NUREG-0940
Vol. 18, No. 2, Part 3
Material Licensees

Enforcement Actions: Significant Actions Resolved Material Licensees

Semiannual Progress Report
July - December 1999

U.S. Nuclear Regulatory Commission
Office of Enforcement
Washington, DC 20555-0001

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NOTICE

NUREG-0940, Enforcement Actions: Significant Actions Resolved, has been published since 1982 to provide NRC-regulated industries and the public with information about the more significant enforcement actions taken by the agency. Recently, the development and widespread use of electronic information dissemination has changed the nature of communicating between federal agencies, their licensees, and the public.

The printed version of NUREG-0940 has been published approximately every six months. Thus, given the time needed to prepare, print, and distribute the document, copies of some actions do not reach licensees and others until 8-9 months after issuance. However, all enforcement actions that are published in NUREG-0940 are now posted on the NRC website, under the Office of Enforcement home page, promptly after issuance. See: www.nrc.gov/OE

Accordingly, the NRC has evaluated the effectiveness of using the resources needed to publish the printed version of NUREG-0940. The NRC has concluded that continuing to publish material in hard copy, when that information is currently and more promptly available electronically, is neither an effective use of resources nor consistent with the Congressional mandate to maximize use of Information Technology and is no longer appropriate. Therefore, this issue is the last that will be issued unless the agency receives significant public comment in favor of continued publication. If you wish to comment, send your views, no later than August 31, 2000, to:

R. W. Borchardt, Director
Office of Enforcement (O-14E1)
U. S. Nuclear Regulatory Commission
Washington, DC 20555-

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ABSTRACT

This compilation summarizes significant enforcement actions that have been resolved during the period (July - December 1999) and includes copies of letters, Notices, and Orders sent by the Nuclear Regulatory Commission to material licensees with respect to these enforcement actions. It is anticipated that the information in this publication will be widely disseminated to managers and employees engaged in activities licensed by the NRC, so that actions can be taken to improve safety by avoiding future violations similar to those described in this publication.

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ENFORCEMENT ACTIONS: SIGNIFICANT ACTIONS RESOLVED
MATERIAL LICENSEES

July - December 1999

INTRODUCTION

This issue and Part of NUREG-0940 is being published to inform Nuclear Regulatory Commission (NRC) Material licensees about significant enforcement actions and their resolution for the second half of 1999. Enforcement actions are issued in accordance with the NRC's Enforcement Policy, published as NUREG-1600, "General Statement of Policy and Procedure for NRC Enforcement Actions." Enforcement actions are issued by the Deputy Executive Director for Regulatory Effectiveness (DEDE), and the Regional Administrators. The Director, Office of Enforcement, may act for the DEDS in the absence of the DEDS or as directed. The NRC defines significant enforcement actions or escalated enforcement actions as civil penalties, orders, and Notices of Violation for violations categorized at Severity Level I, II, and III (where violations are categorized on a scale of I to IV, with I being the most significant).

The purpose of the NRC Enforcement Program is to support the agency's safety mission in protecting the public and the environment. Consistent with that purpose, the NRC makes this NUREG available to all materials licensees in the interest of avoiding similar significant noncompliance issues. Therefore, it is anticipated that the information in this publication will be widely disseminated to managers and employees engaged in activities licensed by NRC.

A brief summary of each significant enforcement action that has been resolved in the second half of 1999 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 in accordance with the Enforcement Policy.

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

Section A of this report consists of copies of completed civil penalty or Order actions involving materials licensees, arranged alphabetically. Section B includes copies of Notices of Violation that were issued to materials licensees for a Severity Level I, II, or III violation, but for which no civil penalties were assessed.

The NRC publishes significant enforcement actions taken against individuals and involving reactor licensees as Parts I and II of NUREG-0940, respectively.

SUMMARIES

A. CIVIL PENALTIES AND ORDERS

Anvil Corporation, Bellingham, Washington
Supplements IV and VI, EA 99-083

A Notice of Violation and Proposed Imposition of Civil Penalty in the amount of $8,800 was issued June 28, 1999. The action was based on a Severity Level II problem involving a radiography incident in Billings, Montana, in which a radiographer and his assistant both received exposures that caused their occupational doses to be in excess of NRC limits. As a result, the radiographer's annual exposure (TEDE) for 1998 was 5.7 rem, and the assistant's annual exposure (TEDE) for 1998 was 12.8 rem. Although the NRC staff determined that the licensee deserved credit for both Identification and Corrective Action, the staff concluded that it should exercise discretion, in accordance with Section VII.A.1 of the Enforcement Policy, to impose a civil penalty based on the two overexposures. Other violations are also cited, including failure to personally supervise a radiographer's assistant, failure to perform an adequate survey following a radiographic exposure, and failure to wear an operating alarm ratemeter. The licensee responded and paid the civil penalty on July 28, 1999.

International Radiography and Inspection Services, Tulsa, Oklahoma
Supplements IV and VI, EAs 98-565 and EA 99-090

A Notice of Violation and Proposed Imposition of Civil Penalties in the amount of $17,600 was issued May 4, 1999. These civil penalties were assessed to emphasize the significance of the total disregard for safety in this case by the involved individuals and the importance of assuring that licensee employees adhere to all radiation safety requirements in the future. This action was based on two Severity Level II problems for: (1) several deliberate violations, including failure to conduct radiation surveys at a job site where radiography was being conducted and failure to utilize personnel radiation monitoring equipment, which resulted in a failure to limit an occupational exposure of an assistant radiographer to NRC limits; and (2) deliberate violations involving resumption of radiography activities after the radiographer's assistant's pocket dosimeter was found to be off-scale and before a determination of the radiographer's assistant's radiation exposure had been made, failure to immediately contact the licensee's radiation safety after a radiographer's assistant's pocket dosimeter was found to be off scale, and resumption of radiography operations with no radiation survey instruments present and without conducting a survey of the radiographic exposure device and the guide tube after each exposure. The staff considered the licensee's efforts in investigating the incident, identifying the violations, and taking prompt and comprehensive corrective actions following the incident. However, given the egregiousness and deliberate nature of the violations in this case, the staff proposed the amount of $17,600 (i.e., base civil penalties for each of the Severity Level II problems). The licensee responded on June 16, 1999, requesting a 50% mitigation based on the licensee's thorough investigation of the violations and their classification as a small entity. In addition, they requested that their payments be paid over time. NRC and the licensee agreed to a $13,200 civil penalty and a settlement was agreed to on July 8, 1999.

Allan A. Myers, Inc., Worcester, Pennsylvania
Supplements VI and VII, EA 99-042

A Notice of Violation and Proposed Imposition of Civil Penalty in the amount of $2,750 was issued July 13, 1999 to emphasize the importance of compliance with regulatory requirements. This action is based on a Severity Level III problem involving a licensee official who deliberately allowed a licensee employee to use a nuclear gauge without being properly trained or certified and without wearing appropriate dosimetry. In addition, the gauge was left unattended at the work site. The staff concluded that no credit was warranted for identification of the problem since the problem was identified by the NRC staff. The staff concluded that credit was warranted for corrective actions. As a part of its corrective actions, the licensee provided refresher training for all gauge users and the individual. The licensee responded and paid the civil penalty on July 29, 1999.

Professional Service Industries, Inc., Lombard, Illinois
Supplement VI, EA 99-194

A Notice of Violation and Proposed Imposition of Civil Penalty in the amount of $8,800 was issued October 22, 1999, to emphasize the significance of deliberate violations of safety requirements and the importance of prompt identification of violations. The action was based on one Severity Level II problem involving the deliberate failure to: (1) conduct radiography with at least two qualified individuals to observe operations; and (2) supervise a radiographer's assistant while performing radiographic operations. Credit for corrective actions was warranted because the licensee took prompt and comprehensive corrective actions. The licensee responded and paid the civil penalty on November 10, 1999.

Roof Survey and Consultants, Inc., Roanoke, Virginia
Supplement VI, EA 99-223

An Order Modifying Order Suspending License (Effective Immediately) and Order Revoking License was issued October 4, 1999. The Order was issued because (1) the Company did not comply with an Order Suspending License that was issued April 3, 1997, and (2) the Company did not pay the annual fee for fiscal year 1996. The license was terminated November 16, 1999.

Testing Engineers & Consultants, Inc., Troy, Michigan
Supplements IV and VII, EAs 99-097 and 99-169

A Notice of Violation and Proposed Imposition of Civil Penalties in the amount of $5,500 was issued July 8, 1999 to emphasize the importance of compliance with all regulatory requirements including the provision of complete and accurate information to the NRC. The action was based on two Severity Level III violations involving a deliberate failure to control and maintain constant surveillance of licensed material in an unrestricted area at a temporary jobsite and a deliberate failure to provide complete and accurate information to NRC inspectors during an NRC inspection. Credit was not warranted for identification of the violations because the NRC staff identified the violations. Credit was warranted for corrective actions because the licensee took prompt and comprehensive actions. The licensee responded on August 4 and 13, 1999 admitting the violations but requesting mitigation or remission of the civil penalties. After consideration of the

licensees responses, the NRC staff concluded that the reasons for remission or mitigation were not warranted. An Order Imposing Civil Monetary Penalty was issued September 24, 1999. The licensee paid the civil penalties on October 7, 1999.

United States Enrichment Corporation, Bethesda, Maryland
Supplement VIII, EA 99-080

A Notice of Violation and Proposed Imposition of Civil Penalty in the amount of $55,000 was issued June 29, 1999 to emphasize the importance of early identification of deficiencies prior to the issues being revealed through an event. This action was based on a Severity Level III violation involving the failure to classify, as an Alert, an emergency situation at USEC's Portsmouth plant which could have led to a release of radioactive material into the environment. Because the Portsmouth plant had been the subject of escalated enforcement action within the last two years, the staff considered whether credit was warranted for *Identification* and *Corrective Action*. Credit for *identification* was not warranted because USEC staff missed opportunities to identify and/or prevent the violation. However, credit for *corrective action* was warranted because USEC took prompt and comprehensive action to define the magnitude of the problem and to implement corrective actions.

United States Enrichment Corporation, Bethesda, Maryland
Supplement VII, EA 99-110

A Notice of Violation and Proposed Imposition of Civil Penalty in the amount of $88,000 was issued December 20, 1999. The action was based on an investigation which involved discrimination against the former Manager of Quality Systems at the Paducah facility by his supervisor, the Manager of Safety, Safeguards, and Quality. The Manager had raised nuclear safety concerns regarding a lack of completeness in the Paducah (QAP) and that non-QAP related activities, required of the manager were negatively impacting his group's responsibilities as outlined in the QAP. Based on these protected activities, the individual was transferred to a non-managerial training department position. The base civil penalty for a Severity Level II was applied since the company informed the NRC that a broad corrective action was planned and training sessions had been initiated prior to the enforcement conference.

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

Department of Veterans Affairs, Edward Hines, Jr. Hospital, Hines, Illinois
Supplement VI, EA 99-284

A Notice of Violation for a Severity Level III violation was issued December 15, 1999, based on a violation involving a brachytherapy misadministration. Specifically, ineffective training resulted in one individual failing to enter a treatment planning parameter into the console of the high dose rate afterloader unit and a second individual failing to ensure the parameters were correctly entered in accordance with written directive prior to commencing treatment. The civil penalty was fully mitigated because: (1) this was the first escalated issue in 2 years, and (2) credit was warranted for corrective action.

Department of Veterans Affairs Medical Center, Iowa City, Iowa
Supplement VI, EA 99-174

A Notice of Violation for a Severity Level III violation was issued October 14, 1999, based on a violation involving the failure to determine that members of the public were not likely to receive a total effective dose equivalent greater than 500 millirem from released human research subjects administered therapeutic doses of Sn-117m and the subsequent failure to provide that released subjects with written instructions on how to maintain doses to others as low as is reasonably achievable. The civil penalty was fully mitigated because: (1) this was the first escalated issue in 2 years, and (2) credit was warranted for corrective action.

Envirocare of Utah, Inc., Salt Lake City
Supplements IV and VI, EA 99-168

A Notice of Violation for a Severity Level III violation was issued August 16, 1999, based on a violation involving the failure to perform adequate surveys in accordance with 10 CFR 20.1501. A civil penalty was not proposed because the licensee had not been the subject of a civil penalty in the past two years and credit was warranted for corrective actions as described in the licensee's February 19, 1999 letter.

Fox Chase Cancer Center, Philadelphia, Pennsylvania
Supplement VI, EA 99-294

A Notice of Violation for a Severity Level III violation was issued November 30, 1999. The action was based on a violation involving the approval of 13 physicians to use radioactive material without meeting all of the training requirements as set forth in the NRC regulations. The civil penalty was fully mitigated because: (1) this was the first escalated issue in 2 years, and (2) credit was warranted for corrective action, as described during the inspection, were considered prompt and comprehensive.

Georgetown University Medical Center, Washington, DC
Supplement VI, EA 99-231

A Notice of Violation for a Severity Level III violation was issued on September 10, 1999. The action was based on the failure to secure from unauthorized removal, access, or tampering and maintain constant surveillance of licensed material (11-Curie irridium-192 sealed source) in accordance with 10 CFR 20.1801 and 10 CFR 20.1802. The civil penalty was fully mitigated because: (1) this was the first escalated issue in 2 years, and (2) credit was warranted for corrective action.

Holy Redeemer Hospital and Medical Center, Meadowbrook, Pennsylvania
Supplement VI, EA 99-246

A Notice of Violation for a Severity Level III violation was issued on November 3, 1999. The action involved the failure to properly implement the Quality Management Program for the facility in that a dose was administered to a patient without preparation of a written directive. This violation contributed to a misadministration at the licensee's facility when a patient, who was to be evaluated for hyperthyroidism via an uptake procedure using approximately 300 microcuries of iodine-123, was given a 5.3 millicurie dose of iodine-131 for a head and neck study. A civil penalty was not proposed

because the licensee had not been the subject of a civil penalty in the past two years and credit was warranted for corrective actions which were prompt and comprehensive.

Howard University, Washington, DC
Supplement VI, EA 99-211

A Notice of Violation for a Severity Level III violation was issued on September 17, 1999. This action was based on: (1) failure to secure from unauthorized removal, access, or tampering and maintain constant surveillance of licensed material; (2) failure to provide to employees instruction about health protection problems associated with exposure to radiation; and (3) failure to immediately report to the NRC loss of licensed material. The civil penalty was fully mitigated because: (1) this was the first escalated issue in 2 years, and (2) credit was warranted for corrective action.

Material Testing Consultants, Inc., Grand Rapids, Michigan
Supplement VI, EA 99-253

A Notice of Violation for a Severity Level III violation was issued on November 22, 1999. The action was based on (1) the failure to control licensed material in an unrestricted area. As a result of this failure, a moisture density gauge containing licensed material was struck and damaged. (2) The operator failed to follow emergency procedures, in that he left the device in its damaged condition unattended to telephone the RSO. Even though the licensee had been the subject of escalated enforcement action within the past two inspections, credit was warranted for identification and corrective actions.

Metorex, Inc., Ewing, New Jersey
Supplements VI and VII, EA 99-043

A Notice of Violation for a Severity Level III violation was issued August 19, 1999, based on an investigation which was conducted after the former President of Metorex, Inc. informed the NRC that Metorex, Inc. had distributed radioactive material prior to obtaining NRC authorization to do so. OI concluded that (1) the former Vice President/Radiation Safety Officer deliberately failed to stop shipments of the devices between January 1998 and July 1998, knowing that Metorex was not authorized to distribute them, and (2) the former RSO deliberately failed to submit quarterly reports to the NRC regarding the transfer of the material for the fourth quarter of 1997 and the first calendar quarter of 1998. A civil penalty was not proposed because the licensee's former President identified the violation and reported it to the NRC and credit was also warranted for corrective actions.

MidMichigan Medical Center, Midland, Michigan
Supplement VI, EA 99-215

A Notice of Violation for a Severity Level III violation was issued November 26, 1999. The action was based on violations involving failures to: (1) consult a written directive before administering a therapeutic quantity of iodine-131 to a patient, (2) report a misadministration in a timely manner, and (3) provide the NRC inspector with complete and accurate information. A civil penalty was not proposed, even though the violations were willful violations, because the licensee's staff identified the violations and exercised considerable effort to determine the root cause, credit was warranted for identification. Credit was also warranted for corrective actions taken and/or planned.

Bill Miller, Inc., Henryetta, Oklahoma
Supplement V, EA 99-013

A Notice of Violation for a Severity Level III violation was issued September 24, 1999, based on the failure to: (1) properly secure a source assembly in a source changer in the fully shielded position, install the safety plug and safety cap, register as a user, and have a copy of the applicable certificate of compliance, (2) always provide 40 hours of radiation safety training for radiographers, (3) administer written examinations Numbers 2 and 3 to previously trained radiographers, (4) perform the required audits of radiographers and radiographer's assistants during actual radiographic operations, and (5) provide the required training to radiographer's assistants. The civil penalty was fully mitigated because: (1) this was the first escalated issue in 2 years, and (2) credit was warranted for corrective action.

North Country Hospital and Health Center, Inc., Newport, Vermont
Supplement VI, EA 99-153

A Notice of Violation for a Severity Level III violation was issued July 20, 1999, based on an inspection which determined that a misadministration had occurred and had not been reported to the NRC. Three of the violations contributed to the misadministration and they involved the failures to (1) instruct the nuclear medicine technologist who administered the dose of approximately 305 microcuries of iodine-131 to the patient for a thyroid uptake study in accordance with the licensee's QMP, (2) supervise the technologist even though he had not been involved in an iodine-131 administration since 1990, and (3) establish, maintain, and implement the QMP for the facility in that the dose was administered without the preparation of a written directive beforehand. Two other violations involved (1) the failure of the RSO to investigate the misadministration, and (2) the failure to notify the NRC, the patient's physician or the patient of the misadministration. A civil penalty was not proposed because this was the first escalated action in two years and credit was warranted for corrective actions.

Nuclear Fuel Services, Inc., Erwin, Tennessee
Supplement III, EA 99-218

A Notice of Violation for a Severity Level III violation was issued October 19, 1999. The action was based on violations involving: (1) the failure to conduct or to conduct adequately two independent visual and detector searches by two individuals for a container removed from an access area. This resulted in the unauthorized removal of seven grams of Uranium-235 contained in high enriched uranium from the Building 233 vault to a Building 236 storage area, and (2) occurred as a result of the first violation, and involved the unauthorized storage of the 55-gallon drum containing the SNM in a location not approved for SNM storage, and the failure to assure that the movement of this material out of the vault was properly documented by the material control and accounting system at the facility. A civil penalty was not proposed because this was the first escalated action in two years and credit was warranted for corrective actions which included long-term training enhancements for security personnel.

Victor E. Rivera Associates, Geotechnical Engineers, Ponce, Puerto Rico
Supplement IV, EA 99-269

A Notice of Violation for a Severity Level III violation was issued November 23, 1999. The action was based on violations involving the failure to: (1) secure licensed materials from unauthorized removal or access, (2) limit the radiation dose in an unrestricted area to levels below two millirem in any one hour, (3) post a radiation area, (4) label containers of licensed material, and (5) check packages for physical condition prior to shipment. A civil penalty was not proposed because this was the first escalated action in two years and credit was warranted for corrective actions.

Saint Clare's Hospital, Dover, New Jersey
Supplement VI, EA 99-210

A Notice of Violation for a Severity Level III violation was issued August 16, 1999. The action was based on the loss of three iodine-125 brachytherapy seeds at the licensee's Dover, New Jersey facility. The NRC also learned that the loss of this material, which amounted to 0.79 millicuries of iodine-125 per seed, was not reported to the NRC as required. The violations involved (1) failure of the physicist to perform an adequate survey prior to cleaning the cartridges, (2) the subsequent loss of control of radioactive material when the seeds were pushed into the sink which resulted in the improper disposal of the radioactive seeds when they were washed down the sink and into the sanitary sewage system, and (3) the failure to notify NRC, within 30 days, after the material was lost. A civil penalty was not proposed because this was the first escalated action in two years and credit was warranted for corrective actions.

Southeastern Plastics Corporation, New Brunswick, New Jersey
Supplement VI, EA 99-297

A Notice of Violation for a Severity Level III violation was issued December 29, 1999. The action was based on the appearance of an Ohmart scanning gauge containing 1200 millicuries of krypton-85 at a warehouse that is owned by Zeta. The gauge was stored on a pallet and was among several other pieces of used machinery and equipment that had been brought to the warehouse from other plants to be sold at auction. The gauge had been acquired by Southeastern under a general license, and subsequently removed and transferred to the Zeta warehouse. This was an unauthorized transfer since Zeta does not have a specific NRC license to possess the gauge. A civil penalty was not proposed because this was the first escalated action in two years and credit was warranted for corrective actions, which once Southeastern was put on notice of the violation, were prompt and comprehensive.

St. John Hospital and Medical Center, Detroit, Michigan
Supplement VI, EA 99-289

A Notice of Violation for a Severity Level III violation was issued December 20, 1999, based on a violation involving a misadministration. Two qualified individuals under the supervision of the licensee's authorized user did not verify that the activity of the dose administered to an individual did not differ from the prescribed dose. A civil penalty was not proposed because this was the first escalated action in two years and credit was warranted for corrective actions.

St. Peter's Community Hospital, Helena, Montana
Supplement Vi, EA 99-245

A Notice of Violation for a Severity Level III violation was issued November 5, 1999. The action was based on the failure of the licensee to secure from unauthorized removal or limit access to millicurie quantities of iodine-131 located in a hallway adjoining the receiving department, an unrestricted area, nor did the licensee control and maintain constant surveillance of this licensed material. A civil penalty was not proposed because this was the first escalated action in two years and credit was warranted for corrective actions which were considered prompt and comprehensive.

The Ohio State University, Columbus, Ohio
Supplement VI, EA 99-175

A Notice of Violation for a Severity Level III violation was issued October 7, 1999. The action was based on the release of a human research subject without determining whether the quantity of radioactive material administered to the individual could potentially cause members of the public to receive radiation exposures greater than 500 millirem. A civil penalty was not proposed because this was the first escalated action in two years and credit was warranted for identification and corrective actions.

Triad Engineering, Inc., Morgantown, West Virginia
Supplement VI, EA 99-134

A Notice of Violation for a Severity Level III violation was issued July 8, 1999. The action was based on the failure to secure from unauthorized removal or limit access to licensed material, and the failure to control and maintain constant surveillance of licensed material stored in the bed of a pick-up truck at a temporary jobsite. A civil penalty was not proposed because this was the first escalated action in two years and credit was warranted for corrective actions.

A. CIVIL PENALTIES AND ORDERS

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

June 28, 1999

EA 99-083

Anvil Corporation
ATTENTION: Vern Grenier, Manager
1675 West Bakerview Road
Bellingham, Washington 98226

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY-$8,800
(NRC Inspection Report No. 030-32816/98-03 and Investigation Report No. 4-1998-055)

Dear Mr. Grenier:

This refers to the predecisional enforcement conference conducted on May 20, 1999, in the NRC Region IV office in Arlington, Texas. The conference was conducted to review the circumstances surrounding an incident that occurred on November 20, 1998, involving exposures to two Anvil employees that were in excess of NRC limits. You notified the NRC of the event on November 23, 1998, and provided a written report on the event by letter dated December 17, 1998. The results of our investigation and inspection activities were discussed with you and other Anvil employees on April 14, 1999. The inspection report was issued on April 30, 1999.

Based on the information developed during the inspection and investigation, and the information that Anvil provided during the conference, the NRC has determined that violations of NRC requirements occurred. These violations are cited in the enclosed Notice of Violation and Proposed Imposition of Civil Penalty. The circumstances surrounding the violations were described in detail in the subject inspection report. The violations involved failures to: (1) maintain occupational radiation doses to less than 5 rem per year; (2) supervise a radiographer's assistant while performing radiographic operations; (3) survey an exposure device and source guide tube after each exposure; and (4) wear an operating alarm ratemeter during radiographic operations (although the radiographer's assistant was wearing an alarm ratemeter, it was not operating since it was not turned on). These violations were identified following an incident in Montana where a radiographer's assistant did not completely retract the source into the radiography camera. As a result, the source was in a geometry such that it would not have been detected unless a survey instrument was placed in front of the port or near the guide tube, which the assistant did not do. Other problems discussed at the conference included: (1) the setup did not permit the radiographer to directly observe the assistant performing the survey and (2) after cranking in the source, the assistant did not try to push the source back out (to ensure the source was fully retracted and locked inside the camera).

As you know by our letter dated April 30, 1999, the NRC was also concerned that the following violations may have involved willfulness: (1) the radiographer and radiographer's assistant may have willfully failed to maintain constant visual surveillance of radiographic operations, (2) the radiographer's assistant may have willfully failed to check his alarm ratemeter at the start of the shift, and (3) the radiographer may have deliberately failed to supervise the radiographer's

assistant during the performance of radiographic operations and surveys. However, based on the information presented at the conference with Anvil and in a separate conference with the radiographer, the NRC has concluded that neither the radiographer nor his assistant willfully violated NRC requirements. However, their conduct constitutes violations of NRC requirements that are of significant concern, and form the basis, in part, for this enforcement action.

The violations are significant because both the radiographer and the radiographer's assistant received doses in excess of the NRC's annual dose limit of 5 rem. The radiographer's assistant received a dose of 11.8 rem which gave him a total annual dose of 12.8 rem. The radiographer received a dose of 3.9 rem which gave him a total annual dose of 5.7 rem. These overexposures were clearly preventable. It is particularly significant that several safety barriers were violated because of the actions of your employees. The barriers included performing complete surveys, properly using alarm ratemeters, and supervising an assistant. Based on the overexposures and these circumstances, the violations identified above are classified in the aggregate in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions" (Enforcement Policy), NUREG-1600 as a Severity Level II problem.

In accordance with the Enforcement Policy, a base civil penalty in the amount of $8,800 is considered for a Severity Level II problem. In accordance with the civil penalty assessment process in Section VI.B.2 of the Enforcement Policy, the NRC considered whether Anvil was deserving of *Identification* and *Corrective Action* credit. After reviewing the circumstances, the NRC concluded that Anvil is deserving of *Identification* credit because Anvil promptly identified the event to the NRC and conducted a thorough investigation. Also, NRC has determined that Anvil is deserving of Corrective Action credit. Anvils's corrective actions included promptly removing the involved individuals from radiographic operations, conducting training for the Billings, Montana radiographic personnel, and establishing an Assistant Radiation Safety Officer position in the Billings, Montana office. Normally, giving a licensee both *Identification* and *Corrective Action* credit would result in no civil penalty. However, because of the significance which NRC assigns to radiation doses in excess of NRC limits which were preventable by basic radiation safety practices, the NRC has decided to exercise discretion to impose a civil penalty in accordance with Section VII.A.1 of the Enforcement Policy. Accordingly, I have been authorized, after consultation with the Director, Office of Enforcement, and the Deputy Executive Director for Regulatory Effectiveness, to issue the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice) in the base amount of $8,800 for the Severity Level II problem. But for your actions in response to this event, the penalty would have been substantially higher. In addition, please note that issuance of this Notice constitutes escalated enforcement action that may subject you to increased inspection effort.

The April 30, 1999, cover letter to the NRC Inspection Report identified two additional apparent violations. These involved failures to: (1) perform surveys to ensure the dose to the unrestricted area is less than 2 millirem in any one hour, and (2) maintain constant visual surveillance of radiographic operations. Since these violations were not associated with the overexposure, they are cited separately in the enclosed Notice of Violation at Severity Level IV.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. The NRC will use your response, in part, to determine whether further enforcement action is necessary to ensure compliance with regulatory requirements.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter, Enclosure 1, and your response will be placed in the NRC Public Document Room.

Sincerely,

Ellis W. Merschoff
Regional Administrator

Docket No. 030-32816
License No. 46-23236-03

Enclosures:
1. Notice of Violation and Proposed Imposition of Civil Penalty
2. NUREG/BR-0254 Payment Methods (Licensee only)

cc w/Enclosure 1:
State of Washington

ENCLOSURE 1

NOTICE OF VIOLATION

Anvil Corporation
Billings, Montana

Docket No. 030-32816
License No. 46-23236-03
EA 99-083

During an NRC inspection and investigation completed on April 14, 1999, violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," NUREG-1600, Revision 1, the NRC proposes to impose a civil penalty pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (Act), 42 U.S.C. and 10 CFR 2.205. The particular violations and associated civil penalty are set forth below:

I. Violations Assessed a Civil Penalty

A. 10 CFR 20.1201(a)(1)(i) requires, with exceptions not applicable here, that the licensee control the occupational dose to individual adults to an annual dose limit of 5 rem total effective dose equivalent.

1. Contrary to the above, the licensee did not limit the annual occupational dose to an adult to an annual dose limit of 5 rem total effective dose equivalent. Specifically, an adult radiographer's assistant received 12.867 rems, total effective dose equivalent for the period January 1 to November 20, 1998. (01012)

2. Contrary to the above, the licensee did not limit the annual occupational dose to an adult to an annual dose limit of 5 rem total effective dose equivalent. Specifically, an adult radiographer received 5.767 rems total effective dose equivalent for the period January 1 to November 20, 1998. (01022)

B. 10 CFR 34.46 requires that whenever a radiographer's assistant uses radiographic exposure devices, associated equipment or sealed sources or conducts radiation surveys required by 10 CFR 34.49(b) to determine that the sealed source has returned to the shielded position after an exposure, he shall be under the personal supervision of a radiographer. 10 CFR 34.46(c) states that the personal supervision shall include the radiographer's direct observation of the assistant's performance of the operations noted above.

Contrary to the above, on November 20, 1998, an individual acted as a radiographer's assistant, used a radiographic exposure device and conducted radiation surveys of the exposure device without the direct observation by the radiographer. (01032)

C. 10 CFR 34.49(b) requires, in part, that the licensee conduct a survey of the radiographic exposure device and the guide tube with a survey instrument that meets the requirements of 10 CFR 34.25 after each radiographic exposure when approaching the device or guide tube. The survey must determine that the sealed source has returned to its shielded position before exchanging films, repositioning the exposure head, or dismantling equipment.

Contrary to the above, on November 20, 1998, a licensee radiographer's assistant did not perform an adequate survey following a radiographic exposure. Specifically, the survey did not determine that the sealed source had returned to its shielded position prior to exchanging films. (01042)

D. 10 CFR 34.47(a) requires, in part, that the licensee may not permit any individual to act as a radiographer's assistant unless, at all times during radiographic operations, each individual wears an operating alarm ratemeter.

Contrary to the above, on November 20, 1998, a licensee radiographer's assistant performed radiographic operations without wearing an operating alarm ratemeter in that the alarm ratemeter was not turned on. (01052)

These violations represent a Severity Level II Problem (Supplements IV and VI).
Civil Penalty - $8,800

II. Violations Not Assessed a Civil Penalty

A. 10 CFR 20.1302 requires, in part, that the licensee shall make or cause to made, as appropriate, surveys of the radiation levels in unrestricted and controlled areas to demonstrate compliance with the dose limits for individual members of the public in 10 CFR 20.1301. 10 CFR 20.1302(b)(2) requires, in part, that the licensee show compliance with the annual dose limit in 10 CFR 20.1301 by demonstrating that if an individual were continuously present in an unrestricted area, the dose from external sources would not exceed 0.002 rem in an hour.

Contrary to the above, on November 20, 1998, the licensee failed to demonstrate, by survey, that if an individual were continuously present in an unrestricted area at a temporary jobsite where radiography was performed, the dose from external sources would not exceed 0.002 rem in an hour. Consequently, dose rates in the unrestricted area, outside the established boundary, were later determined to be 0.005 rem in an hour. (02014)

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

B. 10 CFR 34.41 requires that during each radiographic operation, the radiographer or radiographer's assistant maintain direct surveillance of the operation to protect against unauthorized entry into a high radiation area, as defined in 10 CFR Part 20, except where the high radiation area is equipped with a control device or alarm system, or locked.

Contrary to the above, on November 20, 1998, at a field site in Billings, Montana, neither the licensee's radiographer nor the radiographer's assistant maintained direct surveillance over the radiographic operation to protect against entry into the high radiation area, and the high radiation area was not equipped with a control device or alarm system or locked. Specifically, the radiographer and his assistant failed to station themselves during each exposure to maintain direct surveillance of the area behind the temporary structure where radiography was being conducted. (03014)

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

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

Within the same time as provided for the response required above under 10 CFR 2.201, the Licensee may pay the civil penalty proposed above in accordance with NUREG/BR-0254 and by submitting to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, DC 20555, a statement indicating when and by what method payment was made, or may protest imposition of the civil penalty in whole or in part, by a written answer addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission. Should the Licensee fail to answer within the time specified, an order imposing the civil penalty will be issued. Should the Licensee elect to file an answer in accordance with 10 CFR 2.205 protesting the civil penalty, in whole or in part, such answer should be clearly marked as an "Answer to a Notice of Violation" and may: (1) deny the violation(s) listed in this Notice, in whole or in part, (2) demonstrate extenuating circumstances, (3) show error in this Notice, or (4) show other reasons why the penalty should not be imposed. In addition to protesting the civil penalty, in whole or in part, such answer may request remission or mitigation of the penalty.

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

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

The response noted above (Reply to Notice of Violation, statement as to payment of civil penalty(ies), and Answer to a Notice of Violation) should be addressed to: Mr. James Lieberman, Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, One White Flint North, 11555 Rockville Pike, Rockville, MD 20852-2738, with a copy to the Regional Administrator, U.S. Nuclear Regulatory Commission, Region IV, 611 Ryan Plaza Drive, Suite 400, Arlington, Texas 76011.

Because your response will be placed in the NRC Public Document Room (PDR), to the extent possible, it should not include any personal privacy, proprietary, or safeguards information so that it can be placed in the PDR without redaction. If personal privacy or proprietary information is necessary to provide an acceptable response, then please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request withholding of such material, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim of withholding (e.g., explain why the disclosure of information will create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.790(b) to support a request for withholding confidential commercial or financial information).

In accordance with 10 CFR 19.11, you may be required to post this Notice within two working days.

Dated this 28th day of June 1999

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

EAs 98-565 & 99-090 May 4, 1999

Mr. Kevin Wieland, Vice President
International Radiography and
Inspection Services, Inc.
1115 W. 41st St.
Tulsa, Oklahoma 74107

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTIES - $17,600 (NRC Inspection Report No. 030-33943/98-02 and Investigation Report No. 4-1998-053)

Dear Mr. Wieland:

This is in reference to the predecisional enforcement conference conducted on March 18, 1999, in NRC's Region IV office in Arlington, Texas. The purpose of the conference was to discuss several apparent violations of NRC requirements, most of which were related to a November 7, 1998 incident. The incident resulted in an assistant radiographer employed by International Radiography and Inspection Services, Inc. (IRIS) receiving a radiation exposure in excess of NRC limits. IRIS notified the NRC of the incident by telephone on November 9, 1999, and submitted a written report on December 7, 1998. The NRC completed its inspection and investigation activities on February 19, 1999, at which time the apparent violations were discussed with you by telephone. The apparent violations also were described in the referenced inspection report, issued on March 3, 1999.

At the conference, IRIS admitted each of the apparent violations, stated that the actions taken by the involved IRIS personnel were contrary to their training and IRIS expectations, and described several enhancements being made to the company's training and audit programs to guard against similar misconduct in the future. On March 22, 1999, IRIS transmitted to the NRC's Region IV office by facsimile a document describing all of its corrective actions in more detail.

Based on the information developed by the NRC during its inspection and investigation, and after consideration of the information that you provided during the conference, the NRC has determined that numerous violations of NRC requirements occurred, as described in the enclosed Notice of Violation and Proposed Imposition of Civil Penalties. The circumstances surrounding these violations were described in detail in the subject inspection report. In brief, the violations include failing to limit an occupational exposure to NRC limits, failing to have a radiation survey instrument and to conduct radiation surveys at a job site where radiography was being conducted, failing to utilize personnel radiation monitoring equipment, failing to stop radiography and contact the radiation safety officer when the incident occurred, and failing to complete and maintain required records.

The NRC also has determined, on the basis of its investigation and after considering information provided by IRIS and the involved employees, that a number of these violations were committed deliberately by IRIS employees. Of those violations described above, the violations that were committed deliberately include failure to have a radiation survey instrument and conduct radiation surveys, failure to utilize personnel radiation monitoring equipment as required, and failure to stop work and contact the radiation safety officer after the incident. In addition, the NRC concluded that the involved employees deliberately provided IRIS with false information immediately following the incident. Based on these deliberate violations, enforcement action is also being taken against each of the involved employees. The NRC is providing IRIS copies of the individual enforcement actions separately. IRIS, however, remains responsible for the actions of its employees, as would any NRC license holder.

Any single violation that results in a radiation overexposure is considered serious, as is any single failure to follow basic radiation safety requirements during radiography operations. In this instance, several radiation safety requirements were deliberately violated, resulting in an overexposure and the potential for a far more serious radiation overexposure. Had any one of several requirements been followed, the overexposure incident would not have occurred. Thus, this incident reflects a total disregard for the radiation safety requirements associated with performing industrial radiography by the involved individuals. Accordingly, the violations have been grouped into two Severity Level II problems in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions" (Enforcement Policy), NUREG-1600. The first group includes all violations of requirements leading up to and including the overexposure incident. The second group includes those violations occurring after the exposure incident.

In accordance with the Enforcement Policy, a civil penalty in the base amount of $8,800 is considered for a Severity Level II problem. In considering the enforcement action in this case, the NRC recognizes IRIS's efforts in investigating this incident and identifying the violations, including the identification of the attempt by the involved employees to cover up the true nature of the incident. Further, the NRC recognizes IRIS's prompt and aggressive corrective actions following the incident. IRIS's investigative efforts contributed to a better understanding of the event and the failures associated with it.

However, given the egregiousness and deliberate nature of the violations in this case, I am issuing the enclosed Notice of Violation and Proposed Imposition of Civil Penalties (Notice) in the amount of $17,600 (i.e., base civil penalties for each of the Severity Level II problems in the enclosed Notice). These civil penalties are being assessed in accordance with Section VII.A.1 of the Enforcement Policy to emphasize the significance of the total disregard for safety in this case by the involved individuals and the importance of assuring that IRIS employees adhere to all radiation safety requirements in the future. Had it not been for IRIS' actions in identifying and correcting these violations, the civil penalties would have been higher.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. The NRC will use your response, in part, to determine whether further enforcement action is necessary to ensure compliance with regulatory requirements. In addition, issuance of this Notice constitutes escalated enforcement action that may subject you to increased inspection effort.

Finally, we note that two of the apparent violations noted in our inspection report dated March 3, 1999 -- involving failing to secure a source in its shielded position each time the source is returned to that position and failing to check the functionality of an alarm ratemeter -- were withdrawn.

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

Sincerely,

Malcolm R. Knapp
Deputy Executive Director
for Regulatory Effectiveness

Docket No. 030-33943
License No. 35-30246-01

Enclosure:
1. Notice of Violation and Proposed Imposition of Civil Penalties
2. NUREG/BR-0254, Civil Penalty Payment Methods (IRIS only)

cc:
American Society of Nondestructive Testing, Inc.
ATTN: Technical Services Manager
1711 Arlingate Lane
P.O. Box 28518
Columbus, Ohio 43228-0518

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTIES

International Radiography and Inspection Services, Inc.
Tulsa, Oklahoma

Docket No. 030-33943
License No. 35-30246-01
EA 98-565

During an NRC inspection and investigation completed February 19, 1999, violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," NUREG-1600, the NRC 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:

Violations Occurring Prior to and Including Overexposure Incident

A. 10 CFR 20.1201(a)(1)(i) requires, with exceptions not applicable here, that a licensee control the occupational dose to individual adults to an annual dose limit of 5 rems total effective dose equivalent.

10 CFR 20.1201(a)(2)(ii) requires, with exceptions not applicable here, that a licensee control the occupational dose to any extremity of individual adults to an annual dose limit of 50 rems shallow dose equivalent.

Contrary to the above, the licensee did not limit the annual occupational dose to a radiographer's assistant to 5 rems total effective dose equivalent. Specifically, as of November 7, 1998, a radiographer's assistant received a deep dose equivalent of approximately 10.8 rems. In addition, the licensee did not limit the annual occupational radiation exposure to a radiographer's assistant's right hand to 50 rems. Specifically, on November 7, 1998, a radiographer's assistant received a shallow dose equivalent to the right hand of approximately 164 rems. (01012)

B. 10 CFR 34.25(a) requires, in part, that the licensee keep sufficient calibrated and operable radiation survey instruments at each location where radioactive material is present.

10 CFR 34.49(b) requires, in part, that the licensee conduct a survey of the radiographic exposure device and the guide tube after each exposure when approaching the device or guide tube.

Contrary to the above, on November 7, 1998, no radiation survey instruments were at a temporary job site at which radiographic operations were being conducted. As a consequence, licensee personnel failed to conduct a survey of the radiographic exposure device and the guide tube after each exposure when approaching the device or guide tube. (01022)

C. 10 CFR 34.47(a) requires, in part, that the licensee may not permit any individual to act as a radiographer or a radiographer's assistant unless, at all times during radiographic operations, each individual wears, on the trunk of the body, a combination of direct reading dosimeter, an operating alarm ratemeter, and either a film badge or TLD.

Contrary to the above, on November 7, 1998, an individual acting as a licensee radiographer failed to wear a direct reading dosimeter, an alarm ratemeter and a TLD while conducting radiographic operations. Additionally, on November 7, 1998, an individual acting as a radiographer's assistant failed to wear an alarm ratemeter while conducting radiographic operations. (01032)

D. 10 CFR 34.47(a)(1) requires, in part, that pocket dosimeters must be recharged at the start of each shift.

Contrary to the above, on November 7, 1998, neither a licensee radiographer nor a radiographer's assistant recharged their pocket dosimeter at the start of the shift. (01052)

E. 10 CFR 34.71(a) requires, in part, that each licensee maintain utilization logs showing specified information for each sealed source.

Contrary to the above, on November 7, 1998, a licensee radiographer started to complete a utilization log but did not finish thereby failing to include required information. Additionally, the log that was started was lost at some time during the work shift. (01062)

These violations represent a Severity Level II problem (Supplements IV and VI).
Civil Penalty - $8,800

Violations Occurring After Overexposure Incident

F. 10 CFR 34.47(d) requires, in part, that if an individual's pocket dosimeter is found to be off-scale and the possibility of radiation exposure cannot be ruled out as the cause, the individual may not resume work associated with licensed material until a determination of the individual's radiation exposure has been made.

Contrary to the above, on November 7, 1998, after a licensee radiographer's assistant's pocket dosimeter was found to be off-scale and a radiation exposure could not be ruled out, the radiographer's assistant resumed work associated with licensed material prior to a determination of the radiographer's assistant's radiation exposure had been made. (02012)

G. Condition 19 of License 35-30246-01 requires, in part, the licensee to conduct its program in accordance with the statements, representations, and procedures contained in a telefacsimile dated February 16, 1998. Item 3.1.2.1 of the International Radiography and Inspection Services, Inc. (IRIS) Radiation Safety Manual, which was submitted as part of the telefacsimile dated February 16, 1998, requires, in part, that IRIS personnel immediately contact the RSO after a pocket dosimeter is found to be off-scale.

Contrary to the above, on November 7, 1998, IRIS personnel failed to immediately contact the RSO after a radiographer's assistant's pocket dosimeter was found to be off scale. (02022)

H. 10 CFR 34.25(a) requires, in part, that the licensee keep sufficient calibrated and operable radiation survey instruments at each location where radioactive material is present.

10 CFR 34.49(b) requires, in part, that the licensee conduct a survey of the radiographic exposure device and the guide tube after each exposure when approaching the device or guide tube.

Contrary to the above, on November 7, 1998, after a radiographer's assistant's pocket dosimeter was found to be off-scale, IRIS personnel continued to conduct radiography operations with no radiation survey instruments present and without conducting a survey of the radiographic exposure device and the guide tube after each exposure when approaching the device or guide tube. (02032)

These violations represent a Severity Level II problem (Supplement VI).
Civil Penalty - $8,800

Pursuant to the provisions of 10 CFR 2.201, International Radiography and Inspection Services, Inc. (Licensee) is hereby required to submit a written statement or explanation to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, within 30 days of the date of this Notice of Violation and Proposed Imposition of Civil Penalties (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each alleged violation: (1) admission or denial of the alleged violation, (2) the reasons for the violation if admitted, and if denied, the reasons why, (3) the corrective steps that have been taken and the results achieved, (4) the corrective steps that will be taken to avoid further violations, and (5) the date when full compliance will be achieved. If an adequate reply is not received within the time specified in this Notice, an order or a Demand for Information may be issued as to why the license should not be modified, suspended, or revoked or why such other 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 proposed above or the cumulative amount of the civil penalties if more than one civil penalty is proposed, in accordance with NUREG/BR-0254 and by submitting to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, DC 20555, a statement indicating when and by what method payment was made, or may protest imposition of the civil penalties in whole or in part, by a written answer addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission. Should the Licensee fail to answer within the time specified, an order imposing the civil penalties will be issued. Should the Licensee elect to file an answer in accordance with 10 CFR 2.205 protesting the civil penalties, in whole or in part, such answer should be clearly marked as an "Answer to a Notice of Violation" and may: (1) deny the violation(s) listed in this Notice, in whole or in part, (2) demonstrate extenuating circumstances, (3) show error in this Notice, or (4) show other reasons why the penalties should not be imposed. In addition to protesting the civil penalties, in whole or in part, such answer may request remission or mitigation of the penalties.

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

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

The response noted above (Reply to Notice of Violation, statement as to payment of civil penalties, and Answer to a Notice of Violation) should be addressed to: James Lieberman, Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, One White Flint North, 11555 Rockville Pike, Rockville, MD 20852-2738, with a copy to Ellis W. Merschoff, Regional Administrator, U.S. Nuclear Regulatory Commission, Region IV, 611 Ryan Plaza Drive, Suite 400, Arlington, Texas 76011.

Because your response will be placed in the NRC Public Document Room (PDR), to the extent possible, it should not include any personal privacy, proprietary, or safeguards information so that it can be placed in the PDR without redaction. If personal privacy or proprietary information is necessary to provide an acceptable response, then please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request withholding of such material, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim of withholding (e.g., explain why the disclosure of information will create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.790(b) to support a request for withholding confidential commercial or financial information). If safeguards information is necessary to provide an acceptable response, please provide the level of protection described in 10 CFR 73.21.

In accordance with 10 CFR 19.11, you may be required to post this Notice within two working days.

Dated this 4th day of May 1999

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

July 13, 1999

EAs 98-565 & 99-090

Mr. Kevin Wieland, Vice President
International Radiography and
Inspection Services, Inc.
1115 W. 41st St.
Tulsa, Oklahoma 74107

SUBJECT: APPROVED SETTLEMENT AGREEMENT CONCERNING NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY DATED MAY 4, 1999

Dear Mr. Wieland:

Enclosed is a copy of the original signed settlement agreement that you have agreed to regarding a payment schedule for the civil penalty proposed by the NRC in a letter dated May 4, 1999. The first of 12 monthly payments of $1,100 is due on August 1, 1999, followed by payments on the first day of each month thereafter.

If you have any questions concerning this matter, please contact Mr. Nader Mamish at (301) 415-2741.

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

Sincerely,

James Lieberman, Director
Office of Enforcement

Docket No. 030-33943
License No. 35-30246-01

Enclosure: As stated

UNITED STATES
NUCLEAR REGULATORY COMMISSION

BEFORE THE OFFICE OF ENFORCEMENT

In the Matter of	)	
	)	
INTERNATIONAL RADIOGRAPHY AND	)	
INSPECTION SERVICES, INC.	)	Docket No. 030-33943
Tulsa, Oklahoma	)	License No. 35-30246-01
	)	EAs 98-565 & 99-090

SETTLEMENT AGREEMENT

1. On May 4, 1999, the Nuclear Regulatory Commission (NRC) issued to International Radiography and Inspection Services, Inc., (Licensee) a Notice of Violation and Proposed Imposition of Civil Penalties (Notice) in the amount of $17,600 for violations involving failure to limit the annual occupational dose to a radiographer's assistant to 5 rems total effective dose equivalent.

2. In a reply and in an answer to the Notice both dated June 16, 1999, the Licensee admitted all the violations described in the Notice, but requested mitigation of 50 percent of the proposed civil penalty based, in part, on: (a) the Licensee's thorough investigation of the violations; and (b) the Licensee's classification as a small entity. In addition, the Licensee requested that the civil penalty be paid over time.

3. The Licensee desires to resolve this matter without litigating it and, therefore, agrees to pay a civil penalty of $13,200 with 12 monthly payments of $1,100 beginning on August 1, 1999, followed by payments on the first day of each month thereafter. The NRC staff concludes that this Settlement Agreement best serves the interests of the public and the parties and the purposes of the Atomic Energy Act and the NRC's requirements.

4. The Licensee agrees that if any payment is not made within the agreed-upon time, then the Licensee shall be in default and payment of the full $13,200 civil penalty proposed by the NRC in its May 4, 1999 Notice shall be due immediately without further notice or order.

5. The Licensee hereby waives the need for the NRC to issue an Order imposing payment of the $13,200 civil penalty. In addition, the Licensee hereby waives the right to request a hearing on the $13,200 civil penalty; and waives any right to contest the payment of the $13,200 civil penalty should the Licensee default on the payment schedule agreed upon in Section 3.

6. The payments required by this Settlement Agreement shall be made by check, draft, money order, or electronic transfer payable to the Treasurer of the United States and addressed to Mr. James Lieberman, Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, 11555 Rockville Pike, Rockville, Maryland 20852-2738.

U. S. NUCLEAR REGULATORY COMMISSION

James Lieberman, Director
Office of Enforcement

7/12/99
Date

INTERNATIONAL RADIOGRAPHY AND
INSPECTION SERVICES, INC.

Kevin Wieland, Vice President

JULY 8, 99
Date

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

July 13, 1999

EA 99-042

Mr. A. Ross Myers, President
Allan A. Myers, Inc.
Post Office Box 98
1805 Berks Road
Worcester, Pennsylvania 19490

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY - $2,750
(NRC Inspection Report 98-001 and NRC Investigation Report No.1-98-046)

Dear Mr. Ross:

This refers to the NRC inspection conducted on October 28, 1998, at a field site in King of Prussia, Pennsylvania, as well as a subsequent investigation conducted by the NRC Office of Investigations (OI). The investigation was conducted, in part, to determine if your Construction Manager deliberately allowed an employee to use a Troxler gauge (containing 6.6 millicuries of cesium-137) without the employee first having (1) completed the required training program; (2) been designated as an authorized user by the Radiation Safety Officer (RSO); (3) been in the presence of the RSO; and (4) worn dosimetry during the use of the gauge. A copy of the synopsis of the OI investigation was forwarded to you on May 19, 1999.

Based on the inspection and OI investigation, three apparent violations of NRC requirements were identified. In the letter dated May 19, 1999, the NRC informed you of the apparent violations, and also informed you that it might not be necessary to conduct a predecisional enforcement conference in order to enable the NRC to make an enforcement decision. Rather, the NRC provided you an opportunity to either (1) respond to the apparent violations addressed in this inspection report within 30 days of the date of the letter, or (2) request a predecisional enforcement conference. You responded in a letter, dated June 17, 1999, in which you admitted the violations, and provided corrective actions.

Based on the information developed during the investigation, and the information provided in your response, three violations of NRC requirements are being cited. The violations, which are described in the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice), involve (1) use of a portable gauge by an unauthorized individual, without being in the presence of an authorized user, and without necessary training; (2) use of the gauge without appropriate dosimetry; and (3) leaving the gauge unattended at the job site. In your June 17, 1999 letter, you indicated that, based on your review, the Construction Manager did not deliberately violate requirements, but did have a lapse in judgement.

Notwithstanding your contention, the NRC maintains that the violations were deliberate in that the Construction Manager was aware of these regulatory requirements, as he admitted in an interview with OI, but did not take action to assure that the regulatory requirements were met. Also, he had served as RSO at your facility for seven years. Therefore, given their willful nature, the violations have been classified as a Severity Level III problem in accordance with the "General Statement of Policy and Procedures for NRC Enforcement Actions" (Enforcement Policy), NUREG-1600, Revision 1.

In accordance with the Enforcement Policy, a base civil penalty in the amount of $2,750 is considered for a Severity Level III violation or problem. Because the violations were willful, the NRC considered whether credit was warranted for *Identification and Corrective Action* in accordance with the civil penalty assessment process in Section VI.B.2 of the Enforcement Policy. Credit for identification is not warranted since the violations were identified by the NRC. Credit for corrective actions is warranted because your corrective actions were considered prompt and comprehensive. These corrective actions, which were described in your June 17, 1999 letter to the NRC, included refresher training for all gauge users and the Construction Manager.

Therefore, to emphasize the importance of compliance with regulatory requirements, I have been authorized, after consultation with the Director, Office of Enforcement, to issue a Notice of Violation and Proposed Imposition of Civil Penalty in the amount of $2,750. If not for your corrective actions, the civil penalty amount would have been higher. In addition, issuance of this Notice constitutes escalated enforcement action that may subject you to increased inspection effort.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. You may reference, as appropriate, your June 17, 1999 response to the NRC. The NRC will use your response, in part, to determine whether further enforcement action is necessary to ensure compliance with 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.

Sincerely,

Hubert J. Miller
Regional Administrator

Docket No. 030-31824
License No. 37-28555-01

Enclosures:
1. Notice of Violation and Proposed Imposition of Civil Penalty
2. NUREG/BR-0524 Payment Methods (Licensee Only)

cc w/encl 1 Only:
Commonwealth of Pennsylvania

ENCLOSURE 1

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

Allan A. Myers, Inc.
Worcester, Pennsylvania

License No. 37-28555-01
Docket No. 030-31824
EA 99-042

During an NRC inspection conducted on October 28, 1998, as well as a subsequent investigation conducted by the NRC Office of Investigations (OI), violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy), NUREG-1600, the NRC 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 violations and associated civil penalty are set forth below:

A. Condition 11.A. of License No. 37-28555-01 requires that licensed material be only used by, or under the supervision and in the physical presence of, individuals who have successfully completed the manufacturer's training program for gauge users, have been instructed in the licensee's routine and emergency operating procedures, and who have been designated in writing by the Radiation Safety Officer (RSO).

Contrary to the above, on October 28, 1998, at a temporary jobsite in King of Prussia, Pennsylvania, an employee used a portable gauge without the employee having:

1. completed the training program for gauge users;
2. been designated in writing by the RSO as an authorized gauge user; or
3. been in the physical presence of an authorized gauge user. **(01013)**

B. Condition 19 of License No. 37-28555-01 requires that licensed material be possessed and used in accordance with statements, representations and procedures contained in an application dated June 23, 1995.

Item 10.1, Personnel Monitoring Program, of the application dated June 23, 1995, requires that when using the gauges, users will wear Troxler Electronic TLD Badges assigned to the specific operator.

Contrary to the above, on October 28, 1998, at a temporary jobsite in King of Prussia, Pennsylvania, an employee used a portable gauge without the employee having worn personal dosimetry while using the gauge. **(01023)**

C. 10 CFR 20.1801 requires that the licensee secure from unauthorized removal or access licensed materials that are stored in unrestricted areas. 10 CFR 20.1802 requires that the licensee shall control and maintain constant surveillance of licensed material that is in a controlled or unrestricted area and that is not in storage. As defined in 10 CFR 20.1003, unrestricted area means an area, access to which is neither limited nor controlled by the licensee.

Contrary to the above, on October 28, 1998, at a temporary jobsite in King of Prussia, Pennsylvania, the licensee did not control and maintain constant surveillance of licensed material that was in a controlled or unrestricted area and was not in storage. Specifically, on that date, a Troxler Model 4640-B portable gauge containing 6.6 millicuries of cesium 137 was left unattended when the gauge user walked approximately 100 feet away from the gauge on several occasions and did not maintain visual contact with the gauge. **(01033)**

These violations, given their willful nature, represent a Severity Level III problem (Supplements VI and VII).

Civil Penalty - $2,750.

Pursuant to the provisions of 10 CFR 2.201, Allan A. Myers, Inc. (Licensee), is 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. Your response may reference or include previous docketed correspondence if the correspondence adequately addresses the required response. If an adequate reply is not received within the time specified in this Notice, an Order or a Demand for Information may be issued as 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.

Within the same time as provided for the response required above under 10 CFR 2.201, the Licensee may pay the civil penalty proposed above in accordance with NUREG/BR-0254 and by submitting to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, a statement indicating when and by what method payment was made, or may protest imposition of the civil penalty in whole or in part, by a written answer addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission. Should the Licensee fail to answer within the time specified, an order imposing the civil penalty will be issued. Should the Licensee elect to file an answer in accordance with 10 CFR 2.205 protesting the civil penalty, in whole or in part, such answer should be clearly marked as an "Answer to a Notice of Violation" and may: (1) deny the violations listed in this Notice, in whole or in part, (2) demonstrate extenuating circumstances, (3) show error in this Notice, or (4) show other reasons why the penalty should not be imposed. In addition to protesting the civil penalty in whole or in part, such answer may request remission or mitigation of the penalty.

In requesting mitigation of the proposed penalty, the factors addressed in Section VI.B.2 of the Enforcement Policy 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, statement as to payment of civil penalty, and Answer to a Notice of Violation) should be addressed to: James Lieberman, Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, One White Flint North, 11555 Rockville Pike, Rockville, MD 20852-2738, with a copy to the Regional Administrator, U.S. Nuclear Regulatory Commission, Region I.

Because your response will be placed in the NRC Public Document Room (PDR), to the extent possible, it should not include any personal privacy, proprietary, or safeguards information so that it can be placed in the PDR without redaction. If personal privacy or proprietary information is necessary to provide an acceptable response, then please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request withholding of such material, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim of withholding (e.g., explain why the disclosure of information will create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.790(b) to support a request for withholding confidential commercial or financial information).

In accordance with 10 CFR 19.11, you may be required to post this Notice within two working days.

Dated at King of Prussia, Pennsylvania
this 13th day of July 1999

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

October 22, 1999

EA 99-194

W. Howell Barnum
Chief Operations Officer
Professional Service Industries, Inc.
510 East 22nd Street
Lombard, IL 60148

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY-$8,800
(NRC Office of Investigations Report No. 4-1999-016)

Dear Mr. Barnum:

This refers to the closed, transcribed predecisional enforcement conference conducted on August 24, 1999, in the NRC Region III Office in Lisle, Illinois. The conference was conducted to discuss apparent violations related to a September 15, 1998, incident in Pocatello, Idaho involving Professional Service Industries, Inc. (PSI) radiography personnel. The apparent violations related to this incident, and the results of an investigation conducted by the NRC's Office of Investigations (OI) to determine whether the violations were willful, were provided in a letter issued to you on August 5, 1999.

Based on the information developed during the investigation and the information provided by your staff during the conference, the NRC has determined that violations of NRC requirements occurred. These violations are cited in the enclosed Notice of Violation and Proposed Imposition of Civil Penalty. The circumstances surrounding the violations were described in detail in the incident review summary in a letter dated August 5, 1999. The violations involved failures to: (1) conduct radiography with at least two qualified individuals to observe operations; (2) supervise a radiographer's assistant while performing radiographic operations; and (3) maintain control and constant surveillance of licensed material that was in an unrestricted area.

On April 6, 1999, an investigation was initiated by OI to determine if PSI employees, deliberately violated NRC regulations which may have resulted in possible overexposures at a jobsite in Pocatello, Idaho. The PSI employees, a radiographer and a radiographer's assistant, conducted radiographic operations at a plant in Idaho during the evening of September 14 and early morning of September 15, 1998. After the last shot, two plant employees breached the boundary set by the PSI workers. The plant employees became concerned that they had received radiation exposures; however, it was determined that the source had been returned to its shielded position and locked prior to the plant employees entry into the barricaded area. Therefore, the individuals did not receive a radiation exposure. During the OI interviews, both PSI individuals acknowledged receiving radiation safety training which included the two-person rule, surveillance procedures during and after radiographic operations, and the conditions under which a radiographer's assistant could conduct radiographic operations. Based on all of the available evidence, the NRC, in conjunction with OI, concludes that the individuals deliberately

violated NRC requirements during and after the third and fourth radiographic shots because they knew or should have known that those actions were violations of NRC requirements. The NRC is particularly concerned about the violations involving the deliberate failure to supervise the assistant radiographer and to follow the two-person rule. It is essential that the NRC be able to maintain the highest trust and confidence that licensees and their employees will act with integrity and abide by requirements designed to protect the health and safety of the public. Therefore, the violations in Section I of the Notice are classified in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions" (Enforcement Policy), NUREG-1600, Revision 1, as a Severity Level II problem.

In accordance with the Enforcement Policy, a base civil penalty in the amount of $8,800 is considered for a Severity Level II problem. In accordance with the civil penalty assessment process in Section VI.B.2 of the Enforcement Policy, the NRC considered whether credit for Identification and Corrective Action was warranted. After reviewing the circumstances, the NRC concluded that credit for Identification is not warranted because NRC staff identified the violations. Corrective actions presented at the conference were comprehensive and included: (1) suspension of the assistant radiographer pending retraining; (2) refresher training for all radiographers and assistants in the PSI Salt Lake City office; (3) a complete corporate level review and investigation of the circumstances surrounding the violations; (4) issuance of memorandums to all staff regarding allowed activities for each certification level and clarifications of the two-man rule; (5) implementation of a new internal incident investigation guide; and (6) creation of an assistant radiographer refresher exam. Based on these and other actions planned, NRC has determined that Corrective Action credit is warranted.

Therefore, to emphasize the significance of deliberate violations of safety requirements and the importance of prompt identification of violations, I am issuing the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice) in the base amount of $8,800 for the Severity Level II problem in Section I of the Notice. In addition, please note that issuance of this Notice constitutes escalated enforcement action that may subject you to increased inspection effort.

The violation in Section II of the Notice involves a failure to secure and limit access to licensed material in an unrestricted area and is categorized as a Severity Level IV violation in accordance with the Enforcement Policy.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. The NRC will use your response, in part, to determine whether further enforcement action is necessary to ensure compliance with regulatory requirements.

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

Sincerely,

Carl J. Paperiello
Deputy Executive Director
for Materials, Research and State Programs

Docket No. 030-33792
License No. 12-16941-03

Enclosure: Notice of Violation and Proposed Imposition of Civil Penalty

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

Professional Service Industries, Inc.
Lombard, Illinois

Docket No. 030-33792
License No. 12-16941-03
EA 99-194

During an NRC inspection and investigation completed on June 22, 1999, violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," NUREG-1600, Revision 1, the NRC 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 34.41(a) requires that whenever radiography is performed at a location other than a permanent radiographic installation, e.g., a temporary jobsite, the radiographer must be accompanied by at least one other qualified radiographer or radiographer's assistant. The additional qualified individual shall observe the operations and be capable of providing immediate assistance to prevent unauthorized entry. Radiography may not be performed if only one qualified individual is present.

Contrary to the above, on September 15, 1998, radiography was performed at a temporary job site at Eaton Metal Products, Pocatello, Idaho, a location other than a permanent radiographic installation, with only one qualified individual present during the third and fourth shots. (01012)

B. 10 CFR 34.46 requires that whenever a radiographer's assistant uses radiographic exposure devices, associated equipment or sealed sources or conducts radiation surveys required by section 34.49(b) to determine that the sealed source has returned to the shielded position after an exposure, the assistant shall be under the personal supervision of a radiographer. The personal supervision must include: (a) the radiographer's physical presence at the site where the sealed sources are being used, (b) the availability of the radiographer to give immediate assistance if required, and (c) the radiographer's direct observation of the assistant's performance of the operations referred to in this section.

Contrary to the above, on September 15, 1998, the licensee's radiographer's assistant operated a radiographic exposure device and conducted radiation surveys without the personal supervision of the licensee's radiographer at Eaton Metal Products, Pocatello, Idaho, following the fourth shot. Specifically, the licensee's radiographer was not available to give immediate assistance if required and did not directly observe the assistant's performance of operations referred to in this section following the fourth shot. (01022)

These violations represent a Severity Level II Problem (Supplement VI).

Civil Penalty - $8,800

II. Violation Not Assessed a Civil Penalty

10 CFR 20.1801 requires that the licensee secure from unauthorized removal or access licensed materials that are stored in unrestricted areas. 10 CFR 20.1802 requires that the licensee shall control and maintain constant surveillance of licensed material that is in a controlled or unrestricted area and that is not in storage. As defined in 10 CFR 20.1003, *unrestricted area* means an area, access to which is neither limited nor controlled by the licensee.

Contrary to the above, on September 15, 1998, the license did not secure from unauthorized removal or access a locked Amersham Model 680 radiographic exposure device that contained a sealed source of about 60 curies of cobalt-60 that was located in a large bay area at Eaton Metal Products, Pocatello, Idaho, an unrestricted area. Nor did the licensee maintain constant surveillance of this material to prevent access by unauthorized personnel. This area was an unrestricted area in that two (2) members of the general public were able to cross the radiation area boundary unchallenged. (01014)

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

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

Within the same time as provided for the response required above under 10 CFR 2.201, the Licensee may pay the civil penalty proposed above in accordance with NUREG/BR-0254 and by submitting to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, DC 20555, a statement indicating when and by what method payment was made, or may protest imposition of the civil penalty in whole or in part, by a written answer addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission. Should the Licensee fail to answer within the time specified, an order imposing the civil penalty will be issued. Should the Licensee elect to file an answer in accordance with 10 CFR 2.205 protesting the civil penalty, in whole or in part, such answer should be clearly marked as an "Answer to a Notice of Violation" and may: (1) deny the violations listed in this Notice, in whole or in part, (2) demonstrate extenuating circumstances, (3) show error in this Notice, or (4) show other reasons why the penalty should not be imposed. In addition to protesting the civil penalty, in whole or in part, such answer may request remission or mitigation of the penalty.

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

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

The response noted above (Reply to Notice of Violation, statement as to payment of civil penalty, and Answer to a Notice of Violation) should be addressed to: Mr. R. W. Borchardt, Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, One White Flint North, 11555 Rockville Pike, Rockville, MD 20852-2738, with a copy to the Regional Administrator, U.S. Nuclear Regulatory Commission, Region III, 801 Warrenville Road, Lisle, Illinois 60532-4351.

Because your response will be placed in the NRC Public Document Room (PDR), to the extent possible, it should not include any personal privacy, proprietary, or safeguards information so that it can be placed in the PDR without redaction. If personal privacy or proprietary information is necessary to provide an acceptable response, then please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request withholding of such material, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim of withholding (e.g., explain why the disclosure of information will create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.790(b) to support a request for withholding confidential commercial or financial information).

In accordance with 10 CFR 19.11, you may be required to post this Notice within two working days.

Dated this 22nd day of October 1999

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

October 4, 1999

EA 99-223

Roof Survey and Consultants, Inc.
ATTN: Mr. Charles R. Akers
President/Radiation Safety Officer
2045 Wesvan Drive, N.E.
Roanoke, VA 24012

SUBJECT: ORDER MODIFYING ORDER SUSPENDING LICENSE (EFFECTIVE IMMEDIATELY) AND ORDER REVOKING LICENSE

NOTIFICATION OF INTENT TO IMPOSE DAILY CIVIL PENALTIES OF $500.00 PER DAY

Dear Mr. Akers:

The enclosed Order is being issued to you because: (1) you have not complied with the Order Suspending License (Effective Immediately) that NRC issued to you on April 3, 1997; and (2) you did not pay the annual fee for fiscal year 1996 required by 10 CFR 171.16 (Code of Federal Regulations) for your Nuclear Regulatory Commission (NRC) license.[1] The reasons that we are taking this action are more fully described in the attached Order.

The NRC Order issued to you on April 3, 1997 suspended your NRC license and required that you either pay the annual fee or else transfer your licensed material (roofing gauge) to someone who has a license for it. The Order also required that you respond to the Order in writing within 30 days. To date, you have not done the things that the Order required you to do.

The enclosed Order requires that you:

1. Continue to keep the roofing gauge in locked storage and not use it.

2. Contact Douglas M. Collins, NRC Region II, at 404-562-4700 or at 1-800-577-8510 within five days.

3. Have the roofing gauge leak tested within 10 days.

4. Transfer the roofing gauge to someone who has a license for it within 30 days.

5. Fill out an NRC Form (Form NRC-314, enclosed) and send it to NRC to show that you completed the transfer of the roofing gauge.

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[1]Byproduct Material License No. 45-23000-02

This is a summary of the requirements in the Order. You should review the requirements in Sections IV and V of the Order, so that you are aware of the specific details of the requirements. After you fulfill these requirements, the enclosed Order revokes your NRC license.

If you need a better explanation of anything in this letter or the enclosed Order, or if you have a question or need help, please contact Douglas M. Collins, Director, Division of Nuclear Materials Safety, Region II at 404-562-4700 or at 1-800-577-8510.

If you do not do the things that the enclosed Order requires, the NRC intends to assess daily civil penalties at the rate of $500.00 per day until you comply with all requirements in the Order. All actions required by the enclosed Order must be completed within the next 30 days. If you do not comply with the Order, we may begin to assess the daily civil penalty beginning on the 31st day following the date of the enclosed Order and continuing at the rate of $500 for each day until you complete all of the required actions. If you transfer your licensed material (roofing gauge) within 30 days as required in the enclosed Order, there will not be any civil penalty.

Pursuant to section 223 of the Atomic Energy Act of 1954, as amended, any person who willfully violates, attempts to violate, or conspires to violate, any provision of the enclosed Order is subject to criminal prosecution.

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

Sincerely,

Carl J. Paperiello

Carl J. Paperiello,
Deputy Executive Director for
Materials, Research, and State Programs

Enclosures:
1. Order Modifying Order Suspending License (Effective Immediately) and Order Revoking License
2. Form NRC-314

cc w/encl:
Commonwealth of Virginia

CERTIFIED MAIL NO. _____
RETURN RECEIPT REQUESTED

UNITED STATES
NUCLEAR REGULATORY COMMISSION

In the Matter of	)	
	)	
Roof Survey and Consultants, Inc.	)	License No. 45-23000-02
2045 Wesvan Drive, N.E.	)	Docket No. 030-33583
Roanoke, Virginia 24012	)	EA 99-223
	)	

ORDER MODIFYING ORDER SUSPENDING LICENSE (EFFECTIVE IMMEDIATELY)
AND ORDER REVOKING LICENSE

I

Roof Survey and Consultants, Inc. (RSCI or (licensee) 2045 Wesvan Drive, N.E., Roanoke, VA 24012, is the holder of Byproduct Material License No. 45-23000-02 (the license), which was issued by the Nuclear Regulatory Commission (NRC or Commission) pursuant to 10 CFR Part 30 on September 14, 1994. The license authorized RSCI to possess byproduct material, i.e., a Troxler Model No. 3216 portable roofing gauge containing a nominal 44 millicuries of Americium-241, for use in measuring the moisture density of roof surfaces in accordance with the conditions specified in the license. Mr. Charles R. Akers, President and Radiation Protection Officer, is the only authorized user listed on the license.

II

Pursuant to 10 CFR 171.16, the licensee is required to pay an annual fee for the license. The licensee's annual fee for License No. 45-23000-02 for fiscal year 1996, as set forth in fee category 3P of 10 CFR 171.16(d), was $1600. In accordance with 10 CFR Part 15, the licensee was sent an original invoice dated August 22, 1996, a second notice dated September 23, 1996,

and a final notice dated October 24, 1996, requesting payment of the annual fee. The final notice of payment due specifically informed RSCI that non-payment of the fee might result in the suspension or revocation of the license in accordance with the Commission's regulations at 10 CFR 171.23. To date, the annual fee for 1996 has not been paid.

On April 3, 1997, NRC issued an Order Suspending License (Effective Immediately) to RSCI, based on non-payment of license fees for fiscal year 1996. The Order of April 3, 1997, required, among other things, that RSCI dispose of any licensed material, acquired or possessed under the authority of License No. 45-23000-02.

As of September 5, 1997, the licensee had not complied with the April 3, 1997 Order, in that no disposal of licensed material had occurred. On July 14, 1997, an inspection was conducted which verified that the gauge was stored at Mr. Akers' residence. Mr. Akers was not present during the inspection. On November 20, 1997, an inspection was attempted but the inspector was not able to contact Mr. Akers. On March 27, 1998, an inspection was again attempted; however, Mr. Akers was not present and security of the device could not be verified. On December 8, 1998, an inspection was again attempted. Mr. Akers was not available. His spouse, however, was home and allowed the inspector to verify that the material was still in safe secure storage. Region II attempted to contact Mr. Akers on April 20, 1999, and left a message requesting a return call on his answering machine. Mr. Akers did not return the call.

On May 20, 1999, NRC sent the licensee a certified letter, return receipt requested, reiterating the requirements of the April 3, 1997 Order, that RSCI dispose of any licensed material, acquired or possessed under the authority of License No. 45-23000-02. No response was

received. On August 3, 1999, the United States Postal Service confirmed that Mr. Akers signed for and received the certified letter on May 28, 1999. On August 4, 1999, the Director of NRC's Region II Division of Nuclear Materials Safety, attempted to contact Mr. Akers via telephone. Mr. Akers was not available, and a message was left with the person answering the call to have Mr. Akers call the NRC Region II office. To date, Mr. Akers has not returned any calls or otherwise contacted the NRC.

Based on the above, two deliberate violations of NRC requirements have been identified. The violations are: (1) failure to pay the annual fees prescribed by 10 CFR 171.16 for Byproduct Material License No. 45-23000-02 for Fiscal Year 1996; and, (2) failure to comply with the terms of the April 3, 1997, Order Suspending License. Specifically, that Order required the licensee to dispose of all licensed nuclear material, acquired or possessed under the authority of License No. 45-23000-02, and to submit an answer in writing and under oath and affirmation and specifically admit or deny each charge made therein. As of this date, the licensee has neither disposed of the material possessed under the license nor answered that Order.

III

The deliberate failures of the licensee to comply with the April 3, 1997 Order and to pay the annual fee as required by Commission regulations demonstrate that the licensee is either unwilling or unable to comply with Commission requirements. Moreover, because the licensee has failed to respond to NRC inquiries, the NRC is unable to ascertain the current status of licensed material in the licensee's possession. Consequently, I lack the requisite reasonable assurance that public health and safety will be protected if the licensee were to continue in possession of licensed material at this time. Therefore, the public health, safety, and interest

require that the licensee report the current location, physical status, and storage arrangements of its licensed material; that the licensee leak test the licensed material; that the licensee transfer the licensed material to an authorized recipient as described below; and that Byproduct Material License No. 45-23000-02 be revoked. Furthermore, pursuant to 10 CFR 2.202, I find that the significance of the violations described above is such that no further notice is required and that the public health, safety and interest require that the provisions of Section IV.A. of this Order be immediately effective.

IV

Accordingly, pursuant to sections 81, 161b, 161c, 161i, 161o, 182 and 186 of the Atomic Energy Act of 1954, as amended, and the Commission's regulations in 10 CFR 2.202, and 10 CFR Parts 30, 170, and 171,

A. IT IS HEREBY ORDERED, EFFECTIVE IMMEDIATELY, THAT:

1. The requirements of Paragraphs A through E of Section III of the Order dated April 3, 1997, and attached hereto remain in effect except where modified below.

2. The licensee shall contact Mr. Douglas M. Collins, Director, Division of Nuclear Materials Safety, NRC Region II, at telephone number 404-562-4700 or 1-800-577-8510, within five days of the date of this Order and report the current location, physical status, and storage arrangements of the licensed material. Additionally, the licensee shall submit a written statement documenting this information under oath or affirmation to the Regional Administrator, NRC Region

II, Atlanta Federal Center, 61 Forsyth Street, SW, Suite 23T85, Atlanta, Georgia 30303, within seven days of the date of this Order.

3. Within ten days of the date of this Order, the licensee shall complete a leak test pursuant to Byproduct Material License No. 45-23000-02, Condition 14.A., B., C., and D. to confirm the absence of leakage and to establish the levels of residual radioactive contamination. The licensee shall, within five days of the date the leak test results are known, submit the results of the leak test in writing to the Regional Administrator, NRC Region II, at the address given in Paragraph 2 above. If the test reveals the presence of 0.005 microcuries or greater of removable contamination, the licensee shall immediately contact Mr. Douglas M. Collins, NRC Region II, at the telephone number given in Paragraph 2 above.

4. Within 30 days of the date of this Order, the licensee shall cause all licensed material in its possession to be transferred to an authorized recipient in accordance with 10 CFR 30.41 and shall submit a completed Form NRC-314 to the Regional Administrator, NRC Region II, at the address given in paragraph 2. above.

B. IT IS FURTHER ORDERED:

1. Upon a written finding by the Regional Administrator, NRC Region II, that no licensed material remains in the licensee's possession and that other applicable

provisions of 10 CFR 30.36 have been fulfilled, Byproduct Material License No. 45-23000-02 is revoked.

The Director, Office of Enforcement, may relax or rescind, in writing, any of the above provisions upon demonstration of good cause by the licensee.

V

In accordance with 10 CFR 2.202, the licensee must, and any other person adversely affected by this Order may submit an answer to this Order, and may request a hearing on this Order, within 20 days of the date of this Order. Where good cause is shown, consideration will be given to extending the time to request a hearing. A request for extension of time must be made in writing to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, and shall include a statement of good cause for the extension. The answer may consent to the Order. Unless the answer consents to this Order, the answer shall, in writing and under oath or affirmation, specifically admit or deny each allegation or charge made in this Order and set forth the matters of fact and law on which the licensee or other person adversely affected relies and reasons as to why the Order should not have been issued. Any answer or request for a hearing shall be submitted to the Secretary, U.S. Nuclear Regulatory Commission, ATTN: Chief, Rulemakings and Adjudications Staff, 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 Materials Litigation and Enforcement at the same address; and to the Regional Administrator, NRC Region II, Atlanta Federal Center, 61 Forsyth Street, S.W., Suite 23T85, Atlanta, Georgia 30303-3415; and to the licensee if the answer or hearing request is by a person other than the

licensee. If a person other than the licensee requests a hearing, that person shall set forth with particularity the manner in which his interest is adversely affected by this Order and shall address the criteria set forth in 10 CFR 2.714(d).

If a hearing is requested by 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.

Pursuant to 10 CFR 2.202(c)(2)(i), the licensee, may, in addition to demanding a hearing, at the time the answer is filed or sooner, move the presiding officer to set aside the immediate effectiveness of the Order on the ground that the Order, including the need for immediate effectiveness, is not based on adequate evidence but on mere suspicion, unfounded allegations, or error.

In the absence of any request for hearing, or written approval of an extension of time in which to request a hearing, the provisions specified in Section IV above shall be final 20 days from the date of this Order without further order or proceedings. If an extension of time for requesting a hearing has been approved, the provisions specified in Section IV shall be final when the

extension expires if a hearing request has not been received. AN ANSWER OR A REQUEST FOR HEARING SHALL NOT STAY THE IMMEDIATE EFFECTIVENESS OF THIS ORDER.

FOR THE NUCLEAR REGULATORY COMMISSION

Carl J. Paperiello,
Deputy Executive Director for
Materials, Research and State Programs

Dated at Rockville, Maryland
this 4 day of October 1999

UNITED STATES
NUCLEAR REGULATORY COMMISSION

In the Matter of	)	
	)	Docket No. 030-33583
Roof Survey and Consultants. Inc.	)	License No. 45-23000-02
2045 Wesvan Drive. N.E.	)	
Roanoke. VA 24012	)	

ORDER SUSPENDING LICENSE
(EFFECTIVE IMMEDIATELY)

I

Roof Survey and Consultants. Inc. (Licensee) is the holder of Materials License No. 45-23000-02. issued by the Nuclear Regulatory Commission (NRC or Commission) pursuant to the Atomic Energy Act of 1954. as amended. that authorizes the activities stated therein. The license has an expiration date of September 30. 1999. and was extended by rulemaking for five years.

II

Pursuant to 10 CFR 171.16. the Licensee is required to pay an annual fee for this license. The Licensee's annual fee for License 45-23000-02 for Fiscal Year 1996. as set forth in fee category 3P of 10 CFR 171.16(d). is $1600. In accordance with 10 CFR Part 15. the Licensee was sent an original invoice dated August 22. 1996. a second notice dated September 23. 1996. and a final notice dated October 24. 1996. requesting payment. The final notice of payment due specifically informed the Licensee that non-payment of your fee may result in the suspension or revocation of your license in accordance with the enforcement provisions of the Commission's regulations. namely. 10 CFR 171.23. To date. the annual fee(s) have not been paid as required by 10 CFR Part 171.

III

Based on the above. I have concluded that the Licensee has willfully violated NRC requirements. In addition. prior notice of the violation and an opportunity to achieve compliance was provided. Therefore. pursuant to 10 CFR 2.202. I find that the violation requires that this Order be immediately effective. In view of the foregoing and pursuant to Sections 81. 161b. 161c. 161i. 161o. 182. and 186 of the Atomic Energy Act of 1954. as amended. and the Commission's regulations in 10 CFR 2.202. 170.41. 171.23. and 10 CFR Part 30. IT IS HEREBY ORDERED. EFFECTIVE IMMEDIATELY. THAT:

A. License No. 45-23000-02 is suspended with respect to receipt and use of licensed nuclear materials: the license remains in effect with respect to the possession. transfer. and storage of licensed nuclear material remaining in the Licensee's possession. as contamination or in other forms. until the Commission notifies the Licensee in writing that the License is terminated:

B. Until notified by the Commission in writing that the License is terminated. the Licensee shall:

   1. restrict activity involving licensed nuclear material to decommissioning and safe. secure storage or transfer of material; and

   2. continue to control entry into restricted areas until the Licensee has determined and NRC has confirmed that such areas are suitable for release for unrestricted use;

C. The Licensee shall dispose of any licensed nuclear material, acquired or possessed under the authority of License No. 45-23000-02, and shall take all actions required by 10 CFR 30.36;

D. Within 30 days from the date of this Order, if the Licensee manufactures, distributes, or provides services to other licensees, the Licensee must notify, in writing, each customer or client that authorization to provide any of these services has been suspended. Furthermore, the Licensee must notify its customers and clients that they may need to amend their licenses to be in compliance with NRC requirements if their license specifically states reliance on the service of the Licensee. The Licensee must provide the Regional Administrator for NRC Region II at 101 Marietta Street, Suite 2900, Atlanta, GA 30323 evidence of the notification and a list of customers or clients notified;

E. The License shall be terminated upon satisfaction of the requirements of 10 CFR 30.36.

The Deputy Chief Financial Officer/Controller may relax or rescind, in writing, any of the above conditions upon a showing by the Licensee of good cause. A request for relaxation of the above conditions shall be submitted to the Deputy Chief Financial Officer/Controller, with a copy to the Regional Administrator, in writing and under oath or affirmation.

IV

In accordance with 10 CFR 2.202, the Licensee must, and any other person adversely affected by this Order may, submit an answer to this Order, and may

request a hearing on this Order, within 30 days of the date of this Order. Where good cause is shown, consideration will be given to extending the time to request a hearing. A request for extension of time must be made in writing to the Controller, and include a statement of good cause for the extension.

The answer shall be in writing and under oath or affirmation, and shall specifically admit or deny each allegation or charge made in this Order and set forth the matters of fact and law on which the Licensee or other person adversely affected relies and the reasons as to why this Order should not have been issued. Any answer or request for hearing shall be submitted to the Secretary, U.S. Nuclear Regulatory Commission, ATTN: Chief, Docketing and Service Branch, Washington, DC 20555. Copies shall also be sent to the Deputy Chief Financial Officer/Controller, U.S. Nuclear Regulatory Commission, Washington, DC 20555; the Assistant General Counsel for Hearings and Enforcement at the same address; the Regional Administrator, NRC Region II, 101 Marietta Street, Suite 2900, Atlanta, GA 30323; and to the Licensee if the answer or hearing request is by a person other than the Licensee. If a person other than the Licensee requests a hearing, that person shall set forth with particularity the manner in which his or her interest is adversely affected by this Order and shall address the criteria set forth in 10 CFR 2.714(d).

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

Pursuant to 10 CFR 2.202(c)(2)(i), the Licensee, or any other person adversely affected by this Order may, in addition to demanding a hearing, at the time the answer is filed or sooner, move the presiding officer to set aside the immediate effectiveness of the Order on the ground that the Order, including the need for immediate effectiveness, is not based on adequate evidence but on mere suspicion, unfounded allegations, or error. The motion must state with particularity the reasons why the order is not based on adequate evidence and must be accompanied by affidavits or other evidence relied on.

V

In the absence of any request for hearing, or written approval of an extension of time in which to request a hearing, this Order shall be final 30 days from the date of this Order without further order or proceedings. If an extension of time for requesting a hearing has been approved, the provisions specified in Part III shall be final when the extension expires if a hearing request has not been received. AN ANSWER OR REQUEST FOR HEARING SHALL NOT STAY THE IMMEDIATE EFFECTIVENESS OF THIS ORDER.

VI

In lieu of filing an answer to the Order, the Licensee may pay the total amount specified below, within 30 days of the date of this Order. This Order is withdrawn if, within 30 days of the date of this Order, the Licensee pays the total amount specified below:

Amounts Due

Calculated Through: March 24, 1997

Invoice Date	Invoice Number	Amount Billed	Late Charges Due	Amount Due
8/22/96	AM6040-96	$1,600	$157.61	$1,757.61

Total Amount: $$1,757.61

The total amount listed above is a delinquent debt to the United States. Failure to pay the total amount within 30 days of the date of this Order may, pursuant to 10 CFR Part 15, result in referral of the delinquent debt to a collection agency, referral to the U.S. General Accounting Office or the U.S. Department of Justice for collection, or other action deemed appropriate. Pursuant to 10 CFR 15.29, the Commission may not consider an application for a license from the Licensee unless all previous delinquent debts of the Licensee to the NRC, including the delinquent debt(s) identified in this Order, have been paid in full. In addition, failure to meet the requirements of this Order may subject the Licensee and its agents to civil penalties and criminal sanctions.

FOR THE NUCLEAR REGULATORY COMMISSION

Ronald M. Scroggins
Deputy Chief Financial
Officer/Controller

Dated at Rockville, Maryland
this 3rd day of April, 1997

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

July 8, 1999

EAs 99-097 & 99-169

Ms. Katherine Banicki, President
Testing Engineers & Consultants, Inc.
1333 Rochester Road
Troy, MI 48099

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTIES - $5,500 (NRC INSPECTION REPORT 030-14016/98001(DNMS) AND OFFICE OF INVESTIGATION REPORT 3-1998-034)

Dear Ms. Banicki:

This refers to the NRC inspection and the investigation conducted by the Office of Investigations (OI) between July 28, 1998 and March 23, 1999, of Testing Engineers & Consultants, Inc. (TEC) at Troy, Lansing, Saginaw, and Pontiac, Michigan, locations. The purpose of the inspection was to review licensed activities and the OI investigation was conducted to follow up on actions and statements made by a TEC employee during the inspection. As a result, apparent violations of NRC requirements were identified and considered for escalated enforcement as discussed in our letter to you dated April 29, 1999. In that letter you were provided an opportunity to either discuss this case and the apparent violations at a predecisional enforcement conference or address the apparent violations in writing. You elected to provide a written response.

Based on the information developed during the inspection, the investigation, and the information provided in your letter dated May 26, 1999, the NRC has determined that violations of NRC requirements occurred. These violations are cited in the enclosed Notice of Violation and Proposed Imposition of Civil Penalties and the circumstances surrounding them are described in our letter dated April 29, 1999.

Violation A of the Notice involves the failure to control and maintain constant surveillance of licensed material in an unrestricted area at a temporary jobsite. Violation B involves the failure of a TEC employee to provide to NRC inspectors during the inspection complete and accurate information about where he stored a gauge during off-duty hours. Both of these violations were found to be deliberate in nature during the OI investigation. Although there were no actual safety consequences as a result of these violations, willful failures to comply with NRC requirements are of significant concern to NRC.. It is essential that the NRC be able to maintain the highest trust and confidence that licensees and their employees will act with integrity and abide by requirements designed to protect public health and safety. Therefore, in accordance with the "General Statement of Policy and Procedures for NRC Enforcement Actions" (Enforcement Policy), NUREG-1600, Revision 1, violations A and B have each been categorized as Severity Level III violations.

In accordance with the Enforcement Policy, a base civil penalty in the amount of $2,750 is considered for a Severity Level III violation. In accordance with the civil penalty assessment process described in Section VI.B.2 of the Enforcement Policy, the NRC considered whether credit was warranted for *Identification* and *Corrective Action*. In this case, the NRC concluded that credit was not warranted for *Identification* because NRC staff identified the violations. Credit for *Corrective Action* is warranted based on the promptness and comprehensiveness of the actions taken. These corrective actions included: (1) retraining of the gauge operator was conducted by TEC management in the importance of securing the device and providing accurate and complete information; (2) circulating a memorandum to all employees reminding them not to leave gauges unattended; (3) conducting refresher training with Troy and Ann Arbor employees which included discussions on security of gauges, license procedures, audit findings, etc.; and (4) planning (by the President) to ensure all employees were reminded of the license requirements through publication in the company newsletter. This results in the assessment of a civil penalty at the base value (i.e., $2,750) for each violation.

Therefore, to emphasize the importance of compliance with all regulatory requirements including the provision of complete and accurate information to the NRC, and the unacceptability of deliberate violations, I have been authorized, after consultation with the Director of the Office of Enforcement, to issue the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice) in the total amount of $5,500 for two Severity Level III violations. In addition, issuance of this Notice constitutes escalated enforcement action that may subject you to increased inspection effort.

The NRC is corresponding directly with the gauge operator concerning these matters. You will receive a copy of that correspondence under separate cover.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. The NRC will use your response, in part, to determine whether further enforcement action is necessary to ensure compliance with regulatory requirements.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter, its enclosure, and your response will be placed in the NRC Public Document Room (PDR). To the extent possible, your response should not include any personal privacy, proprietary, or safeguards information so that it can be placed in the PDR without redaction.

Sincerely,

for James P. Caldwell

J. E. Dyer
Regional Administrator

Docket No. 030-14016
License No. 21-18668-01

Enclosures: 1. Notice of Violation and Proposed Imposition of Civil Penalties
2. NUREG/BR-0254 Payment Methods

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTIES

Testing Engineers & Consultants, Inc.
Troy, Michigan

Docket No. 030-14016
License No. 21-18668-01
EA 99-097 & 99-169

During an NRC inspection and OI investigation conducted between July 28, 1998 and March 23, 1999, violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedures for NRC Enforcement Actions," NUREG-1600, Revision 1, the NRC proposes to impose civil penalties pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (Act), 42 U.S.C. 2282, and 10 CFR 2.205. The particular violations and associated civil penalties are set forth below:

A. 10 CFR 20.1801 requires that the licensee secure from unauthorized removal or access licensed materials that are stored in unrestricted areas. 10 CFR 20.1802 requires that the licensee control and maintain constant surveillance of licensed material that is in an unrestricted area and that is not in storage. As defined in 10 CFR 20.1003, unrestricted area means an area, access to which is neither limited nor controlled by the licensee.

Contrary to the above, on July 28, 1998, the licensee did not secure from unauthorized removal or limit access to a moisture density gauge containing eight millicuries (0.30 gigabecquerels) of cesium-137 and 40 millicuries (1.48 gigabecquerels) of americium-241, located at a temporary jobsite in Saginaw, Michigan, which is an unrestricted area, nor did the licensee control and maintain constant surveillance of this licensed material. (01013)

This is a Severity Level III violation (Supplement IV).
Civil Penalty - $2,750.

B. 10 CFR 30.9(a) requires, in part, that information provided to the Commission by a licensee or information required by statute or 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, on July 28, 1998 and August 12, 1998, information provided by a licensee's engineer during a routine inspection was not complete and accurate in all material respects. Specifically, the engineer told NRC inspectors that between July 8 and 27, 1998, he returned a moisture density gauge to the office at the end of each day when in fact at the end of each work day he stored the gauge at his residence. This information is material because it had the potential to influence the NRC as to whether a violation of NRC requirements had occurred. (01023)

This is a Severity Level III violation (Supplement VII).
Civil Penalty - $2,750.

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

Within the same time as provided for the response required above under 10 CFR 2.201, the Licensee may pay the civil penalties proposed above or the cumulative amount of the civil penalties if more than one civil penalty is proposed, in accordance with NUREG/BR-0254 and by submitting to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, DC 20555, a statement indicating when and by what method payment was made, or may protest imposition of the civil penalties in whole or in part, by a written answer addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission. Should the Licensee fail to answer within the time specified, an order imposing the civil penalties will be issued. Should the Licensee elect to file an answer in accordance with 10 CFR 2.205 protesting the civil penalties, in whole or in part, such answer should be clearly marked as an "Answer to a Notice of Violation" and may: (1) deny the violations listed in this Notice, in whole or in part, (2) demonstrate extenuating circumstances, (3) show error in this Notice, or (4) show other reasons why the penalties should not be imposed. In addition to protesting the civil penalties in whole or in part, such answer may request remission or mitigation of the penalties.

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

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

The response noted above (Reply to Notice of Violation, statement as to payment of civil penalties, and Answer to a Notice of Violation) should be addressed to: James Lieberman,

Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, One White Flint North, 11555 Rockville Pike, Rockville, MD 20852-2738, with a copy to the Regional Administrator, U.S. Nuclear Regulatory Commission, Region III.

Because your response will be placed in the NRC Public Document Room (PDR), to the extent possible, it should not include any personal privacy, proprietary, or safeguards information so that it can be placed in the PDR without redaction. If personal privacy or proprietary information is necessary to provide an acceptable response, then please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request withholding of such material, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim of withholding (e.g., explain why the disclosure of information will create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.790(b) to support a request for withholding confidential commercial or financial information). If safeguards information is necessary to provide an acceptable response, please provide the level of protection described in 10 CFR 73.21.

In accordance with 10 CFR 19.11, you may be required to post this Notice within two working days.

Dated this 8th day of July 1999

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

September 24, 1999

EAs 99-097 & 99-169

Ms. Katherine Banicki, President
Testing Engineers & Consultants, Inc.
1333 Rochester Road
Troy, MI 48099

SUBJECT: ORDER IMPOSING CIVIL MONETARY PENALTY - $5,500

Dear Ms. Banicki:

This refers to your letters dated August 4 and August 13, 1999, in response to the Notice of Violation and Proposed Imposition of Civil Penalties (Notice) sent to you by our letter dated July 8, 1999. The Notice described two violations identified during an NRC inspection and an investigation. To emphasize the importance of compliance with all regulatory requirements, including the provision of complete and accurate information to the NRC and the unacceptability of deliberate violations, we proposed civil penalties totaling $5,500. In your letters, you admit to the violations addressed in the Notice but request mitigation or remission of the civil penalties.

After consideration of your responses, we have concluded for the reasons given in the Appendix attached to the enclosed Order Imposing Civil Monetary Penalty that neither mitigation nor remission of the civil penalties is warranted. Accordingly, we hereby serve the enclosed Order on Testing Engineers & Consultants, Inc., imposing a civil monetary penalty in the amount of $5,500. As provided in Section IV of the enclosed Order, payment should be made within 30 days in accordance with NUREG/BR-0254. In addition, at the time payment is made, a statement indicating when and by what method payment was made, is to be mailed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, One White Flint North, 11555 Rockville Pike, Rockville, MD 20852-2738. We will review the effectiveness of your corrective actions during a subsequent inspection.

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

Sincerely,

R. W. Borchardt

R. W. Borchardt, Director
Office of Enforcement

Docket No. 030-14016
License No. 21-18668-01

Enclosures: 1. Order Imposing Civil Monetary Penalty
2. NUREG/BR-0254 Payment Methods

UNITED STATES
NUCLEAR REGULATORY COMMISSION

In the Matter of	)	
	)	
Testing Engineers & Consultants, Inc.	)	Docket No. 030-14016
Troy, Michigan	)	License No. 21-18668-01
	)	EAs 99-097 & 99-169

ORDER IMPOSING CIVIL MONETARY PENALTY

I

Testing Engineers & Consultants, Inc. (Licensee) is the holder of Byproduct Materials License No. 21-18668-01 which was last renewed in its entirety by the Nuclear Regulatory Commission (NRC or Commission) on September 17, 1996. The license authorizes the Licensee to use certain byproduct material in accordance with the conditions specified therein.

II

Between July 28, 1998 and March 23, 1999, an inspection and an investigation of the Licensee's activities were conducted. The results of the inspection and the investigation indicated that the Licensee had not conducted its activities in full compliance with NRC requirements. A written Notice of Violation and Proposed Imposition of Civil Penalties (Notice) was served upon the Licensee by letter dated July 8, 1999. The Notice states the nature of the violations, the provisions of the NRC's requirements that the Licensee had violated, and the amount of the civil penalties proposed for the violations.

The Licensee responded to the Notice in letters dated August 4 and 13, 1999. In its responses, the Licensee agreed with the information presented in the Notice, admitted the violations, but requested mitigation or remission of the civil penalties.

III

After consideration of the Licensee's response and the statements of fact, explanation, and argument for mitigation contained therein, the NRC staff has determined, as set forth in the Appendix to this Order, that 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 $5,500 within 30 days of the date of this Order, in accordance with NUREG/BR-0254. In addition, at the time of making the payment, the Licensee shall submit a statement indicating when and by what method payment was made, to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, One White Flint North, 11555 Rockville Pike, Rockville, MD 20852-2738.

V

The Licensee may request a hearing within 30 days of the date of this Order. Where good cause is shown, consideration will be given to extending the time to request a hearing. A request for extension of time must be made in writing to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, DC 20555, and include a statement of good

cause for the extension. A request for a hearing should be clearly marked as a "Request for an Enforcement Hearing" and shall be submitted to the Secretary, U.S. Nuclear Regulatory Commission, ATTN: Rulemakings and Adjudications Staff, Washington, DC 20555. Copies also shall be sent to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, DC 20555, to the Assistant General Counsel for Hearings and Enforcement at the same address, and to the Regional Administrator, NRC Region III, 801 Warrenville Road, Lisle, Illinois 60532.

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 (or if written approval of an extension of time in which to request a hearing has not been granted), the provisions of this Order shall be effective without further proceedings. If payment has not been made by that time, the matter may be referred to the Attorney General for collection.

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

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

FOR THE NUCLEAR REGULATORY COMMISSION

R.W. Borchardt

R. W. Borchardt, Director
Office of Enforcement

Dated this 24th day of September 1999

APPENDIX

EVALUATIONS AND CONCLUSION

On July 8, 1999, a Notice of Violation and Proposed Imposition of Civil Penalty (Notice) was issued for violations identified during an NRC inspection and an investigation. Testing Engineers & Consultants, Inc. (Licensee or TEC) responded to the Notice by two letters dated August 4 and 13, 1999. The Licensee admitted the violations occurred, but requested mitigation or remission of the civil penalties. The NRC's evaluation and conclusion regarding the licensee's requests are as follows:

Summary of Licensee's Request for Remission or Mitigation

The Licensee states that no escalated enforcement has occurred since September 1995 and that its overall performance of licensed activities has been good. The Licensee contends that compliance with license requirements as well as prompt identification and comprehensive corrective action of violations has always been emphasized and encouraged. The Licensee states that it understands the severity of the violations and will make every effort to regain the trust and confidence of the NRC by ensuring that it acts with integrity and abides by requirements designed to protect public health and safety.

The Licensee maintains that every effort is made to educate its employees to implement all of the terms and conditions of its NRC license. According to the Licensee, the employee involved had been properly trained and instructed and there was little else that could have been done to prevent this incident from occurring. The Licensee suggested that the NRC should fine the individual as well as the company.

NRC Evaluation of Licensee's Request for Remission or Mitigation

The NRC concurs with the Licensee regarding its enforcement history and overall good performance. Enforcement history and licensee performance are used in determining which enforcement action will be taken. In accordance with Section VI.B.2. of the "General Statement of Policy and Procedures for NRC Enforcement Actions" (Enforcement Policy), NUREG 1600, Revision 1, enforcement history is considered in two of the four decisional points in the civil penalty assessment process. Specifically, when the NRC determines that a non-willful Severity Level III violation has occurred, and the licensee has not had any previous escalated actions during the past 2 years or 2 inspections, whichever is longer, the NRC considers whether the licensee's corrective action for the violation is reasonably prompt and comprehensive. If a willful Severity Level III violation has occurred--or if, during the past 2 years or 2 inspections, the licensee has been issued at least one other escalated action--the civil penalty assessment normally considers the factor of identification *in addition* to corrective action. As to the second decisional point, the NRC may exercise discretion by either escalating or mitigating a sanction based, in part, on the enforcement history. For example, the NRC may either propose a civil penalty where application of the factors would otherwise result in zero penalty or escalate the amount of the resulting civil penalty in cases involving particularly poor licensee performance, or involving willfulness. On the other hand, the NRC may exercise discretion and refrain from issuing a civil penalty in cases where the overall sustained performance of the licensee has been good.

In this case, the Licensee's enforcement history is irrelevant with regard to the first decisional point because the violations were willful. As to the second decisional point, the NRC considered the Licensee's enforcement history and determined that, on balance, neither escalation nor mitigation was warranted because, while the Licensee's enforcement history has been good, the violations involved willfulness. Willful violations are of particular concern because the Commission's regulatory program is based on licensees acting with integrity and communicating with candor.

With regard to the assessment factors, both noncompliances were characterized as willful Severity Level III violations and, consistent with Section VI.B.2. of the Enforcement Policy, the NRC considered both identification and corrective action. In this case, the NRC concluded that credit was not warranted for identification because NRC staff identified the violations, but credit was warranted for corrective action based on the promptness and comprehensiveness of the actions taken. Consideration of the identification and corrective action factors yielded a base civil penalty of $2,750 for each of the violations described in the Notice.

As to the Licensee's argument about its efforts to educate employees and to prevent the incident, according to Section VI.B of the Enforcement Policy, management involvement, direct or indirect, in a violation may lead to an increase in the civil penalty; however, the lack of management involvement in a violation may not be used to mitigate a civil penalty. The Licensee is responsible for violations caused by its employees, whether arising from inadvertent error or willful acts. The licensee hires, trains, and supervises its employees. All licensed activities are carried out by employees of the licensee and, therefore, all violations are caused by employees of the licensee. A licensee enjoys the benefits of good employee performance and suffers the consequences of poor employee performance. To not hold the licensee responsible for the actions of its employees, whether such actions result from incompetence, negligence, or willfulness, is equivalent to not holding the licensee responsible for its use and possession of licensed material. If the NRC were to adopt such a premise, there would be no incentive for licensees to assure compliance with NRC requirements.

With respect to the licensee's suggestion about fining the individual as well as the company, the NRC notes that while it is not the Commission's general policy to monetarily penalize individuals, the NRC takes enforcement sanctions against individuals. Notices of Violation and Orders are examples of enforcement actions that may be appropriate against individuals. The Notice of Violation issued to the Licensee's employee was deemed the appropriate action in this case.

NRC Conclusion

The NRC has concluded that the Licensee did not provide an adequate basis for remission or mitigation of the civil penalties. Consequently, the proposed civil penalty in the amount of $5,500 should be imposed.

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

June 29, 1999

EA 99-080

Mr. J. N. Adkins
Vice President - Production
United States Enrichment Corporation
Two Democracy Center
6903 Rockledge Drive
Bethesda, MD 20817

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY-$55,000 (NRC Inspection Report 70-7002/99006(DNMS))

Dear Mr. Adkins:

This refers to the inspection conducted March 22 through 26, 1999, at the United States Enrichment Corporation's (USEC) Portsmouth Gaseous Diffusion Plant in Piketon, Ohio. The inspection report detailing our findings was issued on April 22, 1999. One apparent violation was identified and considered for escalated enforcement action, and you were provided an opportunity to respond to the apparent violation or request a predecisional enforcement conference. At your request, a predecisional enforcement conference was held on June 10, 1999, to discuss the apparent violation, the root causes, and the corrective action. A summary report of the conference will be sent to you by separate correspondence.

Based on the information developed during the inspection, the information provided in your letter dated March 19, 1999, and the information provided during the conference, the NRC has determined that a violation of NRC requirements occurred. The violation is cited in the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice), and the circumstances surrounding the violation are described in detail in the subject inspection report. The violation involves a failure to classify an emergency situation as an Alert.

On December 9, 1998, the Portsmouth Gaseous Diffusion Plant experienced a significant fire in the first cell of the Side Purge Cascade located in Building X-326. During the two hour duration of the fire, firefighters observed thick smoke, twenty foot flames, and large quantities of oil on the cell floor indicating that the fire had the potential to affect the health and safety of personnel in Building X-326 and the immediate surrounding area. In addition, visible holes in the process gas cascade piping showed that the piping barrier between the process gas (uranium hexafluoride) and the environment had been breached and that the single control relied upon for nuclear criticality safety had been violated.

The failure to declare an Alert during this event resulted in not activating the onsite emergency operations facility which would have provided technical and management support to the onsite incident response efforts. This increased the duration of your event response and prevented prompt corrective actions to reestablish criticality controls. Failure to declare an Alert also

resulted in not notifying local, state and Federal agencies of the event, or its significance, so that they could fulfill their emergency response functions.

During the enforcement conference, USEC stated that the immediate cause of the violation was an inconsistency between the Emergency Plan and the Emergency Plan Implementing Procedure. Section 3 of the Emergency Plan states that significant emergencies are classified as either Alerts or Site Area Emergencies (SAE). Section 3.1.1 of the Plan further defined an Alert as an emergency situation that: (1) could lead to a release to the environment of radioactive or other hazardous material, or (2) could have a direct effect on the health and safety of plant personnel. Plant Procedure XP2-EP-EP1050, Appendix B included guidance, in the form of emergency action levels to aid in the proper classification of emergency situations. However, the procedure also included a note which indicated that fire should not be classified as an Alert. Specifically, the note stated that "Events or conditions that do not meet the criteria for Alert or SAE such as fire, bomb threat, natural phenomena, and others are considered to be Operational Emergencies and may be reportable to NRC and DOE. Refer to applicable event reporting procedures for guidance." While this inconsistency was identified on the day of the event by both the NRC and USEC, the NRC inspection team identified several additional inconsistencies in March 1999 between the Plan and the Implementing Procedures.

The NRC has considered all of the information surrounding this violation and concluded that while the actual safety consequences were minimal, the violation is of significant safety concern. Therefore, the violation has been categorized in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions (Enforcement Policy)," NUREG-1600, as a Severity Level III violation.

In accordance with the Enforcement Policy, a base civil penalty in the amount of $55,000 is considered for a Severity Level III violation. Because Portsmouth has been the subject of escalated enforcement actions within the last two years[1], the NRC considered whether credit was warranted for *Identification* and *Corrective Action* in accordance with the civil penalty assessment process in Section VI.B.2 of the Enforcement Policy. *Identification* credit is not warranted for the following reasons. In accordance with the Enforcement Policy, the NRC evaluated missed opportunities for your staff to identify the causes of the violation. The Emergency Plan is required to be implemented by approved procedures, and since March 1997, activities that should have identified deficiencies in the Emergency Plan Implementing Procedures such as response to emergencies, training, drills and exercises, failed to detect the inconsistencies between the Emergency Plan and the required Implementing Procedures. Your staff also stated at the enforcement conference that a root cause of the violation was a reluctance on the part of managers to activate the Emergency Operations Facility because they had been criticized for doing so in the past. This appears to be a pre-certification cultural issue that USEC had not resolved prior to this event. Further,

[1] A Severity Level III violation with a $55,000 civil penalty was issued July 14, 1998-EA's 98-249, 98-250, 98-251 - Air to close containment valve failures.

Compliance Plan Issue 30, "Procedures Program," required upgrade of procedures; however, required Alarm Response Procedures for cell alarms or cell coolant alarms had not been developed at the time of the event. Your staff's failure to develop these procedures contributed to the magnitude and duration of the event. In addition, the NRC staff also questioned the USEC facility staff about whether the event classification was appropriate during the event. At the enforcement conference, senior USEC managers stated that they questioned the lack of an emergency declaration on the day of the event, but after the fire was out; however, because of these numerous missed opportunities, identification credit is not warranted.

Corrective Action credit is warranted because your corrective actions were both prompt and comprehensive. These actions, which were described in your March 19, 1999, letter and discussed during the conference included but were not limited to: (1) the Portsmouth Operations Department issued a lessons learned to the Incident Commanders regarding the need to activate the Emergency Operations Center for conditions such as fire, explosion or natural phenomena that could potentially impact personnel or public health and safety; (2) a Long-Term Order was issued clarifying actions to be taken for emergency action levels associated with a fire, security-related incident, natural phenomena, or equipment failure; (3) Procedure XP2-EP-EP1050 was revised to add an emergency action level consistent with NRC Regulatory Guide 3.67 and local and state emergency agency officials were briefed on the procedure changes; (4) affected personnel were trained on the revision of XP2-EP-EP1050; (5) emergency action levels in all Emergency Plan Implementing Procedures are being reviewed, and annual refresher training has been instituted on the emergency action levels; and (6) incident response teams are being established on each shift.

Therefore, to emphasize the importance of early identification of deficiencies prior to the issues being revealed through an event, 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 base amount of $55,000 for the Severity Level III violation.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. The NRC will use your response, in part, to determine whether further enforcement action is necessary to ensure compliance with regulatory requirements.

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

Sincerely,

J. E. Dyer
Regional Administrator

Docket No. 70-7002
Certificate No. GDP-2

Enclosure: Notice of Violation and Proposed
Imposition of Civil Penalty

cc w/encl: J. M. Brown, Portsmouth General Manager
P. J. Miner, Manager, Nuclear Regulatory Affairs, Portsmouth
H. Pulley, Paducah General Manager
S. A. Toelle, Manager, Nuclear Regulatory
Assurance and Policy, USEC
Portsmouth Resident Inspector Office
Paducah Resident Inspector Office
R. M. DeVault, Regulatory Oversight Manager, DOE
E. W. Gillespie, Portsmouth Site Manager, DOE

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

United States Enrichment Corporation
Portsmouth Gaseous Diffusion Plant
Piketon, Ohio

Docket No. 70-7002
Certificate No. GDP-2
EA 99-080

During an NRC inspection conducted March 22 through 26, 1999, a violation of NRC requirements was identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy), NUREG-1600, the NRC 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 violation and associated civil penalty is set forth below:

> 10 CFR 76.91 requires, in part, that the Corporation shall establish, maintain, and be prepared to follow a written emergency plan.
>
> Section 3 of the Emergency Plan, Revision 26, dated November 6, 1998, states, in part, that significant emergencies are classified as either Alerts or Site Area Emergencies. Section 3 of the Plan further defined an Alert, in part, as an emergency situation that has led or could lead to a release to the environment of radioactive or other hazardous material, or could have a direct effect on the health and safety of plant personnel.
>
> Contrary to the above, on the morning of December 9, 1998, the Corporation failed to classify, as an Alert, an emergency situation which could have led to a release to the environment of radioactive or hazardous material, or could have had a direct effect on the health and safety of plant personnel. Specifically, on that date, the corporation failed to classify, as an Alert, a substantial ongoing fire in Building X-326, which: (1) involved the process gas cascade; (2) had the potential to release uranium hexafluoride or other hazardous materials to the environment; and (3) could have had a direct effect on the health and safety of plant personnel. (01013)

This is a Severity Level III violation (Supplement VIII).
Civil Penalty $55,000

Pursuant to the provisions of 10 CFR 76.70, the United States Enrichment Corporation (Certificatee) is hereby required to submit a written statement or explanation to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, within 30 days of the date of this Notice of Violation and Proposed Imposition of Civil Penalty (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each alleged violation: (1) admission or denial of the alleged violation; (2) the reasons for the violation if admitted, and if denied, the reasons why; (3) the corrective steps that have been taken and the results achieved; (4) the corrective steps that will be taken to avoid further violations; and (5) the date when full compliance will be achieved. If an adequate reply is not received within the

time specified in this Notice, an order or a Demand for Information may be issued as to why the Certificate of Compliance 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 76.70, the Certificatee 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 Certificatee fail to answer within the time specified, an order imposing the civil penalty will be issued. Should the Certificatee elect to file an answer in accordance with 10 CFR 2.205 protesting the civil penalty, in whole or in part, such answer should be clearly marked as an "Answer to a Notice of Violation" and may: (1) deny the violation listed in this Notice, in whole or in part; (2) demonstrate extenuating circumstances; (3) show error in this Notice; or (4) show other reasons why the penalty should not be imposed. In addition to protesting the civil penalty in whole or in part, such answer may request remission or mitigation of the penalty.

In requesting mitigation of the proposed penalty, the factors addressed in Section VI.B.2 of the Enforcement Policy 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 76.70, but may incorporate parts of the 10 CFR 76.70 reply by specific reference (e.g., citing page and paragraph numbers) to avoid repetition. The attention of the Certificatee 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: James Lieberman, Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, One White Flint North, 11555 Rockville Pike, Rockville, MD 20852-2738, with a copy to the Regional Administrator, U.S. Nuclear Regulatory Commission, Region III, 801 Warrenville Road, Lisle, Illinois 60532 and a copy to the NRC Resident Inspector at the facility that is the subject of this Notice.

Because your response will be placed in the NRC Public Document Room (PDR), to the extent possible, it should not include any personal privacy, proprietary, or safeguards information so that it can be placed in the PDR without redaction. If personal privacy or proprietary information is necessary to provide an acceptable response, then please provide a bracketed copy of your

response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request withholding of such material, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim of withholding (e.g., explain why the disclosure of information will create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.790(b) to support a request for withholding confidential commercial or financial information). If safeguards information is necessary to provide an acceptable response, please provide the level of protection described in 10 CFR 73.21.

Dated at Lisle, Illinois
this 29th day of June 1999

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

December 20, 1999

EA 99-110

Mr. J. N. Adkins
Vice President - Production
United States Enrichment Corporation
Two Democracy Center
6903 Rockledge Drive
Bethesda, MD 20817

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY - $88,000 (NRC OFFICE OF INVESTIGATIONS REPORT NO. 3-1998-033)

Dear Mr. Adkins:

This refers to the investigation completed by the NRC Office of Investigations (OI) on March 26, 1999, at the United States Enrichment Corporation's (Corporation) Paducah Gaseous Diffusion Plant. Based on the findings of the investigation, an apparent violation was identified involving discrimination against the former Manager of Quality Systems (Manager of QS) at the Paducah facility by his supervisor, the Manager of Safety, Safeguards, and Quality. On May 18, 1999, the NRC provided a copy of the synopsis of the OI report and a summary of the relevant facts to the Corporation. A closed, transcribed, predecisional enforcement conference was held on June 30, 1999, in the NRC Region III office between representatives of the Corporation, including the Manager of Safety, Safeguards, and Quality, and the NRC to discuss the apparent violation, its cause, and your corrective actions.

After a review of the information developed during the investigation, the information provided during the predecisional enforcement conference, and the information provided subsequent to the conference, including information provided by the Manager of QS in a letter dated July 17, 1999, and by the Corporation and the Manager of Safety, Safeguards, and Quality in separate letters dated July 23, 1999, the NRC has determined that a violation of NRC requirements occurred. The violation is cited in the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice) and the circumstances surrounding it are described in the previously provided OI report summary. The violation involved employment discrimination in violation of the Commission's requirements in 10 CFR 76.7, "Employee Protection," by the Manager of Safety, Safeguards, and Quality against the Manager of QS.

The Manager of QS had raised nuclear safety concerns. Among other issues, he had informed his supervisor that the Paducah Plant Quality Assurance Plan (QAP) did not incorporate all of the requirements of ASME NQA-1, "Quality Assurance Program for Nuclear Facilities." The Manager of QS also told his supervisor he was concerned that the Quality System Group's ability to effectively perform its responsibilities, as outlined in the QAP (*e.g.*, auditing vendors, dedicating commercial grade components, and conducting receipt inspections of new materials), was being negatively impacted by a requirement to perform non-QAP activities;

specifically, in-plant surveillances. Thereafter, the Manager of QS was transferred from a managerial position in the Safety, Safeguards and Quality Department to a non-managerial position in the Training Department on August 10, 1998.

At the predecisional enforcement conference, the Corporation's representatives stated that the Manager of QS was transferred due to legitimate performance considerations. The NRC recognizes that the Corporation can assign, transfer, rate, or discipline its employees for legitimate reasons. However, the NRC concluded, based on the record developed in this matter, that performance considerations were not the only reason the Manager of QS was transferred. The NRC determined that the decision to transfer the Manager of QS was due, in part, to his participation in protected activities.

Since the adverse employment action was taken against the Manager of QS by the Manager of Safety, Safeguards, and Quality, a mid-level plant management official, this violation has been categorized in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions" (Enforcement Policy), NUREG-1600, at Severity Level II.

In accordance with the Enforcement Policy, a base civil penalty in the amount of $88,000 is considered for a Severity Level II violation. Because the Paducah Plant was the subject of escalated enforcement actions within the two years preceding this violation,[1] the NRC considered whether credit was warranted for *Identification* and *Corrective Action* in accordance with the civil penalty assessment process in Section VI.B.2 of the Enforcement Policy. Credit was not warranted for the *Identification* factor because the OI investigation identified the violation. Normally, credit for *Corrective Action* is not warranted when corrective actions are not taken or proposed as of the date of the predecisional enforcement conference. The assessed civil penalty without credit for *Identification* or *Corrective Action* would normally be twice the base penalty. However, the NRC learned since the conference that the Corporation has proposed extensive actions to address the safety conscious work environment at its facilities and reached a settlement with the Manager of QS. In a letter dated October 29, 1999, the Corporation described programs that it has implemented or plans to implement to ensure a safety conscious work environment at its NRC-certified facilities. The Corporation's letter indicated that the initiatives are designed to: (1) help management effectively address employee concerns; (2) improve employees' confidence in line management and the employee concern program; and (3) strengthen management expectations in a nuclear-safety conscious work environment. As indicated in the Corporation's letter, initial management training sessions were implemented in June 1999, prior to the predecisional enforcement conference. In recognition of the broad measures the Corporation has taken and plans to take to improve the nuclear safety conscious work environment, the NRC is exercising the discretion authorized in the Enforcement Policy, Section VII.B.6, and mitigating the amount of the civil penalty.

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[1] A Notice of Violation was issued on September 22, 1997, for a Severity Level III problem (EA 97-267), and a Notice of Violation and Proposed Imposition of Civil Penalty - $55,000 was issued on December 8, 1997 (EA 97-431).

Therefore, to emphasize the seriousness of a violation of the Commission's employee protection regulation, to emphasize the need for prompt identification of violations, and in recognition of the previous escalated enforcement actions, I have been authorized, after consultation with the Director, Office of Enforcement, to issue the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice) with the civil penalty assessed in the base amount of $88,000 for the Severity Level II violation.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. The NRC will use your response, in part, to determine whether further enforcement action is necessary to ensure compliance with regulatory requirements.

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

Sincerely,

J. E. Dyer
Regional Administrator

Docket No. 70-7001
Certificate No. GDP-1

Enclosures: 1. Notice of Violation and Proposed Imposition of Civil Penalty
2. NUREG/BR-0254 Payment Methods

cc w/encl 1 only:
H. Pulley, Paducah General Manager
L. L. Jackson, Paducah Regulatory Affairs Manager
J. M. Brown, Portsmouth General Manager
S. A. Toelle, Manager, Nuclear Regulatory Assurance and Policy
Paducah Resident Inspector Office
Portsmouth Resident Inspector Office
R. M. DeVault, Regulatory Oversight Manager, DOE
D. Jackson, Acting Site Manager, Paducah

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

United States Enrichment Corporation
Paducah Gaseous Diffusion Plant
Paducah, Kentucky

Docket No. 70-7001
Certificate No. GDP-1
EA 99-110

During an NRC investigation completed on March 26, 1999, a violation of NRC requirements was identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," NUREG-1600 (64 FR 61142), the NRC 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 76.7(a) prohibits, in part, discrimination by the United States Enrichment Corporation (Corporation) Paducah Gaseous Diffusion Plant against an employee for engaging in certain protected activities. Discrimination includes discharge and other actions that relate to compensation, terms, conditions or privileges of employment. The protected activities were established in Section 211 of the Energy Reorganization Act of 1974, as amended, and in general are related to the administration or enforcement of a requirement imposed under the Atomic Energy Act or the Energy Reorganization Act. Protected activities include providing the Corporation with information about nuclear safety at an NRC-regulated facility.

Contrary to the above, the Corporation discriminated against the Manager of Quality Systems, through the actions of the Manager of Safety, Safeguards, and Quality, for having engaged in protected activities. Specifically, from March 1997 to June 1998, the Manager of Quality Systems engaged in protected activities when he expressed nuclear safety concerns to his supervisor, the Manager of Safety, Safeguards, and Quality. These safety concerns included: the Paducah Plant was not implementing all of the requirements of ASME NQA-1, "Quality Assurance Program for Nuclear Facilities," and implementation of the Paducah Plant Quality Assurance Program could be adversely impacted by a requirement for the Quality Systems Group to perform in-plant surveillances. Based, in part, on these protected activities, on August 10, 1998, the Manager of Safety, Safeguards and Quality transferred the Manager of Quality Systems from a managerial position in the Safety, Safeguards, and Quality Department to a non-managerial position in the Training Department at the Paducah Plant. (01012)

This is a Severity Level II violation (Supplement VII).
Civil Penalty - $88,000.

Pursuant to the provisions of 10 CFR 76.70, the 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 (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each alleged violation: (1) admission or denial of the alleged violation; (2) the reasons for the violation if admitted, and if denied, the reasons why; (3) the corrective steps that have been taken and the results achieved; (4) the corrective steps that will be taken to avoid further violations; and (5) the date when full compliance will be achieved. If an

adequate reply is not received within the time specified in this Notice, an order or a Demand for Information may be issued as why the certification 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.

Within the same time as provided for the response required above under 10 CFR 76.70, the Corporation may pay the civil penalty proposed above, in accordance with NUREG/BR-0254 and by submitting to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, a statement indicating when and by what method payment was made, 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 Corporation fail to answer within the time specified, an order imposing the civil penalty will be issued. Should the Corporation elect to file an answer in accordance with 10 CFR 2.205 protesting the civil penalty, in whole or in part, such answer should be clearly marked as an "Answer to a Notice of Violation" and may: (1) deny the violation listed in this Notice, in whole or in part; (2) demonstrate extenuating circumstances; (3) show error in this Notice; or (4) show other reasons why the penalty should not be imposed. In addition to protesting the civil penalty in whole or in part, such answer may request remission or mitigation of the penalty.

In requesting mitigation of the proposed penalty, the factors addressed in Section VI.B.2 of the Enforcement Policy 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 76.70, but may incorporate parts of the 10 CFR 76.70 reply by specific reference (e.g., citing page and paragraph numbers) to avoid repetition. The attention of the Corporation 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, statement as to payment of civil penalty, and Answer to a Notice of Violation) should be addressed to: Richard W. Borchardt, Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, One White Flint North, 11555 Rockville Pike, Rockville, MD 20852-2738, with a copy to the Regional Administrator, U.S. Nuclear Regulatory Commission, Region III, 801 Warrenville Road, Lisle, IL 60532-4351.

Because your response will be placed in the NRC Public Document Room (PDR), to the extent possible, it should not include any personal privacy, proprietary, or safeguards information so that it can be placed in the PDR without redaction. If personal privacy or proprietary information is necessary to provide an acceptable response, then please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request withholding of such material, you <u>must</u> specifically identify the portions of your response that you seek to have withheld and provide in

detail the basis for your claim of withholding (e.g., explain why the disclosure of information will create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.790(b) to support a request for withholding confidential commercial or financial information). If safeguards information is necessary to provide an acceptable response, please provide the level of protection described in 10 CFR 73.21.

In accordance with 10 CFR 19.11, you may be required to post this Notice within two working days.

Dated this 20th day of December 1999.

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

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

December 15, 1999

EA 99-284

Mr. John DeNardo, Director
Department of Veterans Affairs
Edward Hines, Jr. Hospital
Building 200
Hines, IL 60141

SUBJECT: NOTICE OF VIOLATION
(NRC Inspection Report 030-01391/99001(DNMS))

Dear Mr. DeNardo:

This refers to the inspection conducted on September 27, 1999, with continued NRC review through November 8, 1999, at the Department of Veterans Affairs, Edward Hines, Jr. Hospital (VAMC Hines) in Hines, Illinois. The purpose of the inspection was to review the circumstances surrounding a reported brachytherapy misadministration. During the inspection, apparent violations of NRC requirements were identified, and are documented in the NRC inspection report sent to you by our letter dated December 1, 1999. In that letter, we indicated that NRC had sufficient information to proceed with enforcement action, however, you were given an opportunity to discuss the apparent violations at a predecisional enforcement conference or to address the apparent violations in writing. During the December 6, 1999, telephone conversation between Mr. L. Case of your staff, and Mr. G. Wright of my staff, VAMC Hines declined a conference and declined to provide additional written correspondence.

Based on the information developed during the inspection and the information provided in your report of misadministration dated October 5, 1999, the NRC has determined that violations of NRC requirements occurred. The violations are cited in the enclosed Notice of Violation (Notice).

The violations are indicative of weakness in the implementation of VAMC Hines quality management program (QMP). Specifically, ineffective training resulted in one individual failing to enter a treatment planning parameter into the console of the high dose rate (HDR) afterloader unit and a second individual failing to ensure the parameters were correctly entered and in accordance with the written directive prior to commencing treatment. As a result, an important factor was overlooked - the change in the starting point was not entered and dose was delivered to an unintended portion of the esophagus. It is likely that had the verification been performed, the misadministration would have been averted. Although we recognize that the misadministration did not likely cause any adverse effects to the patient, the violation is of concern because of the significant potential for serious patient treatment errors.

The QMP implementation weakness is further evidenced by another VAMC Hines employee, the therapist administering the treatment described above, failing to follow the two step patient identification procedure. Fortunately, there was no incident involved with this violation. Nonetheless, incumbent upon each NRC licensee is the responsibility to ensure that all requirements of the NRC license are met and any potential violations of NRC requirements are identified and corrected expeditiously. Therefore, the violations are categorized in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions" (Enforcement Policy), NUREG-1600, as a Severity Level III problem.

In accordance with the Enforcement Policy, a base civil penalty in the amount of $2,750 is considered for a Severity Level III problem. Because your facility has not been the subject of escalated enforcement actions within the last two inspections, the NRC considered whether credit was warranted for *Corrective Action* in accordance with the civil penalty assessment process in Section VI.B.2 of the Enforcement Policy. Credit for *Corrective Action* is warranted based on the following corrective actions planned or taken: (1) the misadministration and its root cause were discussed with appropriate staff; (2) a memorandum of instructions was issued describing in detail the procedures to be followed by each staff member on keying in HDR skip treatments (Included in this instruction is a specific requirement for both individuals to inspect the pretreatment tape (GAMHUR card) against the data on the treatment record and the data on the screen before treatment); (3) the HDR planning and treatment record was revised to include signatures of individuals who checked the pretreatment tape against the data on the treatment record immediately before treatment; (4) the QMP was revised to include use of the pretreatment information from the simulated treatment to verify that the information not only agrees with the data entered into the console, but also agrees with the treatment data on the treatment record form; and (5) the QMP was revised to require methods of patient identification to be described in writing and signed by the individual identifying the patient.

Therefore, to encourage prompt and comprehensive correction of violations, and in recognition of the absence of previous escalated enforcement action, I have been authorized not to propose a civil penalty in this case. However, significant violations in the future could result in a civil penalty. In addition, issuance of the Severity Level III problem constitutes escalated enforcement action that may subject you to increased inspection effort.

The NRC has concluded that information regarding the reasons for the violation, and the corrective actions taken and planned to correct the violation and prevent recurrence are already adequately addressed in the inspection report and in your letter dated October 5, 1999. Therefore, you are not required to respond to this letter unless the description therein does not accurately reflect your corrective actions or your position. In that case, or if you choose to provide additional information, you should follow the instructions specified in the enclosed Notice.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter, the enclosed Notice, and your response if you choose to respond, will be placed in the NRC Public Document Room.

Sincerely,

J. E. Dyer
Regional Administrator

Docket No. 030-01391
License No. 12-01087-07

Enclosure: Notice of Violation

NOTICE OF VIOLATION

Department of Veterans Affairs
Edward Hines, Jr. Hospital
Hines, Illinois

Docket No. 030-01391
License No. 12-01087-07
EA 99-284

During an NRC inspection conducted on September 27, 1999, with continuing NRC review through November 8, 1999, violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," NUREG-1600, the violations are listed below:

10 CFR 35.25(a)(2) requires, in part, that a licensee that permits the use of byproduct material by an individual under the supervision of an authorized user shall require the supervised individual to follow the written quality management procedures established by the licensee.

A. The licensee's quality management procedure, dated July 15, 1994, Quality Management Program for Teletherapy and Brachytherapy page 3, requires, in part, that technologists, dosimetrists, or physicists entering treatment planning parameters into the operating console of a remotely controlled afterloading device will have their computer entries verified and documented, by signature or initial, by a second technologist, dosimetrist, physicist before commencing therapy.

Contrary to the above, on September 23, 1999, individuals under the supervision of the licensee's authorized user, did not follow the written quality management procedures established by the licensee in that treatment planning parameters entered into the operating console of a remotely controlled afterloading device were not verified and documented, by signature or initial, by a second technologist, dosimetrist, or physicist before commencing therapy. (01013)

B. The licensee's quality management procedure, revised April 22, 1999, Quality Management Program for Teletherapy and Brachytherapy page 2, requires, in part, that those administering treatments will ask the patient to state their full name - first name and last name. Additionally, they will ask the patient to state their birth date. They will confirm both identifiers agree with the same in the patient's chart.

Contrary to the above, on September 23, 1999, the identity of a therapy patient was not verified as required by the quality management program. Specifically, the therapist did not ask the patient to state their full name or date of birth. (01023)

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

The NRC has concluded that information regarding the reasons for the violations, and the corrective actions taken and planned to correct the violations and prevent recurrence is already adequately addressed in the NRC inspection report and in a letter from Department of Veterans Affairs, Edward Hines, Jr. Hospital dated October 5, 1999. However, you are required to respond to the provisions of 10 CFR 2.201 if the description therein does not accurately reflect

your corrective actions or your position. In that case, or if you choose to respond, clearly mark your response as a "Reply to a Notice of Violation," and send it to the U. S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555, with a copy to the Regional Administrator, Region III, 801 Warrenville Road, Lisle, Illinois 60532-4351, within 30 days of the date of the letter transmitting this Notice of Violation.

If you contest this enforcement action, you should also provide a copy of your response, with the basis for your denial, to the Director, Office of Enforcement, United States Nuclear Regulatory Commission, Washington, D.C. 20555-0001.

If you choose to respond your response will be placed in the NRC Public Document Room (PDR). Therefore, to the extent possible, it should not include any personal, privacy, proprietary, or safeguards information so that it can be placed in the PDR without redaction. Under the authority of Section 182 of Act 42 U.S.C. 2232, any response shall be submitted under oath or affirmation.

In accordance with 10 CFR 19.11, you may be required to post this Notice within two working days.

Dated this 15th day of December 1999

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

October 14, 1999

EA 99-174

Gary L. Wilkinson
Medical Center Director
Department of Veterans Affairs
Medical Center
Iowa City, IA 52246-2208

SUBJECT: NOTICE OF VIOLATION
(NRC Inspection Report 030-01680/99001(DNMS))

Dear Mr. Wilkinson:

This refers to the inspection conducted at the Veterans Affairs Medical Center (VAMC), Iowa City, Iowa, on February 16 through 18, 1999, with continued review through October 1, 1999. The purpose of the inspection was to review the circumstances surrounding VAMC's failure to assess dose consequences to members of the public following the administration of Sn-117m to two human research subjects. Unresolved issues were identified and documented in the inspection report sent to you by our letter dated April 1, 1999. After further review, the unresolved issues were determined to be apparent violations of NRC requirements and were discussed in our letter dated August 10, 1999. As stated in that letter, the apparent violations were being considered for escalated enforcement and you were given an opportunity to request a predecisional enforcement conference and/or respond to the apparent violations. You elected to provide a written response.

Based on the information developed during the inspection and the information provided in your letter dated September 7, 1999, the NRC has determined that a violation of NRC requirements occurred. The violation is cited in the enclosed Notice of Violation (Notice) and the circumstances surrounding it are described in detail in the subject inspection report. The violation involved failure to determine that members of the public were not likely to receive a total effective dose equivalent (TEDE) greater than 500 millirem from released human research subjects administered therapeutic doses of Sn-117m and the subsequent failure to provide the released subjects with written instructions on how to maintain doses to others as low as is reasonably achievable.

In 1998 VAMC participated in a double blind comparative study to evaluate the effectiveness of Sn-117m and Metastron (Sr-89) for pain relief in patients with bone metastasis. During the course of this study, two research subjects received dosages of 40 millicuries and 8 millicuries of Sn-117m respectively. Neither subject was evaluated by the staff to show compliance with 10 CFR 35.75 prior to release. On May 13, 1998, one research subject received 40 millicuries of Sn-117m, an amount requiring hospitalization for radiation purposes unless a calculation and/or radiation measurement determined that the subject was releasable.

The evaluation was not performed and the subject was released but remained in the hospital for medical reasons.

Because the subject was not being held for radiation purposes, the subject's room was not posted with a "Radioactive Materials" sign, dose rates in contiguous restricted and unrestricted areas were not measured, items removed from the subject's room were not surveyed, and the room was not surveyed before it was occupied by another patient or human research subject. Release of this subject resulted in a significant potential for members of the public to receive a TEDE in excess of 500 millirem. In addition, the subject dosed with 8 millicuries of Sn-117m in December 1998 was not given adequate written instructions addressing actions recommended to maintain doses to other individuals as low as is reasonably achievable. The failure of VAMC's radiation safety committee to recognize that the human use research protocol for Sn-117m included dosages that would normally require hospitalization and that the model instructions to the human research subjects were inadequate for the radiation emitted is unacceptable.

The NRC provides significant latitude to its broadscope licensees to oversee their own use of byproduct material. Incumbent upon such licensees, including VAMC, is the responsibility to thoroughly review all proposed uses of byproduct material to ensure that all potential radiological implications are identified and addressed prior to approving the application for use. The NRC recognizes that VAMC has historically used the resources of a neighboring facility to support its review of such activities; however, the ultimate responsibility for those reviews rests with VAMC, including any errors or omissions on the part of that facility. The NRC concluded that VAMC's failure to evaluate the possible doses to family members and others resulted in a substantial potential for exposures to members of the public in excess of the regulatory limit of 500 millirem. Fortunately, in these two instances, doses to members of the public (including family members) did not exceed regulatory limits; however, individuals received between 113 millirem and 250 millirem. Therefore, the violation is categorized in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions" (Enforcement Policy), NUREG-1600 at Severity Level III.

In accordance with the Enforcement Policy, a base civil penalty in the amount of $2,750 is considered for a Severity Level III violation. Because your facility has not been the subject of escalated enforcement actions within the last two inspections, the NRC considered whether credit was warranted for *Corrective Action* in accordance with the civil penalty assessment process in Section VI.B.2 of the Enforcement Policy. The NRC has determined that credit for Corrective Action is warranted based on the following actions taken and/or planned: (1) the radiation safety officer (RSO) has been administratively moved and will report to the Chief Operations Officer; (2) the Radiation Safety Committee (RSC) implemented a policy requiring the use of a form, "Worksheet for Documentation of Release of Patients Administered I-131 or Therapeutic Amounts of Radioactive Material"; (3) technical and clerical staff received training covering the release of patients, the provision of written instructions for safety purposes, and documentation of the justification of early release of patients; and (4) all human use research proposals involving radiation will be forwarded to the RSO with an abstract of the research and the consent form for RSC review.

Therefore, to encourage prompt comprehensive correction of violations, I have been authorized not to propose a civil penalty in this case. However, significant violations in the future could result in a civil penalty.

The NRC has concluded that information regarding the reason for the violation, the corrective actions taken and planned to correct the violation and prevent recurrence and the date when full compliance was achieved is already adequately addressed on the docket in a letter from VAMC dated September 7, 1999. Therefore, you are not required to respond to this letter unless the description therein does not accurately reflect your corrective actions or your position. In that case, or if you choose to provide additional information, you should follow the instructions specified in the enclosed Notice.

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

Sincerely,

J. E. Dyer
Regional Administrator

Docket No. 030-01680
License No. 14-00822-01

Enclosure: Notice of Violation

cc w/encl: E. Lynn McGuire
National Health Physics Program (1 15HP/NLR)
Department of Veterans Affairs
Veterans Health Administration
2200 Fort Roots Drive
North Little Rock, Arkansas 72114

NOTICE OF VIOLATION

Department of Veterans Affairs Medical Center
Iowa City, Iowa

Docket No. 030-01680
License No. 14-00822-01
EA 99-174

During an NRC inspection conducted on February 16 through 18, 1999, with continued review through October 1, 1999, a violation of NRC requirements was identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," NUREG-1600, the violation is listed below:

> 10 CFR 35.75 (a) and (b) require, in part, that (1) the licensee may authorize the release from its control any individual who has been administered radiopharmaceuticals if the total effective dose equivalent to any other individual is not likely to exceed 5 millisieverts (0.5 rem) and (2) the licensee provide released individuals with instructions, including written instructions, on actions recommended to maintain doses to other individuals as low as is reasonably achievable if the total effective dose equivalent to any other individual is likely to exceed 1 millisievert (100 millirems).
>
> Contrary to the above, the licensee released individuals who had been administered radiopharmaceuticals and the licensee did not determine if the exposure to any other individual could potentially exceed 5 millisieverts (0.5 rem). In addition, the licensee did not provide instructions to the individuals on actions recommended to maintain doses to those other individuals as low as is reasonably achievable when the total effective dose equivalent to other individuals was likely to exceed 1 millisievert. Specifically, on May 20, 1998 and December 9, 1998, the licensee released human research subjects who had been administered 40 millicuries and 8 millicuries of Sn-117m without determining if the exposure to any other individual could potentially exceed 5 millisieverts (0.5 rem) and without providing written instructions on actions recommended to maintain doses to other individuals as low as is reasonably achievable. (01013)

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

The NRC has concluded that information regarding the reason for the violation, the corrective actions taken and planned to correct the violation and prevent recurrence and the date when full compliance was achieved is already adequately addressed on the docket in a letter from the Department of Veterans Affairs Medical Center dated September 7, 1999. However, you are required to submit a written statement or explanation pursuant to 10 CFR 2.201 if the description therein does not accurately reflect your corrective actions or your position. In that case, or if you choose to respond, clearly mark your response as a "Reply to a Notice of Violation," and send it to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555 with a copy to the Regional Administrator, Region III, within 30 days of the date of the letter transmitting this Notice of Violation (Notice).

If you contest this enforcement action, you should also provide a copy of your response, with the basis for your denial, to the Director, Office of Enforcement, United States Nuclear Regulatory Commission, Washington, DC 20555-0001.

If you choose to respond, your response will be placed in the NRC Public Document Room (PDR). Therefore, to the extent possible, the response should not include any personal privacy, proprietary, or safeguards information so that it can be placed in the PDR without redaction.

In accordance with 10 CFR 19.11, you may be required to post this Notice within two working days.

Dated this 14th day of October 1999

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

August 16, 1999

EA 99-168

Charles A. Judd, President
Envirocare of Utah, Inc.
American Towers Commercial
46 West Broadway, Suite 240
Salt Lake City, Utah 84101

SUBJECT: NRC INSPECTION REPORT 40-8989/99-02 AND NOTICE OF VIOLATION

Dear Mr. Judd:

This refers to the routine inspection conducted on May 11-13, 1999, at the South Clive disposal facility. This inspection consisted of a review of management organization and controls, site operations, radiation protection, and environmental monitoring. A preliminary exit briefing was conducted onsite on May 13, 1999, a followup telephonic exit briefing was conducted on July 2, 1999, and a final telephonic exit briefing was conducted on August 4, 1999 with members of your staff. The enclosed report presents the results of that inspection.

During the inspection, the NRC reviewed the circumstances associated with Envirocare's January 20, 1999, telephonic notification to the NRC that doses in certain unrestricted areas might have exceeded the 100 mrem per year limit specified in 10 CFR 20.1301(a)(1). In accordance with 10 CFR 20.2203(a)(2), Envirocare submitted a written report on this issue by letter dated February 19, 1999. The NRC requested further information on April 7, 1999, to which you responded on May 7, 1999.

During the July 2 exit briefing, we informed Envirocare that the NRC was considering a violation for escalated enforcement action in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions" (Enforcement Policy), NUREG-1600, and offered Envirocare an opportunity to request a conference or to respond to the apparent violation in writing. The violation involved a failure to perform adequate surveys in accordance with 10 CFR 20.1501 in order to demonstrate compliance with 10 CFR 20.1301(a)(1). We informed Envirocare that, based on our review of the inspection findings and Envirocare's letters of February 19 and May 7, 1999, the NRC believed that it had sufficient information to make an enforcement decision. In addition, we noted that since your staff identified the violation and based on our understanding of your corrective action, a civil penalty may not be warranted in accordance with Section VI.B.2 of the Enforcement Policy. However, we stressed that a final decision had not yet been made. Your staff agreed that Envirocare had no more substantive information to provide, and did not see any benefit to discussing the issue further. As such, the NRC is making its final enforcement decisions.

Based on the information obtained during the inspection and Envirocare's letters dated February 19 and May 7, 1999, the NRC has concluded that a violation of 10 CFR 20.1501 occurred. Although no member of the public was actually overexposed, we note that one of your employees (who is not a radiation worker) received approximately 82 mrem for calendar year 1998. (Employees who are not radiation workers are considered members of the public.) The significance of the violation rests with the potential that a member of the public realistically could have received an exposure in excess of the 100 mrem per year limit. Our conclusion about the realistic potential for an overexposure is based on the fact that Envirocare was not controlling either the source term or the exposure time. The source term could realistically have been greater, resulting in an overexposure, and exposure time could have been longer, also resulting in an overexposure. As a result, this violation is classified at Severity Level III in accordance with the Enforcement Policy.

In accordance with the Enforcement Policy, a civil penalty in the base amount of $5500 is considered for a Severity Level III violation. Because your facility has not been the subject of escalated enforcement actions within the last 2 years, the NRC considered whether credit was warranted for *Corrective Action* in accordance with the civil penalty assessment process in Section VI.B.2 of the Enforcement Policy. The corrective actions were described in your February 19, 1999 letter, and included items such as performing a detailed dose rate survey of the restricted area boundary, relocating items in order to reduce the radiation levels in unrestricted areas, notifying regulatory agencies, conducting additional training, and revising appropriate procedures. As a result of your corrective actions, the NRC has determined that Envirocare is deserving of *Corrective Action* credit.

Therefore, to encourage prompt and comprehensive correction of violations, and in recognition of the absence of previous escalated enforcement action, I have been authorized, not to propose a civil penalty in this case. However, significant violations in the future could result in a civil penalty. In addition, issuance of this Severity Level III violation constitutes escalated enforcement action that may subject you to increased inspection effort.

The NRC has concluded that information regarding the reason for this violation, the corrective actions taken and planned to correct this violation and prevent recurrence and the date when full compliance was achieved is already adequately addressed on the docket in the attached inspection report and in the letters from Envirocare dated February 19 and May 7, 1999. Therefore, you are not required to respond to this violation unless the description therein does not accurately reflect your corrective actions or your position. In that case, or if you choose to provide additional information, you should follow the instructions specified in the enclosed Notice.

During this inspection, the NRC identified two additional violations as cited in the attached Notice of Violation both of which have been classified as Severity Level IV violations. One of these violations involved a failure to submit to the NRC a consolidated groundwater sampling report that summarizes the quarterly groundwater data and analyses as part of the annual reporting requirement specified in License Condition 12.2. License Condition 12.6 requires, in part, that annual reports be submitted by March 31 of the following year. This violation is of concern because of the importance NRC places on the accuracy and timeliness of reporting required information. The final violation involved a failure to comply with the requirements of Criterion 7A, 10 CFR Part 40, Appendix A for effectively implementing a ground-water detection

monitoring program. This violation is of concern because it indicates that your groundwater monitoring program was not capable of detecting levels of certain constituents requiring action on your part as required by your license.

With respect to your response to this final violation, we also request that you provide information concerning original data provided with your license application to support site specific license limits. Specifically, as discussed in Section 4.1 of the report, you now question whether your analytical laboratories can provide detection limits lower than the license limits. However, we note that the license limits were based on analytical results originally submitted with your license application which met lower limits of detection. Therefore, we request that you discuss the reliability of the original data provided in support of the license and why the lower limits of detection could be met at the time of license application but not now.

You are required to respond to these Severity Level IV violations and should follow the instructions specified in the enclosed Notice when preparing your response. For your consideration and convenience, NRC Information Notice 96-28, "SUGGESTED GUIDANCE RELATING TO DEVELOPMENT AND IMPLEMENTATION OF CORRECTIVE ACTION," is enclosed. The NRC will use your response, in part, to determine whether further enforcement action is necessary to ensure compliance with regulatory requirements.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter, its enclosures, and your response should you choose to provide one will be placed in the NRC Public Document Room.

Should you have any questions concerning this inspection, please contact Mr. Douglas Simpkins at (817) 860-8220 or Dr. D. Blair Spitzberg at (817) 860-8191.

Sincerely,

/s/

Ellis W. Merschoff
Regional Administrator

Docket No.: 40-8989
License No.: SMC-1559

Enclosures:
1. Notice of Violation
2. NRC Inspection Report 40-8989/99-02
3. NRC Information Notice 96-28

cc w/Enclosures:
Mr. K. Alkema
Envirocare of Utah, Inc.
46 Broadway, Ste. 240
Salt Lake City, Utah 84101

Mr. Pat Mackin, Assistant Director
Systems Engineering & Integration
Center for Nuclear Waste Regulatory Analyses
6220 Culebra Road
San Antonio, Texas 78238-5166

Utah Radiation Control Program Director

ENCLOSURE 1

NOTICE OF VIOLATION

Envirocare of Utah, Inc.
Clive, Utah

Docket No.: 40-8989
License No.: SMC-1559
EA 99-168

During an NRC inspection conducted from May 11 through August 4, 1999, three violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," NUREG-1600, the violations are listed below:

A. 10 CFR 20.1501 requires that each licensee make or cause to be made surveys that may be necessary for the licensee to comply with the regulations in Part 20 and that are reasonable under the circumstances to evaluate the extent of radiation levels, concentrations or quantities of radioactive materials, and the potential radiological hazards that could be present.

Pursuant to 10 CFR 20.1003, *survey* means an evaluation of the radiological conditions and potential hazards incident to the production, use, transfer, release, disposal, or presence of radioactive material or other sources of radiation.

Contrary to the above, for calendar year 1998, the licensee did not make adequate surveys to assure compliance with 10 CFR 20.1301(a)(1), which limits the total effective dose equivalent from licensed operation to individual members of the public to 0.1 rem in a year. Specifically, the licensee had not been monitoring certain locations at the restricted area boundary, and found certain locations in the unrestricted area that exceeded the 0.1 rem in a year limit. Adequate surveys were not performed in these areas, which are accessible to members of the public and realistically could have resulted in doses in excess of 10 CFR 20.1301(a)(1). (01013)

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

B. License Condition 12.2 states, in part, the licensee shall submit to the NRC a consolidated groundwater sampling report that summarizes the quarterly groundwater data and analyses as part of the licensee's annual reporting requirement. License Condition 12.6 requires, in part, that annual reports be submitted by March 31 of the following year.

Contrary to the above, as of the date of this inspection, the licensee had not submitted a consolidated sampling report that summarizes the quarterly groundwater data and analyses as part of the licensee's annual reporting requirement. (02014)

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

C. License Condition 11.1states, in part, that the licensee shall implement groundwater monitoring programs throughout the duration of the license, to include a) that the licensee shall conduct detection monitoring, compliance monitoring, corrective action monitoring, and post-closure monitoring in accordance with Criteria 5 and 7 of 10 CFR Part 40, Appendix A. Criterion 7A states, in part, the initial purpose of the [detection

monitoring] program is to detect leakage of hazardous constituents from the disposal area so that the need to set ground-water protection standards is monitored. (03014)

Contrary to the above, a detailed review of the licensee's groundwater monitoring program found that from the third quarter of 1997 to the time of the inspection, the licensee's groundwater monitoring program was not conducted in a manner such that it was capable of detecting leakage of hazardous constituents as required by 10 CFR Part 40, Appendix A. During that period, various laboratory analytical results reported by the licensee did not have sufficient lower limits of detection to detect exceedance above limits specified in the NRC license. Specifically, during this period the licensee's lower limits of detection exceeded the site specific license limits for beryllium, molybdenum, selenium, thorium-230, and thorium-232.

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

For Violation A, the NRC has concluded that information regarding the reasons for the violation, the corrective actions taken and planned to correct the violation and prevent recurrence and the date when full compliance will be achieved is already adequately addressed on the docket in this inspection report and in the letters from Envirocare dated February 19 and May 7, 1999. However, you are required to submit a written statement or explanation pursuant to 10 CFR 2.201 if the description therein does not accurately reflect your corrective actions or your position. In that case, or if you choose to respond, clearly mark your response as a "Reply to a Notice of Violation," and send it to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555 with a copy to the Regional Administrator, Region IV, 611 Ryan Plaza Drive, Suite 400, Arlington, Texas 76011, within 30 days of the date of the letter transmitting this Notice of Violation.

For Violations B and C, pursuant to the provisions of 10 CFR 2.201, Envirocare of Utah, Inc., 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, U.S. Nuclear Regulatory Commission, Region IV, 611 Ryan Plaza Drive, Suite 400, Arlington, Texas 76011, within 30 days of the date of the letter transmitting this Notice of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each violation: (1) the reason for the violation, or, if contested, the basis for disputing the violation or severity level, (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. Your response may reference or include previous docketed correspondence, if the correspondence adequately addresses the required response. If an adequate reply is not received within the time specified in this Notice, an order or a Demand for Information may be issued as to why the license should not be modified, suspended, or revoked, or why such other action as may be proper should not be taken. Where good cause is shown, consideration will be given to extending the response time.

If you contest any of these violations, you should also provide a copy of your response, with the basis for your denial, to the Director, Office of Enforcement, United States Nuclear Regulatory Commission, Washington, DC 20555-0001. Under the authority of Section 182 of the Atomic Energy Act, 42 U.S.C. 2232, any such response shall be submitted under oath or affirmation.

Because your response will be placed in the NRC Public Document Room (PDR), to the extent possible, it should not include any personal privacy, proprietary, or safeguards information so that it can be placed in the PDR without redaction. If personal privacy or proprietary information is necessary to provide an acceptable response, then please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request withholding of such material, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim of withholding (e.g., explain why the disclosure of information will create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.790(b) to support a request for withholding confidential commercial or financial information).

In accordance with 10 CFR 19.11, you may be required to post this Notice within two working days.

Dated this 16th day of August 1999

November 30, 1999

EA 99-294

Patricia Harsche
Vice President, Business Development
and Regulatory Affairs
Fox Chase Cancer Center
7701 Burholme Avenue
Philadelphia, PA 19111

SUBJECT: Notice of Violation and NRC Inspection Report 030-03026/99-01

Dear Ms. Harsche:

This refers to the NRC inspection conducted on November 1, 2, 5, and 9, 1999, at your facility in Philadelphia, Pennsylvania, to determine whether activities authorized by your NRC broad-scope license were conducted safely and in accordance with requirements. During the inspection, a violation of NRC requirements was identified. In a telephone conversation on November 24, 1999, you informed Dr. M. Shanbaky of my staff that Fox Chase Cancer Center did not believe that a predecisional enforcement conference, nor a written response, was needed, prior to the NRC deciding on appropriate enforcement action. The NRC agrees that it has sufficient information to take the action described below.

Based on the information developed during the inspection, the NRC has determined that one violation of NRC requirements occurred. The violation, which is described in the enclosed Notice of Violation (Notice) and inspection report, involves your Radiation Safety Committee approving certain physicians to use radioactive material without those physicians meeting all of the training requirements set forth in the NRC regulations. As a result of this violation, the NRC issued a Confirmatory Action Letter to you on November 12, 1999, confirming your commitment to take appropriate correct actions to address this violation.

As a broad scope medical licensee, you have the authority to authorize physicians to use licensed material in or on humans. At the same time, you have the responsibility for ensuring that these physicians first meet all of the training criteria set forth in NRC regulations prior to authorizing such use. That responsibility was not met since your Medical Isotope Sub-Committee of the Radiation Safety Committee approved 16 radiologists to use of radiopharmaceuticals for various medical procedures, even though 13 of those physicians did not meet the training requirements.

The NRC recognizes that this violation did not result in any actual safety consequences since only one dose was administered by an unqualified physician and that administration appears to have been performed properly. Nonetheless, the potential existed for misuse of the radiopharmaceuticals, which could have been detrimental to the patients and technical staff involved in such dose administrations. Therefore, given the number of physicians who did not meet the training requirements, and the potential safety consequences, the violation is categorized at

Severity Level III violation in accordance with the "General Statement of Policy and Procedures for NRC Enforcement Actions" (Enforcement Policy), NUREG-1600.

In accordance with the Enforcement Policy, a base civil penalty in the amount of $2,750 is considered for a Severity Level III violation. Because your facility has not been the subject of an escalated enforcement action within the last two years or two inspections, the NRC considered whether credit was warranted for Corrective Action in accordance with the civil penalty assessment process in Section VI.B.2 of the Enforcement Policy. Credit for corrective actions is warranted because your corrective actions, as described during the inspection, as well as in the Confirmatory Action Letter (CAL), were considered prompt and comprehensive. These actions include, but are not limited to, (1) issuance of a memorandum from your Radiation Safety Officer to the physicians who did not satisfy all of the training requirements, which revoked their authorizations to use material; (2) plans to establish and implement procedures for RSC review and approval of authorizations; and (3) training of the RSC staff in NRC requirements.

Therefore, to encourage prompt and comprehensive correction of violations, I have been authorized to not propose a civil penalty in this case. However, similar violations in the future could result in further escalated enforcement action. In addition, issuance of this Notice constitutes escalated enforcement action that may increase the NRC inspection effort at your facility.

The NRC has concluded that information regarding the reason for the violation, and the corrective actions taken and planned to correct the violation and prevent recurrence, were already described adequately during the inspection, in the NRC November 12, 1999, CAL, and in this letter. Therefore, you are not required to respond to this letter unless the description therein does not accurately reflect your corrective actions or your position. In that case, or if you choose to provide additional information, you should follow the instructions specified in 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, and your response (if any) will be placed in the NRC Public Document Room (PDR).

Sincerely,

Original Signed by:
James T. Wiggins for

Hubert J. Miller
Regional Administrator

Docket Nos. 030-03026
License Nos. 37-02766-01

Enclosures:
1. Notice of Violation
2. Inspection Report

cc w/encls:
Nancy D. Moldofsky, Radiation Safety Officer
Commonwealth of Pennsylvania

ENCLOSURE

NOTICE OF VIOLATION

Fox Chase Cancer Center
New Brunswick, New Jersey

Docket No. 030-03026
License No. 37-02766-01
EA 99-294

During an NRC inspection conducted on November 1, 2, 5, and 9, 1999, a violation of NRC requirements was identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy), NUREG -1600, the violation is listed below:

> Condition 11.B of NRC License No. 37-02766-01, Amendment No. 54, requires that the physicians that are designated to use licensed material in or on humans meet the training criteria established in 10 CFR Part 35, Subpart J and be designated by the licensee's Radiation Safety Committee. 10 CFR Part 35.930 (Subpart J), in part, requires the authorized user of radiopharmaceuticals in 10 CFR 35.300 to be a physician who is certified by The American Board of Radiology in Radiology, Therapeutic Radiology, or Radiation Oncology.
>
> Contrary to the above, on September 23, 1999, the Medical Isotope Committee of the Radiation Safety Committee approved 13 physicians for therapeutic use of radiopharmaceuticals in 10 CFR Part 35.300 and these physicians were not certified by the American Board of Radiology in Radiology, Therapeutic Radiology or Radiation Oncology. **(01013)**
>
> This is a Severity Level III violation (Supplement VI).

The NRC has concluded that information regarding the reason for the violation, and the corrective actions taken and planned to correct the violation and prevent recurrence were adequately described during inspection, and are already adequately addressed on the docket in the letter transmitting this Notice, as well as in the NRC Confirmatory Action letter issued on November 12,, 1999. However, you are required to submit a written statement or explanation pursuant to 10 CFR 2.201 if the description therein does not accurately reflect your corrective actions or your position. In that case, or if you choose to respond, clearly mark your response as a "Reply to a Notice of Violation," and send it to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555 with a copy to the Regional Administrator, Region I, within 30 days of the date of the letter transmitting this Notice of Violation (Notice).

If you contest this enforcement action, you should also provide a copy of your response, with the basis for your denial, to the Director, Office of Enforcement, United States Nuclear Regulatory Commission, Washington, DC 20555-0001.

If you choose to respond, your response will be placed in the NRC Public Document Room (PDR). Therefore, to the extent possible, the response should not include any personal privacy or proprietary information so that it can be placed in the PDR without redaction.

Dated this 30th day of November 1999

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

September 10, 1999

EA 99-231

Sam Wiesel, MD
Executive Vice President for Health Sciences
Georgetown University Medical Center
LM12, Preclinical Science Building
3900 Reservoir Road, NW
Washington, DC 20007

SUBJECT: NOTICE OF VIOLATION
(NRC Inspection Report No. 030-01315/99-001)

Dear Dr. Wiesel:

This refers to the NRC inspection conducted on August 16 through 19, 1999, at your facility in Washington, DC. The inspection was performed to determine whether activities authorized by your license were conducted safely and in accordance with NRC requirements. During the inspection, two apparent violations were identified, one of which involved the loss of control of a package containing a high dose rate (HDR) afterloader source (11.1 curies of iridium-192) that was delivered to your Washington, DC, facility in August 1999. In a telephone conversation on August 31, 1999, Ms. Sharon Flynn-Hollander, Hospital Chief Executive, informed Dr. M. Shanbaky of my staff that Georgetown University Medical Center did not believe that a predecisional enforcement conference, nor a written response, was needed, prior to the NRC deciding on appropriate enforcement action. The NRC agrees that it has sufficient information to take the action described below.

Based on the information developed during the inspection, the NRC has determined that two violations of NRC requirements occurred. These violations are cited in the enclosed Notice of Violation (Notice). The most significant violation involved the failure to provide appropriate security of the HDR source. After the package was erroneously delivered to your Radiation Oncology Department without the normal source receipt process being used, the package was placed in an unrestricted area (reception area) that is frequented by patients and other personnel from your staff. Although the package was unsecured for only a relatively short duration of time, its removal could have occurred as previously happened at your facility under similar circumstances in 1990.

The violation is a significant concern because of the potential for high radiation exposure to unauthorized personnel or the public if the source had been opened by unauthorized personnel or transferred to an unauthorized facility. Therefore, the violation is categorized as a Severity Level III violation in accordance with the "General Statement of Policy and Procedures for NRC Enforcement Actions" (Enforcement Policy), NUREG-1600 and is described in Item A in the enclosed Notice of Violation (Notice).

In accordance with the Enforcement Policy, a base civil penalty in the amount of $2,750 is considered for a Severity Level III violation or problem. Because your facility has not been the subject of an escalated enforcement action within the last two years or two inspections, the NRC considered whether credit was warranted for *Corrective Action* in accordance with the civil penalty assessment process in Section VI.B.2 of the Enforcement Policy. Credit for corrective actions is warranted because your corrective actions, at the time of the inspection, were considered prompt and comprehensive. These actions include, but are not limited to, (1) immediate control of the package after discovery, (2) training of all staff for identification of packages that contain radioactive material, and (3) contacting the shipper of the package to explain the correct delivery procedure.

Therefore, to encourage prompt and comprehensive correction of violations, I have been authorized to not propose a civil penalty in this case. However, similar violations in the future could result in further escalated enforcement action. In addition, issuance of this Notice constitutes escalated enforcement action, that may subject you to increased inspection effort.

A second violation was also identified by our inspectors during our recent inspection of your facility. The second violation involved the failure to determine prior occupational radiation dose and obtain records of cumulative radiation dose for individuals working at your facility. This violation was a concern due to the possibility of workers accumulating occupational radiation exposure above the NRC limits. This violation is also described in the enclosed Notice.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. The NRC will use your response, in part, to determine whether further enforcement action is necessary to ensure compliance with regulatory requirements. The NRC has concluded that the actions taken and planned to correct Violation A and prevent recurrence, were already addressed described adequately during the inspection as already described herein. Therefore, you are not required to respond Violation A unless this description does not accurately reflect your corrective actions. In that case, or if you choose to provide additional information, you should follow the instructions specified in the enclosed Notice.

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

Sincerely,

Hubert J. Miller
Regional Administrator

Docket No. 030-01315
License No. 08-01709-04

Enclosure:
Notice of Violation

cc w/encl:
Catalina Kovats, Radiation Safety Officer
District of Columbia

ENCLOSURE

NOTICE OF VIOLATION

Georgetown University Medical Center
Washington, DC

Docket No. 030-01315
License No. 08-01709-04
EA 99-231

During an NRC inspection conducted on August 16-19, 1999, two violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy), NUREG -1600, the violations are listed below:

A. 10 CFR 20.1801 requires that the licensee secure from unauthorized removal or access licensed materials that are stored in controlled or unrestricted areas. 10 CFR 20.1802 requires that the licensee control and maintain constant surveillance of licensed material that is in a controlled or unrestricted area and that is not in storage. As defined in 10 CFR 20.1003, *controlled area* means an area, outside of a restricted area but inside the site boundary, access to which can be limited by the licensee for any reason; and *unrestricted area* means an area, access to which is neither limited nor controlled by the licensee.

Contrary to the above, between approximately 10:40 a.m. and 11:30 a.m. on August 2, 1999, the licensee did not secure from unauthorized removal or limit access to an 11 curie iridium-192 sealed source (for a high dose rate afterloader) located in the radiation oncology reception area, which is an unrestricted area, nor did the licensee control and maintain constant surveillance of this licensed material. **(01013)**

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

B. 10 CFR 20.2104(a) requires that for each individual who is likely to receive in a year an occupational dose requiring monitoring pursuant to 10 CFR 20.1502, the licensee shall: (1) determine the occupational radiation dose received during the current year; and (2) attempt to obtain the records of cumulative occupational radiation dose.

Contrary to the above, as of August 19, 1999, the licensee did not determine the occupational radiation dose received during the current year and did not attempt to obtain the records of cumulative occupational radiation dose for individuals requiring monitoring pursuant to 10 CFR 20.1502. Specifically, from January to August, 1999, the licensee did not determine prior or cumulative occupational dose for individuals requiring monitoring. **(01024)**

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

The NRC has concluded that information regarding the reason for Violation A and the corrective actions taken and planned to correct the violation and prevent recurrence were adequately described during the inspection, and are already adequately addressed on the docket in the cover letter for this Notice.

With regard to the Violation B, pursuant to the provisions of 10 CFR 2.201,Georgetown University Medical Center 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, 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: (1) the reason for the Violation B, or, if contested, the basis for disputing the violation or severity level, (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. Your response may reference or include previous docketed correspondence, if the correspondence adequately addresses the required response. If an adequate reply is not received within the time specified in this Notice, an order or a Demand for Information may be issued as to why the license should not be modified, suspended, or revoked, or why such other action as may be proper should not be taken. Where good cause is shown, consideration will be given to extending the response time. Also, you are required to submit a written statement or explanation if the description for the Violation A therein does not accurately reflect your corrective actions or your position.

Because your response will be placed in the NRC Public Document Room (PDR), to the extent possible, it should not include any personal privacy, proprietary, or safeguards information so that it can be placed in the PDR without redaction. If personal privacy or proprietary information is necessary to provide an acceptable response, then please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request withholding of such material, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the basis for your claim of withholding (e.g., explain why the disclosure of information will create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.790(b) to support a request for withholding confidential commercial or financial information). If safeguards information is necessary to provide an acceptable response, please provide the level of protection described in 10 CFR 73.21.

If you contest any part of this enforcement action, you should also provide a copy of your response, with the basis for your denial, to the Director, Office of Enforcement, United States Nuclear Regulatory Commission, Washington, DC 20555-0001.

In accordance with 10 CFR 19.11, you may be required to post this Notice within two working days.

Dated this 10th day of September 1999

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

November 3, 1999

EA 99-246

Ms. Cass Egan
Vice President
Holy Redeemer Hospital and Medical Center
1648 Huntingdon Pike
Meadowbrook, PA 19406

SUBJECT: NOTICE OF VIOLATION
(NRC Inspection Report No. 030-03044/99-01)

Dear Ms. Egan:

This refers to the NRC inspection conducted on September 17, 1999, at your facility in Meadowbrook, Pennsylvania. The inspection was conducted to review the circumstances associated with a misadministration of iodine-131 to a patient at your facility on September 14, 1999. The problem was reported to the NRC by your staff on September 16, 1999. During the inspection, one apparent violation of NRC requirements was identified. The apparent violation was described in our inspection report sent to you on October 6, 1999. We also received a letter from you, dated September 21, 1999, that described your immediate corrective actions taken to prevent recurrence. On October 28, 1999, a predecisional enforcement conference was held with you and other members of your staff to discuss the apparent violation, its causes, and your corrective actions, including long term actions planned after your letter was sent to us and you had completed a quality process review of your procedures. A copy of the enforcement conference report is attached.

Based on the information developed during the inspection, and the information provided in your September 21, 1999 response and during the predecisional enforcement conference, a violation of NRC requirements is being cited. The violation is described in the enclosed Notice of Violation (Notice) and the circumstances surrounding it are described in detail in the subject inspection report. The violation involved the failure to properly implement the Quality Management Program (QMP) for the facility in that a dose was administered to a patient without preparation of a written directive. This violation contributed to a misadministration at your facility when a patient, who was to be evaluated for hyperthyroidism via an uptake procedure using approximately 300 microcuries of iodine-123, was instead administered a 5.3 millicurie dose of iodine-131 for a head and neck study.

The wrong study was conducted due to: (1) an error by the scheduling department where a procedure was scheduled that was different than that prescribed by the referring physician because of ambiguity in the referral slip; (2) failure of the technologist, who received both the referral slip and the procedure schedule, to question the discrepancy; (3) failure of the technologist to obtain and review the patient's history which would have raised questions

regarding the need for the procedure; and (4) failure of the technologist to obtain a written directive and follow the established QMP before the dose was administered to the patient. These findings represent programmatic weaknesses in the implementation of your QMP which resulted in a misadministration. Therefore, the violation is categorized as a Severity Level III problem in accordance with the "General Statement of Policy and Procedures for NRC Enforcement Actions" (Enforcement Policy), NUREG-1600.

In accordance with the Enforcement Policy, a base civil penalty in the amount of $2,750 is considered for a Severity Level III violation or problem. Because your facility has not been the subject of an escalated enforcement action within the last two years, the NRC considered whether credit was warranted for *Corrective Action* in accordance with the civil penalty assessment process in Section VI.B.2 of the Enforcement Policy. Credit for corrective actions is warranted because your corrective actions, at the time of the predecisional enforcement conference, were considered prompt and comprehensive. These actions include, but are not limited to: (1) adding more detail to the computer scheduling system to indicate the types of treatments available to schedule; (2) review by the nuclear medicine supervisor before an appointment date and time is scheduled for an iodine-131 procedure; (3) verification with the referring physician's office by the nuclear medicine supervisor before the dose is ordered for a scheduled iodine-131 study; (4) witnessing, for one year, by the nuclear medicine supervisor of all iodine-131 treatments performed by the technologist who contributed to the violation; (5) development of standard language for physician referrals and prescriptions; (6) review and signature by the authorized user on the completed written directive prior to the ordering of iodine-131; (7) commitment to resolve any ambiguity in the referring physician request to the satisfaction of the authorized user prior to dose administration; and (8) plans to have the authorized user see all patients for therapeutic iodine-131 treatment (10 millicuries and above) and be physically present during dose administration.

Therefore, to encourage prompt and comprehensive correction of violations, I have been authorized to not propose a civil penalty in this case. However, similar violations in the future could result in further escalated enforcement action. In addition, issuance of this Notice constitutes escalated enforcement action, that may subject you to increased inspection effort.

The NRC has concluded that information regarding the reason for the violations, and the corrective actions taken and planned to correct the violations and prevent recurrence, were already described adequately during the enforcement conference, and are adequately addressed on the docket in your letter, dated September 21, 1999, or in this letter. Therefore, you are not required to respond to this letter unless the description therein does not accurately reflect your corrective actions or your position. In that case, or if you choose to provide additional information, you should follow the instructions specified in the enclosed Notice.

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 (PDR).

Sincerely,

Hubert J. Miller
Regional Administrator

Docket No. 030-03044
License No. 37-05089-01

Enclosures:
1. Notice of Violation
2. Predecisional Enforcement Conference Summary
   (Report No. 030-03044/99-002)

cc w/encls:
Lester H. Wurtele, M.D., Radiation Safety Officer
Commonwealth of Pennsylvania

ENCLOSURE

NOTICE OF VIOLATION

Holy Redeemer Hospital and Medical Center
Meadowbrook, PA

Docket No. 030-03044
License No. 37-05089-01
EA 99-246

During an NRC inspection conducted on September 17, 1999, a violation of NRC requirements was identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy), NUREG -1600, the violation is listed below:

> 10 CFR 35.25(a)(2) requires, in part, that a licensee that permits the use of byproduct material by an individual under the supervision of an authorized user shall require the supervised individual to follow the written quality management procedures established by the licensee.
>
> The licensee's quality management procedure, dated July 15, 1994, Item 1.0, requires that the authorized user or physician under the supervision of an authorized user must date and sign a written directive for a specific patient prior to administration of any therapeutic dosage of a radio pharmaceutical or any dosage of quantities greater than 30 microcuries of either iodine-125 or iodine-131.
>
> Contrary to the above, on September 14, 1999, the licensee's technologist, an individual who was working under the supervision of the licensee's authorized user, did not follow the written quality management procedures established by the licensee in that no written directive was prepared prior to the administration of iodine-131. As a result, the technologist administered approximately 5 millicuries of iodine-131, instead of the intended dose of approximately 300 microcuries of iodine-123. This resulted in unplanned dose to the patient. **(01013)**
>
> This is a Severity Level III violation (Supplement VI).

The NRC has concluded that information regarding the reason for the violations, and the corrective actions taken and planned to correct the violation and prevent recurrence were adequately described during the enforcement conference on October 28, 1999, and are already adequately addressed on the docket in the NRC letter. However, you are required to submit a written statement or explanation pursuant to 10 CFR 2.201 if the description therein does not accurately reflect your corrective actions or your position. In that case, or if you choose to respond, clearly mark your response as a "Reply to a Notice of Violation," and send it to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555 with a copy to the Regional Administrator, Region I, within 30 days of the date of the letter transmitting this Notice of Violation (Notice).

If you contest this enforcement action, you should also provide a copy of your response, with the basis for your denial, to the Director, Office of Enforcement, United States Nuclear Regulatory Commission, Washington, DC 20555-0001.

If you choose to respond, your response will be placed in the NRC Public Document Room (PDR). Therefore, to the extent possible, the response should not include any personal privacy or proprietary information so that it can be placed in the PDR without redaction.

In accordance with 10 CFR 19.11, you may be required to post this Notice within two working days.

Dated this 3rd day of November 1999

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

September 17, 1999

EA 99-211

Celia J. Maxwell, M.D.
Assistant Vice President for Health Affairs
Howard University
2041 Georgia Avenue, NW
Washington, DC 20060

SUBJECT: NOTICE OF VIOLATION
(NRC Inspection Report Nos. 030-11063/99-01 and 030-01321/99-01)

Dear Dr. Maxwell:

This refers to the NRC inspection conducted on July 27 and 28, 1999, at your facility in Washington, DC. The inspection was performed, in part, to review the circumstances associated with the loss of a package containing radioactive material (2.0 millicuries of iodine-125) that was reported to the NRC by your Radiation Safety Officer on July 13, 1999. The inspection also included a review of another incident involving the apparent loss of control of 1.3 millicuries of iodine-131 in August 1998.

In our letter to you, dated August 19, 1999, we informed you that three apparent violations associated with the loss of control of licensed material were being considered for escalated enforcement in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions" (Enforcement Policy), NUREG-1600. The apparent violations related to the loss of radioactive material on two occasions, inadequate training of certain members of the shipping and receiving and mail room staff which may have contributed to one of the occurrences, and the failure to report one of the losses in a timely manner. In a letter dated September 10, 1999, Howard University Hospital provided its understanding of the facts, the corrective actions taken and planned, and your assessment of the safety significance of the issues. In addition, a predecisional enforcement conference was held in our Region I office in King of Prussia, Pennsylvania, on September 13, 1999, with you and other members of your staff to discuss the apparent root cause(s) and corrective actions implemented by your staff. A copy of the predecisional enforcement conference summary report is enclosed.

Based on the information developed during the inspection and the information that you provided during the conference and in your September 10, 1999 letter, the NRC has determined that three violations of NRC requirements occurred. These violations are cited and described in the enclosed Notice of Violation (Notice). The violations involve: (1) failure to control and maintain constant surveillance of licensed radioactive material on two occasions; (2) failure to provide required radiological safety training to certain members of your shipping and receiving and mail room staff;

and (3) failure to make immediate notifications to the NRC once the material was determined to be lost on one of the occasions.

In the first instance, a package containing radioactive material (1.3 millicuries of iodine-131) was delivered to the wrong place in your hospital on August 25, 1998, and was inadvertently discarded in the regular hospital waste. Although the radiation detector in the hospital's shipping and receiving area alarmed, an employee thought it was a false alarm and sent the waste to a waste hauling facility. The package was retrieved from the commercial waste hauler (about 24 hours later) after the radiation detectors alarmed at the waste hauling facility. In the second instance, a package of radioactive material (2.0 millicuries of iodine-125) was received in your shipping and receiving area on June 7, 1999, and was signed for by one of your employees. However, after receipt, the package was not appropriately controlled. Further, the employee who received the package did not follow your procedures for receipt of radioactive materials in that no inventory entry was made in the logbooks. Although your staff searched for the package, the material has not been found.

The loss of the radioactive material on these occasions is significant because the iodine was in liquid form which could readily be absorbed through the skin during inadvertent leakage or inappropriate handling of the package, causing unnecessary radiation exposure. The violation is of additional concern because the corrective actions for the first occurrence of the lost material in August 1998 did not preclude the subsequent occurrence in June 1999. Therefore, the three violations described in the attached Notice represent a Severity Level III problem in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions" (Enforcement Policy), NUREG-1600.

In accordance with the Enforcement Policy, a base civil penalty in the amount of $2,750 is considered for a Severity Level III violation or problem. Because your facility has not been the subject of an escalated enforcement action within the last two years or two inspections, the NRC considered whether credit was warranted for Corrective Action in accordance with the civil penalty assessment process in Section VI.B.2 of the Enforcement Policy. Credit for corrective actions is warranted because your corrective actions, as described in your letter and at the conference, were considered prompt and comprehensive. These actions include, but are not limited to, (1) instruction of personnel in the shipping/receiving area and the mail room, (2) posting of instructional signs, (3) implementing uniform delivery procedures for all radioactive materials, (4) implementing a policy that requires all radioactive material deliveries to be recorded in a logbook, (5) installing a video camera and recorder on the radioactive material receiving vault, and (6) installing additional alarming radiation monitoring equipment.

Therefore, to encourage prompt and comprehensive correction of violations, I have been authorized to not propose a civil penalty in this case. However, similar violations in the future could result in further escalated enforcement action. In addition, issuance of this Notice constitutes escalated enforcement action that may increase the NRC inspection effort at your facility.

The NRC has concluded that information regarding the reason for the violations, and the corrective actions taken and planned to correct the violations and prevent recurrence, were already described adequately during the inspection, in your September 10, 1999 letter, and in the predecisional enforcement conference. Therefore, you are not required to respond to this letter unless the

description therein does not accurately reflect your corrective actions or your position. In that case, or if you choose to provide additional information, you should follow the instructions specified in 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, and your response (if any) will be placed in the NRC Public Document Room (PDR).

Sincerely,

Hubert J. Miller
Regional Administrator

Docket Nos. 030-11063
030-01321
License Nos. 08-00386-19
08-03075-07

Enclosure:
1. Notice of Violation
2. Predecisional Enforcement Conference Summary Report

cc w/encl:
Gregory Talley, Radiation Safety Officer
District of Columbia

ENCLOSURE

NOTICE OF VIOLATION

Howard University/ Howard University Hospital

Washington, DC

Docket Nos 030-11063
030-01321

License Nos. 08-00386-19
08-03075-07

EA 99-211

During an NRC inspection conducted on July 27-28, 1999, violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy), NUREG -1600, the violations are listed below:

A. 10 CFR 20.1802 requires the licensee to control and maintain constant surveillance of licensed material that is in a controlled or unrestricted area and that is not in storage. As defined in 10 CFR 20.1003, *controlled area* means an area, outside of a restricted area but inside the site boundary, access to which can be limited by the licensee for any reason; and *unrestricted area* means an area, access to which is neither limited nor controlled by the licensee.

Contrary to the above, the licensee did not maintain constant surveillance of licensed material that was in a controlled or unrestricted area and that was not in storage on two occasions. Specifically,

1. On June 7, 1999, the licensee received a package of licensed material (containing 2.0 millicuries of iodine-125) and the licensee did not control and maintain constant surveillance of the package and the material was lost; and

2. On August 25, 1998, the licensee did not maintain constant surveillance and lost control of a package of licensed material (containing 1.3 millicuries of iodine-131) and the package was inadvertently discarded in the trash. The material was later discovered and retrieved from a commercial waste hauling facility on August 26, 1998. **(01013)**

B. 10 CFR 19.12 requires, in part, that all individuals who in the course of employment are likely to receive in a year an occupational dose in excess of 100 mrem (1 mSv) shall be instructed in the health protection problems associated with exposure to radiation and/or radioactive material, in precautions or procedures to minimize exposure, and in the purposes and functions of protective devices employed.

Contrary to the above, prior to July 1999, the licensee did not provide instruction to the shipping and receiving and mail room personnel who in the course of their employment duties are likely to receive in a year an occupational dose in excess of 100 mrem. Specifically, the shipping and receiving and mail room personnel routinely handled packages containing radioactive material and are likely to be exposed to an occupational

dose of radiation in excess of 100 mrem through contaminated or damaged packages or improper handling of the packages. **(01023)**

C. 10 CFR 20.2201(a)(1) requires, in part, that each licensee shall report to the NRC by telephone immediately after its occurrence becomes known to the licensee, any lost, stolen, or missing licensed material in an aggregate quantity equal to or greater than 1,000 times the quantity specified in Appendix C to Part 20 under such circumstances that it appears to the licensee that an exposure could result to persons in unrestricted areas.

Contrary to the above, on June 7, 1999, the licensee did not immediately report to the NRC after it became aware of the loss of two millicuries of iodine-125 which is an amount greater than 1,000 times the quantity in Appendix C to Part 20 (which amounts to one microcurie). **(01033)**

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

The NRC has concluded that information regarding the reason for the violations, and the corrective actions taken and planned to correct the violation and prevent recurrence were adequately described during inspection, and are already adequately addressed on the docket in the NRC inspection report and in previous correspondence. However, you are required to submit a written statement or explanation pursuant to 10 CFR 2.201 if the description therein does not accurately reflect your corrective actions or your position. In that case, or if you choose to respond, clearly mark your response as a "Reply to a Notice of Violation," and send it to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555 with a copy to the Regional Administrator, Region I, within 30 days of the date of the letter transmitting this Notice of Violation (Notice).

If you contest this enforcement action, you should also provide a copy of your response, with the basis for your denial, to the Director, Office of Enforcement, United States Nuclear Regulatory Commission, Washington, DC 20555-0001.

If you choose to respond, your response will be placed in the NRC Public Document Room (PDR). Therefore, to the extent possible, the response should not include any personal privacy or proprietary information so that it can be placed in the PDR without redaction.

Dated this 17th day of September 1999

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

November 22, 1999

EA 99-253

Mr. Steven M. Elliot, P.E., President
Material Testing Consultants, Inc.
693 Plymouth NE
Grand Rapids, MI 49505

SUBJECT: NOTICE OF VIOLATION
(NRC Inspection Report 030-13918/99002(DNMS)

Dear Mr. Elliot:

This refers to the inspection conducted on September 10 through October 5, 1999, at Materials Testing Consultants, Inc. in Grand Rapids, Michigan. The purpose of the inspection was to review an incident involving damage to a moisture-density gauge on July 13, 1999. As a result, two apparent violations of NRC requirements were identified and considered for escalated enforcement as discussed in our letter to you dated October 13, 1999. In that letter you were provided an opportunity to either discuss this case and the apparent violations at a predecisional enforcement conference or address the apparent violations in writing. You elected to provide a written response.

Based on the information developed during the inspection and the information provided in your letter dated November 10, 1999, the NRC has determined that violations of NRC requirements occurred. These violations are cited in the enclosed Notice of Violation (Notice) and the circumstances surrounding them are described in detail in the subject inspection report.

One violation involves the failure to control licensed material in an unrestricted area. As a result of this failure, a density gauge containing a nominal 8 millicuries of cesium-137 and 40 millicuries of americium-241 was struck and damaged on July 13, 1999. Specifically, while at a temporary jobsite in Grand Rapids, Michigan, the gauge operator removed the device from his vehicle and placed it on the ground. He then got into his truck and moved it approximately 100 feet away from the gauge. In the meantime, a front-end loader ran over the device causing damage to the source rod and to the internal electronics. The second violation occurred when the operator failed to follow the emergency procedures, in that he left the device in its damaged condition unattended to telephone the Radiation Safety Officer.

Incumbent upon each NRC licensee is the responsibility to protect public health and safety by ensuring that radioactive materials are controlled at all times. The NRC recognizes that radiation surveys revealed no excessive radiation or contamination levels from the damaged moisture/density gauge. Nevertheless, the failure to maintain security or constant surveillance of licensed material and to fully follow emergency procedures, represents a significant failure to meet license commitments and responsibilities and is of concern to the NRC. Therefore, these violations are classified in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions" (Enforcement Policy), NUREG-1600, as a Severity Level III problem.

In accordance with the Enforcement Policy, a base civil penalty in the amount of $2,750 is considered for a Severity Level III problem. Because your facility has been the subject of escalated enforcement actions within the last two inspections, the NRC considered whether credit was warranted for *Identification* and *Corrective Action* in accordance with the civil penalty assessment process in Section VI.B.2 of the Enforcement Policy. Since the violations were identified by the Licensee, the NRC has determined that credit for identification is warranted. The NRC has also determined that credit is warranted for corrective actions based on the following: (1) a safety review meeting was held with all authorized gauge users to discuss the incident and to review security and control at temporary jobsites; (2) the operator was suspended for three days and placed on probationary work status for three months; and (3) management increased its supervision of licensed activities to emphasize the importance of maintaining control of licensed material.

Therefore, to encourage prompt and comprehensive corrective actions, I have been authorized, after consultation with the Director, Office of Enforcement, not to propose a civil penalty in this case. However, significant violations in the future could result in a civil penalty. In addition, issuance of this Severity Level III violation constitutes escalated enforcement action that may subject you to increased inspection effort.

The NRC has concluded that information regarding the reasons for the violation, and the corrective actions taken and planned to correct the violation and prevent recurrence are already adequately addressed in your letter dated November 10, 1999. Therefore, you are not required to respond to this letter unless the description therein does not accurately reflect your corrective actions or your position. In that case, or if you choose to provide additional information, you should follow the instructions specified in the enclosed Notice.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter, the enclosed Notice, and your response if you choose to respond, will be placed in the NRC Public Document Room.

Sincerely,

James L. Caldwell

for J. E. Dyer
Regional Administrator

Docket No. 030-13918
License No. 21-15281-02

Enclosure: Notice of Violation

NOTICE OF VIOLATION

Material Testing Consultants, Inc.
Grand Rapids, Michigan

Docket No. 030-13918
License No. 21-15281-02
EA 99-253

During an NRC inspection conducted on September 10 through October 5, 1999, violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," NUREG-1600, the violations are listed below:

1. 10 CFR 20.1801 requires, in part, that the licensee secure from unauthorized removal or access licensed materials that are stored in unrestricted areas. 10 CFR 20.1802 requires, in part, that the licensee control and maintain constant surveillance of licensed material that is in an unrestricted area and that is not in storage. As defined in 10 CFR 20.1003, *unrestricted area* means an area, access to which is neither limited nor controlled by the licensee.

   Contrary to the above, on July 13, 1999, the licensee did not secure from unauthorized removal, limit access to, nor control and maintain constant surveillance of licensed material in an unrestricted area. Specifically, a Troxler moisture density gauge containing a nominal 8 millicuries (0.3 GBq) of cesium-137 and 40 millicuries (1.48 GBq) of americium-241 was left unattended and was damaged while at a temporary jobsite. (01013)

2. Condition 19 of License Number 21-15281-02 requires that licensed material be possessed and used in accordance with statements, representations and procedures contained in the application dated October 28, 1994.

   Item VII of the application dated October 28, 1994, requires, in part, in the section entitled, "Emergency Procedures," that in the event of an accident causing damage to the gauge, the authorized user shall maintain control of the gauge and the surrounding area and enlist the help of others at the scene to call the Radiation Safety Officer (RSO).

   Contrary to the above, on July 13, 1999, an accident causing damage to a moisture density gauge containing licensed material occurred at a temporary jobsite and the authorized user did not maintain control of the device or the surrounding area and did not enlist the help of others to contact the RSO. Specifically, the authorized user left the device unattended to call the RSO. (01023)

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

The NRC has concluded that information regarding the reasons for the violation, and the corrective actions taken and planned to correct the violation and prevent recurrence is already adequately addressed in a letter from Material Testing Consultants, Inc. dated November 10, 1999. However, you are required to respond to the provisions of 10 CFR 2.201 if the description therein does not accurately reflect your corrective actions or your position. In that case, or if you choose to respond, clearly mark your response as a "Reply to a Notice of Violation," and send it to the U. S. Nuclear Regulatory Commission, ATTN: Document Control

Desk, Washington, D.C. 20555, with a copy to the Regional Administrator, Region III, 801 Warrenville Road, Lisle, Illinois 60532-4351, within 30 days of the date of the letter transmitting this Notice of Violation.

If you contest this enforcement action, you should also provide a copy of your response, with the basis for your denial, to the Director, Office of Enforcement, United States Nuclear Regulatory Commission, Washington, DC 20555-0001.

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

If you choose to respond, your response will be placed in the NRC Public Document Room (PDR). Therefore, to the extent possible, the response should not include any personal privacy, proprietary, or safeguards information so that it can be placed in the PDR without redaction.

In accordance with 10 CFR 19.11, you may be required to post this Notice within two working days.

Dated this 22nd day of November 1999

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

August 19, 1999

EA 99-043

John I. H. Paterson, Ph. D.
President
Metorex, Inc.
Princeton Crossroads Corporate Center
250 Phillips Boulevard
Ewing, NJ 08618

SUBJECT: NOTICE OF VIOLATION
(NRC Inspection Report 98-001 and NRC Investigation Report No.1-98-036)

Dear Dr. Paterson:

This refers to the NRC inspection conducted on August 20, 1998, and a subsequent investigation conducted by the NRC Office of Investigations (OI). The investigation was conducted after the former President informed the NRC that Metorex, Inc. had distributed approximately 25 x-ray fluorescence analyzer devices containing radioactive material (iron-55, cadmium-109, and americium-241) between October 1997 and July 1998 prior to obtaining NRC authorization to do so. The investigation was initiated to determine, in part, whether the company's actions were willful.

Based on the investigation, OI concluded, that (1) the former Vice President/Radiation Safety Officer (RSO) deliberately failed to stop shipments of the devices between January 1998 and July 1998, knowing that Metorex was not authorized to distribute them; and (2) the former RSO deliberately failed to submit quarterly reports to the NRC regarding the transfer of the material for the fourth calendar quarter of 1997 and the first calendar quarter of 1998. A copy of the synopsis of the OI investigation was forwarded to you with our letter, dated July 26, 1999.

Based on the inspection and OI investigation, three apparent violations of NRC requirements were identified. In a letter dated July 26, 1999, the NRC informed you of the apparent violations. Prior to the letter, the NRC also informed you that it might not be necessary to conduct a predecisional enforcement conference in order to enable the NRC to make an enforcement decision. Rather, the NRC provided you an opportunity to either (1) respond to the apparent violations discussed in the letter within 30 days of the date of the letter, or (2) request a predecisional enforcement conference. You initially requested a conference which was to be held on August 16, 1999 to discuss the apparent violations, their causes, and your

corrective actions. However, on August 10, 1999, your attorney, Mr. Dave Lewis, informed Ms. Judy Joustra of my staff that if the NRC could reach an enforcement decision without conducting an enforcement conference, Metorex would have no objection to responding in writing in lieu of a conference. Your response was provided to the NRC in a letter dated, August 12, 1999.

Based on the information developed during the investigation, and the information provided in your response, three violations of NRC requirements are being cited. The violations, which are described in the enclosed Notice of Violation (Notice), involve (1) unauthorized transfer, between October 1997 and July 1998, of devices containing millicurie quantities of radioactive material (this violation was deliberate in that the former Vice President failed to stop such transfers when he became aware in January 1998 that the devices were being distributed without NRC approval); (2) deliberate failure to submit to the NRC the required quarterly reports when such transfers of the devices were made to persons for use under a general license during the fourth calendar quarter of 1997 and the first calendar quarter of 1998; and (3) as of June 30, 1998, the individual named as the Radiation Safety Officer on your license was no longer employed by your company.

The first two violations are of particular concern because of their deliberate nature. It is essential that the NRC be able to maintain the highest trust and confidence that licensees and their employees will act with integrity, communicate with candor, and abide by requirements designed to protect the health and safety of the public. Therefore, the first two violations have been classified as a Severity Level III problem in accordance with the "General Statement of Policy and Procedures for NRC Enforcement Actions" (Enforcement Policy), NUREG-1600, Revision 1. The third violation is classified at Severity Level IV.

In accordance with the Enforcement Policy, a base civil penalty in the amount of $2,750 is considered for a Severity Level III violation or problem. Because the violations were willful, the NRC considered whether credit was warranted for *Identification and Corrective Action* in accordance with the civil penalty assessment process in Section VI.B.2 of the Enforcement Policy. Credit for identification is warranted since the violations were identified by your former President and reported to the NRC. Credit for corrective actions is warranted because your corrective actions were considered prompt and comprehensive. These corrective actions were described in your referenced August 12, 1999 letter, as well as a previous letter, dated August 28, 1998, from the former President of Metorex, in response to a Confirmatory Action Letter issued by the NRC on August 12, 1998. These actions included: (1) immediately stopping distribution of the unauthorized probes, and obtaining registration of the probes; (2) amending your license to identify a new RSO; (2) training the staff on NRC requirements, including instruction regarding your penalties associated with willful violations, which you stated will result in immediate termination; and (4) conducting an audit of the entire radiation safety program.

Therefore, I have been authorized, after consultation with the Director, Office of Enforcement, to not issue a civil penalty in this case. If not for your identification and corrective actions,

a civil penalty would have been issued. In addition, issuance of this Notice constitutes escalated enforcement action that may subject you to increased inspection effort.

The NRC has concluded that information regarding the reason for the violations, and the corrective actions taken and planned to correct the violations and prevent recurrence, were already described adequately in your August 28, 1998 and August 12, 1999 letters to the NRC. Therefore, you are not required to respond to this letter unless the description therein does not accurately reflect your corrective actions or your position. In that case, or if you choose to provide additional information, you should follow the instructions specified in 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.

Sincerely,

Hubert J. Miller
Regional Administrator

Docket Nos. 030-34247; 030-34246
License Nos. 29-30342-02G; 29-30342-01

Enclosure: Notice of Violation

cc w/encl:
State of New Jersey

ENCLOSURE

NOTICE OF VIOLATION

Metorex, Inc.
Ewing, New Jersey

Docket Nos. 030-34247; 030-34246
License Nos. 29-30342-02G; 29-30342-01
EA 99-043

During an NRC inspection conducted on August 20, 1998, as well as a subsequent investigation conducted by the NRC Office of Investigations (OI), violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy), NUREG-1600, the violations are set forth below:

A. 10 CFR 30.3 requires, in part, that except for persons exempted, no person shall transfer or use byproduct material except as authorized by a specific or general license issued pursuant to NRC regulations.

Contrary to the above, from October 1997 to July 31, 1998, the licensee transferred 26 SIPS probes containing millicurie quantities of cadmium-109 and iron-55 to unauthorized persons without a valid NRC license authorizing such transfers, and was not exempt from the requirements for a license. **(01013)**

B. 10 CFR 32.52(a) requires, in part, that each person licensed under 32.51 to initially transfer devices to generally licensed persons shall report to the Director of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, all transfers of such devices to persons for use under the general license in 10 CFR 31.5. The report must cover each calendar quarter and must be filed within 30 days thereafter.

Contrary to the above, as of August 1998, the licensee did not report to the Commission all transfers of devices to persons for use under a general license. Specifically, the licensee transferred devices to persons for use under a general license during the fourth calendar quarter of 1997 and the first calendar quarter of 1998 and did not submit the required quarterly reports. **(01023)**

These violations represent a Severity Level III problem (Supplements VI and VII).

C. Condition 11.B of License No. 29-30342-01 identifies the Radiation Safety Officer (RSO) by name.

Contrary to the above, from June 30, 1998 to November 12, 1998, the individual named as the RSO on the license was no longer the RSO. Specifically, as of June 30, 1998, the individual named as the RSO was no longer employed by the licensee during that time, and a license amendment naming a new RSO was not submitted to the NRC until November 9, 1998, and not approved until November 12, 1998. **(02014)**

This is a Severity Level IV violation (Supplement VI)

The NRC has concluded that information regarding the reason for the violations, and the corrective actions taken and planned to correct the violation and prevent recurrence were adequately described during inspection, and are already adequately addressed on the docket in the licensee's letters dated August 28, 1998, and August 12, 1999. However, you are required to submit a written statement or explanation pursuant to 10 CFR 2.201 if the description therein does not accurately reflect your corrective actions or your position. In that case, or if you choose to respond, clearly mark your response as a "Reply to a Notice of Violation," and send it to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555 with a copy to the Regional Administrator, Region I, within 30 days of the date of the letter transmitting this Notice of Violation (Notice).

If you contest this enforcement action, you should also provide a copy of your response, with the basis for your denial, to the Director, Office of Enforcement, United States Nuclear Regulatory Commission, Washington, DC 20555-0001.

If you choose to respond, your response will be placed in the NRC Public Document Room (PDR). Therefore, to the extent possible, the response should not include any personal privacy or proprietary information so that it can be placed in the PDR without redaction.

Dated this 19thday of August 1999

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

November 26, 1999

EA 99-215

David Reece, Administrator/CEO
MidMichigan Medical Center
4005 Orchard Drive
Midland, MI 48670

SUBJECT: NOTICE OF VIOLATION
(NRC Inspection Report 030-02013/99001(DNMS) and Office of Investigation Report 3-1999-019)

Dear Mr. Reece:

This refers to the inspection conducted June 7 through 17, 1999, and the investigation completed by the Office of Investigations (OI) on August 23, 1999, at MidMichigan Medical Center (MMC or Licensee) in Midland, Michigan. The inspection was conducted to review the circumstances concerning a reported iodine-131 misadministration and a report documenting the inspection was issued by our letter dated July 2, 1999. The OI investigation was conducted to determine if apparent violations identified during the inspection were deliberate. Summaries of the OI findings and of the apparent violations identified were transmitted to you by letter dated September 7, 1999. A closed, transcribed predecisional enforcement conference was conducted on September 17, 1999, in the Region III office to discuss the apparent violations, their root causes, and your corrective actions taken or planned.

Based on the information developed during the inspection, the investigation, and the information that was provided during the conference, the NRC has determined that violations of NRC requirements occurred. These violations are cited in the enclosed Notice of Violation (Notice) and the circumstances surrounding them are described in detail in the subject inspection report. The violations involve failures to: (1) consult a written directive before administering a therapeutic quantity of iodine-131 to a patient, (2) report a misadministration in a timely manner, and (3) provide the NRC inspector with complete and accurate information.

A misadministration occurred when a patient received approximately 100 millicuries of iodine-131 on May 24, 1999, instead of 150 millicuries as prescribed. The root causes of the misadministration consist of: 1) one individual ordered the incorrect amount of iodine; and 2) a second individual failed to review the written directive as required by MMC's quality management program before administering the dosage. The administering individual identified the inconsistency shortly after dosing the patient, but did not alert the physician or management. Two days later, the prescribing physician not only discovered that a misadministration had occurred, but also determined that the written directive had been altered to reflect the actual dose administered. Your staff reported the misadministration to the NRC on June 1, 1999. Based on all available information, the NRC concluded that an MMC employee engaged in deliberate misconduct by willfully failing to consult the physician's written directive prior to

administering a therapeutic dosage to a patient, altering the written directive and providing incomplete and inaccurate information to the NRC inspector, and that his actions, in part, caused MMC to file an untimely report. It is essential that the NRC be able to maintain the highest trust and confidence that licensees and their employees will act with integrity and abide by the requirements designed to ensure that doses prescribed are delivered. The use of therapeutic quantities of radioactive material requires rigor on the part of all involved in its administration. Under these circumstance, the patient could have received a substantial overdose of iodine-131, because the safeguards in place in your medical quality management program were not followed. Because these violations involve willfulness, they are classified in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions" (Enforcement Policy), NUREG-1600, as a Severity Level III problem.

During the predecisional enforcement conference, you disagreed with the OI synopsis in that you do not feel that your technologist willfully administered the incorrect dosage. Within the context of the NRC enforcement policy, "willfulness" encompasses both deliberate violations and violations involving careless disregard. Careless disregard connotes conduct which demonstrates reckless disregard or reckless indifference as to whether a requirement will be violated. In this case, we agree that the individual did not deliberately administer the wrong dose. However, we found the individual to have displayed careless disregard when he failed to verify the dose to be administered against the written directive. His failure to verify was more than just the result of negligence or oversight. Therefore, the NRC concluded that his actions constituted careless disregard and as such were considered willful.

In accordance with the Enforcement Policy, a base civil penalty in the amount of $2,750 is considered for a Severity Level III problem. Because the violations described in the enclosed Notice are willful violations, the NRC considered whether credit was warranted for *Identification* and *Corrective Action* in accordance with the civil penalty assessment process in Section VI.B.2 of the Enforcement Policy. Since your staff identified the violations and exercised considerable effort to determine the root cause, credit for identification is warranted. The NRC has also determined that credit is warranted for corrective actions taken and/or planned. The actions include: (1) a memo sent to all nuclear medicine physicians and staff which covered the following topics: (A) a reminder to review the written directive prior to administration; (B) definition of a misadministration, and (C) an explanation of reporting procedures; (2) combining the written directive and ordering documentation into a single form for clarity; and (3) suspension of the individual involved and removing him from a supervisory position.

In addition to the corrective actions stated above, it is our understanding, based on an October 5, 1999 telephone conversation between Mr. Ohle, MMC Vice President and Mr. D. Wiedeman of the Region III staff, that for the next 24 months additional oversight of the individual will be performed. This oversight will include: (1) supervision by another technologist or the physician whenever he administers therapy dosages; (2) all daily NRC regulated activities conducted by this individual, such as dose calibrator constancy, wipe tests, surveys, etc., will be double checked by another technologist; and (3) the radiation safety officer or his assistant will conduct weekly reviews of the work performed by the individual in question and provide periodic reports of his performance to MMC administration. If our understanding is in error, please contact Mr. G. Wright immediately at (630) 829-9602.

To encourage prompt identification and comprehensive correction of violations, a civil penalty in this case is not being proposed. However, significant violations in the future could result in a civil penalty. In addition, issuance of this Severity Level III violation constitutes escalated enforcement action that may subject you to increased inspection effort.

The NRC is corresponding separately with the individual involved with this matter. You will receive a copy of that correspondence under separate cover.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. The NRC will use your response, in part, to determine whether further enforcement action is necessary to ensure compliance with regulatory requirements.

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

Sincerely,

R.W. Borchardt

R. W. Borchardt, Director
Office of Enforcement

Docket No. 030-02013
License No. 21-01549-02

Enclosure: Notice of Violation

cc w/encl: Larry Langrill, Ph.D., RSO

NOTICE OF VIOLATION

MidMichigan Medical Center
Midland, Michigan

Docket No. 030-02013
License No. 21-01549-02
EA 99-215

During an NRC inspection and investigation completed on June 17, 1999, and August 23, 1999, respectively, violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," NUREG-1600, the violations are listed below:

A. 10 CFR 35.25(a)(2) requires, in part, that a licensee that permits the use of byproduct material by an individual under the supervision of an authorized user shall require the supervised individual to follow the written quality management procedures established by the licensee.

The Licensee's quality management procedure, dated January 20, 1992, in Item 3 under RADIOPHARMACEUTICAL USES, requires that the radiopharmaceutical, the dosage, and the route of administration to be verified, with the script in hand, prior to dose administration.

Contrary to the above, on May 24, 1999, a nuclear medicine technologist, an individual under the supervision of the licensee's authorized user, did not follow the written quality management procedures established by the licensee in that he did not verify that the administered dosage was in accordance with the prescribed dosage. (01013)

B. 10 CFR 35.33(a) requires, in part, that for a misadministration, the licensee notify by telephone the NRC Operations Center not later than the next calendar day after discovery of a misadministration. 10 CFR 35.2 defines in part, "misadministration" to mean the administered dosage differs from the prescribed dosage by more than 20 percent of the prescribed dosage.

Contrary to the above, on May 26, 1999, the licensee discovered that a misadministration occurred and the licensee did not notify the NRC until June 1, 1999, which was later than the next calendar day. The misadministration involved administration of a dosage of iodine-131 that differed by approximately 33 percent from the prescribed dosage. (01023)

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

Contrary to the above, on June 7 and 8, 1999, a licensee representative (nuclear medicine technologist) did not provide to the Commission information that was complete and accurate in all material respects. Specifically, the nuclear medicine technologist stated to the NRC inspector that he did not know who changed the physician's written directive or why it had been changed without the physician's approval. This technologist subsequently acknowledged that he modified the written directive without the physician's approval. This information was material because a misadministration is an event

required to be reported to the NRC and a written directive is an NRC required record. (01033)

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

Pursuant to the provisions of 10 CFR 2.201, MidMichigan Medical Center 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 III, within 30 days of the date of the letter transmitting this Notice of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each violation: (1) the reason for the violation, or, if contested, the basis for disputing the violation or severity level; (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. Your response may reference or include previous docketed correspondence, if the correspondence adequately addresses the required response. If an adequate reply is not received within the time specified in this Notice, an order or a Demand for Information may be issued as to why the license should not be modified, suspended, or revoked, or why such other action as may be proper should not be taken. Where good cause is shown, consideration will be given to extending the response time.

If you contest this enforcement action, you should also provide a copy of your response, with the basis for your denial, to the Director, Office of Enforcement, United States Nuclear Regulatory Commission, Washington, DC 20555-0001.

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

Because your response will be placed in the NRC Public Document Room (PDR), to the extent possible, it should not include any personal privacy, proprietary, or safeguards information so that it can be placed in the PDR without redaction. If personal privacy or proprietary information is necessary to provide an acceptable response, then please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request withholding of such material, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim of withholding (e.g., explain why the disclosure of information will create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.790(b) to support a request for withholding confidential commercial or financial information). If safeguards information is necessary to provide an acceptable response, please provide the level of protection described in 10 CFR 73.21.

In accordance with 10 CFR 19.11, you may be required to post this Notice within two working days.

Dated this 26th day of November 1999

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

September 24, 1999

EA 99-013

Bill Miller, President
Bill Miller, Inc.
P. O. Box 1107
Henryetta, Oklahoma 74437

SUBJECT: NOTICE OF VIOLATION
(NRC Inspection Report No. 030-15283/98-01 and Investigation Report 4-1998-048)

Dear Mr. Miller:

This refers to the predecisional enforcement conference conducted on August 11, 1999, in the NRC's office in Arlington, Texas. The conference was conducted to discuss the results of our inspection and investigation which were documented in the subject inspection report. The exit briefing following the inspection and investigation had been conducted with you and members of your staff on July 8, 1999. During that exit briefing, we identified five apparent violations involving failures to: (1) properly secure a source assembly in a source changer in the fully shielded position, install the safety plug and safety cap, register as a user, and have a copy of the applicable certificate of compliance; (2) always provide 40 hours of radiation safety training for radiographers; (3) administer written examinations Numbers 2 and 3 to previously trained radiographers; (4) perform the required audits of radiographers and radiographer's assistants during actual radiographic operations; and (5) provide the required training to radiographer's assistants. The first apparent violation was identified following a transportation incident in which a vendor received a source changer from Bill Miller, Inc. (BMI) that had radiation dose rates in excess of NRC-required limits. In addition, with regard to the fifth apparent violation, we expressed concern that certain BMI employees might have deliberately failed to provide the required training to two radiographer's assistants prior to assigning these individuals to perform radiographic operations.

The NRC has evaluated the information that you provided during the conference, as well as the information developed during the inspection and investigation, and has determined that violations of NRC requirements occurred. These violations are cited in the enclosed Notice of Violation and the circumstances surrounding them were described in detail in the subject inspection report. The first violation, which is the most significant, involves BMI's failure to properly secure a source assembly in a source changer in the fully shielded position, install the safety plug and safety cap, register as a user, and have a copy of the applicable certificate of compliance. This violation was identified following a shipping incident in November 1998, in which a source dislodged from the shielded position during shipment resulting in radiation levels of 280 millirem per hour (mrem/hr) on contact of the side of the drum overpack and 1500 mrem/hr on the bottom. As described in the subject inspection report, and based on the state of California's investigation of this incident, it was determined that BMI had not properly secured the source in the shielded position and had failed to properly install the safety plug and safety cap. The resultant dose rates were in excess of the 200 mrem/hr limit and, although there is no indication that any person actually received a radiation dose in excess of NRC limits,

this is significant because the dose rates created a potential for radiation doses to workers or members of the public in excess of NRC limits. Therefore, this violation has been categorized in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions" (Enforcement Policy), NUREG-1600 at Severity Level III.

In accordance with the Enforcement Policy, a base civil penalty in the amount of $5,500 is considered for a Severity Level III violation. Because your facility has not been the subject of escalated enforcement actions within the last 2 years, the NRC considered whether credit was warranted for *Corrective Action* in accordance with the civil penalty assessment process in Section VI.B.2 of the Enforcement Policy. Your corrective actions included developing a procedure with a detailed checklist to ensure that the safety plug and safety cap are properly installed, obtaining an up-to-date copy of the certificate of compliance, and registering as a user of the source changer. As a result, the NRC has determined that BMI is deserving of *Corrective Action* credit.

Therefore, to encourage prompt and comprehensive correction of violations, and in recognition of the absence of previous escalated enforcement action, I have been authorized not to propose a civil penalty in this case. However, significant violations in the future could result in a civil penalty. In addition, issuance of this Severity Level III violation constitutes escalated enforcement action that may subject you to increased inspection effort.

The remaining violations have been classified at Severity Level IV and are not considered for civil penalties. Regarding the apparent violation of failing to train two radiographer's assistants, which the NRC was concerned might have involved deliberate misconduct, BMI's position during the conference was that the two individuals received the required training prior to assigning them to perform radiographic operations; and that, through an oversight, the individuals were assigned to perform radiographic operations without being administered a written examination. Specifically, the company President assigned the two individuals under the mistaken assumption that the radiation safety manager had completed their testing. BMI's position was that the failure to administer the written examinations was not the result of deliberate misconduct. Based on all available information, the failure to administer written examinations was identified as a violation (Violation B in the attached Notice of Violation), and the NRC did not conclude that any willfulness was involved. Regarding the apparent violation involving 40-hour training for radiographers, the BMI Radiation Safety Manager clarified his position that the required 40-hour training had been provided to each BMI radiographer. Therefore, it was determined that no violation had occurred.

With regard to the apparent violation involving failures to administer written examinations Numbers 2 and 3 to previously trained radiographers, BMI stated that, although the license condition was not specific, this requirement was meant to apply to radiographers who had been terminated and subsequently rehired, or to radiographers who were inactive for greater than 6 months. BMI maintained that its radiographers were generally laid-off, not terminated. During the conference, BMI did confirm that one individual who was inactive for greater than 6 months was not administered the required written examination. This single example was the basis for Violation C in the attached Notice.

In discussing the apparent violation regarding 6-month job performance inspections, during the inspection, BMI stated that it does sometimes conduct job performance inspections during

mock-up radiography in the shop, and not during actual radiographic operations. However, during the conference, BMI clarified that these in-shop inspections are conducted only for radiographers who had been laid-off and were being rehired, and that these in-shop inspections were only meant to ensure their job proficiency. BMI maintained that, in accordance with NRC requirements, job performance inspections were always conducted during actual industrial radiographic operations within the required 6-month interval for radiographers who had been employed continuously. Therefore, no violation was identified regarding this issue.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. The NRC will use your response, in part, to determine whether further enforcement action is necessary to ensure compliance with regulatory requirements.

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

Sincerely,

org signed by

Ellis W. Merschoff
Regional Administrator

Docket No. 030-15283
License No. 35-19048-01

Enclosure:
Notice of Violation

cc w/enclosure:
Oklahoma Radiation Control Director
California Radiation Control Director

NOTICE OF VIOLATION

Bill Miller, Inc.
Henryetta, Oklahoma

Docket No. 030-15283
License No. 35-19048-01
EA 99-013

During an NRC inspection completed on July 8, 1999, three violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," NUREG-1600, the violations are listed below:

A. 10 CFR 71.12 (c) states that the general license applies only to a licensee who: (1) has a current copy of the certificate of compliance (COC),or other approval of the package, and has the drawings and other documents referenced in the approval relating to the use and maintenance of the packaging and to the actions to be taken before shipment, (2) complies with the terms and conditions of the license, certificate, or other approval, as applicable, and the applicable requirements of subparts A, G, and H of this part, and (3) submits in writing to the Director, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, before the licensee's first use of the package, the licensee's name and license number and the package identification number specified in the package approval.

10 CFR 71.5(a) requires that a licensee who transports licensed material outside of the site of usage, as specified in the NRC license, or where transport is on public highways, or who delivers licensed material to a carrier for transport, comply with the applicable requirements of the regulations appropriate to the mode of transport of the Department of Transportation (DOT) in 49 CFR Parts 170 through 189. 49 CFR 173.441(a) requires in part, with exceptions not applicable here, that each package of radioactive materials offered for transportation be designed and prepared for shipment so that under conditions normally incident to transportation, the radiation level does not exceed 2 millisievert per hour (200 millirem per hour) at any point on the external surface of the package.

Contrary to the above, as of January 5, 1999, the licensee did not: (1) have a current copy of the COC, or other approval, for the INC Model IR-50 (COC No. 9156, Revision 5) source changer, (2) comply with the terms and conditions of the COC, in that the licensee failed to secure the source in the shielded position of the packaging by source assembly, lock, and lock cap (dust cap), and (3) submit in writing its name to the Director, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission before the licensee's first use of the package. The failure to follow the terms and conditions of the COC for the IR-50 source changer resulted in the source becoming dislodged from the shielded position and radiation levels of 2.8 millisieverts per hour (280 millirem per hour) on the surface of the source changer upon receipt of a shipment at a vendor's facility. This dose rate exceeds the 2 millisievert per hour (200 millirem per hour) limit specified in 49 CFR 173.441(a). (01013)

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

B. 10 CFR 34.43 (c)(3) requires, in part, that a licensee may not permit any individual to act as a radiographer's assistant until the individual has demonstrated understanding of the

instructions provided under (c)(1) of this section by successfully completing a written test on the subjects covered.

Contrary to the above, two radiographer's assistants had performed radiographic operations in calendar years 1997-1998, without first demonstrating understanding of the instructions by successful completion of a written test. (02014)

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

C. License Condition 19 requires, in part, that the licensee conduct its program in accordance with statements, representations, and procedures contained in the licensee's application dated February 27, 1991.

Item 5 of the attachment to the licensee's application dated February 27, 1991 states that previously trained radiographers will be required to successfully complete written examinations Numbers 2 and 3 .

Contrary to the above, in November 1998, one previously trained radiographer was not administered written examinations Numbers 2 and 3 as required. (03014)

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

Pursuant to the provisions of 10 CFR 2.201, Bill Miller, Inc. 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, U.S. Nuclear Regulatory Commission, Region IV, 611 Ryan Plaza Drive, Suite 400, Arlington, Texas 76011, within 30 days of the date of the letter transmitting this Notice of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each violation: (1) the reason for the violation, or, if contested, the basis for disputing the violation or severity level, (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. Your response may reference or include previous docketed correspondence, if the correspondence adequately addresses the required response. If an adequate reply is not received within the time specified in this Notice, an order or a Demand for Information may be issued as to why the license should not be modified, suspended, or revoked, or why such other action as may be proper should not be taken. Where good cause is shown, consideration will be given to extending the response time.

If you contest this enforcement action, you should also provide a copy of your response, with the basis for your denial, to the Director, Office of Enforcement, United States Nuclear Regulatory Commission, Washington, DC 20555-0001.

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

Because your response will be placed in the NRC Public Document Room (PDR), to the extent possible, it should not include any personal privacy, proprietary, or safeguards information so that it can be placed in the PDR without redaction. If personal privacy or proprietary information is necessary to provide an acceptable response, then please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your

response that deletes such information. If you request withholding of such material, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim of withholding (e.g., explain why the disclosure of information will create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.790(b) to support a request for withholding confidential commercial or financial information).

In accordance with 10 CFR 19.11, you may be required to post this Notice within two working days.

Dated this 24th day of September 1999

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

July 20, 1999

EA 99-153

Sidney Toll, President
North Country Hospital and Health Center, Inc.
Prouty Drive
Newport, VT 05855

SUBJECT: NOTICE OF VIOLATION
(NRC Inspection Report No. 030-17817/99-01)

Dear Mr. Toll:

This refers to the NRC inspection conducted on June 3, 1999, at your facility in Newport, Vermont. The inspection was performed to determine whether activities authorized by your license were conducted safely and in accordance with NRC requirements. During the inspection, the NRC learned that there was a misadministration of iodine-131 to a patient at your facility in February 1999. The problem was initially identified to you by the medical institution where the patient received follow up treatment. Despite having this information, your staff apparently did not conclude that a misadministration occurred, and did not inform the NRC, the patient's physician, nor the patient, as required by NRC requirements. In addition, other apparent violations of NRC requirements were identified including violations that contributed to the misadministration. On July 1, 1999, a predecisional enforcement conference was held with you and other members of your staff to discuss the apparent violations, their causes, and your corrective actions. A copy of the enforcement conference report will be sent to you by separate correspondence.

Based on the information developed during the inspection and the information provided during the predecisional enforcement conference, five violations of NRC requirements are being cited. The violations are described in the enclosed Notice of Violation (Notice) and the circumstances surrounding them are described in detail in the subject inspection report. The first three violations, all of which contributed to the misadministration, involved the failures to: (1) instruct the nuclear medicine technologist who administered the dose of approximately 305 microcuries of iodine-131 to the patient for a thyroid uptake study in accordance with your Quality Management Program; (2) supervise the technologist even though he had not been involved in an iodine-131 administration since 1990; and (3) establish, maintain, and implement the QMP for the facility in that the dose was administered without the preparation of a written directive beforehand. The remaining two violations involve (1) the failure of the Radiation Safety Officer to investigate the misadministration; and (2) the failure to notify the NRC, the patient' physician, or the patient of the misadministration.

During the conference, you noted that the technologist lacked familiarity with the study, not having been involved in such an administration since 1990, and your facility had not performed such an administration since 1993. Nonetheless, you are responsible, through your QMP, for assuring that licensed material is administered as directed by an authorized user. In this case, your QMP failed to provide this assurance, and this failure resulted in a patient receiving a significant amount of unnecessary exposure from this diagnostic procedure. Further, you failed to conclude that a misadministration occurred. As a result, this occurrence was not investigated and neither the NRC nor the patient's physician was informed. Collectively, these violations represent weaknesses in your QMP that resulted in a misadministration. Therefore, these violations are categorized as a Severity Level III problem in accordance with the "General Statement of Policy and Procedures for NRC Enforcement Actions" (Enforcement Policy), NUREG-1600.

In accordance with the Enforcement Policy, a base civil penalty in the amount of $2,750 is considered for a Severity Level III violation or problem. Because your facility has not been the subject of an escalated enforcement action within the last two years, the NRC considered whether credit was warranted for *Corrective Action* in accordance with the civil penalty assessment process in Section VI.B.2 of the Enforcement Policy. Credit for corrective actions is warranted because your corrective actions, at the time of the predecisional enforcement conference, were considered prompt and comprehensive. These actions include, but are not limited to: (1) development of a new form and new procedures for the handling and approval for use of iodine-131; (2) revision to the nuclear imaging policy and procedures manual for ease of form and information retrieval; (3) an increase in the time allotted for reviews of the program by a consultant and the Radiation Safety Committee; and (4) plans to obtain an additional radiologist on a part-time basis to assist at the facility.

Therefore, to encourage prompt and comprehensive correction of violations, I have been authorized to not propose a civil penalty in this case. However, similar violations in the future could result in further escalated enforcement action. In addition, issuance of this Notice constitutes escalated enforcement action, that may subject you to increased inspection effort.

The NRC has concluded that information regarding the reason for the violations, and the corrective actions taken and planned to correct the violations and prevent recurrence, were already described adequately during the enforcement conference and are adequately addressed on the docket in this letter. Therefore, you are not required to respond to this letter unless the description therein does not accurately reflect your corrective actions or your position. In that case, or if you choose to provide additional information, you should follow the instructions specified in 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 (PDR).

Sincerely,

Hubert J. Miller
Regional Administrator

Docket No. 030-17817
License No. 44-19518-01

Enclosure: Notice of Violation

cc w/encl:
State of Vermont

ENCLOSURE

NOTICE OF VIOLATION

North Country Hospital and Health Center, Inc.
Newport, VT

Docket No. 030-17817
License No. 44-19518-01
EA 99-153

During an NRC inspection conducted on June 3, 1999, violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy), NUREG -1600, the violations are listed below:

A. 10 CFR 35.25(a)(1) requires, in part, that a licensee that permits the use of byproduct material under the supervision of an authorized user will instruct the supervised individual in the licensee's written quality management program.

Contrary to the above, as of June 3, 1999, the licensee did not instruct a nuclear medicine technologist in the licensee's written quality management program. **(01013)**

B. 10 CFR 35.25(a)(2) requires, in part, that a licensee that permits the use of byproduct material by an individual under the supervision of an authorized user shall require the supervised individual to follow the instructions of the supervising authorized user.

The instructions of the supervising authorized user, entitled "Thyroid Uptake" requires, in part, that 8-16 microcuries of iodine-131 be administered for thyroid uptake studies.

Contrary to the above, on February 4, 1999, the technologist, an individual under the supervision of the licensee's authorized user, administered 305 microcuries of iodine-131 for a thyroid uptake study, an amount not in accordance with the instructions of the supervising authorized user. **(01023)**

C. 10 CFR 35.32(a)(1) requires, in part, that the licensee establish and maintain a quality management program which must include written policies and procedures to meet the objective that, prior to administration, a written directive is prepared for any administration of quantities greater than 30 microcuries of iodine-131.

10 CFR 35.2 defines a written directive as an order in writing for a specific patient, dated and signed by an authorized user prior to the administration of a radiopharmaceutical or radiation and containing certain information including, for greater than 30 microcuries of iodine-131, the dosage.

Contrary to the above, as of June 3, 1999, the licensee's quality management program did not include a written procedure to meet the objective that a written directive be prepared prior to administering quantities greater than 30 microcuries of iodine-131. Specifically, the licensee's quality management program only addressed the use of greater than 30 microcuries of iodine-131 for therapy and not for thyroid uptake studies. **(01033)**

D. 10 CFR 35.21(b)(1) requires, in part, that the Radiation Safety Officer investigate misadministrations.

10 CFR 35.32(b)(1)(iii) requires, in part, that the licensee shall develop procedures and conduct a review of the quality management program, including evaluation of all misadministrations, to verify compliance with all aspects of the quality management program.

10 CFR 35.2 defines, in part, "misadministration," to mean when both the administered dosage differs from the prescribed dosage by more than 20 percent of the prescribed dosage and the difference between the administered dosage and the prescribed dosage exceeds 30 microcuries.

Contrary to the above, as of June 3, 1999, the licensee's Radiation Safety Officer had not investigated a misadministration that occurred on February 4, 1999, and had not evaluated the event to verify compliance with all aspects of the quality management program. **(01043)**

E. 10 CFR 35.33(a) requires, in part, that, for a misadministration, the licensee shall (1) notify by telephone the NRC Operations Center not later than the next calendar day after discovery of the misadministration; (2) submit a written report to the appropriate NRC Regional Office within 15 days after discovery of the misadministration; (3) notify the1 referring physician and also notify the individual receiving the misadministration of the misadministration no later than 24 hours after its discovery; and (4) furnish a written report to the individual within 15 days.

Contrary to the above, in February 1999, the licensee became aware of an event that they should have known was a misadministration and as of June 3, 1999, the licensee did not notify and report the event to the NRC, the referring physician, or the individual as required. The misadministration involved the administration of a dosage of 305 microcuries of iodine 131 when the prescribed dose was 8-16 microcuries. **(01053)**

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

The NRC has concluded that information regarding the reason for the violations, and the corrective actions taken and planned to correct the violation and prevent recurrence were adequately described during the enforcement conference on July 1, 1999, and are already adequately addressed on the docket in the NRC letter. However, you are required to submit a written statement or explanation pursuant to 10 CFR 2.201 if the description therein does not accurately reflect your corrective actions or your position. In that case, or if you choose to respond, clearly mark your response as a "Reply to a Notice of Violation," and send it to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555 with a copy to the Regional Administrator, Region I, within 30 days of the date of the letter transmitting this Notice of Violation (Notice).

If you contest this enforcement action, you should also provide a copy of your response, with the basis for your denial, to the Director, Office of Enforcement, United States Nuclear Regulatory Commission, Washington, DC 20555-0001.

If you choose to respond, your response will be placed in the NRC Public Document Room (PDR). Therefore, to the extent possible, the response should not include any personal privacy or proprietary information so that it can be placed in the PDR without redaction.

Dated this 20 day of July 1999

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION II
SAM NUNN ATLANTA FEDERAL CENTER
61 FORSYTH STREET, SW, SUITE 23T85
ATLANTA, GEORGIA 30303-3415

October 19, 1999

EA 99-218

Nuclear Fuel Services, Inc.
ATTN: Mr. Dwight Ferguson
President
P. O. Box 337, MS 123
Erwin, TN 37650

SUBJECT: NOTICE OF VIOLATION (NRC INSPECTION REPORT NO. 70-143/99-01)

Dear Mr. Ferguson:

This refers to the inspection conducted during the period January 3 through February 13, 1999, at your Erwin facility. The purpose of the inspection was to determine whether activities authorized by the license were conducted safely and in accordance with regulatory requirements. The results of the inspection including three apparent violations were discussed with members of your staff at an exit meeting on February 10, 1999, and formally transmitted to you by letter dated March 19, 1999. Subsequent to the completion of a related Office of Investigations investigation, which did not substantiate deliberate misconduct, a closed, predecisional enforcement conference was conducted at the NRC Region II office in Atlanta, Georgia, on October 12, 1999, to discuss the apparent violations, the root causes, and your corrective actions. A list of conference attendees and a copy of the Nuclear Regulatory Commission's (NRC) presentation material are enclosed. The Nuclear Fuel Services' (NFS) presentation material will provided to the NRC by separate docketed correspondence.

Based on the information developed during the inspection and the information that you provided during the conference, the NRC has determined that three violations of NRC requirements occurred. The violations are cited in the enclosed Notice of Violation (Notice) and the circumstances surrounding them are described in detail in the subject inspection report. Violation A involved a failure to conduct or to conduct adequately two independent visual and detector searches by two individuals for a container removed from a Material Access Area (MAA). The failure resulted in the unauthorized removal of seven grams of Uranium-235 contained in high enriched uranium (special nuclear material (SNM)) from the Building 233 vault (an MAA) to a Building 306 storage area. The SNM was contained in a two-liter bottle inside a 55-gallon drum without a closure lid, and was discovered missing from the vault by your staff on January 11, 1999, during an inventory reconciliation. Violations B and C occurred as a result of Violation A, and involved the unauthorized storage of the 55-gallon drum containing the SNM in a location not approved for SNM storage, and the failure to assure that the movement of this SNM out of the Building 233 vault was properly documented by the material control and accounting system at the facility. Your review of the issue identified the root causes as procedural shortcomings, poor lighting which may have inhibited the proper search of empty containers, security guard training deficiencies, as well as other causal factors.

We recognize there was no actual loss or diversion of SNM, and the quantity was below that defined as low strategic significance. However, the NRC considers this issue to be significant because of the failure of multiple controls designed to prevent the loss, theft, or diversion of SNM. These controls included two procedurally required independent searches by your security personnel, with each independent search consisting of a visual search followed by a detector search for SNM. An additional failed control involved Operations personnel, who did not confirm that the 55-gallon drum was, in fact, empty prior to transfer of the drum containing SNM to the MAA boundary. Confirmation by Operations personnel was not a procedural requirement at the time; however, it nonetheless represented a control and a missed opportunity to identify and prevent the unauthorized movement and storage of this SNM. The NRC places the highest emphasis on the ability to prevent or detect the theft, loss, or diversion of SNM at the MAA boundary. In this case, the failed barriers at the MAA represented a potential diversion pathway which could have been exploited under different circumstances. The NRC concluded that the failure to conduct an adequate search of a container exiting an MAA represents a significant failure of safeguards systems, and as stated previously, resulted in two additional violations. Therefore, the three violations have been classified in the aggregate in accordance with the "General Statement of Policy and Procedures for NRC Enforcement Actions" (Enforcement Policy), NUREG-1600, as a Severity Level III problem.

In accordance with the Enforcement Policy as amended in Federal Register Notice 63 FR 71314, Policy and Procedure for Enforcement Actions; Fuel Cycle Facilities Civil Penalties and Notices of Enforcement Discretion, dated December 24, 1998, a base civil penalty in the amount of $27,500 is considered for a Severity Level III problem at a Category I fuel facility. Because your facility has not been the subject of escalated enforcement action within the last two years or two inspections, the NRC considered whether credit was warranted for Corrective Action in accordance with the civil penalty assessment process described in Section VI.B.2 of the Enforcement Policy. Your corrective actions included an immediate search of the facility to locate the material, initiation of a diversion path analysis, suspension of empty container movement for a period of time to allow a thorough understanding of the event, reemphasis of empty container searches, and initiation of a root cause analysis. To address the root causes, your staff implemented immediate and long term training enhancements for security personnel, developed and implemented a proceduralized method for Operations personnel to identify and inspect empty containers, issued flashlights to improve security guard visual searches of empty containers in low lighting conditions, and your Quality Assurance staff conducted follow up reviews to confirm the effectiveness of overall corrective actions. Additional details of your corrective actions were thoroughly discussed at the conference and are contained in your presentation material. Based on these actions, the NRC determined that corrective actions for the violations were prompt and comprehensive, and that credit was warranted for the factor of Corrective Action.

Therefore, to encourage prompt and comprehensive correction of violations, I have been authorized, after consultation with the Director, Office of Enforcement, not to propose a civil penalty in this case. However, significant violations in the future could result in a civil penalty.

Based on the information you provided at the conference, the NRC normally would not require a written response to the enclosed Notice. However, previous NRC inspections have identified procedural compliance issues at the facility in other functional areas. Because of the

procedural compliance issues associated with the failure to conduct an adequate search of a container exiting the MAA, the NRC continues to be concerned with NFS management actions to achieve consistent procedural compliance. Therefore, you are required to provide a written response to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. Your response should also address the corrective actions taken to assure NFS management and the NRC that procedural compliance in all functional areas at the facility is clearly communicated, understood, and implemented by all supervisory and staff personnel. The NRC will use your response, in part, to determine whether further enforcement action is necessary to ensure compliance with regulatory requirements.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter, its enclosures, and your response will be placed in the Public Document Room (PDR). To the extent possible, your response should not include any personal privacy, proprietary, classified, or safeguards information so that it can be placed in the PDR without redaction.

If you have any questions regarding this letter, please contact Douglas M. Collins, Director, Division of Nuclear Materials Safety, at (404) 562-4700.

Sincerely,

Original signed by L. A. Reyes

Luis A. Reyes
Regional Administrator

Docket No. 70-143
License No. SNM-124

Enclosures: 1. Notice of Violation
2. Conference Attendees
3. NRC Presentation Material

cc w/encls: see page 4

cc w/encls (continued):
D. T. Baer
Vice President
Safety and Regulatory Management
Nuclear Fuel Services, Inc.
P. O. Box 337, MS 123
Erwin, TN 37650

Debra Shults, Manager
Technical Services
Division of Radiological Health
Electronic Mail Distribution

NOTICE OF VIOLATION

Nuclear Fuel Services, Inc.
Erwin, TN

Docket No. 70-143
License No. SNM-124
EA No. 99-218

During an NRC inspection conducted on January 3 through February 13, 1999, violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedures for NRC Enforcement Actions" (Enforcement Policy), NUREG-1600, the violations are listed below:

A. License Condition SG-6.1 requires the licensee to follow the measures described in the current version of the physical protection plan.

Chapter 21 of the Physical Safeguards Plan requires that non-contaminated wastes and trash being removed from Material Access Areas be searched by two guards working as a team at the removal portal using appropriate hand-held detection equipment for concealed Strategic Special Nuclear Material and for metal which could be used to shield Special Nuclear Material.

Paragraph 7.3 of Security Procedure #24, Procedure for Handling Removal of Equipment or Items from a Material Access Area to the Protected Area, which implements Chapter 21 of the Physical Safeguards Plan, requires metallic items with no concealed cavities to be searched by a watchteam. The search shall be conducted visually of the interior and exterior of drums and empty metal objects, as well as by separate and independent detector searches for unshielded special nuclear material.

Contrary to the above, between September 4, 1998 and January 11, 1999, the licensee failed to conduct or to conduct adequately two independent visual and detector searches of a 55-gallon drum, which was moved from the Building 233 Material Access Area vault. This resulted in the failure to identify the presence of seven grams of Uranium-235
(U-235) contained in a two-liter bottle inside the 55-gallon drum prior to its transfer to a Building 306 storage area. (01013)

B. License Condition S-1 requires the use of licensed material in accordance with the statements, representations, and conditions of the License Application and supplements.

License Application Section 2.7 states, in part, that "SNM operation and safety function activities are conducted in accordance with written procedures."

Licensee procedure NFS-HS-CL-10, Revision 6, "Nuclear Criticality Safety for Building 302/303/306," Section 7.0 requires, in part, that "No SNM-bearing containers may be placed or stored at a location or area unless that specific location or area is approved for SNM storage or processing by a posted station limit card."

Contrary to the above, on January 11, 1999, a 55-gallon drum containing seven grams of U-235 was stored in Building 306 East which was not approved for SNM storage by a

Enclosure 1

posted station limit card. The specific duration of the storage of the material at the unauthorized location was indeterminate. (01023)

C. 10 CFR 74.51(a)(4) requires material control and accounting systems to achieve the objective of ongoing confirmation of the presence of Strategic Special Nuclear Material (SSNM) in assigned locations.

License Condition SG-5.1 requires, in part, that the licensee follow Section 4, Revision 5, "QA and Accounting," of its Fundamental Nuclear Material Control (FNMC) Plan.

10 CFR 74.59(b)(2) requires provision for the adequate review, approval, and use of those material control and accounting procedures that are identified in the approved Fundamental Nuclear Material Control (FNMC) plan as being critical to the effectiveness of the described system.

Table 4.1.2-1 in Section 4.1 of the approved FNMC plan specifies procedure SOP-326, Rev. 19, "Procedure for SNM Material Control - High Enriched Recovery Facility," as a critical procedure within the meaning of 10 CFR 74.59(b)(2).

Section 5.0, "SNM Material Control in 233 Vault," of procedure SOP-326 requires that all SNM movements into or out of the vault be under the direction or supervision of the production foreman or a designated custodian, and all relocation transactions must be completed and documented by using the NuMAC network transfer transaction.

Contrary to the above, at some time between September 4, 1998 and January 11, 1999, a container of seven grams of SSNM having identification number 002670610 was unknowingly moved from the Building 233 vault to a Building 306 storage area without the relocation transaction being completed and documented by using the NuMAC network transfer transaction which degraded the ability to achieve the objective of ongoing confirmation of the presence of SSNM in assigned locations. (01033)

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

Pursuant to the provisions of 10 CFR 2.201, Nuclear Fuel Services, Inc. is required to submit a written statement of explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555 with a copy to the Regional Administrator, Region II, and a copy to the NRC Resident Inspector at the facility that is the subject of this Notice, within 30 days from 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. Your response may reference or include previous docketed correspondence, if the correspondence adequately addresses the required response. If an adequate reply is not received within the time specified in this Notice, an order or a Demand for Information may be issued as to why the license should not be modified, suspended, or revoked, or why such other action as may be proper should not be taken. Where good cause is shown, consideration will be given to extending the response time.

If you contest this enforcement action, you should also provide a copy of your response, with the basis for your denial, to the Director, Office of Enforcement, United States Nuclear Regulatory Commission, Washington, DC 20555-0001.

Because your response will be placed in the NRC Public Document Room (PDR), to the extent possible, it should not include any personal privacy, proprietary, classified, or safeguards information so that it can be placed in the PDR without redaction. If personal privacy or classified information is necessary to provide an acceptable response, then please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request withholding of such material, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim of withholding (e.g., explain why the disclosure of information will creates an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.790(b) to support a request for withholding confidential commercial or financial information). If safeguards information is necessary to provide an acceptable response, please provide the level of protection described in 10 CFR 73.21.

In accordance with 10 CFR 19.11, you may be required to post this Notice within two working days.

Dated this 19th day of October 1999

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION II
SAM NUNN ATLANTA FEDERAL CENTER
61 FORSYTH STREET, SW, SUITE 23T85
ATLANTA, GEORGIA 30303-3415

November 23, 1999

EA 99-269

Víctor E. Rivera Associates
Geotechnical Engineers
ATTN: Mr. Víctor E. Rivera Roldan, P.E., MBA
President
P.O. Box 198
Ponce, Puerto Rico 00732

SUBJECT: NOTICE OF VIOLATION AND EXERCISE OF ENFORCEMENT DISCRETION (NRC INSPECTION REPORT NO. 52-19885-01/99-02)

Dear Mr. Rivera:

This refers to the inspection conducted on September 29, 1999, at your Ponce, Puerto Rico facility. The purpose of the inspection was to determine whether activities authorized by your license were conducted safely and in accordance with Nuclear Regulatory Commission (NRC) requirements. The results of the inspection, including five apparent violations, were discussed with Mr. Jose R. Rivera Nazario of your staff on September 29, 1999, and formally transmitted to you by letter dated October 22, 1999. An open, predecisional enforcement conference was conducted at the Holiday Inn in Ponce, Puerto Rico, on November 9, 1999, to discuss the apparent violations, the root causes, and your corrective actions. By letter dated November 8, 1999, you provided additional information regarding your corrective actions. A copy of your November 8, 1999 letter, a listing of conference attendees, and a copy of NRC presentation materials are enclosed.

Based on the information developed during the inspection and the information that you provided during the conference, the NRC has determined that violations of NRC requirements occurred. The violations are cited in the enclosed Notice of Violation (Notice), and the circumstances surrounding them were described in detail in the subject inspection report. The violations involve (1) two examples of the failure to secure licensed materials (e.g., moisture/density gauges containing approximately 10 millicuries of cesium-137 and 50 millicuries of americium-241) from unauthorized removal or access; (2) failure to limit the radiation dose in an unrestricted area to levels below two millirem in any one hour; (3) failure to post a radiation area; (4) failure to label containers of licensed material; and (5) failure to check packages for physical condition prior to shipment. At the conference, you admitted the violations; although you expressed concern regarding our conclusions relating to the potential for exposure to members of the public.

Regarding Violation A in the enclosed Notice, the failure to secure licensed materials from unauthorized removal or access in this case did not result in any of the gauges becoming lost or otherwise unaccounted for. However, the failure to adequately secure and limit access to licensed material is a significant safety issue. Implementation of adequate security measures for licensed materials is intended to prevent members of the public from being unknowingly and unnecessarily exposed to radiation. The NRC is also concerned that you failed to correct

violations of NRC regulatory requirements, including the requirement to adequately secure licensed material, following identification by your health physics consultant. The health physics consultant reported these findings to your Radiation Safety Officer (RSO), an official of your company. However, the RSO failed to take immediate corrective actions. Although the NRC recognizes your initiative both in obtaining the services of a health physics consultant to ensure compliance with regulatory requirements and in constructing a storage room for securing the gauges, your failure to implement immediate corrective actions indicates a lack of management attention and involvement in ensuring adherence to regulatory requirements. Therefore, based on the potential safety significance of this issue, in accordance with the "General Statement of Policy and Procedures for NRC Enforcement Actions" (Enforcement Policy), 64 *Federal Register* 61142, issued on November 9, 1999, Violation A described in the Notice has been categorized at Severity Level III.

In accordance with the Enforcement Policy, a base civil penalty in the amount of $2,750 is considered for a Severity Level III violation. Because you have not been the subject of escalated enforcement action within the last two inspections, the NRC considered whether credit was warranted for *Corrective Action* in accordance with the civil penalty assessment process in Section VI.B.2 of the Enforcement Policy. At the conference, you stated that your corrective actions included: (1) completion of a storage facility appropriately labeled and equipped with locking devices and radiation postings; (2) locks on the gauge cases and handles; (3) appropriate security of restricted areas from unauthorized access; and (4) training of your employees on security and other license requirements. We note that your health physics consultant identified the failure to implement adequate security measures in October 1998 and in April 1999, yet you failed to implement corrective actions to restore compliance until after the NRC inspection conducted on September 29, 1999. Based on this, the NRC determined that your initial actions were not prompt and comprehensive and credit was not warranted for the factor of *Corrective Action*.

Based on this assessment of *Corrective Action*, under the Enforcement Policy a base civil penalty of $2,750 for the Severity Level III violation would normally be proposed. However, after review of this violation with the Director, Office of Enforcement, the NRC has concluded that while a violation did occur, enforcement discretion is warranted, and the issuance of a civil penalty is not appropriate in this case. Discretion is being exercised pursuant to Section VII.B.6 of the Enforcement Policy because once the NRC put you on notice of the regulatory violation and its significance, you implemented immediate and effective actions, and Victor E. Rivera Associates, Geotechnical Engineers is a small entity pursuant to the Small Business Regulatory Enforcement Fairness Act. However, significant violations in the future could result in a civil penalty. In addition, issuance of this Severity Level III violation constitutes escalated enforcement action, that may subject you to increased inspection effort.

The remaining violations being cited are described in the enclosed Notice and are classified separately at Severity IV, as discussed above. In addition to the corrective action described above, you also purchased new transport cases for the portable nuclear gauges with legible plates for appropriate labeling.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. The NRC will use your response, in part, to determine whether further enforcement action is necessary to ensure compliance with regulatory requirements.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter, its enclosures, and your response will be placed in the Public Document Room (PDR). To the extent possible, your response should not include any personal privacy, proprietary, or safeguards information so that it can placed in the PDR with redaction.

If you have any questions regarding this letter, please contact Douglas M. Collins, Director, Division of Nuclear Materials Safety at (404) 562-4700.

Sincerely,

Luis A. Reyes
Regional Administrator

Enclosures:
1. Notice of Violation
2. Conference Attendees
3. November 8, 1999, letter from licensee
4. Material Presented by NRC

Docket No.: 030-30301
License No.: 52-19885-02

cc w/encls:
Commonwealth of Puerto Rico

Víctor E. Rivera Associates
Geotechnical Engineers

Docket No. 030-30301
License No. 52-19885-02
EA 99-269

During an NRC inspection conducted on September 29, 1999, violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedures for NRC Enforcement Actions," 64 *Federal Register* 61142, issued on November 9, 1999, the violations are listed below:

A. 10 CFR 20.1801 requires the licensee to secure from unauthorized removal or access licensed materials that are stored in controlled or unrestricted areas. 10 CFR 20.1802 requires that the licensee control and maintain constant surveillance of licensed material that is in a controlled or unrestricted area and that is not in storage. As defined in 10 CFR 20.1003, controlled area means an area, outside of a restricted area but inside the site boundary, access to which can be limited by the licensee for any reason; an unrestricted area means an area, access to which is neither limited nor controlled by the licensee.

Condition 19 of NRC License No. 52-19885-02, requires, in part, that gauges or their containers be locked when in storage.

Contrary to the above, on September 29, 1999:

1. The licensee failed to secure from unauthorized removal or limit access to five Campbell Pacific Nuclear moisture/density portable gauges, containing approximately 10 millicuries of cesium-137 and 50 millicuries of americium-241 each, located on a storage rack, within the geotechnical laboratory, an unrestricted area, and failed to control and maintain constant surveillance of this licensed material.

2. Four moisture/density gauges were stored in the geotechnical laboratory and neither the gauges nor their respective containers were locked. (01013)

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

B. 10 CFR 20.1902(a) requires that the licensee post each radiation area with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, RADIATION AREA." 10 CFR 20.1003 defines *radiation area,* as an area accessible to individuals, in which radiation levels could result in an individual receiving a dose equivalent in excess of 0.005 rem (0.05 mSv) in 1 hour at 30 centimeters from the radiation source or from any surface that the radiation penetrates.

Contrary to the above, on September 29, 1999, the hallway in front of the storage rack for the portable moisture/density gauges, an area accessible to individuals, had radiation

levels of approximately 6.7 millirem in one hour at 30 centimeters, such that an individual could receive a dose equivalent in excess of 0.005 rem (0.05 mSv) in 1 hour

Enclosure 1

at 30 centimeters, yet this area was not posted with any signs bearing the words "CAUTION RADIATION AREA". (02014)

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

C. 10 CFR 20.1301(a)(2) requires that the licensee conduct its operations so that the dose in any unrestricted area from external sources does not exceed 2 millirem in any one hour.

Contrary to the above, on September 29, 1999, the licensee conducted operations which resulted in a dose, from external sources, of 6.7 millirem in one hour in the hallway in front of the storage rack for its portable gauges, within the geotechnical laboratory, an unrestricted area. (03014)

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

D. 10 CFR 20.1904(a) requires the licensee to ensure that each container of licensed material bears a durable, clearly visible label bearing the words "CAUTION, RADIOACTIVE MATERIAL," or "DANGER, RADIOACTIVE MATERIAL." The label must also provide sufficient information (such as the radionuclide(s) present, an estimate of the quantity of radioactivity, the date for which the activity is estimated, etc.) to permit individuals handling or using the containers, or working in the vicinity of the containers, to take precautions to avoid or minimize exposures.

Contrary to the above, on September 29, 1999, a container bearing a Campbell Pacific Nuclear portable moisture/density gauge, containing approximately 10 millicuries of cesium-137 and 50 millicuries of americium-241, did not have a clearly visible label bearing the words "CAUTION, RADIOACTIVE MATERIAL," or "DANGER, RADIOACTIVE MATERIAL", nor did this container or one other container bearing a moisture/density gauge, identify the radionuclides present, the quantity of radioactivity, or other sufficient information to permit individuals handling or using the container, or working in the vicinity of the containers, to take precautions to avoid or minimize exposure. (04014)

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

E. 10 CFR 71.5(a) requires a licensee who transports licensed material outside of the site of usage, as specified in the NRC license, or where transport is on public highways, or who delivers licensed material to a carrier for transport, to comply with the applicable requirements of the Department of Transportation (DOT) in 49 CFR Parts 170 through 189, appropriate to the mode of transport.

49 CFR 173.475(b) requires, in part, that before each shipment of any Class 7 (radioactive) materials package, the offeror (licensee) must insure by examination or appropriate tests, that the packaging is in an unimpaired physical condition, except for superficial marks.

Enclosure 1

Contrary to the above, on September 29, 1999, the licensee transported Class 7 (Radioactive) materials in two packages which were cracked (non-superficial marks) and otherwise failed to insure by examination or appropriate tests, that the packaging was in an unimpaired physical condition. (05014)

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

Pursuant to the provisions of 10 CFR 2.201, Víctor Rivera Associates is required to submit a written statement of explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555 with a copy to the Regional Administrator, Region II, within 30 days from 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. Your response may reference or include previously docketed correspondence, if the correspondence adequately addresses the required response. If an adequate reply is not received within the time specified in this Notice, an order or a Demand for Information may be issued as to why the license should not be modified, suspended, or revoked, or why such other action as may be proper should not be taken. Where good cause is shown, consideration will be given to extending the response time.

If you contest this enforcement action, you should also provide a copy of your response, with the basis for your denial, to the Director, Office of Enforcement, United States Nuclear Regulatory Commission, Washington, DC 20555-0001.

Because your response will be placed in the NRC Public Document Room (PDR), to the extent possible, it should not include any personal privacy, proprietary, or safeguards information so that it can be placed in the PDR without redaction. However, if you find it necessary to include such information, you should clearly indicate the specific information that you desire not to be placed in the PDR, and provide the legal basis to support your request for withholding the information from the public.

In accordance with 10 CFR 19.11, you may be required to post this Notice within two working days.

Dated this November 23rd day of November 1999

Enclosure 1

LIST OF ATTENDEES

Nuclear Regulatory Commission:

L. Reyes, Regional Administrator
A. Boland, Enforcement Officer
M. Lesser, Chief, Materials Licensing/Inspection Branch 2, DNMS
J. Díaz-Vélez, Health Physicist

Víctor E. Rivera & Associates
Luis J. Urquiza
José R. Rivera Nazario
Víctor E. Rivera Roldán

Members of the Public
Three members of the Commonwealth of Puerto Rico, Department of Health were present
One industry representative was present

Enclosure 2

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

August 16, 1999

EA 99-210

Stanley R. Sebastian
Vice President, Professional Services
Saint Clare's Hospital
400 W. Blackwell Street
Dover, NJ 07801-2525

SUBJECT: NOTICE OF VIOLATION
(NRC Inspection Report No. 030-02576/99-01)

Dear Mr. Sebastian:

This refers to the NRC inspection conducted on July 27 and 28, 1999, at your facility in Denville, New Jersey. The inspection was performed to determine whether activities authorized by your license were conducted safely and in accordance with NRC requirements. During the inspection, the NRC learned, during a review of the minutes of one of your Radiation Safety Committee (RSC) meetings, that there was a loss of three iodine-125 brachytherapy seeds at your Dover, New Jersey, facility in April 1998. The NRC also learned that the loss of this material, which amounted to 0.79 millicuries of iodine-125 per seed, was not reported to the NRC as required. In a telephone conversation on August 11, 1999, you informed Dr. M. Shanbaky of my staff that St Clare's Hospital did not believe that a predecisional enforcement conference was needed to discuss this matter, nor did you believe that you needed to provide a written response prior to the NRC deciding on appropriate enforcement action.

The loss of the three seeds occurred after 57 other seeds had been implanted in a patient at your Dover facility. Prior to the implant procedure, a physicist loaded 80 seeds into cartridges (10 seeds per cartridge) which in turn were placed in a surgical instrument used to implant the seeds. After a physician performed the implant procedure, the physicist took the instrument and the used cartridges to a sink for cleaning, even though such cleaning was not specified in your written procedures. Apparently, the physicist was not aware that one of the cartridges contained three seeds which had not been implanted. Further, he did not perform a survey to determine whether the cartridge contained any seeds. Subsequently, when the physicist disassembled the cartridge, a spring in the cartridge pushed the three remaining seeds out of the cartridge into the sink where they were immediately washed down the drain and into the sewage system.

Based on the information developed during the inspection, three violations of NRC requirements are being cited. The violations are described in the enclosed Notice of Violation (Notice). The violations involve (1) failure of the physicist to perform an adequate survey prior to cleaning the cartridges; (2) the subsequent loss of control of radioactive material when the seeds were pushed into the sink which resulted in the improper disposal of the radioactive seeds when they were washed down the sink and into the sanitary sewage system; and (3) the failure to notify NRC, within 30 days, after the material was lost. The licensee subsequently reported the loss of material to the NRC on July 28, 1999.

During the inspection, the NRC determined that this incident appeared to be an isolated occurrence which you identified, and for which you took appropriate corrective action. Nonetheless, these violations were significant because they resulted in the improper disposal of radioactive material into the sanitary sewage system. Therefore, collectively, these three violations are categorized as a Severity Level III problem in accordance with the "General Statement of Policy and Procedures for NRC Enforcement Actions" (Enforcement Policy), NUREG-1600.

In accordance with the Enforcement Policy, a base civil penalty in the amount of $2,750 is considered for a Severity Level III violation or problem. Because your facility has not been the subject of an escalated enforcement action within the last two years or two inspections, the NRC considered whether credit was warranted for *Corrective Action* in accordance with the civil penalty assessment process in Section VI.B.2 of the Enforcement Policy. Credit for corrective actions is warranted because your corrective actions, at the time of the inspection, were considered prompt and comprehensive. These actions include, but are not limited to, instruction of all personnel to (1) not clean the appliance or any cartridges in a sink; and (2) sterilize the equipment and to disassemble it on a stainless steel table. Also, your Radiation Safety Committee directed that the procedures be revised to include monitoring and surveying of applicators.

Therefore, to encourage prompt and comprehensive correction of violations, I have been authorized to not propose a civil penalty in this case. However, similar violations in the future could result in further escalated enforcement action. In addition, issuance of this Notice constitutes escalated enforcement action, that may subject you to increased inspection effort.

The NRC has concluded that information regarding the reason for the violations, and the corrective actions taken and planned to correct the violations and prevent recurrence, were already described adequately during the inspection and are adequately addressed on the docket in this letter. Therefore, you are not required to respond to this letter unless the description therein does not accurately reflect your corrective actions or your position. In that case, or if you choose to provide additional information, you should follow the instructions specified in 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 (PDR).

Sincerely,

Hubert J. Miller
Regional Administrator

Docket No. 030-02576
License No. 29-13746-02

Enclosure:
1. Notice of Violation

cc w/encl:
State of New Jersey

ENCLOSURE

NOTICE OF VIOLATION

St. Clare's Hospital
Denville, New Jersey

Docket No. 030-02576
License No. 29-13746-02
EA 99-210

During an NRC inspection conducted on June 27-28, 1999, violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy), NUREG -1600, the violations are listed below:

A. 10 CFR 20.1501 (a) requires, in part, that each licensee shall make or cause to be made, surveys that may be necessary for the licensee to comply with the regulations in this part; and are reasonable under the circumstances to evaluate the extent of radiation levels; and concentrations or quantities of radioactive material; and the potential radioactive hazard that could be present.

Contrary to the above, the licensee did not make or cause to be made surveys that may be necessary for the licensee to comply with the regulations in this part, and are reasonable under the circumstances to evaluate the extent of radiation levels, and concentrations or quantities of radioactive material, and the potential radioactive hazard that could be present. Specifically, on April 27, 1998, the licensee did not survey a surgical instrument that contained radioactive iodine (I-125) seeds, before cleaning the instrument in the operating room sink. As a result, the iodine seeds contained in the surgical instrument were washed down the sink drain and lost into the sewage system. **(01013)**

B. 10 CFR 20.1802 requires that the licensee shall control and maintain constant surveillance of licensed material that is in a controlled or unrestricted area and that is not in storage.

10 CFR 20.2001 (a) requires, in part, that a licensee shall dispose of licensed material only by certain specified procedures.

Contrary to the above, the licensee did not maintain constant surveillance of licensed material that was in a controlled or unrestricted area and that was not in storage. Specifically, on April 27, 1998 the licensee lost control of licensed material consisting of three seeds of iodine-125 with a total activity of approximately 2.1 millicuries when the seeds were inadvertently pushed into a sink in the operating room with water running. As a result, the licensee disposed of licensed material in a manner not authorized by 10 CFR 20.2001(a). This method of disposal is not authorized for encapsulated I-125 seeds. **(01023)**

C. 10 CFR 20.2201 (a)(i)(ii) requires, in part, that each licensee report by telephone to the NRC Operations Center, within 30 days after the occurrence of any lost, stolen, or missing licensed material becomes known to the licensee, all licensed material in a quantity greater than 10 times the quantity specified in appendix C to part 20 that is still missing at this time.

Contrary to the above, the licensee did not report the loss of licensed material by telephone to the NRC Operations Center, within 30 days after it became aware that the material was missing. Specifically, the licensee did not report the loss of 3 iodine-125 seeds with a total activity of 2.1 millicurie, a quantity greater than 10 times the quantity specified in Appendix C to Part 20. These seeds were determined to be lost on April 27, 1998 when they were inadvertently disposed of to the sanitary sewer system. **(01033)**

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

The NRC has concluded that information regarding the reason for the violations, and the corrective actions taken and planned to correct the violation and prevent recurrence were adequately described during inspection, and are already adequately addressed on the docket in the NRC inspection report. However, you are required to submit a written statement or explanation pursuant to 10 CFR 2.201 if the description therein does not accurately reflect your corrective actions or your position. In that case, or if you choose to respond, clearly mark your response as a "Reply to a Notice of Violation," and send it to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555 with a copy to the Regional Administrator, Region I, within 30 days of the date of the letter transmitting this Notice of Violation (Notice).

If you contest this enforcement action, you should also provide a copy of your response, with the basis for your denial, to the Director, Office of Enforcement, United States Nuclear Regulatory Commission, Washington, DC 20555-0001.

If you choose to respond, your response will be placed in the NRC Public Document Room (PDR). Therefore, to the extent possible, the response should not include any personal privacy or proprietary information so that it can be placed in the PDR without redaction.

Dated this 16th day of August 1999

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

December 29, 1999

EA 99-297

Carl Buckland
Plant Manager
Southeastern Plastics Corporation
15 Home News Row
New Brunswick, NJ 08901

SUBJECT: NOTICE OF VIOLATION
(NRC Inspection Report No. 999-90001/99-008)

Dear Mr. Buckland:

This refers to the NRC inspection conducted from October 27 through November 23, 1999, at the Zeta Consumer Products Corporation (Zeta), 555 Route 57 East, Washington Township, New Jersey, and at Southeastern Plastics Corporation (Southeastern), 15 Home News Row, New Brunswick, New Jersey. The purpose of the inspection was to review the circumstances leading to the appearance of an Ohmart scanning gauge containing 1200 millicuries of krypton-85 at a warehouse that is owned by Zeta. The gauge was stored on a pallet and was among several other pieces of used machinery and equipment that had been brought to the warehouse from other plants to be sold at an auction.

During the inspection, the NRC learned that Southeastern had acquired the Ohmart gauge under a general license, and installed it at the Southeastern facility in July 1991. Subsequently, the gauge was removed and transferred to the Zeta warehouse. This was an unauthorized transfer since Zeta does not have a specific NRC license to possess the gauge. As such, Southeastern's actions constituted an abandonment of the gauge, contrary to NRC requirements for a general licensee. Other apparent violations were also identified during the inspection, including the abandonment of another thickness gauge (manufactured by NDC), containing 150 millicuries of americium-241, that Southeastern had acquired in March of 1986. The NDC gauge is considered abandoned since it could not be located at the time of the inspection. Details were provided in the inspection report sent to you on December 2, 1999. On December 15, 1999, a predecisional enforcement conference was held with you in our Region I office in King of Prussia, Pennsylvania, to discuss the violations, their causes and Southeastern's corrective actions. A copy of the predecisional enforcement conference summary report is enclosed.

Based on the information developed during the inspection and the information that you provided during the conference, the NRC has determined that four violations of NRC requirements occurred. The most significant problem involved Southeastern's abandonment of the two gauges, including the Ohmart gauge, which, fortuitously, was found at the Zeta warehouse

before it could be sold at an auction. While the entire gauge unit, at the time it was found, appeared to be intact with the source assembly shielded, this occurrence, along with the failure to account for the other gauge, represents a significant safety issue. Implementation of adequate controls of licensed material is intended to prevent members of the public from being unknowingly and unnecessarily exposed to radiation. Abandonment of generally licensed radioactive material constitutes a violation of 10 CFR (Code of Federal Regulations) 31.5.

Three other violations were identified during the inspection regarding the use of generally licensed sources at the Southeastern facility. The violations are fully described in the referenced inspection report. Between 1986 and 1992, Southeastern used four generally licensed gauges containing byproduct material, and did not assure that the devices were tested for proper operation of their on-off mechanisms and indicators. The labels affixed to an Ohmart Gauge (Scanning Gauge, Serial No. 8529) required that device dismantling and relocation be performed by persons specifically licensed by the NRC or an Agreement State. Contrary to this requirement, at some time prior to October 1999, Southeastern allowed the dismantling/removal of the Ohmart Model gauge by employees or contractors who were not specifically licensed to perform these activities. Also, on at least four occasions between 1986 and 1992, Southeastern installed and subsequently removed from installation, the four generally licensed gauges containing byproduct material, and did not maintain records of their installation and removal.

As you stated at the predecisional enforcement conference, three of the gauges have been permanently removed from the Southeastern facility and returned to the manufacturers. The search for the remaining NDC thickness gauge included a walk-down of the Southeastern facility in New Brunswick, New Jersey and the Zeta facility in Washington Township, New Jersey. In addition, you have alerted the scrap dealer, and employees and contractors working at the facility, to inform you if they find the gauge. Other than the missing NDC gauge, Southeastern has no other generally licensed devices remaining at the facility. We have received your written report, dated December 21, 1999, regarding the missing NDC gauge containing a radioactive source.

The violation involving abandonment of the Ohmart gauge is being cited in the attached Notice and is classified as a Severity Level III violation in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions" (Enforcement Policy), NUREG 1600. This violation was identified based upon a contact between a third party and the NRC. The abandonment of the missing NDC gauge is not being cited as part of this violation for the reasons discussed below.

In accordance with the Enforcement Policy, a base civil penalty in the amount of $2,750 is considered for a Severity Level III violation or problem. Because the Southeastern facility has not been the subject of an escalated enforcement action within the last two years or two inspections, the NRC considered whether credit was warranted for Corrective Action in accordance with the civil penalty assessment process in Section VI.B.2 of the Enforcement Policy. Credit for corrective actions is warranted because once you were put on notice of the apparent violation, Southeastern's actions, as described at the conference, were considered prompt and comprehensive. These actions include, but are not limited to, (1) returning the Ohmart gauge to the manufacturer for disposal; (2) making arrangements to have two other

thickness gauges in your possession returned to their manufacturer (NDC) for proper disposal; (3) continuing efforts to locate the other missing NDC gauge, including searching the facility and alerting your staff and contractors to the loss of the gauge and the safety implications. We understand that there are no other generally licensed devices left at the Southeastern facility, with the possible exception of the missing gauge.

Therefore, to encourage prompt and comprehensive correction of violations, I have been authorized to not propose a civil penalty for the abandoned Ohmart gauge. However, similar violations in the future could result in further escalated enforcement action.

The NRC is not taking enforcement action for the remaining violations identified during the inspection, including the abandonment of the missing NDC gauge. Southeastern assisted in identifying these violations during the portion of the NRC inspection conducted at your facility and through your continued efforts to locate the missing NDC gauge after the NRC inspector left the Southeastern facility. Under the Interim Enforcement Policy for Generally Licensed Devices, 63 FR 66492, enforcement action normally will not be taken for violations of 10 CFR 31.5 if they are identified by the general licensee, and reported to the NRC if reporting is required, provided (among other things) that the general licensee takes appropriate corrective action to address the specific violations and prevent recurrence of similar problems. This approach is intended to encourage general licensees to determine if applicable requirements have been met, to search their facilities to assure that sources are located, and to develop appropriate corrective action when deficiencies are found. The NRC recognizes your cooperation in this regard.

The NRC has concluded that information regarding the reason for the violations, and the corrective actions taken and planned to correct the violations and prevent recurrence, were already described adequately during the inspection, and in the predecisional enforcement conference, as documented herein and in the enforcement conference report. Therefore, you are not required to respond to this letter unless the description therein does not accurately reflect Southeastern's corrective actions or Southeastern's position. In that case, or if you choose to provide additional information, you should follow the instructions specified in 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, and your response (if any) will be placed in the NRC Public Document Room (PDR).

Sincerely,

for Hubert J. Miller
Regional Administrator

Docket No. 999-90001

Enclosure:
1. Notice of Violation
2. Predecisional Enforcement Conference Summary Report

cc w/encl:
Alfred Teo, President
John Reier, Chief Financial Officer
State of New Jersey

ENCLOSURE

NOTICE OF VIOLATION

Southeastern Plastics Corporation
New Brunswick, NJ

Docket No. 999-90001
License No. GL
EA 99-297

During an NRC inspection conducted between October 27 and November 23, 1999, at the Zeta Consumer Products Corporation, 555 Route 57 East, Washington Township, New Jersey, and at Southeastern Plastics Corporation, 15 Home News Row, New Brunswick, New Jersey, a violation of NRC requirements was identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy), NUREG-1600, the violation is listed below:

> 10 CFR 31.5(c)(6) requires that any person who acquires, receives or possesses byproduct material in a device pursuant to the general license in 10 CFR 31.5(a), not abandon the device containing byproduct material.
>
> Contrary to the above, at some time prior to October 1999, the licensee abandoned an Ohmart gauge containing 1200 millicuries of krypton-85, a byproduct material, that was acquired by the licensee in 1991, in that the device was found in a warehouse at the Zeta Consumer Products Corporation, 555 Route 57 East, Washington Township, New Jersey, where it was to be sold at auction. (01013)
>
> This is a Severity Level III violation (Supplement VI).

The NRC has concluded that information regarding the reason for the violation, and the corrective actions taken and planned to correct the violation and prevent recurrence were adequately described during the inspection, and are already adequately addressed on the docket in the NRC inspection report and in the letter transmitting this Notice. However, you are required to submit a written statement or explanation pursuant to 10 CFR 2.201 if the description therein does not accurately reflect your corrective actions or your position. In that case, or if you choose to respond, clearly mark your response as a "Reply to a Notice of Violation," and send it to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555 with a copy to the Regional Administrator, Region I, within 30 days of the date of the letter transmitting this Notice of Violation (Notice).

If you contest this enforcement action, you should also provide a copy of your response, with the basis for your denial, to the Director, Office of Enforcement, United States Nuclear Regulatory Commission, Washington, DC 20555-0001.

If you choose to respond, your response will be placed in the NRC Public Document Room (PDR). Therefore, to the extent possible, the response should not include any personal privacy or proprietary information so that it can be placed in the PDR without redaction.

Dated this 29th day of December 1999

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

December 20, 1999

EA 99-289

Ms. Diane M. Radloff
Vice President Patient Care Services
St. John Hospital and Medical Center
22101 Moross Road
Detroit, MI 48236-2172

SUBJECT: NOTICE OF VIOLATION
(NRC Inspection Report 030-02028/99001(DNMS))

Dear Ms. Radloff:

This refers to the inspection conducted on October 19 through 23, 1999, at St. John Hospital and Medical Center (St. John) in Detroit, Michigan. The purpose of the inspection was to review the circumstances surrounding a reported radiopharmaceutical misadministration. During the inspection, apparent violations of NRC requirements were identified and were documented in the NRC inspection report sent to you by our letter dated December 1, 1999. In that letter we indicated that NRC had sufficient information to proceed with the enforcement action, however, you were given an opportunity to discuss the apparent violations at a predecisional enforcement conference or address the apparent violations in writing. During a telephone conversation between Dr. W. Nikesch of your staff and Mr. G. Wright of my staff on December 7, 1999, St. John declined a conference and declined to provide additional written correspondence.

Based on the information developed during the inspection and the information provided in your report of misadministration dated October 29, 1999, the NRC has determined that violations of NRC requirements occurred. The violations are cited in the enclosed Notice of Violation (Notice).

Violation A of the Notice is indicative of a weakness in the implementation of the St. John quality management program (QMP). At the request of the authorized user, orders were placed for iodine-131 therapy doses of 250 and 300 millicuries to be administered to two patients. On September 7, 1999, before the completion of the written directives, the acting pharmacy technologist unpacked the two iodine I-131 vials, measured each dose in the dose calibrator (264 and 296.7 millicuries), and printed out the labels with the information regarding the doses and the patients names. Later, the authorized user prescribed a treatment dose of 200 millicuries for patient A and 300 millicuries for patient B. The administering technologist took the written directives for both patients and proceeded to the nuclear pharmacy with patient A. Both doses were re-assayed and the amounts posted on the written directive forms. At that point, the administering technologist failed to compare the ordered dose with the written directive to assure that patient A would receive the proper dose of 200 millicuries. In addition, the second party verification was not performed. As a result of these failures, patient A

received a 32 percent overdose. NRC regulations and licensee policies are in place to ensure physician's prescriptions are administered as written. Failure to adhere to these regulations and policies can result in serious consequences to patients. It is imperative that the utmost care and attention to detail are used when dealing with radioactive material. Therefore, violation A of the Notice is classified in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions" (Enforcement Policy), NUREG-1600, as a Severity Level III violation.

In accordance with the Enforcement Policy, a base civil penalty in the amount of $2,750 is considered for a Severity Level III violation. Because your facility has not been the subject of escalated enforcement actions within the last two inspections, the NRC considered whether credit was warranted for *Corrective Action* in accordance with the civil penalty assessment process in Section VI.B.2 of the Enforcement Policy. Credit for *Corrective Action* is warranted based on the following corrective actions planned or taken: (1) the two technologists involved were prohibited from administering therapy doses until the licensee was satisfied that they had a complete understanding of and could correctly implement the QMP; (2) all individuals involved with the therapy program have received retraining on the QMP including the form revisions; and (3) the written directive form has been modified to clarify the methods of dose verification to be used.

Therefore, to encourage prompt and comprehensive correction of violations and in recognition of the absence of previous escalated enforcement action, I have been authorized not to propose a civil penalty in this case. However, significant violations in the future could result in a civil penalty. In addition, issuance of the Severity Level III violation constitutes escalated enforcement action that may subject you to increased inspection effort.

Violation B of the Notice addresses the release of two patients who had received a therapeutic quantity of a radiopharmaceutical without determining whether the exposure to any other individual would likely exceed 5 millisieverts (0.5 rem). This violation is classified as a Severity Level IV.

The NRC has concluded that information regarding the reasons for the violations, and the corrective actions taken and planned to correct the violation and prevent recurrence are already adequately addressed in our inspection report and in your letter dated October 29, 1999. Therefore, you are not required to respond to this letter unless the description therein does not accurately reflect your corrective actions or your position. In that case, or if you choose to provide additional information, you should follow the instructions specified in the enclosed Notice.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter, the enclosed Notice, and your response if you choose to respond, will be placed in the NRC Public Document Room.

Sincerely,

J. E. Dyer
Regional Administrator

Docket No. 030-02028
License No. 21-03210-01

Enclosure: Notice of Violation

NOTICE OF VIOLATION

St. John Hospital and Medical Center
Detroit, Michigan

Docket No. 030-02028
License No. 21-03210-01
EA 99-289

During an NRC inspection conducted on October 19 through 23, 1999, violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," NUREG-1600, the violations are listed below:

A. 10 CFR 35.25(a)(2) requires, in part, that a licensee that permits the use of byproduct material by an individual under the supervision of an authorized user shall require the supervised individual to follow the written quality management procedures established by the licensee.

The licensee's quality management procedure, dated May 28, 1998, section (3.) "Verification of Radio-pharmaceutical Identity and Activity," requires that prior to issuance by the radiopharmacy, the identity and activity of each dose containing iodine-131 will be independently confirmed by two qualified individuals, one of whom is the person who will administer the dose. The procedure requires that all therapeutic doses will be independently evaluated by two qualified individuals to verify that the activity of the dose does not differ from the prescribed activity by more than ten percent.

Contrary to the above, two qualified individuals under the supervision of the licensee's authorized user did not verify that the activity of the dose administered did not differ from the prescribed activity. Specifically, on September 7, 1999, the activity of one dose containing 264 millicuries I-131 sodium iodide and another dose containing 296 millicuries were not independently evaluated by two qualified individuals to verify the activity of the doses were within ten percent of the written directive, resulting in a misadministration in one of the two cases. (01013)

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

B. 10 CFR 35.75 (a) requires, in part, that the licensee may authorize the release from its control any individual who has been administered radiopharmaceuticals if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 5 millisieverts (0.5 rem).

Contrary to the above, on September 7, 1999, the licensee released from its control two individuals who had been administered radiopharmaceuticals and did not determine if the total effective dose equivalent to any other individual from exposure to the released individual was not likely to exceed 5 millisieverts (0.5 rem). Specifically, the licensee released from its control two patients who had been administered 265 millicuries, and 297 millicuries iodine-131 respectively, without determining if the exposure to any other individuals was not likely to exceed 5 millisieverts (0.5 rem). (02014)

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

The NRC has concluded that information regarding the reasons for the violations, and the corrective actions taken and planned to correct the violation and prevent recurrence is already adequately addressed in our inspection report and in a letter from St. John Hospital and Medical Center dated October 29, 1999. However, you are required to respond to the provisions of 10 CFR 2.201 if the description therein does not accurately reflect your corrective actions or your position. In that case, or if you choose to respond, clearly mark your response as a "Reply to a Notice of Violation," and send it to the U. S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555, with a copy to the Regional Administrator, Region III, 801 Warrenville Road, Lisle, Illinois 60532-4351, within 30 days of the date of the letter transmitting this Notice of Violation.

If you contest this enforcement action, you should also provide a copy of your response, with the basis for your denial, to the Director, Office of Enforcement, United States Nuclear Regulatory Commission, Washington, D.C. 20555-0001.

If you choose to respond your response will be placed in the NRC Public Document Room (PDR). Therefore, to the extent possible, it should not include any personal, privacy, proprietary, or safeguards information so that it can be placed in the PDR without redaction. Under the authority of Section 182 of Act 42 U.S.C. 2232, any response shall be submitted under oath or affirmation.

In accordance with 10 CFR 19.11, you may be required to post this Notice within two working days.

Dated this 20th day of December 1999.

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

November 5, 1999

EA 99-245

Mr. Rick Monk
Vice President Information Services
St. Peter's Community Hospital
2475 Broadway
Helena, Montana 59601

SUBJECT: NRC INSPECTION REPORT 030-10917/99-01 AND NOTICE OF VIOLATION

Dear Mr. Monk:

On October 5, 1999, the NRC completed an inspection of your nuclear medicine program. The purpose of the inspection was to review activities conducted under Byproduct Materials License 25-12453-02. A preliminary exit briefing was conducted at the conclusion of the onsite portion of the inspection with you; Martie L. Moore, R.N., Risk Manager; and Dan Owens, Administrative Director of Radiology. Subsequently, on October 5, a final telephonic exit briefing was conducted with you and your staff.

During the October 5 exit briefing, we informed you that the NRC was considering escalated enforcement for a violation involving a failure to secure from unauthorized removal or access licensed material in unrestricted areas. Further, we informed you that the NRC had sufficient information regarding the violation and your corrective actions to make an enforcement decision without a predicisional enforcement conference or a written response. You and your staff agreed that no further relevant information was available. As such, the NRC is making its final enforcement decisions on that violation.

Based on the information developed during the inspection and the information provided by your staff during a telephone conversation on September 15, 1999, the NRC has determined that two violations of NRC requirements occurred. These violations are cited in the enclosed Notice of Violation (Notice). The first violation is the most significant and involved a failure to secure from unauthorized removal or access licensed materials that had been stored in unrestricted areas. Specifically, between January 1998 and August 1999, millicurie quantities of byproduct material were delivered to your facility and left unattended, and unsecured, in a public hallway adjoining the receiving department.

The inspectors determined that receiving personnel handled byproduct material shipments in the same manner as all other incoming packages and did not recognize the significance of not maintaining surveillance over radioactive materials. In this case, the actual risk to members of

the general public was limited in that: 1) the activity of each shipment was relatively low, 2) receipts of material were infrequent, and 3) dose rates at surface of each were low due to internal package shielding. However, the NRC considers the failure to control byproduct material to be of significant concern because of the potential for members of the public to receive unintended and possibly significant radiation exposures. Therefore, this violation has been categorized in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions" (Enforcement Policy), NUREG-1600, at Severity Level III.

In accordance with the Enforcement Policy, a base civil penalty in the amount of $5,500 is considered for a Severity Level III violation. Because your facility has not been the subject of escalated enforcement actions within the last two inspections, the NRC considered whether credit was warranted for *Corrective Action* in accordance with the civil penalty assessment process in Section VI.B.2 of the Enforcement Policy. Credit is warranted because your corrective actions were considered prompt and comprehensive. These corrective actions included modifying receipt practices and procedures to ensure licensed material was delivered to the nuclear medicine department where it would be controlled, and training receiving department personnel on the new receipt procedures.

Therefore, to encourage prompt and comprehensive correction of violations, I have been authorized, not to propose a civil penalty in this case. However, significant violations in the future could result in a civil penalty. In addition, issuance of this Severity Level III violation constitutes escalated enforcement action that may subject you to increased inspection effort.

The second violation involved the failure to apply for and receive a license amendment prior to establishing a new area of use within your facility, and it is categorized at Severity Level IV. The inspectors determined that from May 21, 1996, to September 3, 1999, byproduct material was routinely used in the stress lab for nuclear cardiology studies. This area had not been identified as an area of use in your license application or prior amendment requests.

The NRC has concluded that information regarding the reason for the violations, the corrective actions taken, and the date when full compliance will be achieved, is already adequately addressed on the docket in Inspection Report 030-10917/99-01 and the licensee's letter dated October 4, 1999. Therefore, you are not required to respond to this letter unless the description therein does not accurately reflect your corrective actions or your position. In that case, or if you choose to provide additional information, you should follow the instructions specified in the enclosed Notice.

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 (PDR).

Should you have any questions concerning this inspection or the enclosed report, please contact Ms. Linda Howell at (817) 860-8213 or Mr. Richard Leonardi, Jr. at (817) 860-8187.

Sincerely,

Ellis W. Merschoff
Regional Administrator

Docket No.: 030-10917
License No.: 25-12453-02

Enclosures:
1. Notice of Violation
2. NRC Inspection Report
   030-10907/99-01

cc w/enclosures:
Montana Radiation Control Program Director

ENCLOSURE 1

NOTICE OF VIOLATION

St. Peter's Community Hospital
Helena, Montana

Docket No. 030-10917
License No. 25-12453-02
EA 99-245

During an NRC inspection conducted September 3 through October 5, 1999, violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," NUREG-1600, the violations are listed below:

A. 10 CFR 20.1801 requires that the licensee secure from unauthorized removal or access licensed materials that are stored in controlled or unrestricted areas. 10 CFR 20.1802 requires that the licensee control and maintain constant surveillance of licensed material that is in a controlled or unrestricted area and that is not in storage. As defined in 10 CFR 20.1003, controlled area means an area, outside of a restricted area but inside the site boundary, access to which can be limited by the licensee for any reason; and unrestricted area means an area, access to which is neither limited nor controlled by the licensee.

Contrary to the above, on multiple dates between January 1998 and August 1999, the licensee did not secure from unauthorized removal or limit access to millicurie quantities of iodine-131 located in a hallway adjoining the receiving department, an unrestricted area, nor did the licensee control and maintain constant surveillance of this licensed material (01013).

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

B. 10 CFR 35.13(e) requires, in part, that a licensee apply for, and receive, a license amendment before adding or changing areas of use identified in the application or on the license.

Contrary to the above, from May 21, 1996 to September 3, 1999, the licensee used byproduct material in a cardiac stress lab, and the area was not identified as an area of use in the license application. The licensee added this area of use on May 21, 1996, and as of September 3, 1999, the licensee had failed to apply for and receive a license amendment authorizing this area of use.

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

The NRC has concluded that information regarding the reason for the violations, the corrective actions taken and planned to correct the violations and prevent recurrence, and the date when full compliance will be achieved, is already adequately addressed on the docket in Inspection Report 030-10917/99-01, and the licensee's letter dated October 4, 1999. However, you are required to submit a written statement or explanation pursuant to 10 CFR 2.201 if the description therein does not accurately reflect your corrective actions or your position. In that case, or if you choose to respond, clearly mark your response as a "Reply to a Notice of Violation," and send it to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555 with a copy to the Regional Administrator, Region IV, 611 Ryan

Plaza Drive, Suite 400, Arlington, Texas 76011, within 30 days of the date of the letter transmitting this Notice of Violation (Notice).

If you contest this enforcement action, you should also provide a copy of your response, with the basis for your denial, to the Director, Office of Enforcement, United States Nuclear Regulatory Commission, Washington, DC 20555-0001.

If you choose to respond, your response will be placed in the NRC Public Document Room (PDR). Therefore, to the extent possible, the response should not include any personal privacy, proprietary, or safeguards information so that it can be placed in the PDR without redaction. If personal privacy or proprietary information is necessary to provide an acceptable response, then please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request withholding of such material, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim of withholding (e.g., explain why the disclosure of information will create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.790(b) to support a request for withholding confidential commercial or financial information).

In accordance with 10 CFR 19.11, you may be required to post this Notice within two working days.

Dated this 5th day of November 1999

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

October 7, 1999

EA 99-175

Ms. Janet Ashe
Vice President for Business
and Administration
The Ohio State University
108 Bricker Hall
190 North Oval Mall
Columbus, OH 43212-1362

SUBJECT: NOTICE OF VIOLATION
(NRC Inspection Report 030-02640/99001(DNMS))

Dear Ms. Ashe:

This refers to the inspection conducted at The Ohio State University (OSU), Columbus, Ohio, campus on March 3 and 4, 1999, with continued review through October 1, 1999. The purpose of the inspection was to review the circumstances surrounding an administration to a human research subject of approximately 45 millicuries of Sn-117m and the subsequent release of said subject. One unresolved item was identified and documented in the inspection report sent to you by our letter dated March 24, 1999. After further review, the unresolved item was determined to be an apparent violation of NRC requirements and was discussed in our letter dated August 5, 1999. As stated in that letter, the apparent violation was being considered for escalated enforcement and you were given an opportunity to request a predecisional enforcement conference and/or respond to the apparent violation. You elected to provide a written response.

Based on the information developed during the inspection and the information that you provided in your letters dated August 23 and 31, 1999, the NRC has determined that a violation of NRC requirements occurred. The violation is cited in the enclosed Notice of Violation (Notice) and the circumstances surrounding it are described in detail in the subject inspection report. The violation involved the release of a human research subject without determining whether the quantity of radioactive material administered to the individual could potentially cause members of the public to receive radiation exposures greater than 500 millirem.

Between December 1998 and February 1999, OSU participated in a human research protocol to evaluate the effectiveness of Sn-117m on pain relief of patients with bone metastasis. The study was a double-blind comparative study of Sn-117m and Metastron (Sr-89). Four patients participated in the project; three were given Sn-117m, and one was administered Sr-89 Metastron. Only OSU's nuclear pharmacist and a nuclear medicine technologist were unblinded because they prepared the radiopharmaceuticals for administration. All proposals to perform human research experiments including this one are reviewed and approved by at least

three formal OSU committees such as the Institutional Review Board and the radiation safety staff. Nonetheless, OSU staff failed to recognize that the quantities of Sn-117m used required an evaluation to determine potential exposures to members of the public (patient family members included) to ensure compliance with 10 CFR Part 35. The NRC provides significant latitude to its broadscope licensees to oversee their own use of byproduct material. Incumbent upon such licensees is the responsibility to thoroughly review all proposed uses of byproduct material to ensure that potential radiological implications are identified and addressed prior to approving the application for use. The NRC concluded that OSU's failure to evaluate the possible dose to family members in this case resulted in a substantial potential for an exposure to the subject's spouse in excess of the regulatory limit of 500 millirem. It is fortunate that the subject's life style was such that the radiation dose to his spouse was only about 440 millirem. Therefore, this violation has been categorized in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions" (Enforcement Policy), NUREG-1600 at Severity Level III.

In accordance with the Enforcement Policy, a base civil penalty in the amount of $2,750 is considered for a Severity Level III violation. Because your facility has been the subject of escalated enforcement actions within the last two inspections,[1] the NRC considered whether credit was warranted for *Identification* and *Corrective Action* in accordance with the civil penalty assessment process in Section VI.B.2 of the Enforcement Policy. The NRC has determined that credit for Identification is warranted based on the Licensee's discovery of problem. Credit is also warranted for Corrective Action which included: (1) the patient questionnaire was revised to include questions relative to patient's living conditions; (2) the patient instruction was revised to include that close contact with family members should be minimized, focusing on time, distance, and shielding; and (3) the pertinent staff received training on 10 CFR 35.75 and Regulatory Guide 8.39.

Therefore, to encourage prompt identification and comprehensive correction of violations, I have been authorized not to propose a civil penalty in this case. However, significant violations in the future could result in a civil penalty.

The NRC has concluded that information regarding the reason for the violation, the corrective actions taken and planned to correct the violation and prevent recurrence and the date when full compliance was achieved is already adequately addressed on the docket in letters from Licensee dated August 23 and 31, 1999. Therefore, you are not required to respond to this letter unless the description therein does not accurately reflect your corrective actions or your position. In that case, or if you choose to provide additional information, you should follow the instructions specified in the enclosed Notice.

[1] A Severity Level III violation and a $13,000 civil penalty was issued on October 23, 1997 (EA 97-258).

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

Sincerely,

J. E. Dyer
Regional Administrator

Docket No. 030-02640
License No. 34-00293-02

Enclosure: Notice of Violation

cc w/encl: Robert Peterson, RSO

NOTICE OF VIOLATION

The Ohio State University
Columbus, Ohio

Docket No. 030-02640
License No. 34-00293-02
EA 99-175

During an NRC inspection conducted on March 3 and 4, 1999, with continued review through October 1, 1999, a violation of NRC requirements was identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," NUREG-1600, the violation is listed below:

> 10 CFR 35.75 (a) requires, in part, that the licensee may authorize the release from its control any individual who has been administered radiopharmaceuticals if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 5 millisieverts (0.5 rem).
>
> Contrary to the above, the licensee released from its control an individual who had been administered radiopharmaceuticals and did not determine if the total effective dose equivalent to any other individual from exposure to the released individual was not likely to exceed 5 millisieverts (0.5 rem). Specifically, on February 2, 1999 the licensee released from its control a human research subject who had been administered 45.43 millicuries of Sn-117m without determining if the exposure to any other individual was not likely to exceed 5 millisieverts (0.5 rem). (01013)

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

The NRC has concluded that information regarding the reason for the violation, the corrective actions taken and planned to correct the violation and prevent recurrence and the date when full compliance was achieved is already adequately addressed on the docket in letters from Licensee dated August 23 and 31, 1999. However, you are required to submit a written statement or explanation pursuant to 10 CFR 2.201 if the description therein does not accurately reflect your corrective actions or your position. In that case, or if you choose to respond, clearly mark your response as a "Reply to a Notice of Violation," and send it to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555 with a copy to the Regional Administrator, Region III, within 30 days of the date of the letter transmitting this Notice of Violation (Notice).

If you contest this enforcement action, you should also provide a copy of your response, with the basis for your denial, to the Director, Office of Enforcement, United States Nuclear Regulatory Commission, Washington, DC 20555-0001.

If you choose to respond, your response will be placed in the NRC Public Document Room (PDR). Therefore, to the extent possible, the response should not include any personal privacy, proprietary, or safeguards information so that it can be placed in the PDR without redaction.

In accordance with 10 CFR 19.11, you may be required to post this Notice within two working days.

Dated this 7th day of October 1999

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION II
SAM NUNN ATLANTA FEDERAL CENTER
61 FORSYTH STREET, SW, SUITE 23T85
ATLANTA, GEORGIA 30303-8931

July 8, 1999

EA 99-134

Triad Engineering, Inc.
ATTN: Mr. Dennis C. Chambers, P.E., Sr. V.P.
Corporate Radiation Safety Officer
P.O. Box 889
Morgantown, West Virginia 26505

SUBJECT: NOTICE OF VIOLATION
(NRC INSPECTION REPORT NO. 47-17742-01/99-01)

Dear Mr. Chambers:

This refers to the inspection conducted on May 11, 1999, at the Winchester, Virginia facility. The purpose of the inspection was to review the circumstances surrounding a portable moisture/density gauge that was stolen from a pick-up truck at a construction site located in Fairfax County, Springfield, Virginia. Triad Engineering, Inc. reported the missing licensed material to the NRC on April 29, 1999. The pick-up truck and the portable moisture/density gauge were found by local police on May 1, 1999. The results of the inspection were formally transmitted to you by letter dated June 2, 1999. That letter also provided you the opportunity to respond to the apparent violation or request a predecisional enforcement conference. By letter dated June 28, 1999, you responded to the apparent violation and addressed the root causes and your corrective actions to prevent recurrence. We have reviewed the inspection results and the additional information you provided and have concluded that sufficient information is available to determine the appropriate enforcement action in this matter.

Based on the information developed during the inspection and the information that was provided in your June 28, 1999, response, the NRC has determined that a violation of NRC requirements occurred. The violation is cited in the enclosed Notice of Violation (Notice) and the circumstances surrounding it are described in detail in the subject inspection report. The violation involves the failure to secure from unauthorized removal or limit access to licensed material, and the failure to control and maintain constant surveillance of licensed material stored in the bed of a pick-up truck at a temporary jobsite, as required by 10 CFR 20.1801 and 10 CFR 20.1802.

The portable moisture/density gauge, contained 7.3 millicuries of cesium 137 and 40 millicuries of americium 241 (Am-241). The 40 millicuries of Am-241 was greater than 1000 times the limit set forth in 10 CFR Part 20, Appendix C. Accordingly, the failure to secure, maintain constant surveillance and restrict access to this licensed material is of concern because members of the public or other personnel could have been exposed to radioactive materials. Therefore, this violation has been caterogized in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions" (Enforcement Policy), NUREG-1600 at Severity Level III.

In accordance with the Enforcement Policy, a base civil penalty in the amount of $2,250 is considered for a Severity Level III violation. Because your facility has not been the subject of escalated enforcement actions within the last two inspections, the NRC considered whether credit was warranted for *Corrective Action* in accordance with the civil penalty assessment process in Section VI.B.2 of the Enforcement Policy. Your corrective actions included

(1) immediately notifying the local police and the NRC Operations Center after the incident occurred, (2) publishing a notice to the public announcing the theft of the moisture/density gauge, (3) issuing a memorandum to your staff emphasizing that vehicle and gauge keys shall not be left unattended in the vehicles and shall be under constant surveillance of employees at all times, and (4) discussing the event and the circumstances relevant to the event to all company employees. Based on the above, the NRC determined that credit was warranted for corrective actions.

Therefore, to encourage prompt identification and comprehensive correction of violations and in recognition of the absence of previous escalated enforcement, I have been authorized not to propose a civil penalty in this case. However, significant violations in the future could result in a civil penalty. In addition, issuance of this Severity Level III violation constitutes escalated enforcement action that may subject you to increased inspection effort.

The NRC has concluded that information regarding the reasons for the violation, the corrective actions taken and planned to correct the violation and prevent recurrence, and the dates when full compliance was achieved are addressed on the docket in Inspection Report No. 47-11741-01/99-01 and in your June 28, 1999, letter. Therefore, you are not required to respond to this letter unless the description therein does not adequately reflect your corrective actions or your position. In that case, or if you choose to provide additional information, you should follow the instructions specified in the enclosed Notice.

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

Sincerely,

for Luis A. Reyes
Regional Administrator

Docket No. 030-13255
License No. 47-17742-01

Enclosure: Notice of Violation

cc w/encl:
Commonwealth of Virginia
State of West Virginia

NOTICE OF VIOLATION

Triad Engineering, Inc.
Morgantown, West Virginia

Docket No. 030-13255
License No. 47-17742-01
EA 99-134

During an NRC special inspection conducted on May 11, 1999, a violation of NRC requirements was identified. In accordance with the "General Statement of Policy and Procedures for NRC Enforcement Actions," NUREG-1600, the violation is listed below:

> 10 CFR 20.1801 requires that licensees secure from unauthorized removal or access licensed materials that are stored in controlled or unrestricted areas. 10 CFR 20.1802 further requires that licensees control and maintain constant surveillance of licensed material that is in a controlled or unrestricted area and that is not in storage.
>
> 10 CFR 20.1003, defines the term "controlled area" as an area, outside of a restricted area but inside the site boundary, access to which can be limited by the licensee for any reason. 10 CFR 20.1003, defines the term "unrestricted area" as an area, access to which is neither limited nor controlled by the license.
>
> Contrary to the above, the licensee failed to secure from unauthorized removal or limit access to licensed material that was located in an unrestricted area. Specifically, on April 29, 1999, the licensee did not secure a portable moisture/density gauge containing 7.3 millicuries of cesium 137 and 40 millicuries of americium 241, in that, the gauge and gauge keys were stolen along with the pick-up truck as a result of the pick-up truck keys being left in the ignition of the unlocked and unattended vehicle. (01013)

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

The NRC has concluded that information regarding the reason for the violation, the corrective actions taken and planned to correct the violation and prevent recurrence, and the date when full compliance was achieved is already adequately addressed on the docket in Inspection Report No. 47-17742-01/99-01 and in Triad Engineering, Inc.'s June 28, 1999, letter. However, you are required to submit a written statement or explanation pursuant to 10 CFR 2.201 if the description therein does not accurately reflect your corrective actions or your position. In that case, or if you chose to respond, clearly mark your response as a "Reply to a Notice of Violation," and send it 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).

If you contest this enforcement action, you should also provide a copy of your response, with the basis for your denial, to the Director, Office of Enforcement, United States Nuclear Regulatory Commission, Washington, DC 20555-0001.

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

If you choose to respond, your response will be placed in the NRC Public Document Room (PDR). Therefore, to the extent possible, the response should not include any personal privacy, proprietary, or safeguards information so that it can be placed in the PDR without redaction.

Enclosure

In accordance with 10 CFR 19.11, you may be required to post this Notice within two working days.

Dated this 8th day of July 1999
at Atlanta, Georgia

NRC FORM 335
(2-89)
NRCM 1102,
3201, 3202

U.S. NUCLEAR REGULATORY COMMISSION

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Same as above

10. SUPPLEMENTARY NOTES

11. ABSTRACT *(200 words or less)*

This compilation summarizes significant enforcement actions that have been reso lved during the period (July - December 1999) and includes copies of letters, Notices of Violation and Orders sent by t he Nuclear Regulatory Commission to material licensees with respect to these enforcement actions. It is anticipated that th e information in this publication will be widely disseminated to managers and employees engaged in activities licensed by the NR C, so that actions can be taken to improve safety by avoiding future violations similar to those described in this publication.

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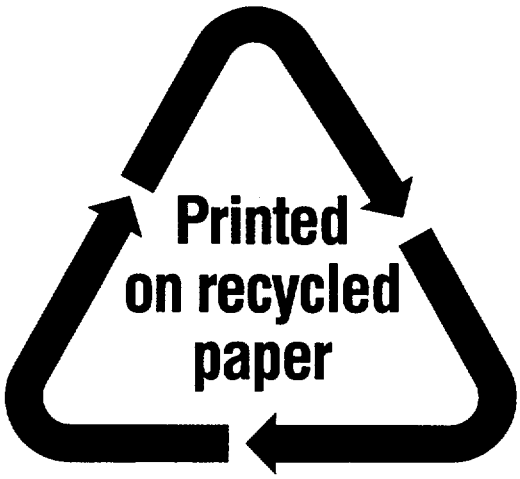

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