radiation monitor installed in each teletherapy room be checked with a dedicated check source for proper operation each day before the teletherapy unit is used for treatment of patients.

Contrary to the above, on those days prior to March 14, 1990 that the teletherapy unit was used for treatment of patients, the permanent radiation monitor in the teletherapy room was not checked with a dedicated check source for proper operation before the teletherapy unit was used for treatment.

- B. 10 CFR 35.634(f) requires, in part, that a licensee's retained record of each spot-check required by 10 CFR 35.634(a) and (d) must include, among other things, the difference between the anticipated output and the measured output of the teletherapy unit.

Contrary to the above, as of March 14, 1990, the licensee's retained spot check records did not include the difference between the anticipated output and the measured output of the teletherapy unit.

- C. 10 CFR 35.70(h) requires, in part, that a licensee retain for three years a record of each survey. 10 CFR 35.70(a) requires, in part, that a licensee survey at the end of each day of use all areas where radiopharmaceuticals are routinely prepared for use or administered.

Contrary to the above, as of March 14, 1990, the licensee did not retain records of daily surveys of areas where radiopharmaceuticals were routinely prepared for use or administered.

- D. 10 CFR 35.632(a)(2)(i) requires that a licensee perform full calibration measurements on each teletherapy unit whenever the spot-check measurements indicate that the output differs by more than 5 percent from the output obtained at the last full calibration, corrected mathematically for radioactive decay.

Contrary to the above, the licensee did not perform full calibration measurements when spot check measurements performed by the licensee in

November 1986, in January, February, March, May and June 1987, and in March 1988, indicated that the teletherapy unit output differed by more than 5 percent from the output obtained at the last full calibration.

- E. 10 CFR 35.21(a) requires that the Licensee appoint a Radiation Safety Officer responsible for implementing the radiation safety program. The licensee, through the Radiation Safety Officer, is required to ensure that radiation safety activities are performed in accordance with approved procedures. 10 CFR 35.21(b)(2) requires, in part, that the Radiation Safety Officer (RSO) establish and implement written policy and procedures for using byproduct material safely and performing checks of survey instruments and other safety equipment.

For using byproduct materials safely and performing checks of survey instruments and other safety equipment, the Licensee's Radiation Safety Officer established the procedures in NRC Regulatory Guide 10.8, Revision 2, Appendix C and D, which are required by Condition 13 of License No. 29-06760-08 to be met.

Appendix C requires, in part, that the measurements obtained during the dose calibrator linearity test be plotted and that the percent deviation be determined. Appendix D requires, in part, that all individuals who are occupationally exposed to ionizing photon radiation on a regular basis be issued a film or TLD whole body monitor and that individuals who, on a regular basis handle radioactive material that emits ionizing photon radiation, be issued a film or TLD finger monitor to be processed on a monthly basis.

Contrary to the above:

1. between January 1987 and February 1988, the dose calibrator linearity test results did not include either a plot of the measurements or a determination of the percent deviation.
 2. as of March 14, 1990, the RSO neither wore the issued whole body monitor while working with radioactive material on a regular basis, nor was he issued a finger monitor for use when handling radioactive material.
- F. 10 CFR 35.50(b)(3) requires, in part, that the Licensee test the dose calibrator for linearity at least quarterly.

Contrary to the above, the Licensee did not test the dose calibrator for linearity during the last three quarters of 1988, nor at any time during 1989.

This is a repeat violation.

- G. 10 CFR 35.51(a)(3) and (c) require that a licensee conspicuously note on each survey instrument the apparent exposure rate from a dedicated check source as determined at the time and date of the calibration and check each survey instrument for proper operation with the dedicated check source each day of use.

Contrary to the above, as of March 14, 1990, the licensee did not conspicuously note on the survey instrument the apparent exposure rate from a dedicated check source as determined at the time and date of the calibration, and did not check each survey instrument for proper operation with a dedicated check source each day of use.

- H. 10 CFR 35.92(b) requires that a licensee retain a record of each disposal of byproduct material held for decay-in-storage as permitted under 10 CFR 35.92(a) for three years. The record must include, among other things, the date on which the byproduct material was placed in storage, the radionuclides disposed, and the background dose rate.

Contrary to the above, as of March 14, 1990, the licensee's retained records of disposal of byproduct material held for decay-in-storage did not include the date on which the byproduct material was placed in storage; the radionuclides disposed; or the background dose rate.

These violations have been classified in the aggregate as a Severity Level III problem. (Supplement VI)

Civil Penalty - \$1,000 - (assessed equally among the 9 violations)

Summary of Licensee's Response

Violation A

The licensee denies Violation A. The Licensee asserts that the permanent radiation monitor in the teletherapy room is checked each day as required, and is also checked before each radiation treatment using the cobalt unit as a dedicated check source. The Licensee states that a special dedicated check source is not used because this would result in unnecessary exposure to the radiation worker. The Licensee also states that no written records of the daily routine checks are kept because the checks are considered a "normal routine."

NRC Evaluation of Licensee's Response

Violation A

The Licensee is required to check the permanent radiation monitor in the teletherapy room with the cobalt unit each day before the teletherapy unit is used for treatment of patients. However, on the day of the inspection, the NRC inspector observed the Licensee treat the day's first patient with the teletherapy unit without checking the radiation monitor with the cobalt unit or any other dedicated check source. Further, when questioned by the inspector, the Radiation Safety Officer stated that he does not check the monitor until he begins the treatment. The regulation clearly requires that

the monitor be checked before the teletherapy unit is used for treatment of a patient. Therefore, the NRC concludes that the violation occurred as stated.

Summary of Licensee's Response

Violation B

The Licensee asserts that the anticipated output and the measured output of the teletherapy unit are recorded, and that the difference between the two measurements is self-explanatory.

NRC Evaluation of Licensee's Response

Violation B

The NRC agrees that the Licensee's records specified the measured output and the anticipated output of the teletherapy unit. However, these records did not include the difference between the two output values expressed as a percentage of the anticipated output as required by 10 CFR 35.634(b)(6). Therefore, the NRC concludes that the violation occurred as stated.

As a separate matter, the NRC acknowledges that, as indicated in 10 CFR 35.634, "Periodic spot-checks," item (a)(6) contains a typographical error. This item references the measured output required by paragraph (a)(5), not paragraph (b)(5) as stated in the regulation. A correction of this typographical error will be incorporated into the NRC's next revision of Part 35.

Summary of Licensee's Response

Violation C

The Licensee denies Violation C. The Licensee states that areas where radiopharmaceuticals are routinely prepared for use and administration are continuously surveyed by a Geiger instrument equipped with an acoustic alarm. The Licensee asserts that the acoustic alarm is better "perceived" than a visual reading of a monitoring instrument which might go unnoticed. Therefore, the Licensee maintains that any excess radioactivity is readily monitored. The Licensee also states that the daily wipe tests of areas where radiopharmaceuticals are used is recorded.

NRC Evaluation of Licensee's Response

Violation C

Continual acoustical monitoring may be superior to a visual reading from a survey instrument for a given purpose. Monitoring with a Geiger instrument, however, does not by itself satisfy the requirements of 10 CFR Part 30.70(h) to retain records of the results of certain surveys. While the NRC agrees that the Licensee performed and documented wipe tests beyond those required by 10 CFR 35.70(e), those tests detect removable surface contamination, and do not measure the ambient radiation exposure rates that 10 CFR Part 35.70(h) requires to be recorded. The Licensee did not retain records of surveys required by 10 CFR Part 35.70(a).

The Licensee did not document these surveys. Therefore, the NRC concludes the violation occurred as stated.

Summary of Licensee's Response

Violation D

The Licensee admits that spot check measurements of the teletherapy unit indicated that the teletherapy unit output differed by more than 5% from the output obtained at the last full calibration. However, the Licensee asserts this fact is irrelevant because: (1) the measuring instruments have an inaccuracy of more than 5%; and (2) Cobalt-60 decay is at a constant rate. Therefore, the Licensee asserts the required tests do not represent a test of the cobalt unit, but only represent a test of the measuring instrument which has no significance concerning the output of the cobalt unit. For these reasons, the Licensee concludes that spot check measurements exceeding +/-5% do not justify the expense it would incur to perform a full calibration of the cobalt unit and suggests that the NRC rescind the requirement for recalibration of the teletherapy unit under these circumstances since it constitutes an unnecessary burden on the workers and patients.

NRC Evaluation of Licensee's Response

Violation D

The Licensee admits the violation. As for the Licensee's contention that the violation is irrelevant to safety, the difference between the measured output and the anticipated output may indicate problems with the teletherapy unit such as malfunction of the timer, the collimator, or the source drive mechanism. The measured dose and doses administered to patients are not solely dependent on the decay of the source. In addition, the formula used to calculate the output dose from a spot check measurement contains a correction factor to compensate for any measuring instrument inaccuracy. Accordingly, the NRC staff concludes that Violation D is a significant violation.

Summary of Licensee's Response

Violation E

The Licensee did not admit or deny Violation E.1 in its response.

With respect to Violation E.2, the Licensee neither admits nor denies the violation. The Licensee asserts that the RSO did in fact wear a whole body monitor while working with radioactive material and that he exhibited the monitor to the inspector at the time of the inspection. The Licensee did acknowledge that the RSO had lost his finger monitor. The Licensee also points out that the RSO always wore a pocket dosimeter which is checked with a cesium source.

NRC Evaluation of Licensee's ResponseViolation E

The Licensee did not admit or deny Violation E.1. The Licensee enclosed a letter concerning a linearity test of the cobalt unit timer, but the violation involves linearity test results for the dose calibrator, which is used for administering radiopharmaceuticals to patients. Therefore, based on the inspector's review during the inspection, the NRC concludes that the violation occurred as stated.

With respect to Violation E.2, the NRC has clarified the citation, upon reconsideration of the matter based on the Licensee's response. The NRC acknowledges that the RSO wore a whole body badge while working with radioactive material. However, the particular badge worn by the RSO is assigned from a local hospital and is not a whole body badge assigned to monitor exposure received exclusively while working at the Licensee's private practice facility. Under these circumstances, if an exposure were to occur, the Licensee would not be able to immediately ascertain from which facility, and under what conditions, the exposure occurred. In addition, the RSO admitted that he had lost his finger monitor and had not been wearing it. Under such conditions (the loss of the finger monitor) activities should not have continued without the finger monitor having been replaced. Therefore, it is clear from the Licensee's response that the RSO did not use a whole body badge issued by the Licensee nor did he use a finger badge issued by the Licensee. Accordingly, the Licensee was in violation of 10 CFR 35.21(a) and (b) as set forth in the amended Violation E.2 and restated below.

Restatement of Violation E.2, as Amended

E.2 10 CFR 35.21(a) requires that the licensee appoint a Radiation Safety Officer responsible for implementing the radiation safety program. The licensee, through the Radiation Safety Officer, is required to ensure that radiation safety activities are performed in accordance with approved procedures. 10 CFR 35.21(b)(2) requires, in part, that the Radiation Safety Officer (RSO) establish and implement written policy and procedures for using byproduct material safely and performing checks of survey instruments and other safety equipment.

For using byproduct materials safely and performing checks of survey instruments and other safety equipment, the licensee's Radiation Safety Officer established procedures in accordance with NRC Regulatory Guide 10.8, Revision 2, (Reg Guide 10.8) Appendix D, which is required by Condition 13 of License No. 29-06760-08 to be met.

Appendix D of Reg Guide 10.8 requires, in part, that all individuals who are occupationally exposed to ionizing photon radiation on a regular basis be issued a film or TLD whole body monitor and that individuals who, on a regular basis handle radioactive material that emits ionizing photon radiation, be issued a film or TLD finger monitor to be processed on a monthly basis.

Contrary to the above as of March 14, 1990, the RSO neither wore a whole body monitor issued by the Licensee while working with radioactive material on a regular basis, nor did he wear a finger monitor issued by the Licensee for use when handling radioactive material.

Summary of Licensee's Response

Violation F

The Licensee did not admit or deny Violation F, but argued that, because of its practices for administering radiopharmaceuticals, it has a wide margin for error in measuring dose activity before any error would cause the Licensee to give any excessive dose to its patients.

NRC Evaluation of Licensee's Response

Violation F

The Licensee did not admit or deny Violation F. The staff finds no validity in the Licensee's argument that, because of its practices for administering radiopharmaceuticals, it has a wide margin for error in measuring dose activity before the error would cause the Licensee to give any excessive dose to its patients. The Licensee had not performed a linearity test of its dose calibrator in over one year. This test is of safety significance because it is one of the quality assurance tests that assures that the dose given is within the parameters set by the regulations of the NRC. Dose calibrator quality assurance testing is also supported by national equipment standards of the American National Standards Institute, safety recommendations of the National Council on Radiation Protection and Measurements, and accepted practice of the American College of Nuclear Physicians. Without such testing, the Licensee cannot assure its dose calibrator response is within the appropriate range over the activity ranges it uses. Without such quality assurance testing, a failure of the dose calibrator would not be detected and could contribute to a misadministration. Therefore, based on the inspector's observation during the inspection, the NRC concludes that the violation occurred as stated and is safety significant.

Summary of Licensee's Response

Violation G

The Licensee did not specifically admit or deny Violation G. The Licensee states that it now has labeled its radiation survey meter and has indicated the apparent exposure rate from a dedicated source of cesium-137. The Licensee also states that it has used dedicated check sources, either Cesium-137 or Radium 227 regularly.

NRC Evaluation of Licensee's Response

Violation G

The Licensee did not admit or deny Violation G. The Licensee stated it now has indicated the apparent exposure rate from a dedicated cesium-137 source

on the label on the radiation survey instrument. The Licensee also states that it has regularly used its dedicated check sources. The NRC acknowledges that during the inspection the Licensee stated it performed a check of its survey instrument for proper operation with a dedicated check source each day of use. However, according to the Licensee's consultant, the Licensee did not supply a dedicated check source to the consultant at the time that the consultant performed the calibration of the Licensee's survey instruments. An apparent exposure rate from a dedicated check source was not determined. Since the exposure rate from a dedicated check source was not determined at the time of instrument calibration, the daily checks by the Licensee did not fulfill the requirements of 10 CFR 35.51(a)(3) and (c) as stated in Violation G. Therefore, the NRC concludes that the violation occurred as stated.

Summary of Licensee's Response

Violation H

The Licensee did not specifically admit or deny Violation H. The Licensee states it "checks" its waste (consisting of alcohol pads) with a crystal probe after every injection before it is put into storage and that it has never encountered any activity in the waste.

NRC Evaluation of Licensee's Response

Violation H

Although the Licensee asserts that its surveys of all waste after use indicated that the waste material was non-radioactive, the Licensee treated the material as byproduct material held for decay-in-storage (radioactive waste). In addition, contrary to the Licensee's assertion, it has been the NRC's experience that alcohol pads (held over injection sites) are radioactively contaminated and should be treated as radioactive waste. Because the Licensee treats its waste material (alcohol pads) as radioactive waste, it is required to maintain waste disposal records which reflect the information required by 10 CFR 35.92(b). Specifically, the Licensee's waste disposal records did not contain: (1) the date on which the byproduct material was placed in storage; (2) the radionuclides disposed; and (3) the background dose rates. Therefore, the NRC concludes that violation occurred as stated.

Summary of Licensee's Request for Mitigation

The Licensee requested cancellation of the civil penalty; however, no basis for this request was provided.

NRC Conclusion

The licensee provided information which the NRC considered in amending Violation E.2 to clarify the citation. However, it is clear from the Licensee's response that it was in violation of Violation E.2, as amended and restated in this Appendix. Therefore, for the reasons set forth above, the NRC has concluded that the violations occurred as stated in the Notice of Violation and as amended and restated in this Appendix. No basis for mitigation of the civil penalty was provided. As a result, the NRC finds that mitigation of the civil penalty is not warranted. Accordingly, the NRC concludes that a civil penalty in the amount of \$1,000 should be imposed for the violations set forth in the Notice.



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

SEP 20 1990

Docket No. 4U-06027
License No. SUB-1010
EA 90-162

Reav Graves, President
Sequoyah Fuels Corporation
Sequoyah Facility
I-40 and Highway 10
Gore, Oklahoma 74435

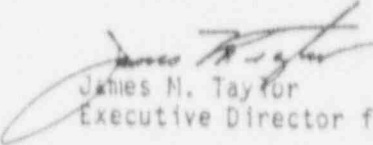
Gentlemen:

Subject: Order Modifying License

Enclosed is an Order Modifying License requiring that Sequoyah Fuels Corporation characterize the site, take actions to prevent further releases of contaminated water, and conduct appropriate monitoring of ground water. The Order is based on concerns that uranium contaminated water seeping from underneath the main process building may contaminate ground water and the environment in the plant's unrestricted area.

The issuance of this Order does not preclude the NRC from considering and taking enforcement actions for the contamination that led to the issuance of this Order. In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter and the enclosed will be placed in the NRC's Public Document Room.

Sincerely,


James N. Taylor
Executive Director for Operations

Enclosure: As stated

UNITED STATES
NUCLEAR REGULATORY COMMISSION

In the Matter of

SEQUOYAH FUELS CORPORATION
Sequoyah Facility
I-40 and Highway 10
Gore, Oklahoma 74435

} Docket No. 40-08027
} License No. SUB-1010
} EA 90-162

ORDER MODIFYING LICENSE

I

Sequoyah Fuels Corporation (SFC or Licensee) is the holder of Source Material License No. SUB-1010 issued by the Nuclear Regulatory Commission (NRC or Commission) pursuant to 10 CFR Part 40. The license authorizes the Licensee to possess and use source material for the purpose of refining uranium from uranium ore concentrates and converting this uranium to uranium hexafluoride (UF₆) for use by enrichment facilities. The license, was most recently renewed on September 20, 1985, and will expire on September 30, 1990, and the licensee has submitted an application for timely renewal.

11

On August 22, 1990, the Licensee notified the NRC that uranium contaminated water had been discovered seeping from under the solvent extraction building into a nearby excavation. The excavation had been dug around two hexane tanks in preparation for enclosing the tanks in a concrete vault. The floor and walks of the vault had been installed and the seepage was discovered in the soil to the south and west sides of the newly constructed vault.

By letter dated August 30, 1990, the Licensee committed to take the following actions prior to the restart of the solvent extraction process:

1. SFC will provide NRC with sufficient information relating to assuring the integrity of the floor and sump of the Solvent Extraction Building to demonstrate that current operations are not contributing to the inventory of licensed material that may have seeped beneath the building.
2. SFC will complete such actions as are necessary to adequately characterize the quantity and location of the pockets of licensed material under or around the Solvent Extraction Building.
3. SFC will identify and check all potential pathways that could contribute to migration of licensed material away from the Solvent Extraction Building.
4. SFC will properly control and maintain contaminated soil and water removed from the excavation north of the Solvent Extraction Building.

In addition, SFC committed that in the very near future, SFC will have an independent party review SFC's entire response to this situation, and a written report of this review and SFC's response to it will be made available for NRC's review. In addition, further commitments establishing a temporary oversight group, additional staff in the health, safety and environment functions, and attention for organizational deficiencies, were made.

On September 14, 1990, based on these commitments, the NRC approved SFC's

restart of the solvent extraction process. Subsequent to the above, on September 14, 1990, SFC reported another discovery of uranium-contaminated water seeping from under the Main Process Building within approximately fifty (50) yards or less of an unrestricted area. The Licensee cannot assure the NRC that all migration pathways to the unrestricted area are known or that the groundwater has not been contaminated through seepage under or around the building.

III

Based on the above, the NRC is concerned that the ground water and environment in the plant's unrestricted area could be contaminated with uranium contaminated water seeping from underneath the main process building or its environs. Consequently, the public health and safety require that the site be characterized, action be taken to prevent further releases of contaminated water, and appropriate monitoring of ground water be conducted. Therefore, because of such concerns and because of the need to have complete and accurate information, License SUB-1010 is being modified to require the Licensee to obtain information and develop characterization studies regarding the seepage of uranium contaminated water from under the main process building and its environs.

IV

Accordingly, pursuant to sections 62, 161b, '61c, 161f, 161o, 182 and 186 of the Atomic Energy Act of 1954, as amended, and the Commission's regulations in 10 CFR 2.204, 10 CFR Part 20, and 10 CFR Part 40, IT IS HEREBY ORDERED, THAT LICENSE NO. SUB-1010 IS MODIFIED AS FOLLOWS:

The Licensee shall within seven (7) calendar days from the effective date of this order:

1. Obtain sufficient information to ensure the integrity of the floor of the Main Process Building and repair the floor as necessary. Minimize process liquids in sumps and on floors. Stop all activities that intentionally place liquids in sumps and on floors until the integrity of sumps and floors has been ensured.
2. Characterize the quantity (volume and activity) and location of licensed material under the Main Process Building floor and outside the Main Process Building, and obtaining, as necessary, soil borings and corings and digging intercept trenches to determine the direction and extent of underground migration.
3. Identify all potential pathways for migration beneath and beyond the Main Process Building, considering the effect of building structures and utilities, the nature and extent of

underground shale and other formations, and construction activities that could have affected the integrity of groundwater barriers.

4. Examine present and past monitoring well data for evidence of licensed material attributable to Main Process Building activities, determining whether the present and past monitoring well program has been adequate, in terms of well location, depth, and sampling, to identify migration from the Main Process Building.
5. Determine whether licensed material is being or has been released beyond the restricted area by migration from the Main Process Building.
6. Develop a plan to identify and characterize other locations on SFC property where past or present operations could have resulted in contaminating the environment.

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

After reviewing the Licensee's response, the NRC will determine what further action is necessary to ensure compliance with regulatory requirements.

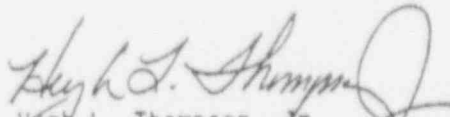
The Licensee or any other person adversely affected by this Order may submit an answer to this Order or request a hearing on this Order within 20 days of the date of this Order. The answer shall set forth the matters of fact and law on which the Licensee or other person adversely affected relies and the reasons why this Order should not have been issued. Any answer filed within 20 days of the date of this Order may include a request for a hearing.

Any answer or request for a hearing shall be submitted to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555. A copy shall be sent to the Assistant General Counsel for Hearings and Enforcement at the same address, and to the Regional Administrator, USNRC Region IV, 611 Ryan Plaza Drive, Suite 1000, Arlington, Texas 76011, and to the Licensee if the answer or hearing request is by a person other than the Licensee. If a person other than the Licensee requests a hearing, that person shall set forth with particularity the manner in which his or her interest is adversely affected by this Order and shall address the criteria set forth in 10 CFR 2.714(d).

If a hearing is requested by the Licensee or a person whose interest is adversely affected, the Commission will issue an Order designating the time and place of any hearing. If a hearing is held, the issue to be considered at such hearing shall be whether this Order should be sustained.

If no hearing is requested, this Order shall become effective upon the Licensee's consent or upon expiration of the time within which a hearing may be requested.

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 19 day of September 1990



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

DEC 04 1990

Docket No. 30-28741
License No. 03-23185-01
EA 90-210

Tumbleweed X-Ray Company
ATTN: Otho G. Jones, Owner
Post Office Box 1210
Greenwood, Arkansas 72936

Gentlemen:

SUBJECT: ORDER MODIFYING LICENSE (EFFECTIVE IMMEDIATELY)

The enclosed Order is being issued to prohibit certain employees of Tumbleweed X-Ray Company from conducting any activities involving licensed radioactive materials without prior NRC approval. This Order is based on NRC's initial inquiry into the circumstances surrounding an apparent radiation overexposure to the hand of one of the individuals as a result of violations of NRC requirements.

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

Sincerely,

A handwritten signature in cursive script, reading "Hugh L. Thompson, Jr.".

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

Enclosure: As Stated

cc:
Oklahoma Radiation Control Program Director
Arkansas Radiation Control Program Director
Texas Radiation Control Program Director

UNITED STATES
NUCLEAR REGULATORY COMMISSION

In the Matter of

Tumbleweed X-Ray Company
Greenwood, Arkansas

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Docket No. 30-28741
License No. 03-23185-01
EA 90-210

ORDER MODIFYING LICENSE
(EFFECTIVE IMMEDIATELY)

I

Tumbleweed X-Ray Company (Licensee or Tumbleweed) is the holder of Materials License No. 03-23185-01 issued by the Nuclear Regulatory Commission (NRC or Commission) pursuant to 10 CFR Parts 30 and 34 on July 25, 1985 (Tumbleweed X-Ray Company previously held NRC Materials License No. 35-21425-01). The license authorizes the possession and use of sealed radioactive sources (iridium-192 and cobalt-60) in various industrial radiography devices. The license was due to expire on September 30, 1988, but remains active due to a timely renewal application having been submitted by the Licensee in August 1988.

II

Under 10 CFR 34.43, personnel performing licensed radiographic operations are required to perform a radiation survey of the camera and guide tube to determine that the sealed source has been returned to its shielded position after each exposure. Under 10 CFR 34.44, an assistant radiographer using radiographic exposure devices must be under the personal supervision of a radiographer. The personal supervision shall include watching the assistant's performance of operations.

On November 26, 1990, the Licensee informed NRC Region IV that David Martin, an assistant radiographer employed by Tumbleweed, may have received a radiation overexposure to his right hand. The Licensee believes the overexposure is connected to an incident that occurred on November 12, 1990, during radiography being performed at a facility in Burns Flat, Oklahoma. Kevin Hill was the radiographer conducting radiographic operations with Mr. Martin that day. The Licensee's radiation safety officer, who contacted NRC in regard to this incident, stated that he learned of the incident and apparent overexposure on November 25, 1990.

Based on information the Licensee submitted to NRC Region IV on November 28, 1990, and NRC Region IV's initial inquiry into this incident on November 29, 1990, NRC believes that: (1) on November 12, 1990, a serious radiation injury occurred to the right hand of David Martin; (2) on that day, David Martin failed to perform a radiation survey after exposing the source and attempting to retract it and prior to approaching the source and guide tube; and (3) during these events Kevin Hill, the radiographer, failed to properly supervise Mr. Martin and failed to watch his performance of operations and that these violations of NRC requirements on November 12, 1990, contributed to this occurrence. Additional violations may be identified as a result of our continuing review of this incident.

In a telephone discussion with NRC Region IV on November 29, 1990, the Licensee agreed to prohibit both the radiographer and assistant radiographer involved in this incident from conducting any activities that involve the use of licensed radioactive materials without prior NRC approval.

III

The circumstances surrounding the November 12, 1990, incident reflect inadequate regard by the individuals involved for NRC requirements designed to ensure the safe use of licensed radioactive material and raise significant concerns relative to adequate protection of the public health and safety. Pending completion of a review of this incident, the NRC does not have reasonable assurance that licensed activities will be properly conducted with these individuals present. Therefore, I have determined that the public health and safety require that this Order be issued. Pursuant to 10 CFR 2.204, I have also determined that the public health and safety require that this Order be immediately effective.

IV

Accordingly, pursuant to sections 81, 161b, 161c, 161f, 161o, 182 and 186 of the Atomic Energy Act of 1954, as amended, and the Commission's regulations in 10 CFR 2.204, 10 CFR Part 30 and 10 CFR Part 34, IT IS HEREBY ORDERED, EFFECTIVE IMMEDIATELY, THAT LICENSE NO. 03-23185-01 IS MODIFIED AS FOLLOWS:

1. Kevin Hill, a radiographer, is prohibited from conducting any activities involving licensed radioactive materials;
2. David Martin, an assistant radiographer, is prohibited from conducting any activities involving licensed radioactive materials.

The Regional Administrator, NRC Region IV, may relax or rescind, in writing, any of the above conditions upon a showing by the Licensee of good cause.

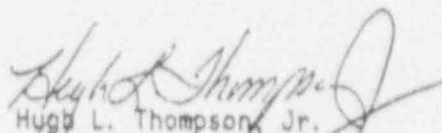
V

The Licensee, Kevin Hill, David Martin, or any person adversely affected by this Order may submit an answer to this Order or request a hearing on this Order within twenty days of its issuance. The answer shall set forth the matters of fact and law on which the Licensee, Kevin Hill, David Martin or other person adversely affected relies and the reasons why the Order should not have been issued. Any answer filed within twenty days of the date of this Order may include a request for a hearing. Any answer or request for a hearing shall be submitted to the Secretary, U.S. Nuclear Regulatory Commission, ATTN: Chief, Docketing and Service Section, Washington, D.C. 20555. Copies also shall be sent to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, to the Assistant General Counsel for Hearings and Enforcement at the same address, to the Regional Administrator, NRC Region IV, 611 Ryan Plaza Drive, Suite 1000, Arlington, Texas 76011, and to the Licensee if the answer or hearing request is by a person other than the Licensee. If a person other than the Licensee or Kevin Hill or David Martin requests a hearing, that person shall set forth with particularity the manner in which his or her interest is adversely affected by this Order and shall address the criteria set forth in 10 CFR 2.714(d).

If a hearing is requested by the Licensee, Kevin Hill, David Martin, 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.

On the Licensee's, Kevin Hill's and David Martin's consent to the provisions set forth in Section IV of this Order or on the failure of the Licensee or Kevin Hill or David Martin to file an answer within the specified time and in the absence of any request for a hearing within the specified time this Order shall be final without further Order or proceeding. A REQUEST FOR A HEARING SHALL NOT STAY THE IMMEDIATE EFFECTIVENESS OF THIS CONFIRMATORY ORDER.

FOR THE NUCLEAR REGULATORY COMMISSION



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

Dated at Rockville, Maryland
this 4th day of December 1990



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

July 25, 1990

Docket No. 030-03465
License No. 48-09843-18
EA 90-098

University of Wisconsin - Madison
ATTN: Ms. Donna Shalala
Chancellor
Room 100 Pascom Hall
500 Lincoln Drive
Madison, Wisconsin 53706-1380

Gentlemen:

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF
CIVIL PENALTIES - \$7,500
(NRC INSPECTION REPORT NO. 030-03465/90001(DRSS))

This refers to the NRC inspection conducted on March 26 through May 2, 1990 of activities authorized by NRC License No. 48-09843-18. The report of the inspection was sent to you on May 21, 1990. During the inspection, violations of NRC requirements were identified. On May 29, 1990, an enforcement conference was conducted in the NRC Region III office between Ms. K. S. Irwin, University Legal Counsel, and other members of your staff and Mr. C. E. Korelius, Director, Division of Radiation Safety and Safeguards, and other members of the NRC staff to discuss the violations, their causes, and your corrective actions.

The violations described in the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice) involved failures to: (1) have trained operators present on two occasions while treating patients with the High Dose-Rate Remote Afterloader (HDR Unit), (2) verify treatment time calculations on 35 occasions, (3) have a second person review at least 35 treatment plans to check for possible errors, (4) test the accuracy of the HDR Unit's timing device against a stop watch during calibration checks, and (5) monitor external radiation levels of packages of radioactive material upon receipt. The failure to verify treatment parameters and plans contributed to the occurrence of two therapeutic misadministrations.

Improper use of the HDR Unit could be very hazardous. Your use of the HDR Unit by unqualified operators as stated in Violation I.A and without appropriate controls over the planning process which resulted in two therapy misadministrations as stated in aggregate Violations I.B.1 and I.B.2 (Violation I.P) is unacceptable. Violation I.A and aggregate Violation I.E in Section I of the Notice are of significant concern to the NRC, and, therefore, have been classified as Severity Level III violations in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions,"

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

July 25, 1990

10 CFR Part 2, Appendix C (1990) (Enforcement Policy). The remaining violations in Section II of the Notice have been classified at Severity Level IV.

During the enforcement conference, you contested the apparent violations now described in Sections I and II of the Notice, as well as several of the other apparent violations. Your staff provided additional information in support of your conclusion that on three occasions patients were not treated with the HDR Unit while untrained operators were present. After reviewing this additional information, we have concluded that your failure to have a trained operator present during patient treatment did not apply in the case of the radiation therapy technologist because that individual had received training in emergency procedures from a physicist. However, the remaining two individuals, a nurse and a dosimetrist, were not adequately trained and Violation I.A. in the enclosed notice remains as stated for these two individuals. In regard to the two violations described in aggregate Violation I.B, you argued that the 35 treatment plans in question, as well as the treatment time calculations, were independently verified by a physicist and a dosimetrist who prepared the treatment plan under the physicist's direction. NRC does not accept this argument since the dosimetrist enters data provided by the physicist and does not have the expertise to independently prepare or evaluate the accuracy of a treatment plan. As a result, aggregate Violation I.B in the enclosed Notice remains as originally stated. We acknowledge that since the two misadministrations you have significantly expanded the scope of your verification process by including a second physicist as well as a physician in the independent review.

In addition, as to the additional information your staff provided regarding the validity of the other apparent violations that were identified during the inspection, we concluded that it was appropriate to revise our conclusions regarding the inspection findings for some of the apparent violations described in the inspection report. In some cases, all or part of individual violations have been withdrawn.

To emphasize the need for compliance with NRC regulatory requirements and University of Wisconsin-Madison radiological safety procedures, 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 in the amount of \$7,500 for the violations described in Section I in the enclosed Notice. The base value of a civil penalty for a Severity Level III violation is \$2,500. The escalation and mitigation factors in the Enforcement Policy were considered.

In this case, the escalation and mitigation factors were considered separately for Violation I.A and aggregate Violation I.B. In regard to Violation I.A, we concluded that on balance 100 percent escalation was appropriate. In reaching this conclusion, 50 percent escalation was deemed appropriate because the violation was identified by the NRC and should have been identified by you, 100 percent escalation was appropriate because there were multiple examples of

July 25, 1990

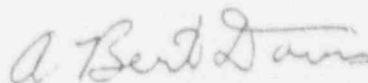
the violation, and 50 percent mitigation was allowed because of your good past performance. In regard to aggregate Violation I.B, we concluded that on balance no mitigation or escalation of the base civil penalty was appropriate. A mitigation of 50 percent was appropriate because you identified and reported the therapy misadministrations and the violations that caused them to occur, and a 50 percent mitigation was allowed because of your good past performance. However, these mitigations were balanced against the 100 percent escalation warranted because there were multiple examples of violations causing the therapy misadministrations. Further mitigation was considered for your comprehensive corrective actions after the second misadministration, but this was balanced by the failure to initiate effective action after the first occurrence, and, therefore, neither mitigation or escalation is warranted for your corrective actions with regard to aggregate Violation I.B. The other adjustment factors in the Policy were considered and no further adjustment to the base civil penalty for each Severity Level III violation 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. Further, you should respond to the areas of concern that are described in Inspection Report No. 030-03465/90001 and which were also discussed with you during the enforcement conference. 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 Section 2.790 of the NRC's "Rules of Practice," Part 2, Title 10, Code of Federal Regulations, a copy of this letter and its enclosure will be placed in the NRC Public Document Room.

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

Sincerely,



A. Bert Davis
Regional Administrator

Enclosures:

1. Notice of Violation and Proposed Imposition of Civil Penalties
2. Inspection Report
No. 030-03465/90001(DRSS)

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTIES

University of Wisconsin-Madison
Madison, Wisconsin

Docket No. 030-03465
License No. 48-09843-18
EA 90-098

During an NRC inspection conducted on March 26 through May 2, 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. VIOLATIONS ASSESSED A CIVIL PENALTY

- A. License Condition No. 23 requires, in part, that the licensee conduct its program in accordance with the statements, representations, and procedures contained in the application dated January 10, 1989.

The application dated January 10, 1989, Attachment VI, Procedures, Section 1, Operating Procedures, requires that operating procedures be established, in writing, and implemented.

An operating procedure reviewed and approved by the Radiation Safety Committee in April 1989, High Dose-Rate Remote Afterloader, Section A.2 requires that a trained operator be present during any use of the unit.

Contrary to the above, on two occasions during the period April 1989 through March 26, 1990, the High Dose-Rate Remote Afterloader was used to treat patients and a trained operator was not present.

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

Civil Penalty - \$5,000

- B. License Condition No. 23 requires, in part, that the licensee conduct its program in accordance with the statements, representations, and procedures contained in the application dated January 10, 1989.

1. The application dated January 10, 1989, Attachment VI, Procedures, Section 4, Treatment Time Calculations, requires that treatment time calculations be independently verified.

Contrary to the above, during the period April 1989 through March 26, 1990, at least 35 treatment plans did not have the treatment time calculations verified.

2. The application dated January 10, 1989, Attachment VI, Procedures, Section 1, Operating Procedures, requires that operating procedures be established, in writing, and implemented.

An operating procedure reviewed and approved by the Radiation Safety Committee in April 1989, High Dose-Rate Remote Afterloader, Section C.1.b. requires that the treatment plan be reviewed by a second person to check for possible errors.

Contrary to the above, during the period April 1989 through March 26, 1990, at least 35 treatment plans were not reviewed by a second person to check for possible errors.

These violations have been classified in the aggregate as a Severity Level III violation (Supplement VI).

Cumulative Civil Penalty - \$2,500 (assessed between the two violations).

11. VIOLATIONS NOT ASSESSED A CIVIL PENALTY

- A. License Condition No. 23 requires, in part, that the licensee conduct its program in accordance with the statements, representations, and procedures contained in the application dated January 10, 1989.

The application dated January 10, 1989, Attachment VI, Procedures, Section 5, Calibration Procedures, describes the calibration procedure for determination of the accuracy of the timing device and requires that the timing device be tested against a stop watch during the calibration check.

Contrary to the above, from the date of receipt in April 1989 until March 26, 1990, the licensee did not test the accuracy of the High Dose-Rate Remote Afterloader's timing device against a stop watch during calibration checks.

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

- B. 10 CFR 20.205(c)(1) requires that each licensee, upon receipt of a package containing quantities of radioactive material in excess of the Type A quantities, monitor the radiation levels external to the package.

Contrary to the above, upon receipt of packages of radioactive material on April 14, 1989, July 19, 1989, September 22, 1989,

January 16, 1990, and April 18, 1990, the licensee did not monitor the radiation levels external to the packages.

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

Pursuant to the provisions of 10 CFR 2.201, the University of Wisconsin-Madison (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: (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 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.

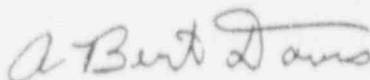
Notice of Violation

- 4 -

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, Region III, U.S. Nuclear Regulatory Commission, 799 Roosevelt Road, Glen Ellyn, IL 60137.

FOR THE NUCLEAR REGULATORY COMMISSION



A. Bert Davis
Regional Administrator

Dated at Glen Ellyn, Illinois
this 25th day of July 1990



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

DEC 28 1990

Docket No. 030-03465
License No. 48-09843-18
EA 90-098

University of Wisconsin - Madison
ATTN: Ms. Donna Shalala
Chancellor
Room 100, Bascom Hall
500 Lincoln Drive
Madison, Wisconsin 53706-1380

Ms. Shalala:

SUBJECT: ORDER IMPOSING CIVIL MONETARY PENALTIES - \$7,500

This refers to your letter dated September 24, 1990 in response to the Notice of Violation and Proposed Imposition of Civil Penalties (Notice) sent to you by our letter dated July 25, 1990. Our letter and Notice describe several violations identified during an NRC inspection conducted on March 26 through May 2, 1990.

To emphasize the need for compliance with NRC regulatory requirements and University of Wisconsin - Madison radiological safety procedures, civil penalties of \$7,500 were proposed.

In your response you admitted Violation I.A but stated that the escalation of the base penalty was unwarranted; you denied Violation I.B; and you admitted Violation II.

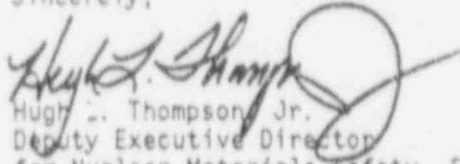
After consideration of your response, we have concluded, for the reasons given in the Appendix attached to the enclosed Order Imposing Civil Monetary Penalties, that the escalation of the base civil penalty for Violation I.A of the Notice was appropriate and that Violation I.B of the Notice did occur as stated. Accordingly, we hereby serve the enclosed Order on the University of Wisconsin - Madison imposing civil monetary penalties in the amount of \$7,500. We have also reviewed your corrective actions regarding these violations, and have no further questions at this time. We will review the effectiveness of your corrective actions during a subsequent inspection.

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

University of Wisconsin - Madison - 2 -

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

Sincerely,



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

Enclosures: As stated

cc w/enclosure:
Jay Noren
Vice Chancellor for
Health Sciences

UNITED STATES
NUCLEAR REGULATORY COMMISSION

In the Matter of)

University of Wisconsin - Madison)
Madison, Wisconsin)

Docket No. 030-03465
License No. 48-09843-18
EA 90-098

ORDER IMPOSING CIVIL MONETARY PENALTIES

I

The University of Wisconsin - Madison (Licensee) is the holder of Byproduct Materials License No. 48-09843-18 (license) initially issued by the Nuclear Regulatory Commission (NRC or Commission) on August 8, 1956. The license was most recently renewed on February 7, 1989 and is due to expire on March 31, 1994. The license authorizes the Licensee to use a variety of byproduct materials for medical and research applications at various locations within the University complex in accordance with the conditions specified therein.

II

An inspection of the Licensee's activities was conducted on March 26 through May 2, 1990. The results of this inspection indicated that the Licensee had not conducted its activities in full compliance with NRC requirements. A written Notice of Violation and Proposed Imposition of Civil Penalties (Notice) was served upon the Licensee by letter dated July 25, 1990. The Notice stated the nature of the violations, the provisions of the NRC's requirements that the Licensee had violated, and the amount of the civil penalties proposed for the Violations. The Licensee responded to the Notice on September 24, 1990. In its response, the Licensee admitted Violation I.A of the Notice, but argued

that escalation of the base civil penalty was unwarranted; denied Violation I.B of the Notice in its entirety; and admitted Violation II of the Notice.

III

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

IV

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

The Licensee pay civil penalties in the amount of \$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 III, 799 Roosevelt Road, Glen Ellyn, Illinois 60137.

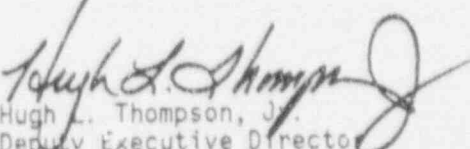
If a hearing is requested, the Commission will issue an Order designating the time and place of the hearing. If the Licensee fails to request a hearing within 30 days of the date of this Order, the provisions of this Order shall be effective without further proceedings. If payment has not been made by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

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

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

(b) whether, on the basis of such violation and the additional violations set forth in the Notice of Violation that the Licensee admitted, this Order should be sustained.

FOR THE NUCLEAR REGULATORY COMMISSION


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

Dated at Rockville, Maryland
this 27th day of December 1990

APPENDIX

EVALUATIONS AND CONCLUSIONS

On July 25, 1990, a Notice of Violation and Proposed Imposition of Civil Penalties (Notice) was issued for violations identified during an NRC inspection on March 26 through May 2, 1990. The University of Wisconsin-Madison (Licensee) responded to the Notice on September 24, 1990. In its response, the Licensee admitted Violations I.A., II.A. and II.B. and denied Violation I.B. In addition, the Licensee requested reduction of the 50 percent escalation of the base civil penalty for Violation I.A. The NRC's evaluation and conclusions regarding the Licensee's requests are as follows:

I. Restatement of Violation I.A.

License Condition No. 23 requires, in part, that the Licensee conduct its program in accordance with statements, representations, and procedures contained in the application dated January 10, 1989.

The application dated January 10, 1989, Attachment VI, Procedures, Section 1, Operating Procedures, requires that operating procedures be established, in writing, and implemented.

An operating procedure reviewed and approved by the Radiation Safety Committee in April 1989, High Dose-Rate Remote Afterloader, Section A.2, requires that a trained operator be present during any use of the unit.

Contrary to the above, on two occasions during the period April 1989 through March 26, 1990, the High Dose-Rate Remote Afterloader was used to treat patients and a trained operator was not present.

Summary of Licensee's Response to Violation I.A.

The Licensee admits this violation occurred as stated. The proposed civil penalty was escalated 50 percent for NRC identification of the violation; however, the Licensee protests this escalation, and requests that, instead, the base civil penalty be mitigated 50 percent because it identified the violation after the first incident occurred.

The first incident occurred when a physicist left a nurse alone at the HDR unit treatment console while a patient was undergoing treatment. The Licensee admits the nurse was an untrained operator. It contends this incident was identified by the University shortly after it occurred and before the NRC inspection. It states the physicist involved was informed this was unacceptable and was not to happen in the future.

The Licensee believes it should not be cited for the second incident involving an untrained operator because it could not have reasonably discovered this violation before it occurred. The second incident occurred when the physicist responsible for the treatment was called away and left an untrained dosimetrist alone at the HDR treatment control console. The Licensee contends the physicist allowed the dosimetrist to be alone at the control console because he assumed she had received the required vendor-provided training since he had seen her name on the attendance roster for

the training. In fact, the dosimetrist had not received this training because she was called away for other duties about ten minutes after the training began. Another attendee signed the dosimetrist's name to the attendance sheet on the assumption that the dosimetrist would return momentarily.

The Licensee notes that its corrective action for this violation includes revising the training of HDR operators and submission of an amendment request setting forth new requirements. This request was approved by the NRC. The new training requirements for operators include 4 hours of training, passing a written exam and performing treatments under the direct supervision of a trained operator.

The Licensee did not contest the other escalation and mitigation factors originally proposed.

NRC's Evaluation of Licensee's Response to Violation I.A.

The Licensee's letter dated September 24, 1990, states it had identified the first example of the violation involving the nurse prior to the NRC inspection. However, it did not provide any documentation to support this contention. During the inspection on March 26, 27, and 28, 1990, the NRC inspectors questioned the Radiation Safety Officer as to whether any incidents, other than the two reported misadministrations which initiated the special inspection documented in NRC's letter dated May 21, 1990, had occurred with the use of the HDR unit. The Radiation Safety Officer denied any other incidents had occurred.

During the inspection, on March 28, 1990, a dosimetrist mentioned the first incident involving the nurse and the inspectors made an inquiry into the event. During a telephone interview with the inspector on April 2, 1990, the nurse was asked whether she had mentioned this incident to the Chief Physicist, Dr. Paliwal, or to anyone else. She stated she could not recall informing her supervisors of this incident, but apparently did mention it to her peers because a dosimetrist told the inspectors about it.

Based on the information collected by the inspectors during and after the inspection, it appears that Licensee management as well as other physicists who were involved in the program were not aware of this event or that corrective actions were to be taken. Had the Licensee identified the incident involving the nurse described in the first example of the violation and reported it to the inspectors in response to their questions during the inspection or reported it internally to Radiation Safety program management, mitigation may have been considered. However, no such report or documentation of the incident supporting the Licensee's contention that it identified this violation was given the inspectors during the inspection or presented or discussed during the enforcement conference. Therefore, the NRC concludes that there was insufficient information provided to show that the Licensee identified this event as a violation, and, as such, there was no basis for mitigation of the base civil penalty.

The second example of Violation I.A involved a dosimetrist. A Nucletron training session attendance list indicated that eight people, including this dosimetrist, attended the training session on April 13, 1989. Also in attendance was the physicist who left this dosimetrist alone at the treatment control console on one of the occasions indicated in Violation I.A. During the inspection, it was learned that this dosimetrist was only present at the course for approximately 10 minutes and another attendee had signed the dosimetrist's name on the attendance sheet on the assumption that she would return shortly and complete the training. However, the dosimetrist did not return and her name was not struck from the attendance roster.

The NRC concludes that the physicist's contention that he reasonably assumed the dosimetrist had completed the training, based on his recollection that the dosimetrist's name was on an attendance roster for training that occurred 11 months prior to the incident, is without merit. It is clear that the dosimetrist was not trained and was left alone at the control panel by the physicist. This was a violation as set forth in Violation I.A. The accuracy of the training list is the responsibility of the Licensee and any mistake regarding that list does not justify or mitigate the instant violation. Moreover, it is reasonable to expect that a person supervising a critical task such as the operation of the High Dose-Rate Remote Afterloader, would confirm that the dosimetrist was qualified prior to leaving the person alone.

The NRC did not escalate or mitigate this case on the basis of corrective actions. However the Licensee discussed its corrective actions as an additional basis for mitigation. Although the Licensee's corrective actions, as submitted in the license amendment request dated April 6, 1990 and incorporated as Amendment No. 73 dated May 3, 1990, are appropriate and extensive, the submission of this amendment was initiated at the request of NRC and therefore not considered prompt. NRC requested that the Licensee prepare an amendment to its license and provided specific information as to what the amendment should contain. Therefore, the NRC still concludes that neither escalation or mitigation is appropriate under the corrective action factor.

II. Restatement of Violation I.B.

License Condition No. 23 requires, in part, that the Licensee conduct its program in accordance with statements, representations, and procedures contained in the application dated January 10, 1989.

1. The application dated January 10, 1989, Attachment VI, Procedures, Section 4, Treatment Time Calculations, requires that treatment time calculations be independently verified.

Contrary to the above, during the period April 1989 through March 26, 1990, at least 35 treatment plans did not have the treatment time calculations verified.

2. The application dated January 10, 1989, Attachment VI, Procedures, Section 1, Operating Procedures, requires that operating procedures be established, in writing, and implemented.

An operating procedure reviewed and approved by the Radiation Safety Committee in April 1989, High Dose-Rate Remote Afterloader, Section C.1.b., requires that the treatment plan be reviewed by a second person to check for possible errors.

Contrary to the above, during the period April 1989 through March 26, 1990, at least 35 treatment plans were not reviewed by a second person to check for possible errors.

Summary of Licensee's Response to Violation I.B.

The Licensee denies the violation and alleges that the NRC does not have regulations or guidance documents establishing the requirements for operation of an HDR unit. The Licensee asserts that the treatment time calculations were independently verified and the treatment plan reviewed by a second person to check for possible errors during preparation of the treatment card when a physicist watched a dosimetrist work up the treatment plan.

The Licensee claims the dosimetrists were trained and capable of preparing HDR treatment plans wholly on their own and that the physicist observing their treatment plan preparation was simultaneously performing the required independent verification of the treatment time calculations and was checking for possible errors.

Until the first misadministration occurred on February 7, 1990, the Licensee claimed it exercised reasonable care in executing an independent verification of treatment plan parameters. After this first misadministration, the Licensee instituted a "functionally independent" verification procedure in which a second physicist working alone checked the plan.

NRC's Evaluation of Licensee's Response to Violation I.B.

Contrary to the Licensee's assertion that NRC does not have regulations or guidance documents for an HDR unit, it should be noted that, on February 20, 1986, NRC issued Policy and Guidance Directive FC 86-4, "Information Required For Licensing Remote Afterloading Devices." Enclosure 2 of this Directive is routinely provided to Licensees upon request, in order to assist in the preparation of an amendment request to add authorization for a remote afterloading device to an existing license. In reviewing the University of Wisconsin-Madison License Amendment No. 68, it is apparent that this guidance document was used to prepare the Licensee's application, dated January 10, 1989, to add the remote afterloading device authorization to its license. The format of the January 10, 1989 application shows a close correlation with the guidance document. This guidance document directs Licensees to make certain commitments in an application for a remote afterloading device, including a commitment to independently verify treatment time calculations before treatment is begun (Section VI. "Operating Procedures," Subitem A.5.). In its application, dated January 10, 1989, the Licensee made this commitment, in accordance with the guidance.

Regarding the dosimetrists' ability to prepare HDR treatment plans on their own, the NRC inspectors interviewed four of the Licensee's dosimetrists

during the inspection. Three of the four indicated discomfort, inexperience and inadequate training for their role in HDR treatment planning. The fourth dosimetrist, who indicated her level of HDR knowledge and experience made her comfortable, was the only one sent to Nucletron for a dedicated three day training session, instead of just having had the four hour training session Nucletron conducted onsite at the Licensee's facilities. Therefore, the NRC has concluded that three of four Licensee dosimetrists, by their own admission, were not qualified to prepare HDR treatment plans on their own. In these cases the physicists were providing assistance in preparing the treatment plan rather than an independent verification. In addition, in its letter, dated September 24, 1990, the Licensee states " . . . following the first misadministration, we realized that a physicist observing the preparation of a plan was not functionally independent and established a procedure in which a second physicist working alone checked the plan. "

The NRC has concluded that the Licensee's argument justifying its interpretation of independent verification of treatment parameters is without merit and does not provide a basis for withdrawing the violation.

III. NRC Conclusion

Based on the information presented by the Licensee and evaluated by the NRC, it has been concluded that the \$7,500 in civil penalties proposed by the NRC in its July 25, 1990 Notice of Violation and Proposed Imposition of Civil Penalties is justified and should be imposed.



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

January 29, 1991

Docket No. 030-10026
License No. 31-02755-05
EA 90-209

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 - \$3,750
(NRC Inspection Report No. 90-001)

This letter refers to the NRC inspection conducted on November 20-21, 1990, at the Veterans Administration Medical Center, Albany, New York, of activities authorized by NRC license No. 31-02755-05. The inspection report was sent to you on December 7, 1990. During the inspection, numerous violations of NRC requirements were identified. On December 13, 1990, an enforcement conference was conducted with you and members of your staff to discuss the violations, their causes and your corrective actions.

The violations, which are described in the enclosed Notice, include, but are not limited to: (1) the failure to secure certain licensed material from unauthorized removal; (2) failure to perform leak tests of sealed sources; (3) consumption of food and beverages in areas where radioactive materials are used; (4) failure to perform the required annual review of the radiation safety program; (5) failure to provide training to personnel in radiological safety; and (6) failure to maintain adequate records of certain required activities, including records of the constancy, linearity, and geometry tests of the dose calibrator.

The violations appear to have been caused by the lack of adequate oversight of, and attention to, the radiation safety program at your facility. Although the RSO listed on the license at the time of the inspection was assigned to the position in October 1989, it is apparent that he did not clearly understand nor implement his responsibilities under the terms of your license. Furthermore, management did not provide sufficient oversight to assure that the RSO, who was also the Chairman of the Radiation Safety Committee at the time, was actively involved in carrying out his routine responsibilities.

The NRC recognizes that 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

CERTIFIED MAIL
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of the radiation safety program, the violations are collectively classified in the aggregate 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 (1990). Since you possess a broad-scope license for the use of licensed material, it is very important that (1) all personnel are adequately trained concerning radiation safety precautions and requirements, and (2) adequate oversight is provided and comprehensive audits are conducted to ensure that all personnel understand and adhere to the terms of your license. If adequate attention and oversight had been provided, the violations should have been prevented, or identified and corrected.

The NRC recognizes that subsequent to the inspection, corrective actions were initiated to effect improvement in the control and implementation of the radiation safety program. These actions, which were described at the enforcement conference, included (1) issuance of a memorandum by the Radiation Safety Officer to your staff on November 26, 1990, concerning the need to adhere to regulatory requirements, and (2) retention of a consultant, as noted in a Confirmatory Action Letter (CAL) issued to you on November 29, 1990, to assess the program and develop an improvement plan. However, these actions were not considered sufficiently prompt and comprehensive in that, while a consultant had been hired, the RSO was not adequately involved in the day-to-day implementation of the radiation safety program as of the date of the enforcement conference. The NRC recognizes that you indicated at the enforcement conference that you were in the process of recruiting for a new RSO. Further, at the conclusion of the enforcement conference, you committed to obtain additional consultant services to assist the RSO in the daily implementation of the program until such time as a new RSO is hired, trained, and added to the license as the approved RSO. These additional commitments were documented in a supplement to the CAL issued on December 14, 1990. In addition, a license amendment was issued on January 22, 1991 to provide for a new interim RSO and a new Chairman of the Radiation Safety Committee.

Notwithstanding these actions, the NRC is concerned that management did not periodically monitor the actions of the RSO to assure that all regulatory requirements were being implemented. Although the RSO is assigned radiation safety responsibilities, management must assure that those responsibilities are being properly discharged. This was not done.

Therefore, to emphasize the importance of adequate management attention to and oversight of the radiation safety program, including proper oversight by the Radiation Safety Officer, 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 \$3,750 for the violations set forth in the enclosed Notice.

The base civil penalty amount for a Severity Level III violation is \$2500. 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, and; therefore, 50% escalation of

the base civil penalty on this factor is warranted; (2) your corrective actions, as described herein, were not considered sufficiently prompt and comprehensive to warrant adjustment of the base civil penalty; (3) although your past performance includes only a total of two violations during the last four NRC inspections, mitigation based on prior good performance is not considered appropriate because your performance has significantly declined since the RSO took over responsibility for the program in October 1989, and the lapse in management control of your licensed activities constitutes an extensive rather than an isolated issue; 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. In addition, you should describe actions taken or planned to improve oversight of your program by management above the level of the RSO and by the RSO. At the conclusion of the enforcement conference, you indicated that, while you were in the process of recruiting for a permanent RSO, you would arrange for a consultant to assist the RSO in the daily implementation of the radiation safety program until a permanent RSO is appointed. While this is acceptable, the licensee retains the responsibility for activities performed by the consultant. In your response, you should also clarify how you intend to exercise your oversight responsibility for activities performed by the consultant. 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

Veterans Administration
Medical Center

4

cc:
Director, Nuclear Medicine Service (115)
ATTN: Helen Malaskiewicz
Department of Veterans Affairs
810 Vermont Avenue, N.W.
Washington, D.C. 20420

Public Document Room (PDR)
Nuclear Safety Information Center (NSIC)
State of New York

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 90-203

During an NRC inspection conducted on November 20-21, 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 the 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 materials in an unrestricted area and not in storage be under the constant surveillance and immediate control of the licensee. As defined in 10 CFR 20.3(a)(17), an unrestricted area is any area access to which is not controlled by the licensee for purposes of protection of individuals from exposure to radioactive materials.

Contrary to the above, on August 3, 1990, a shipment of radioactive material (1 millicurie of tritium) was left unsecured in an unrestricted area (window sill in the hallway) and was not under the constant surveillance or immediate control of the licensee.

- B. 10 CFR 35.315(a)(8) requires, in part, that for each patient receiving radiopharmaceutical therapy and hospitalized for compliance with 10 CFR 35.75, the licensee shall measure the thyroid burden of each individual who helped prepare or administer a dosage of iodine-131 within 3 days after administering the dosage.

Contrary to the above, the licensee did not, within three days after the administration of the dosage, measure the thyroid burden of an individual who prepared and administered a radiopharmaceutical therapy dosage of iodine-131 on July 13, 1990; and the patient who received this dosage was hospitalized for compliance with 10 CFR 35.75.

- C. 10 CFR 35.22(b)(6) requires that the Radiation Safety Committee review annually, with the assistance of the Radiation Safety Officer, the radiation safety program.

Contrary to the above, as of November 21, 1990, the Radiation Safety Committee, with the assistance of the Radiation Safety Officer, did not perform an annual review of the radiation safety program for 1989.

- D. 10 CFR 35.205(c) requires, in part, that before receiving, using or storing a radioactive gas, licensees calculate the amount of time needed after a spill to reduce the concentration in the room to the limit listed in 10 CFR Part 20, Appendix B.

Contrary to the above, as of November 21, 1990, no calculation was performed of the time needed after a spill of xenon-133 to reduce the concentration in the imaging room (Room 626D) to the applicable limit.

- E. 10 CFR 20.303 describes requirements for the disposal of radioactive materials by release into the sanitary sewerage system. 10 CFR 20.401(c)(3) requires that each licensee maintain records of disposals made under 10 CFR 20.303.

Contrary to the above, as of November 21, 1990, adequate records were not maintained, as required under 10 CFR 20.401, of disposals in 1988 and 1989 of radioactive material released into the sanitary sewerage system. For 1988, the records were disorganized and confusing in that one record indicated that 24,014.9 microcuries were disposed while another record indicated that 971.4 microcuries were disposed. For 1989, no records were maintained.

- F. 10 CFR 35.70(d) requires that a licensee shall establish radiation dose rate trigger levels for area surveys required by paragraphs (a) and (b) of 10 CFR 35.70.

Contrary to the above, as of November 21, 1990, the licensee did not establish radiation dose rate trigger levels for the area surveys required under 10 CFR 35.70.

- G. 10 CFR 35.59(b)(2) requires, in part, that each sealed source or brachytherapy source be tested for leakage at intervals not to exceed 6 months or at intervals approved by the Commission or an Agreement State.

Contrary to the above, as of November 21, 1990, sealed sources (containing licensed material) were not tested for leakage from October 14, 1989 to November 21, 1990, an interval which exceeded 6 months, and no other interval was approved.

- H. 10 CFR 35.205(e) requires, in part, that licensees measure the ventilation rates available in areas of use of radioactive gases each 6 months.

Contrary to the above, as of November 21, 1990, the ventilation rates available in Room 609D had not been measured during the last 12 months and, during that period, radioactive xenon gas was used in that room.

- I. 10 CFR 35.315(a)(7) requires that, for each patient receiving radiopharmaceutical therapy and hospitalized for compliance with 10 CFR 35.75, the licensee must 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 and that the room not be reassigned until removable contamination is less than 200 disintegrations per minute per 100 square centimeters.

Contrary to the above, on July 16, 1990, a radiopharmaceutical therapy patient's room was reassigned before a survey was performed to ensure that removable contamination was less than 200 disintegrations per minute per 100 square centimeters, and the patient was hospitalized for compliance with 10 CFR 35.75.

- J. 10 CFR 19.12 requires, in part, that all individuals working in or frequenting any portion of a restricted area shall be instructed in the health protection problems associated with exposure to radioactive materials or radiation, in precautions and procedures to minimize exposure, and in the applicable provisions of Commission regulations and licenses for the protection of personnel from exposures to radiation or radioactive materials.

Contrary to the above, as of November 21, 1990, the licensee did not adequately instruct individuals working in or frequenting any portion of a restricted area in the health problems associated with exposure to radioactive materials, in precautions and procedures to minimize exposure and the applicable provisions of Commission regulations and licenses for the protection of personnel from exposures to radioactive materials. For example, some research laboratory personnel did not know that contamination surveys were required after they performed experiments with radioactive material and others were unaware of the requirement to maintain accurate radioactive material inventories and waste disposal records.

- K. License Condition 18 states, in part, that the license is based on the licensee's statements and representations in the application dated December 6, 1985.

1. The licensee's "General Rules for Safe Use of Radioactive Materials for Research Laboratories" described in Appendix 20 of the license application, dated December 6, 1985, require that individuals do not eat, drink, smoke or apply cosmetics in any area where radioactive material is stored or used.

Contrary to the above, on November 20, 1990, as observed by the NRC inspector, there was evidence of eating and drinking in five research laboratories (Rooms A607, A625, A629, B607 and B630) where radioactive material was stored or used. Specifically, the evidence involved soft drinks on radioactive material work counters, candy wrappers in trash cans, and a microwave oven which smelled like popcorn in a room designated as a radioactive material use area. Furthermore, a researcher confirmed that the microwave oven had been used for making popcorn.

46
10-7

2. The licensee's procedures described in Section 3.1.4.G. of the license application, dated December 5, 1985, require that authorized users notify the Radiation Safety Officer whenever there is a change in laboratory personnel or location.

Contrary to the above, as of November 21, 1990, two authorized users did not notify the Radiation Safety Officer of changes in laboratory location. Specifically, a room designated as a research laboratory used for radioactive materials was converted into a general storage area, and another laboratory was no longer used for radioactive materials, but was still posted as a radioactive materials use area, and neither the RSO nor the RSC were notified of these changes.

3. The licensee's procedures described in Section 3.1.4.A. of the license application require authorized users to maintain on file, up-to-date records of the use, disposition, storage and disposal of all radionuclides including the amount of radioactivity, isotope, chemical form, volume or weight, date of analysis, company and location of isotope.

Contrary to the above, as of November 21, 1990, up-to-date records of radioactive waste disposal were not maintained by the authorized user for radioactive waste generated in Room A607.

- L. 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 under a specific set of conditions.

Contrary to the above, the licensee did not make surveys to assure compliance with 10 CFR 20.103 and 20.106, which, respectively, limit exposure of individuals to concentrations of radioactive materials in air in restricted areas, and limit radioactivity in releases to unrestricted areas. Specifically, as of November 21, 1990, xenon airborne concentrations in restricted areas (room 626D) and in releases to unrestricted areas were not calculated to demonstrate compliance with the requirements of 10 CFR 20.103 and 20.106.

- M. 10 CFR 35.13(e) requires that a licensee shall apply for and must receive a license amendment before it adds to or changes the areas of use or address or addresses of use (of licensed material) identified in the application or in the license.

Contrary to the above, as of November 21, 1990, the licensee changed the location of use of radioactive xenon gas from room 609D to 626D without applying for or receiving a license amendment.

- N. 10 CFR 35.50(e)(3) requires that licensees retain records of quarterly dose calibrator linearity tests for 3 years unless directed otherwise and that the record include the model and serial number of the dose calibrator, the calculated activities, the measured activities, the date of the test and the signature of the Radiation Safety Officer.

Contrary to the above, as of November 21, 1990, records of quarterly linearity tests did not contain the serial number of the dose calibrator nor the signature of the Radiation Safety Officer.

- O. 10 CFR 35.50(e)(1) requires that licensees retain records of daily constancy checks of dose calibrators for 3 years unless directed otherwise and that the records include the model and serial number of the dose calibrator, the identity of the radionuclide contained in the check source, the date of the check, the activity measured and the initials of the individual who performed the test.

Contrary to the above, as of November 21, 1990, records of daily constancy checks did not include the model and serial number of the dose calibrator.

- P. 10 CFR 35.50(e)(4) requires that licensees retain records of tests for dose calibrator geometrical dependence for 3 years unless directed otherwise and that the records include the model and serial number of the dose calibrator, the configuration of the source measured, the activity measured for each volume measured, the date of the test, and the signature of the Radiation Safety Officer.

Contrary to the above, as of November 21, 1990, the records of tests for geometrical dependence did not include the serial number of the dose calibrator nor the signature of the Radiation Safety Officer.

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

Cumulative Civil Penalty - \$3,750 (assessed equally among the 18 violations)

Pursuant to the provision of 10 CFR 2.201, Veterans Administration Medical Center is hereby required to submit a written statement or explanation to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, within 30 days of the date of the Notice of Violation and Proposed Imposition of 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 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, 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. 2282(c).

The responses to the Director, Office of Enforcement, noted above (Reply to a Notice of Violation, letter with payment of civil penalty, and Answer to a Notice of Violation) should be addressed to: Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, 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 29th day of January 1991

II.B. MATERIAL LICENSEES, SEVERITY LEVEL III VIOLATION,
NO CIVIL PENALTY



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

MAR 01 1991

Docket No. 030-14871
License No. 45-18332-01
EA 91-010

Stuart Circle Hospital
ATTN: Mr. David A. Schertz
Administrator
413 Stuart Circle
Richmond, Virginia 23220

Gentlemen:

SUBJECT: NOTICE OF VIOLATION
(NRC INSPECTION REPORT NO. 45-18332-01/91-01)

This refers to the Nuclear Regulatory Commission (NRC) inspection conducted by Mr. W. Loo on January 11, 1991, at the Stuart Circle Hospital facility in Richmond, Virginia, which included a review of the facts and circumstances related to the improper transfer of NRC licensed byproduct material to an unauthorized individual on September 29, 1990. The incident, which was identified by the licensee on October 1, 1990, and reported to the NRC by letter dated October 4, 1990, involved the alleged theft of a Lixiscope device from the facility. The inspection also identified weaknesses in the radiation safety program. The report documenting this inspection was sent to you by letter dated January 28, 1991. As a result of the inspection to review the loss of control of the Lixiscope, a significant failure to comply with NRC regulatory requirements was identified. An Enforcement Conference was held on February 5, 1991, in the Region II office to discuss the violation, its cause, and your corrective actions to preclude recurrence. The report summarizing this conference was sent to you by letter dated February 28, 1991.

On September 29, 1990, at approximately 6:00 p.m., an individual identifying himself as an employee of the nuclear pharmacy used by the licensee allegedly approached a contract x-ray technologist who was working the weekend shift and indicated that he was there to pick up the Lixiscope device. The individual also informed the technologist that the Director of Radiology was aware that he was coming to pick up the Lixiscope. The technologist gave the Lixiscope to the individual.

On October 1, 1990, the Director of Radiology reviewed the Lixiscope logbook and noticed that the Lixiscope had not been logged in after being used the previous week by an authorized user. The Director of Radiology contacted the user and was informed by that individual that the Lixiscope had been returned on September 29, 1990, however, no notation was entered into the log. The Director of Radiology later checked the storage cabinet and noted that the device was not in the cabinet. He then contacted the technologist who was on duty over the weekend and learned that he had given the Lixiscope to an individual who claimed to be from the nuclear pharmacy. Subsequent contact with the pharmacy revealed that they did not have the device and that no one from the pharmacy had been to the facility on September 29, 1990. Based on that

MAR 01 1991

information, the Director of Radiology contacted the Richmond Police Department and reported the device as stolen.

Violations A and B described in the enclosed Notice of Violation (Notice) involved the improper transfer of licensed byproduct material estimated to be approximately 49 millicuries of iodine-125 as a sealed source in the Lixi-scope device at the time of the transfer. The violation was in part a result of the lack of training regarding the proper transfer of byproduct material as the technologist had not been properly trained with regard to the procedures and policy for control and handling of the device. Furthermore, the carrying case containing the device was unlocked and the keys for activating the device were in the carrying case when it was given to the unidentified individual. The NRC is concerned because this incident constitutes a significant failure to control licensed material. There is the potential for unnecessary radiation exposure should the device be used on humans or should the sealed source be compromised in some way since the device is not in the control of the licensee. Therefore, these violations are classified in the aggregate as a Severity Level III problem, in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy) 10 CFR Part 2, Appendix C (1990).

A civil penalty is considered for a Severity Level III problem. However, after consultation with the Director, Office of Enforcement, I have decided that a civil penalty will not be proposed in this case. Full mitigation of the base civil penalty was warranted for your identification and reporting of the incident and for good past performance. While NRC acknowledges your corrective action, which included controlling all licensed material in use at your facility through the Nuclear Medicine Department, procedures requiring positive identification of personnel removing licensed material from controlled areas, and enhanced training for personnel involved in the control and handling of licensed material; additional actions were warranted in attempting to alert personnel to the loss and to recover the device, such as notification of the general hospital staff, notification of local medical and professional organizations, and closer coordination with law enforcement authorities regarding the progress of the investigation.

Violations C through E in the enclosed Notice involved the failure to perform required accuracy and linearity testing on a dose calibrator, failure to perform radiation surveys with a radiation detection survey instrument, and failure to perform required constancy checks on the dose calibrator. These violations have been categorized at Severity Level IV. The NRC is concerned that these violations indicate a lack of sensitivity to requirements to ensure that radiation measuring instruments function properly and failure to ensure that radiation surveys were performed on weekends to detect any residual contamination from nuclear medicine procedures.

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

Stuart Circle Hospital

- 3 -

MAR 01 1991

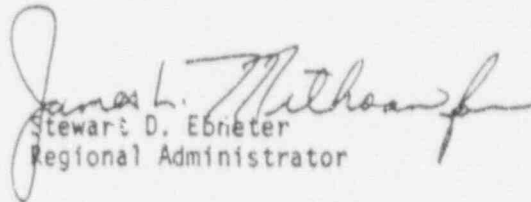
inspections, the NRC will determine whether further NRC enforcement action is necessary to ensure compliance with NRC regulatory requirements.

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. Ebrieter
Regional Administrator

Enclosure:
Notice of Violation

NOTICE OF VIOLATION

Stuart Circle Hospital
Richmond, Virginia

Docket No. 030-14871
License No. 45-18332-01
EA 91-010

During an NRC inspection conducted on January 11, 1991, violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C (1990), the violations are listed below:

- A. 10 CFR 30.41(a) and (b)(5) require, in part, that no licensee transfer byproduct material except to a person authorized to receive such byproduct material under the terms of a specific or general license issued by the Commission or Agreement State.

Contrary to the above, on September 29, 1990, the licensee transferred a Lixiscope device containing approximately 49 millicuries of iodine 125 to 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.

- B. 10 CFR 35.21(a) requires that a licensee appoint a Radiation Safety Officer responsible for implementing the radiation safety program. The licensee, through the Radiation Safety Officer, is required to ensure that radiation safety activities are being performed in accordance with approved procedures. 10 CFR 35.21(b)(2) requires, in part, that the Radiation Safety Officer implement procedures for training personnel who work in or frequent areas where byproduct material is used or stored.

Contrary to the above, as of September 29, 1990, the licensee's appointed Radiation Safety Officer did not implement procedures for training a contract radiologic technologist who worked in or frequented areas where byproduct material was used or stored, including training in the licensee's procedure for controlling the Lixiscope, which resulted in the transfer of byproduct material to an unauthorized person.

Violations A and B have been categorized in the aggregate as a Severity Level III problem. (Supplements IV and VI).

- C. 10 CFR 35.50(b)(2) and (3) require, in part, that the licensee test each dose calibrator for accuracy and linearity upon installation.

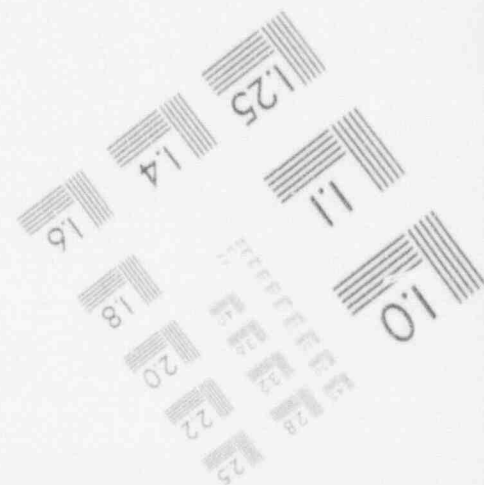
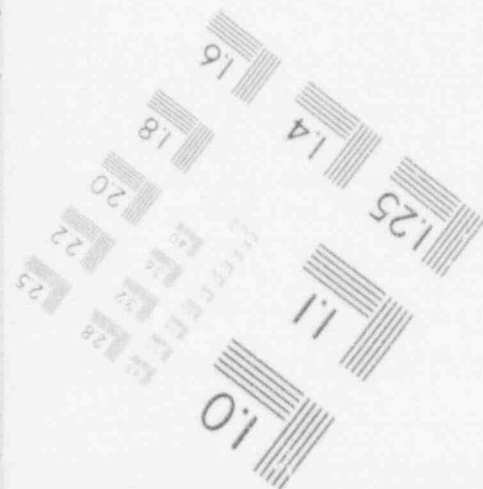
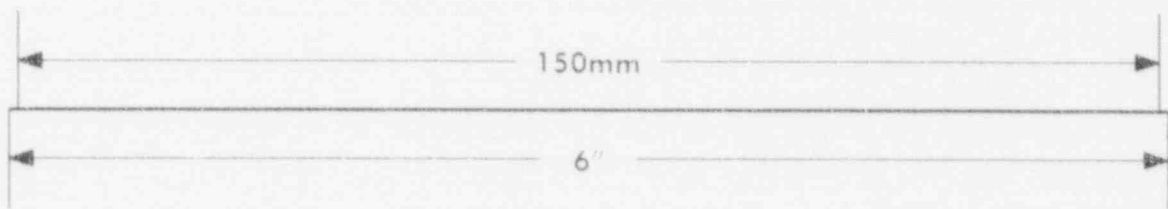
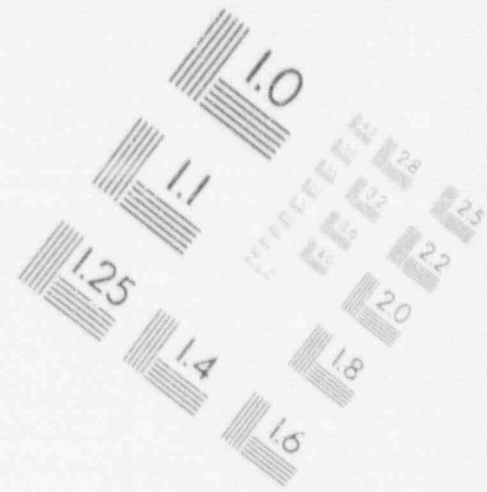
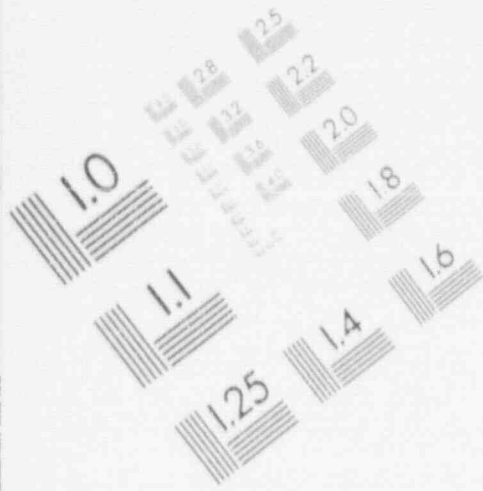
Contrary to the above, on May 1, 1990, the licensee installed and put into use a new dose calibrator; however, accuracy and linearity tests were not performed until June 19, 1990 and May 21, 1990, respectively.

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

- D. 10 CFR 35.70(a) requires, in part, that the licensee survey with a radiation detection survey instrument at the end of each day of use all

2

IMAGE EVALUATION TEST TARGET (MT-3)



PHOTOGRAPHIC SCIENCES CORPORATION
770 BASKET ROAD
P.O. BOX 338
WEBSTER, NEW YORK 14580
(716) 265-1600

areas where radiopharmaceuticals are routinely prepared for use or administered.

Prior to January 30, 1990, Condition 18 of NRC License No. 45-18332-01 required that licensed material be possessed and used in accordance with the statements, representations and procedures described in the license application dated December 28, 1983, and in the documents submitted in support of that application.

Item 17.1 of the license application required that preparation and injection areas will be surveyed on a daily basis with an appropriately low range G-M survey meter.

Contrary to the above, between November 2, 1988 and January 11, 1991, the licensee did not survey with a radiation detection survey instrument at the end of each day of use areas where radiopharmaceuticals were prepared for use or administered. Specifically, on 28 occasions when nuclear medicine studies were performed on weekends, the surveys were not conducted.

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

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

Prior to January 30, 1990, Condition 18 of NRC License No. 45-18332-01 required that licensed material be possessed and used in accordance with the statements, representations and procedures described in the license application dated December 28, 1983, and in the documents submitted in support of that application.

Item 10.1 of the license application required that the constancy of the dose calibrator will be determined on a daily basis.

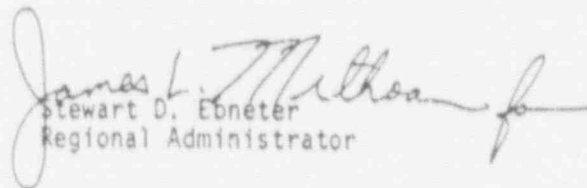
Contrary to the above, between November 2, 1988 and January 11, 1991, the dose calibrator was not checked for constancy with a dedicated checked source at the beginning of each day the dose calibrator was used to measure patient doses of radiopharmaceuticals. Specifically, on 28 occasions when nuclear medicine studies were performed on weekends the constancy check was not performed.

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

Pursuant to the provisions of 10 CFR 2.201, Stuart Circle Hospital is hereby required to submit a written statement of explanation to the 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, Suite 2900, 101 Marietta Street, N.W., Atlanta, Georgia 30323, within 30 days of the date of 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 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 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. Where good cause is shown, consideration will be given to extending the response time. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, this response shall be submitted under oath or affirmation.

FOR THE NUCLEAR REGULATORY COMMISSION


Stewart D. Ebner
Regional Administrator

Dated at Atlanta, Georgia
this 1st day of March 1991



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

MAR 01 1991

Docket No. 030-14716
License No. 47-06067-03
EA 91-013

Union Carbide Chemicals and
Plastics Company, Inc.
Silicones Plant, Esters Unit
ATTN: Mr. L. W. Phair
Plant Manager
P.O. Box 180
Sisterville, West Virginia 26175

Gentlemen:

SUBJECT: NOTICE OF VIOLATION
(NRC INSPECTION REPORT NO. 47-06067-03/91-01)

This refers to the Nuclear Regulatory Commission (NRC) inspection conducted by D. Collins on January 3-4, 1991, at the Union Carbide Chemicals and Plastics Company facility located in Sisterville, West Virginia. This special announced safety inspection was conducted to review the misalignment of a 37 millicurie cesium-137 sealed source holder with an open shutter that had been rotated away from the condenser tank where it was intended to monitor the tank content level. The incident, which had been identified by the licensee on December 9, 1990, initially occurred on December 6, 1990, and became known to the NRC through an allegation received on December 15, 1990. A Confirmation of Action Letter was sent to you on December 19, 1990. The report documenting this inspection was sent to you by letter dated January 25, 1991. As a result of this inspection, significant failures to comply with NRC regulatory requirements were identified. An Enforcement Conference was held on February 4, 1991, in the Region II office to discuss the violations, their cause, and your corrective actions to preclude recurrence. The report summarizing this conference was sent to you by letter dated February 15, 1991.

On December 6, 1990, after 4:00 p.m., and continuing until identification at 2:45 a.m. on December 9, 1990, a 37 millicurie cesium-137 sealed source holder (level detector) with an open shutter was rotated about 90 degrees horizontally away from the condenser tank it was intended to monitor. Although the level detector was not pointed into a nearby general walkway, it was pointed toward a space between tanks and other piping in the immediate vicinity. The nearest general walkway position was about eight feet from the source head.

During the approximate 59-hour period that the level detector was misaligned, 58 individuals were known to have spent some portion of their workday in the vicinity of the source's radiation beam. Two individuals were identified as having spent a significant portion of their work time in the area and within the radiation field. Dose calculations for these individuals concluded that they received 270 millirem. Further dose calculations for the remaining 56 individuals determined that ten individuals could have received between approximately 10 and 50 millirem and the others could have received less than 2 millirem. A plant investigation determined that the radiation field from

MAR 01 1991

the level detector was 162 millirem per hour (mRem/hr) at 12 inches from the source holder's face; 72 mRem/hr at 18 inches; 18 mRem/hr at 3 feet; and 2 mRem/hr at 8 feet.

Although the specific cause of the misalignment of the level detector cannot be accurately determined, it is apparent that had the source holder been locked or closed prior to the start of maintenance activities, workers would not have been subjected to unnecessary radiation exposure. In addition, management controls to assure there was no radiation exposure to non-radiation workers were ineffective.

The violations described in the enclosed Notice of Violation (Notice) involved radiation levels in unrestricted areas that exceeded levels established by regulatory requirements; unauthorized relocation of a sealed source on at least three occasions in connection with the incident; and various labeling and posting requirements directed by license conditions and NRC regulations. This incident had the potential for serious consequences to health and safety of workers in that individuals were unnecessarily exposed to radiation. Therefore, in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions" (Enforcement Policy), 10 CFR Part 2, Appendix C (1990), four of the violations which were directly related to the incident are classified in the aggregate as a Severity Level III problem. A fifth violation involving the failure to post required documents was classified as a Severity Level V violation.

NRC recognizes that immediate corrective action was taken when the violation was identified and that the facts and circumstances of this incident will be disseminated throughout the Union Carbide Corporation to facilitate a lessons-learned review at all facilities utilizing NRC licensed radioactive material.

A civil penalty is considered for a Severity Level III problem. However, after consultation with the Director, Office of Enforcement, I have decided that a civil penalty will not be proposed in this case. Mitigation of the base civil penalty was warranted for your identification and reporting of the incident and for good past performance. Some additional mitigation was warranted for corrective action in that once you were aware of the problem, you acted quickly to secure the sealed source and initiate an investigation to determine the facts and circumstances of the event. However, we note that there was an initial reluctance to initiate modifications in procedures and training relative to radiation safety. Your proposed long-term corrective actions now do include revision of procedures and training to include added emphasis on radiation safety.

While a civil penalty is not being proposed, it is important to emphasize that the loss of control of licensed material is of serious regulatory concern and that any recurrence may result in escalated enforcement action, including civil penalties and modification, suspension, or revocation of your license. Further, as stated in the Enforcement Policy, when a violation is discovered at one

MAR 01 1991

facility or location, NRC expects corporate managers to take action as appropriate to prevent similar violations from occurring at other facilities or divisions where licensed material is used.

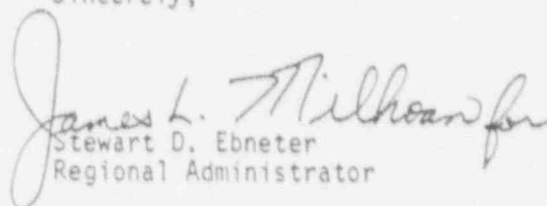
You are required to respond to this letter and should follow the instructions specified in the enclosed Notice of Violation (Notice) when preparing your response. In your response, you should document the specific actions taken and any additional actions you plan to prevent recurrence. In doing so, you may make reference to any correspondence previously submitted to the NRC. In addition, you should include with, or append to, your response a description of actions that have been taken or will be taken by Union Carbide Corporation to prevent similar incidents at other facilities or divisions that use radioactive gauges under NRC licenses. After reviewing your response to this Notice, including your proposed corrective actions and the results of future inspections, the NRC will determine whether further NRC enforcement action is necessary to ensure compliance with NRC regulatory requirements.

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

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

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

Sincerely,


Stewart D. Ebner
Regional Administrator

Enclosure:
Notice of Violation

cc w/encl:
State of West Virginia

NOTICE OF VIOLATION

Union Carbide Chemicals
and Plastics Company, Inc.
Sistersville, West Virginia

Docket No. 030-14716
License No. 47-06067-03
EA 91-013

During an NRC inspection conducted on January 3-4, 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 (1990), the violations are listed below:

- A. 10 CFR 20.105(b) requires that, except as authorized by the Commission in 10 CFR 20.105(a), no licensee allow the creation of radiation levels in unrestricted areas so that an individual who was continuously present in the area could receive a dose in excess of 2 millirems in any one hour or 100 millirems in any seven consecutive days.

Contrary to the above, from about 4:00 p.m. on December 6 until 2:45 a.m. on December 9, 1990, a period exceeding one hour, the licensee allowed the creation of radiation levels in the modification work area on the third level of the Esters Tower, an unrestricted area, such that an individual who was continuously present in the area could have received a dose in excess of 2 millirems in any one hour or 100 millirems in any seven consecutive days. Specifically, the radiation beam from a misaligned fixed gauge with an open shutter and 37 millicuries of cesium-137 projected a whole body radiation dose of 125 millirem per hour at 1 foot, and 12 millirem per hour at 1 meter.

- B. 10 CFR 20.203(f) requires that, except as provided by 10 CFR 20.203(f)(3), each container of specified amounts of licensed material bear a durable, clearly visible label identifying the radioactive contents.

Contrary to the above, on December 6 through 8, 1990, a fixed gauge housing on the Esters Tower did not have a clearly visible and legible label identifying the 37 millicurie cesium-137 sealed source contents, and the container was not exempt from such labeling.

- C. Condition 14 of License No. 47-06067-03 requires that installation, relocation and removal of fixed gauges may be performed by Union Carbide Corporation, under the provision of NRC License No. 47-06067-02 or others specifically authorized to perform those services.

Contrary to the above, three individuals not authorized by NRC License No. 47-06067-02 or otherwise specifically licensed to perform this service, relocated from its position a 37 millicurie cesium-137 sealed source housing as follows:

1. On December 6, 1990, an individual relocated the sealed source housing with the shutter in the open position by rotating the housing approximately 90 degrees from its intended position.

2. On December 9, 1990, an individual removed the sealed source housing from its mount and subsequently replaced the housing with the shutter in the closed position.
3. On December 10, 1990, an individual removed the sealed source housing from its bracket, and adjusted the unit with the shutter in the closed position to restore the unit to its service position.
- D. 10 CFR 203(b) requires that each radiation area be conspicuously posted with a sign or signs bearing the radiation caution symbol and words "Caution - Radiation Area."

Contrary to the above, from December 6 through 9, 1990, a radiation area exceeding 12 millirem per hour at 1 meter was created on the third level of the Esters Tower and no signs bearing the radiation caution symbol and the words "Caution - Radiation Area" were posted.

Violations A through D are categorized in the aggregate as a Severity Level III problem (Supplements IV and VI).

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

Contrary to the above, on January 3, 1991, the licensee did not have any of the required documents or notices posted.

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

Pursuant to the provisions of 10 CFR 2.201, Union Carbide Chemicals and Plastics Company, Inc. is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555, with a copy to the Regional Administrator, Region II, within 30 days of the date of the letter transmitting this Notice of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each violation: (1) the reason for the violation, or, if contested, the basis for disputing the violation, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken to avoid further violations, and (4) the date when full compliance will be achieved. If an adequate reply is not received within the time specified in this Notice, an order may be issued to show cause why the license should not be modified, suspended, or revoked, or

Notice of Violation

3

why such other action as may be proper should not be taken. Where good cause is shown, consideration will be given to extending the response time. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, this response shall be submitted under oath or affirmation.

FOR THE NUCLEAR REGULATORY COMMISSION

James L. Milburn
Stewart D. Elinger
Regional Administrator

Dated at Atlanta, Georgia
this ~~20th~~ day of February 1991

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11. ABSTRACT (200 words or less)

This compilation summarizes significant enforcement actions that have been received during one quarterly period (January - March 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.

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