NUREG-0940 Vol. 15, No. 2, Part 3 Material Licensees

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NUREG-0940 Vol. 15, No. 2, Part 3 Material Licensees

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# Enforcement Actions: Significant Actions Resolved Material Licensees

Semiannual Progress Report July – December 1996

**U.S. Nuclear Regulatory Commission** 

Office of Enforcement





9705140378 970430 PDR NUREG 0940 R PDR

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NUREG-0940 Vol. 15, No. 2, Part 3 Material Licensees

# Enforcement Actions: Significant Actions Resolved Material Licensees

Semiannual Progress Report July – December 1996

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



# ABSTRACT

This compilation summarizes significant enforcement actions that have been resolved during the period (July - December 1996) 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.

# CONTENTS

																								Pi	30	16	4	
ABSTRACT																												
INTRODUCTION. SUMMARIES																												

# MATERIAL LICENSEES

# A. CIVIL PENALTIES AND ORDERS

Applied Health Pnysics, Inc., Bethel Park, Pennsylvania EA 96-009
Applied Health Physics, Inc., Bethel Park, Pennsylvania EA 96-353
Canspec Materials Testing, Inc., Middlesex, New Jersey EA 95-163
Community Hospital, Torrington, Wyomirg EA 96-056
CTI, Alaska, Inc., Anchorage, Alaska Supplement VI, EA 96-232A-53
Diagnostic Reagents, Inc., Dearborn, Michigan EA 96-140
Eastern Testing and Inspection, Inc., Thorofare, New Jersey EA 96-085
Jose L. Fernandez, San Juan, Puerto Rico EA 96-154
Gamma Tech Industries, Inc., San Diego, California EA 96-093
GCME, Inc., DePere, Wisconsin EAs 96-256 and 96-377
GRD Steel Corporation, Monongahela, Pennsylvaniz Ea 96-302
HNU Systems, Inc., Newton Highlands, Massachusetts EA 96-234
Industrial Marine Testing Labs, Inc., San Diego, California EA 96-065
Middle Monongahela Industrial Development Association Donora, Pennsylvania EA 96-288

NUREG-0940, PART III

	NDT Services, Inc., Caguas, Puerto Rico EA 94-029
	Nuclear Fuel Services, Inc., Erwin, Tennessee EA 96-213
	Roy Sadovsky, D.V.M., Floral Park, New York EA 96-349
	Syncor International Corporation, Chatsworth, California EA 96-104
	Temple University, Philadelphia, Pennsylvania EA 95-152
	Testco, Inc., Greensboro, North Carolina EA 95-101
	The Dial Corporation, London, Ohio EA 96-041
	University of Oklahoma, Oklahoma City, Oklahoma EA 96-049
Β.	SEVERITY LEVEL I. II. AND III VIOLATIONS, NO CIVIL PENALTY
	Abington Memorial Hospital, Abington, Pennsylvania EA 96-186B-1
	Anderson Columbia Construction, Inc., Lake City, Florida EA 96-314B-6
	EquiMed, Inc., Lehighton, Pennsylvania EA 96-247B-10
	Evart Products, Evart, Michigan EA 96-254B-15
	Geisinger Medical Center, Danville, Pennsylvania EA 96-189B-19
	Lucent Technologies, Inc., Lee's Summit, Missouri EA 96-233B-25
	New Britain General Hospital, New Britain, Connecticut EA 96-396B-29
	New England Medical Center, Boston, Massachusetts EA 96-398B-34
	Niblock Excavating, Inc., Bristol, Indiana EA 96-298B-38
	Pensacola Testing Laboratories, Inc., Pensacola, Florida EA 96-315B-44
NUREG	-0940, PART III vi

Raytheon Engineers & Constructors, Inc., Honolulu, Hawaii EA 96-205B-48
South Haven Community Hospital, South Haven, Michigan EA 96-099B-53
The Pennsylvania State University, University Park, Pennsylvania EA 96-499B-58
Universal Imaging, Inc., Taylor, Michigan EA 96-157B-64
University of Connecticut Health Center, Farmington, Connecticut EA 96-454B-70
U.S. Engineering Labs, Inc., Rahway, New Jersey EA 96-245B-75
Wilcox Associates, Cadillac, Michigan EA 96-257

# ENFORCEMENT ACTIONS: SIGNIFICANT ACTIONS RESOLVED MATERIAL LICENSEES

July - December 1996

#### 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 1996. 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 Nuclear Materials Safety, Safeguards, and Operations (DEDS), 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 1996 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		Transportation
Supplement		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 Civil Penalties and Orders

Applied Health Physics, Inc., Bethel Park, Pennsylvania EA 96-009

> A Confirmatory Order (Effective Immediately) was issued March 29, 1996. The action was based on three violations of NRC requirements involving: (1) failure to limit possession of byproduct material to those authorized, as required by 10 CFR 30.3; (?) failure to limit possession of special nuclear materia? to those authorized, as required by 10 CFR 70.19; and (3) possession of radioactive waste for a period exceeding 180 days, as required by a license condition, a repeat violation.

Applied Health Physics, Inc., Bethel Park, Pennsylvania EA 96-353

> A Confirmatory Order (Effective Immediately) was issued September 27, 1996. The action was based on: (1) information learned by the NRC that the U.S. Internal Revenue Service seized AHP's bank accounts, thereby preventing disposal of radioactive waste possessed by AHP; and (2) AHP's consent to the issuance of this Order and agreement to waive its rights for a hearing.

Canspec Materials Testing, Inc., Middlesex, New Jersey Supplements IV and VI, EA 95-163

> A Notice of Violation and Proposed Imposition of Civil Penalty in the amount of \$5,000 was issued September 13, 1995, to emphasize the importance of (1) aggressive oversight of the radiation safety program so as to ensure that licensed activities are conducted safely, and violations, when they exist, are identified and corrected promptly, and (2) the submittal of complete and accurate information to the NRC. The violations included failure to: (1) perform quarterly audits of radiographers and assistants, (2) properly secure licensed material (while in storage at the Middlesex, NJ facility), (3) properly post a high radiation area created during the performance of radiography at the Marcus Hook jobsite, (4) calibrate alarm ratemeters at the required frequency, (5) calibrate survey meters at the required frequency, (6) calibrate pocket dosimeters at the required frequency, and (7) maintain training records for radiographers and radiographers' assistants, and (8) the submittal of inaccurate information to the NRC. The licensee responded in two letters dated October 11, 1995 admitting to all of the violations but one and requested mitigation of the civil penalty. An agreement for a payment plan was issued on December 6, 1995. However, licensee failed to sign the agreement and an Order Imposing Civil Monetary Penalty in the amount of \$5,000 was issued February 2, 1996. On March 20, 1996, the NRC was notified by the licensee's attorney that the licensee had filed for bankruptcy, that no funds were available, and that the licensee had terminated all business activities.

Community Hospital, Torrington, Wyoming Supplement VI, EA 96-056

A Notice of Violation and Proposed Imposition of Civil Penalty in the amount of \$2,500 was issued June 12, 1996, to emphasize the significance of a deliberate violation of NRC requirements and to emphasize the importance of licensee management responsibility for ensuring that licersed activities are conducted in accordance with applicable requirements. The action was based on a problem concerning two sodium iodide I-131 misadministrations and failure to maintain complete and accurate records pertaining the misadministrations. The licensee responded and paid the civil penalty on July 5, 1996.

CTI Alaska, Inc., Anchorage, Alaska Supplement VI, EA 96-232

> A Notice of Violation and Proposed Imposition of Civil Penaltics in the amount of \$13,000 was issued October 31, 1996, to emphasize the importance of compliance with radiation safety procedures, the unacceptability of willful violations, and prompt identification of violations. The action was based on a violation involving a failure to (1) perform an adequate survey of a radiographic device, (2) immediately notify the licensee's radiation safety officer about the potential malfunction of a radiographic device and off-scale discharge of a pocket dosimeter, (3) immediately send for processing a radiographer's film badge after the pocket dosimeter assigned to him discharged beyond its range, and (4) post a high radiation area and failure to maintain complete and accurate records regarding the posting of such areas. The licensee responded and paid the civil penalty on November 26, 1996

Diagnostic Reagents, Inc., Dearborn, Michigan Supplements VI and VII, EA 96-140

> A Notice of Violation and Proposed Imposition of Civil Penalty in the amount of \$1,000 was issued August 5, 1996, to emphasize that willful violations are not acceptable, and violations must be identified and corrected as promptly as possible. The action was based on deliberate possession of licensed material at a street address not authorized on the license and alteration of the street address stated on the license as the authorized place of use. The licensee responded on August 15, 1996, requesting mitigation and contested the amount of the civil penalty. Subsequently, by letters dated October 3 and 10, 1996, the licensee requested termination of the license. On November 4, 1996, the license was terminated and the proposed civil penalty was withdrawn.

Eastern Testing and Inspection, Inc., Thorofare, New Jersey EA 96-085

An Order Suspending Licenses (Effective Immediately) was issued March 29, 1996 based on (1) the results of an investigation which revealed significant willful violations of NRC requirements, including certifying an individual as a radiographer when the individual was not qualified and trained, (2) the results of two inspections, which revealed numerous other violations, and (3) the poor enforcement history of the licensee.

NUREG-0940, PART III

On April 16, 1996, the licensee requested a hearing. A Settlement was agreed to on June 6, 1996. The licensee agreed that prior to resuming NRC-licensed activities an independent auditor would be hired and that the President and current Radiation Safety Officer would not be involved in the supervision of NRC-licensed activities. The NRC agreed to withdraw the Order of March 29, 1996.

Dr. Jose L. Fernandez, San Juan, Puerto Rico EA 96-154

> An Order Modifying NRC Materials License (Effective Immediately) was issued October 21, 1996, based on the results of two inspections, which revealed numerous violations, including the failure to: (1) establish and maintain a quality management program which resulted in at least 104 Strontium-90 misadministrations, (2) maintain the security of byproduct material, (3) perform quarterly physical inventories of byproduct material, (4) test sealed sources for leakage at six-month intervals, (5) notify individuals of a misadministration within 24-hours of discovery, (6) provide written reports to individuals within 15 days of discovery of misadministration, (7) maintain misadministration records, and (8) amend its license prior to permitting ar individual to work as an authorized user.

Gamma Tech Industries, Inc., San Diego, California Supplement VI, EA 96-093

> A Notice of Violation and Proposed Imposition of Civil Penalty in the amount of \$1,500 was issued June 6, 1996, to emphasize the significance of making a deliberate decision to violate an NRC requirement and the importance of complying with all NRC requirements in the future. The action was based on a violation involving an Agreement State Licensee performing radiography in exclusive federal jurisdiction without obtaining an NRC license or filing NRC form 241. Gamma Tech Industries responder and paid the civil penalty on June 28, 1996.

GCME, Inc., DePere, Wisconsin Supplements IV, V, and VI, EA 96-256 and EA 96-377

> A Notice of Violation and Proposed Imposition of Civil Penalty in the amount of \$5,000 and a Demand for Information was issued October 4, 1996, to emphasize the need to immediately identify violations, to assure that the root cause of each violation is fully identified and understood, and to ensure that corrective actions are prompt and comprehensive to avoid repetition of a violation. The action was based on failure to: (1) ensure that users of byproduct material were issued film badges, (2) secure licensed material from unauthorized removal, (3) provide training to users of byproduct material and (4) transport licensed material in accordance with DOT requirements. The licensee responded November 12, 1996 and paid the civil penalty on December 2, 1996.

GRD Steel Corporation, Monongahela, Pennsylvania EA 96-302

> An Order Suspending License (Immediately Effective), and Requiring Transfer of Licensed Material, and Demand for Information was issued September 13, 1996. The action was based on an NRC inspection that identified that a foreclosure on the facility which housed two licensed gauges had been sold to Monongahela Industrial Development Association, a nor-licensee.

HNU Systems, Inc., Newton Highlands, Massachusetts EA 96-234

A Confirmatory Order Modifying License (Effective Immediately) was issued August 22, 1996. The Order was based on the findings of an inspection in which numerous violations were identified. These included the failure to: (1) notify the NRC that the RSO listed on the license had been laid off and had not been replaced, (2) conduct a physical inventory of radioactive materials, (3) conduct leak tests of sealed sources at the required six months intervals, (4) calibrate survey instruments at the required six month interval, (5) perform monthly surveys, (6) monitor exposures of individuals to radiation and radioactive material, (7) review the radiation protection program content and implementation at least annually, (8) report to the NRC any transfers of generally licensed devices, (9) maintain radiation safety record notebook, and (10) provide training to licensee staff. The licensee signed a written consent in which the licensee agreed to the issuance of the Order and waived its right for a hearing.

Industrial Marine Testing Labs, Inc., San Diego, California Supplement VI, EA 96-065

A Notice of Violation and Proposed Imposition of Civil Penalty in the amount of \$1,500 was issued June 6, 1996 to emphasize the significance of making a deliberate decision to violate an NRC requirement and the importance of complying with all NRC requirements in the future. The action was based on a violation involving an Agreement State licensee performing radiography in exclusive federal jurisdiction without obtaining an NRC license or filing NRC form 241. Industrial Marine Testing responded on July 1, 1996 acknowledging the violation and requesting mitigation. After consideration of their response, an Order Imposing Civil Monetary Penalty in the amount of \$1,500 was issued July 31, 1996. Industrial Marine Testing paid the civil penalty on August 27, 1996.

Middle Monongahela Industrial Development Association, Inc., (MIDA Donora, Pennsylvania, EA 96-288

A Confirmatory Order was issued August 12, 1996. The action was based on the results of communications between the NRC and the former RSO of GRD Steel who indicated that MIDA now owns the building that housed the GRD Steel operation. MIDA purchased the building a foreclosure sale and was in possession of two gauges containing highly radioactive byproduct material, cobalt-60, without an NRC license. The Order required that

NUREG-0940, PART III

MIDA: (1) assure that it maintain control of the gauges and that the gauges remain locked at all times, (2) request additional patrols from the local police in the area, until such time as the material is transferred to an authorized recipient, (3) perform a daily walk through of the plant to ensure that the gauges had not been tampered with, and (4) in the absence of obtaining an NRC-license, transfer the gauges back to the manufacturer, or to another authorized recipient.

NDT Services, Inc., Caguas, Puerto Rico Supplements VI and VII, EA 94-029

A Notice of Violation and Proposed Imposition of Civil Penalties in the amount of \$15,000 was issued July 16, 1996 to emphasize the importance of compliance with NRC requirements and the necessity for complete and accurate information. The action was based on (1) a violation involving deliberate failures to train radiographers and to provide complete and accurate information to the NRC, and (2) a violation involving a failure to wear alarm ratemeters. The licensee responded and paid the civil penalties on August 15, 1996.

Nuclear Fuel Services, Inc., Erwin, Tennessee Supplement VI, EA 96-213

> A Notice of Violation and Proposed Imposition of Civil Penalty in the amount of \$12,500 was issued August 21, 1996 to emphasize the importance of effective management and control of equipment and systems important to safety. The action was based on the failure to: (1) implement and maintain an adequate configuration control system, (2) follow written safety procedures for special nuclear material operations, (3) adequately establish written procedures, and (4) provide adequate training to the licensee's incinerator operators. The licensee responded and paid the civil penalty on September 20, 1996.

Roy Sadovsky, D.V.M., Floral Park, New York EA 96-349

> An Order Suspending License (Effective Immediately) and Demand for Information was issued September 13, 1996. The action was based on violations involving: (1) an apparent willful use of byproduct material at an unauthorized location, (2) failure to secure from unauthorized removal or access licensed material, (3) transportation of licensed material without complying with the applicable requirements of the U.S. DOT, (4) failure to provide individual monitoring devices to personnel in at least one instance, (5) conduct of operations with material, so as to cause dose rates in an unrestricted area to exceed 2 millirem in any one hour.

Syncor International Corporation, Chatsworth, California Supplement VI, EA 96-104

A Notice of Violation and Proposed Imposition of Civil Penalty in the amount of \$2,500 was issued July 25, 1996 to emphasize the significance of deliberate violations and the importance of aggressive action to prevent deliberate misuse of licensed material. The action was based on

NUREG-0940, PART III

a violation involving the deliberate misuse of licensed material. The lock on a locker used by a customer service assistant at the licensee's Pittsburgh facility was deliberately contaminated with technetium-99m by another Syncor employee. The licensee responded and paid the civil penalty on August 23, 1996.

Temple University, Philadelphia, Pennsylvania Supplement VII, EA 95-152

> A Notice of Violation and Proposed Imposition of Civil Penalty in the amount of \$8,000 was issued December 15, 1995, to emphasize the importance of continuously assuring a work environment that is free of any harassment, intimidation, or discrimination against those who raise safety concerns. The action was based on the results of a DOL Order and Remand issued by the Department of Labor. According to the DOL findings, a former employee hired to become the RSO had raised safety concerns and was given a threat and warning of termination. The termination occurred 14 days after the warning. The licensee responded January 17, 1996 and paid the civil penalty July 19, 1996.

Testco, Inc., Greensboro, North Carolina Supplements VI and VII, EA 95-101

> A Notice of Violation and Proposed Imposition of Civil Penalty in the amount of \$5,000 was issued October 31, 1995, to emphasize the importance of strict adherence to all regulatory requirements and that deliberate failures to comply with NRC regulations cannot be tolerated. The action was based on failure to file an NRC Form 241 before conducting operations in NRC jurisdiction. Testco, Inc. replied in letters dated December 20 and 21, 1995, requesting a hearing. The NRC replied December 28, 1996, indicating that a request for a hearing was premature and requesting that Testco provide additional documentation. An Order Imposing Civil Monetary Penalty in the amount of \$5,000 was issued March 19, 1996 when Testco did not comply with the request. A settlement agreement was signed September 16, 1996 and approved by the Licensing Board October 1, 1996, agreeing that Testco would pay \$1,000. The company paid the penalty on October 29, 1996.

The Dial Corporation, London, Ohio Supplement VI, EA 96-041

> A Notice of Violation and Proposed Imposition of Civil Penalty in the amount of \$2,500 was issued June 18, 1996, to emphasize the need to strictly control licensed material. The action was based on a violation involving the loss of control of a gauge containing byproduct material. The licensee responded in letters dated July 16, 1996, admitting the violation but requesting mitigation. After consideration of the licensee's responses, an Order Imposing Civil Monetary Penalty in the amount of \$2,500 was issued October 31, 1996. The licensee paid the civil penalty on November 15, 1996.

University of Oklahoma, Oklahoma City, Oklahoma Supplement IV, EA 96-049

> A Notice of Violation and Proposed Imposition of Civil Penalty in the amount of \$2,500 was issued June 17, 1996, to emphasize the significance of failing to secure radioactive material left unattended in the public domain, as well as the importance of identifying such problems, and ensuring that the employees are complying with all NRC requirements. The action was based on a violation involving a licensee driver who left radiopharmaceuticals unattended in an unlocked vehicle during a delivery. The licensee responded and paid the civil penalty on July 12, 1996.

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

Abington Memorial Hospital, Abington, Pennsylvania Supplement IV, EA 96-186

> A Notice of Violation was issued July 12, 1996 involving the failure to conduct, for a period of time (possibly up to 20 years), a quarterly physical inventory of a particular brachytherapy source. A civil penalty was not issued because the licensee had no previous escalated enforcement actions and the licensee took comprehensive and corrective actions which included: (1) performing a complete inventory of all brachytherapy sources, (2) color coding all brachytherapy sources, (3) obtaining source certificates for all brachytherapy sources in the licensee's possession, and (4) requiring the RSO and physicist, upon termination, to turn over all required documentation to assure that all source certificates and inventories are retained by the hospital.

Anderson Columbia Construction, Inc., Lake City, Florida Supplement VI, EA 96-314

> A Notice of Violation was issued October 2, 1996 based on a violation involving the use of a moisture density gauge at locations within NRC's jurisdiction without obtaining a license or filing a form-241. A civil penalty was not issued because the company had no previous escalated actions and took comprehensive and corrective actions which included a request for the appropriate forms from NRC, and directing the RSO to contact the appropriate federal official in the event that future work is performed on federal property.

Equimed, Inc., Lehighton, Pennsylvania Supplement VI, EA 96-247

> A Notice of Violation was issued November 7, 1996 based on violations involving the failure to follow the Quality Management Program, which caused two patient misadministrations, and the failure to submit written notification of the misadministrations. A civil penalty was not issued because the licensee had not been the subject of escalated enforcement action in the past two years and the licensee took comprehensive corrective actions which included: (1) initiating a new requirement for

all HDR treatments requiring the authorized user and authorized physicist to remove the pre-treatment printout from the treatment console, review the parameters input and initial the printout before initiating treatment; and (2) reviewing the QMP in detail to identify other weaknesses.

Evart Products, Evart, Michigan Supplements IV and VI, EA 96-254

> A Notice of Violation was issued September 3, 1996 based on violations involving the failure to properly transfer or dispose of generally licensed material and the failure to notify the NRC within 30 days of the discovery that licensed material was lost, stolen or missing. A civil penalty was not issued because the licensee had not been the subject of escalated enforcement action in the past two years and the licensee took comprehensive corrective actions. These included the accounting for devices from shift-to-shift, storing the devices in a locked container, training supervisors about the control of licensed material, and developing a safety manual that included discussions on radiation safety.

Geisinger Medical Center, Danville, Pennsylvania Supplements IV and VII, EA 96-189

> A Notice of Violation was issued July 3, 1996 based on violations involving: (1) two examples of failure to maintain complete and accurate information concerning the amount of radioactive material in a container, as well as whether a survey had been done prior to disposal of certain waste, (2) two examples of failure to perform required radiological surveys at the facility, and (3) failure to follow required procedures for ordering iodine-131. A civil penalty was not issued because credit was warranted for identification and corrective actions. The corrective actions included: (1) immediate removal from the nuclear medicine department those individuals responsible for inaccurate records, (2) establishing a new disciplinary department, (3) revision of decay-in-storage form, (4) retention of a new Chairman of Radiology, and (5) establishment of a multi-disciplinary investigation team to review incidents at the facility.

Lucent Technologies, Inc., Lee's Summit, Missouri Supplements VI and VII, EA 96-233

> A Motice of Violation was issued November 1, 1996 based on violations involving providing the NRC with incomplete and inaccurate information on Form-241 and retaining NRC-licensed material for more than two years after the license had been terminated. A civil penalty was not proposed because the licensee shipped all remaining licensed material for disposal.

New Britain General Hospital, New Britain, Connecticut Supplement VII, EA 96-396

A Notice of Violation was issued December 20, 1996 based on a violation involving false entries into the licensee's dose calibrator constancy

NUREG-0940, PART III

record. A civil penalty was not proposed because the licensee identified the violation and took comprehensive corrective actions.

New England Medical Center, Boston, Massachusetts Supplements IV and V, EA 96-398

> A Notice of Violation was issued November 13, 1996 based on violations involving the licensee's failure to assure that a package of radioactive material for shipment complied with the NRC regulations, and the failure to perform an adequate survey to assure compliance with exposure limits for members of the public. A civil penalty was not proposed because the licensee had not had an escalated enforcement action in the past two years and also took prompt and comprehensive corrective actions.

Niblock Excavating, Inc., Bristol, Indiana Supplement VI, EA 96-298

> A Notice of Violation was issued September 25, 1996 based on violations involving: (1) the use of NRC-licensed material at facilities other than those listed on the license, (2) the use of licensed material not designated by the licensee's RSO, (3) failure to test or survey for leakage or contamination material being transferred to another person, (4) failure to conduct inventory every six months, and (5) the transportation of a gauge containing licensed material outside the confines of the plant without shipping papers. A civil penalty was not proposed because the licensee had not had an escalated enforcement action in the past two years and also took extensive corrective actions.

Pensacola Testing Laboratories, Inc., Pensacola, Florida Supplement VI, EA 96-315

A Notice of Violation was issued October 23, 1996 based on the company's use of moisture density gauges at locations within NRC's jurisdiction without first obtaining a specific NRC license or filing Form-241. A civil penalty was not proposed because the company had not had an escalated enforcement action in the past two years and also took prompt and comprehensive corrective actions.

Raytheon Engineers and Constructors, Inc., Honolulu, Hawaii Supplement IV, EA 96-205

A Notice of Violation was issued September 20, 1996 based on a violation involving a source being stored and used in an unrestricted area and the source was not secured from unauthorized removal nor tended under constant surveillance and immediate control of the licensee. A civil penalty was not proposed because the licensee had not had an escalated enforcement action in the past two years and also took extensive corrective actions.

South Haven Community Hospital, South Haven, Michigan Supplements VI and VII, EA 96-099

A Notice in Violation was issued July 17, 1996 based on violations involving receipt of material at locations other than those listed on

NUREG-0940. PART III

the license, not measuring dosages of technetium-99m prior to administering the doses to patients, and inaccurate records. A civil penalty was not issued because the licensee identified the violation and prompt and corrective actions were taken which included removing the nuclear medicine technologist from NRC-licensed activities at the hospital, ceasing to transport radioactive materials to remote sites, and instructing the remaining nuclear medicine technologist about adherence to NRC license conditions.

The Perinsylvania State University, University Park, Pennsylvania Supplements IV and VI, EA 96-499

A Notice of Violation was issued December 30, 1996 based on violations involving failure to secure licensed material or limit access to material. A civil penalty was not proposed because the licensee had not been subject to escalated enforcement action in the past two years and the licensee took comprehensive and corrective actions which included among others: (1) sending a written notice to all supervisors of idioisotope laboratories informing them that 10 CFR 20.1801 and 1802 will be used to ensure security of radioactive material, (2) evaluating compliance, (3) training the health physics staff on requirements, and (4) security audits of laboratories.

Universal Imaging, Inc., Taylor, Michigan Supplement III, EA 96-157

> A Notice of Violation was issued August 2, 1996 based on violations that resulted in a misadministration which occurred when the wrong pharmaceutical was administered to the patient. The violation involved lack of a system for ordering and receiving radioactive material; and problems in verifying that material was received, providing required training, and providing a timely and complete report of the event. A civil penalty was not issued because the licensee had not been the subject to escalated enforcement action in the past two years and the licensee took comprehensive and corrective actions.

University of Connecticut Health Center, Farmington, Connecticut Supplement VI, EA 96-454

A Notice of Violation was issued November 29, 1996 based on violations involving the failure to secure licensed material at the facility and as a result material was removed by an unknown person from the stock material located in an unlocked freezer. A civil penalty was not proposed because the licensee had not been the subject of escalated enforcement action in the past two years and the licensee took prompt and comprehensive corrective actions.

U.S. Engineering Labs, Incorporated, Rahway, New Jersey Supplement IV, EA 96-245

A Notice of Violation was issued August 5, 1996 based on violations involving the failure to maintain control of licensed material not in

NUREG-0940, PART III

storage, and the use of licensed material by unauthorized users. A civil penalty was not proposed because the licensee had not been the subject of escalated enforcement action in the past two years and the licensee took prompt and comprehensive corrective actions.

Wilcox Associates, Cadillac, Michigan Supplement IV, EA 96-257

> A Notice of Violation was issued September 3, 1996 based on violations involving the circumstances surrounding damage to a Troxler moisture/density gauge that occurred on August 19, 1995, located at a highway construction site in Kent County, Michigan. A civil penalty was not proposed because the licensee had not been the subject of a civil penalty in the past two years and the licensee took prompt and comprehensive corrective actions.

A. CIVIL PENALTIES AND ORDERS



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

March 29, 1996

EA No. 96-009

Mr. Robert G. Gallagher, P.E., CHP President and CEO Applied Health Physics, Inc. 2986 Industrial Boulevard Bethel Park, Pennsylvania 15102

SUBJECT: CONFIRMATORY ORDER (EFFECTIVE IMMEDIATELY) (NRC INSPECTION REPORT NOS. 030-10859/95-002 AND 030-06198/95-002)

Dear Mr. Gallagher:

The enclosed Confirmatory Order (Effective Immediately) is being issued to confirm your commitments described in your letter dated February 19, 1996, in your facsimiles dated February 23 and March 15, 21, and 25, 1996, and in a telephone call on March 28, 1996. The Order requires that: (1) authorization for the receipt of pre-packaged radioactive waste at the Bethel Park facility be suspended; (2) you dispose of radioactive waste as specified in your disposal schedule dated February 19, 1996, as amended by your facsimiles dated February 23 and March 15, 1996; (3) you dispose of the radioactive waste in containers W-1995-010, W-1995-050 through W-1995-062, S-1995-002, and S-1995-007 through S-1995-010, by December 31, 1996; (4) you establish an escrow account within 30 days of the date of this Order to provide financial assurance for waste handling and disposal of the waste; (5) you inform the NRC of the name, address and location of the escrow agent; (6) all revenues coming from customers for waste brokerage be delivered into escrow within 7 business days; and (7) you provide the NRC with monthly bank account statements pertaining to the escrow account.

As to your request for withholding escrow account information, we are prepared to do this to the extent provided by the law, provided you submit the information described in the enclosed Order.

In the above referenced telephone call between James H. Joyner, Technical Assistant to Director, Division of Nuclear Materials Safety, U.S.N.R.C., Region I, and Daniel Haber, Assistant to the President, Applied Health Physics, on March 28, 1996, you agreed to the issuance of the enclosed Order.

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 this Order shall be subject to criminal prosecution as set forth in that section. Violation of this Order also may subject the person to civil monetary penalty.

Questions concerning this Order should be addressed to Mr. James Lieberman, Director, Office of Enforcement, at (301) 415-2741.

Applied Health Physics, Inc. - 2 -

This letter also refers to your facsimiles received November 9, 21, and 29, 1995, and December 1, and 8, 1995, in response to our Confirmatory Action Letter (CAL) 1-95-019. dated November 8, 1995. Based on your responses, the NRC has found that all the commitments listed in the CAL have been met. No further response is required regarding the CAL.

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,

James Liebe

Dames Lieberman, Director Office of Enforcement

Docket Nos. 030-10859 030-06198 License Nos. 37-14600-01 37-09135-01

Enclosures: As Stated

## UNITED STATES HUCLEAR REGULATORY COMMISSION

In the Matter of APPLIED HEALTH PHYSICS, INC. Bethel Park, Pennsylvania

Docket Nos. 030-10859 030-06198 License Nos. 37-14600-01 37-09135-01 EA 96-009

CONFIRMATORY ORDER (EFFECTIVE IMMEDIATELY)

Applied Health Physics, Inc. (Licensee) is the holder of NRC License Nos. 37-14600-01 and 37-09135-01 issued by the Nuclear Regulatory Commission (NRC or Commission) pursuant to 10 CFR Part 30. The licensee's facility is located on the Licensee's site in Bethel Park, Pennsylvania. License No. 37-14600-01 currently authorizes the receipt, possession, and storage of pre-packaged wastes. License No. 37-09135-01 currently authorizes leak tests services, analysis of samples, calibrations of instruments, and fixed gauge services. Overall, the Licensee provides services to customers in a variety of areas such as radioactive waste brokerage, surveys, leak tests and analysis, calibration of instrumentation, sample analysis, training, and consultation. License No. 37-14600-01 initially was issued on September 4, 1975, and is due to expire on January 30, 1997. License No. 37-09135-01 was initially issued on February 19, 1963, and is due to expire on October 31, 2000.

II

On May 19, 1994, representatives from NRC Region I spoke with Licensee representatives concerning the need for financial assurance. The NRC representatives discussed options with Licensee representatives with respect to meeting the financial assurance requirements. The result of the

conversation was that the Licensee decided to reduce the radioactive material possession limits on License No. 37-14600-01 such that financial assurance would not be required.

- 2 -

In a letter dated May 24, 1994, the Licensee requested a license amendment to lower possession limits, add specifically listed radionuclides for its waste broker License No. 37-14600-01, and limit possession to sealed sources only for its calibration service License No. 37-09135-01. The NRC approved these amendments on June 28, 1994.

On March 9, 1995, the Licensee voluntarily filed for bankruptcy under Chapter 11 of the U.S. Bankruptcy Code in the U.S. Bankruptcy Court for the Western District of Pennsylvania. On March 20 and 22, 1995, respectively, the NRC Office of the Controller filed for proofs of claim for 1994 license and Freedom of Information Act fees owed by the Licensee to the NRC. (On November 14 and 15, 1995, respectively, the NRC filed an additional proof of claim for 1995 license fees owed and amended the proof of claim previously filed for the 1994 fees.)

During a routine safety inspection conducted on April 18-19, 1995, the NRC identified seven violations as described in the Notice of Violation (Notice) dated May 22, 1995. One of the seven violations cited the Licensee for holding radioactive waste for more than 180 days, contrary to the requirements of Condition 14 of License No. 37-14600-01.

NUREG-0940, PART III

On May 26, 1995, four days after the issuance of the Notice, the Licensee took possession of two drums of radioactive waste. One drum contained approximately 23 microcuries of unsealed americium-241, which is not authorized on its waste broker license. The authorization for unsealed americium-241 was deleted from License No. 37-14600-01 in accordance with the Licensee's May 24, 1994 request.

- 3 -

In a letter dated June 26, 1995, the Licensee responded to the Notice and indicated that the Licensee's president would provide the management commitment and oversight needed to maintain compliance with conditions of both licenses. This response indicated that procedures would be developed to provide for immediate review of received material to determine acceptability for storage at the Licensee's facility.

On October 25, 1995, the date that the Licensee was to file a Chapter 11 disclosure statement and plan, the Chapter 11 case was converted to a Chapter 7 case. The conversion occurred due to the Licensee's inability to file the disclosure statement and plan by the October 25, 1995 deadline.

Due to the NRC's concern about the financial status of the Licensee and the possibility of abandoned radioactive material at the Bethel Park, Pennsylvania, facility, the NRC issued a Confirmatory Action Letter (CAL) to the Licensee on November 8, 1995, confirming the Licensee's commitment to:

cease acquiring any additional radioactive waste from customers;

NUREG-0940, PART III

(2) provide an up-to-date inventory of the radioactive material in its possession at the Bethel Park facility to the NRC by November 9, 1995;

- 4 -

- (3) provide a schedule of any shipments of radioactive waste planned for 1995; and
- (4) provide a copy of the Licensee's plans over the next six months with regard to the bankruptcy proceedings.

The Licensee responded in a letter dated November 9, 1995, that included a current inventory of radioactive waste held at the Licensee's Bethel Park, Pennsylvania, facility, a schedule of shipments planned for 1995, a commitment not to accept any additional waste, and a commitment to inform the NRC, upon notification from the Licensee's attorney, of the Licensee's financial status.

The NRC conducted an inspection at the site on November 15, 1995, and reviewed the storage and security of licensed material, inventory, and storage of radioactive waste. As a result of this inspection, NRC found three apparent violations, as follows:

- failure to limit possession of byproduct material (unsealed Am-241) to those isotopes listed on the license, as required by 10 CFR 30.3;
- (2) failure to limit possession of special nuclear material (Pu-239) to those authorized by the service license, as required by 10 CFR 70.19; and

(3) failure to limit possession of licensed material waste to a period not to exceed 180 days (May 26, 1995 acquisition of 2 drums), as required by License Condition No. 14 of License No. 37-14600-01, a repeat violation.

- 5 -

The Licensee met with the NRC staff during a predecisional enforcement conference at the NRC Region I office on January 30, 1996, to review the circumstances that led to these violations. During the enforcement conference, the Licensee proposed corrective actions that included: (1) establishing a separate bank account for payment of costs incurred due to waste disposal; (2) setting a disposal date of 100 days from the date of receipt of waste to assure that the waste is disposed prior to 180 days; (3) checking the Licensee's license prior to obtaining waste in order to assure compliance; and (4) hiring an Assistant to the President who will streamline procedures, maintain control of day-to-day business activities, and ensure that the RSO has the necessary resources to maintain compliance.

The NRC requested the Licensee to submit, by February 15, 1996, a more detailed, thorough plan describing the Licensee's plans for achieving compliance with all license requirements. A plan was received from the Licensee on February 15, 1996, but additional information was requested by the NRC staff.

#### III

By a letter dated February 19, 1996, and facsimiles dated February 23 and March 15, 21, and 25, 1996, the Licensee agreed that: 1) with the exception of

the radioactive waste in containers W-1995-010, and W-1995-050 through W-1995-062, the Licensee will achieve compliance with Condition 14 of License No. 37-14600-01 by April 30, 1996; 2) with respect to the radioactive waste in containers W-1995-010, W-1995-050 through W-1995-062, S-1995-002, and S-1995-007 through S-1995-010, the Licensee will achieve compliance with Condition 14 of License No. 37-14600-01 by December 31, 1996; and 3) the Licensee will establish a separate bank account for radioactive waste disposal and use the account exclusively for the deposit of payments made by the Licensee's customers for the disposal of NRC-licensed radioactive waste materials.

- 6 -

I find that the Licensee's commitments as set forth in its letter of February 19, 1996 and facsimiles dated February 23 and March 15, 21, and 25, 1996, are acceptable and necessary and conclude that with these commitments the public health and safety are reasonably assured. In view of the foregoing, I have determined that the public health and safety require that the Licensee's commitments in its February 19, 1996 letter and February 23 and March 15, 21, and 25, 1996 facsimiles be confirmed by this Order. The Licensee has agreed to this action in a telephone call on March 28, 1996, between James H. Joyner, Technical Assistant to Director, Division of Nuclear Materials Safety, U.S.N.R.C., Region I, and Daniel Haber, Assistant to the President, Applied Health Physics. Pursuant to 10 CFR 2.202, I also have determined, based on the Licensee's consent and on the significance of the violations described above, that the public health and safety require this Order to be immediately effective.

NUREG-0940, PART III

Accordingly, pursuant to sections 81, 161b, 161i, 161o, 182 and 186 of the Atomic Energy Act of 1954, as amended, and the Commission's regulations in 10 CFR 2.202 and 10 CFR Part 30, IT IS HEREBY ORDERED, EFFECTIVE IMMEDIATELY, that:

- A. Authorization for the receipt of pre-packaged radioactive waste at the Bethel Park facility be suspended.
- B. Radioactive waste be disposed of as specified in the Licensee's disposal schedule dated February 19, 1996, as amended by the Licensee's facsimiles dated February 23 and March 15, 21, and 25, 1996. With the exception of the radioactive waste in containers W-1995-010, and W-1995-050 through W-1995-062, S-1995-002, and S-1995-007 through S-1995-010, compliance with Condition 14 of License No. 37-14600-01 must be achieved by April 30, 1996.
- C. Radioactive waste in containers W-1995-010, and W-1995-050 through W-1995-062, S-1995-002, and S-1995-007 through S-1995-010, be disposed of by December 31, 1996.
- D. An escrow account be established in accordance with this Order within 30 days of the date of this Order to provide financial assurance for waste handling and disposal of the Licensee's waste. For the purposes of this paragraph, an escrow account is an account where money is put

into the custody of a third party for delivery to a grantee only after the fulfillment of specified conditions. The escrow agent shall be provided a copy of this Order.

- 8 -

- E. The NRC be informed of the name, address, and location of the escrow agent within 72 hours of the Licensee's opening of the esc. w account. Such escrow account information as well as any other information required by this Order shall be submitted to the Director, Division of Nuclear Materials Safety, NRC Region I, 475 Allendale Road, King of Prussia, Pennsylvania 19406.
- F. All revenues coming from customers for waste brokerage required to pay for the direct costs of transportation, permits, disposal, and a 10 % contingency fee will be delivered into the escrow account established under Paragraph D above within 5 business days and will remain in this escrow account until one of the following three conditions has been satisfied:
  - the Licensee formally notifies the NRC, by telephone and facsimile, of the planned withdrawal of funds for the purpose of waste handling or disposal at least 5 business days prior to withdrawal of funds and the NRC has not provided within this time period an objection to the dispersal of the funds; or
  - the escrow agent has been notified by the NRC, in writing, that the Licensee has defaulted on its obligation to carry out waste

handling and disposal for the Bethel Park, Pennsylvania, facility; or

 the escrow account has been terminated by joint notice, in writing, from the Licensee and NRC.

- 9 -

Upon the escrow agent receiving written notification from the NRC of the Licensee's default, the escrow agent shall make payments from the escrow account as the NRC shall direct, in writing, to provide for payment of the costs of the required waste handling and disposal activities covered by this agreement.

G. The NRC be provided with monthly bank account statements pertaining to the escrow account.

If personal privacy or proprietary information is included in any submittal required by this Order, the Licensee shall provide a bracketed copy that identifies the information that should be protected and a redacted copy that deletes such information. If the Licensee requests withholding of such material, the Licensee <u>must</u> specifically identify the portions that it seeks to have withheld and provide in detail the bases for its 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).

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

- 10 -

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

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

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

In the absence of any request for hearing, 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

Dames Lieberman, Director Office of Enforcement

A-13

Dated at Rockville, Maryland this 29<sup>44</sup> day of March 1996

NUREG-0940, PART III

- 11 -



UNITED STATES NUCLEAR REGULATORY COMMISSION WASHINGTON, D.C. 2000-0001

September 27, 1996

EA 96-353

Mr. Robert G. Gallaghar, P.E., CHP President and CEO Applied Health Physics, Inc. 2986 Industrial Boulevard Bethel Park, Pennsylvania 15102

SUBJECT: CONFIRMATORY ORDER (EFFECTIVE IMMEDIATELY)

Dear Mr. Gallaghar:

Applied Health Physics, Inc. (AHP) was issued a Confirmatory Order on March 29, 1996, (the Order) as a result of its storage of radioactive waste for more than 180 days, which was a repeat violation; possessing radioactive material which AHP was not authorized to possess; and NRC's concern about the financial status of the licensee and the possibility of abandoned radioactive material at the licensee's facility.

In letters dated May 2 and 16, 1996, AHP stated that they had complied with the Order which suspended authorization for AHP to receive pre-packaged radioactive wastes at their Bethel Park facility and requested a relaxation of the Order. In particular, these letters described AHP's actions which included the disposal of certain specified waste and the establishment of an escrow account into which revenues from customers whose waste is transferred to its Bethel Park, Pennsylvania facility would be deposited. These revenues would be deposited into escrow within five business days and would include the revenues required to pay for the direct costs of transportation, permits, disposal, and a 10% contingency fee.

The NRC reviewed your relaxation request and, based on the information provided in your letters cited above, found that AHP had satisfactorily complied with the requirements of the Order to be met as of that date and had made satisfactory progress toward completion of the remaining requirement, Paragraph IV.C of the Order, which is to be completed by December 31, 1996. Therefore, in accordance with Section IV of the Order, Paragraph IV.A. of the March 29, 1996. Order was rescinded by letter dated May 31, 1996, to the extent that AHP was authorized to receive prepackaged radioactive waste at its Bethel Park, Pennsylvania facility. The other requirements of the Order remained in effect.

Since that time, the NRC learned that the United States Internal Revenue Service seized AHP's bank accounts, thereby preventing disposal of radioactive waste located at your Bethel Park, Pennsylvania facility. As a result, the NRC no longer has confidence that AHP will be able to dispose of the Mr. Gallaghar

- 2 -

radioactive waste on-site. Accordingly, in AHP's facsimile dated September 3, 1995, you agreed to suspend all receipt of pre-packaged radioactive waste at your Bethel Park, Pennsylvania facility. The enclosed Confirmatory Order confirms that commitment.

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 this Order shall be subject to criminal prosecution as set forth in that section. Violation of this Order also may subject the person to civil monetary penalty.

Questions concerning this Order should be addressed to Mr. James Lieberman, Director, Office of Enforcement, at (301) 415-2741.

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,

appen Lieben

James Lieberman, Director Office of Enforcement

Docket Nos. 030-10859 030-06198 License Nos. 37-14600-01 37-09135-01

Enclosures: As Stated

cc:w/encl State of New Jersey State of New York

# UNITED STATES NUCLEAR REGULATORY COMMISSION

In the Matter of APPLIED HEALTH PHYSICS, INC. Bethel Park, Pennsylvania

Docket Nos. 030-10859 030-GeiSS License Nos. 37-14600-01 37-09135-01 FA 96-353

CONFIRMATORY ORDER (EFFECTIVE IMMEDIATELY)

Applied Health Physics, Inc. (Licenser or AHP) is the holder of NRC License Nos. 37-14600-01 and 37-09135-01 issued by the Nuclear Regulatory Commission (NRC or Commission) pursuant to 10 CFR Part 30. The Licenser's facility is located on the Licensee's site in Bethel Park, Pennsylvania. License No. 37-14600-01 currently authorizes the receipt, possession, and storage of prepackaged wastes. License No. 37-09135-01 currently authorizes leak tests services, analysis of samples, calibrations of instruments, and fixed gauge services. License No. 37-14600-01 initially was issued on September 4, 1975, and is due to expire on January 30, 1997. License No. 37-09135-01 was initially issued on February 19, 1963, and is due to expire on October 31, 2000.

II

AHP was issued a Confirmatory Order on March 29, 1996, (the Order) as a result of its storage of radioactive waste for more than 180 days, which is a repeat violation, possessing radioactive material which AHP was not authorized to possess, and NRC's concern about the financial status of the licensee and the possibility of abandoned radioactive material at the licensee's facility.

NUREG-0940, PART III

In letters dated May 2 and 16, 1996, AHP stated that it had complied with the Order and requested a relaxation of the Order which would authorize AHP to receive pre-packaged radioactive wastes at their Bethel Park facility. In particular, these letters described AHP's actions which included the disposal of certain specified waste and the establishment of an escrow account into which would be deposited revenues from customers whose waste is transferred to its Bethel Park, Pennsylvania facility. These revenues would be deposited into escrow within five business days and would include the revenues required to pay for the direct costs of transportation, permits, disposal, and a 10% contingency fee.

- 2 -

The NRC reviewed the AHP request and, based on the information provided in its letters cited above, the NRC found that AHP had satisfactorily complied with the requirements of the Order to be met to date and had made satisfactory progress toward completion of the remaining requirement, Paragraph IV.C of the Order, which is to be completed by December 31, 1996. In accordance with Section IV of the Order, Paragraph IV.A. of the Order was rescinded by letter dated May 31, 1996, so as to authorize AHP to receive prepackaged radioactive waste at its Bethel Park, Pennsylvania facility. The other requirements of the Order remained in effect.

Since that time, the NRC learned that the United States Internal Revenue Service seized AHP's bank accounts, thereby preventing disposal of radioactive waste located at AHP's Bethel Park, Pennsylvania facility. As a result, the NRC no longer has confidence that AHP will be able to dispose of the radioactive waste on-site. Accordingly, in AHP's facsimile dated September 3,

1996, AHP agreed to suspend all receipt of pre-packaged radioactive waste at your Bethel Park, Pennsylvania facility.

- 3 -

III

I find that the Licensee's commitments as set forth in its facsimile of September 3, 1996 are acceptable and necessary and conclude that with these commitments, the public health and safety are reasonably assured. In view of the foregoing. I have determined that the public health and safety require that the Licensee's commitments in its September 3, 1996 facsimile be confirmed by this Order. The Licensee has agreed to this action in a telephone call on September 12, 1996, between Francis M. Costello, Chief, Industrial Applications Branch, Division of Nuclear Materials Safety, U.S. NRC, Region I, and Daniel Haber, Assistant to the President, Applied Health Physics. In addition, during a telephone call on September 20, 1996, between Ms. Kathleen Dolce, Health Physicist, NRC Region I, and Mr. Robert Gallaghar, President of AHP, the Licensee understood that, by consenting to insuance of this Order, it waived its rights to a hearing. Pursuant to 10 CFR 2.202, I also have determined, based on the Licensee's consent and on the significance of the underlying violation described above, that the public health and safety require this Order to be immediately effective.

IV

Accordingly, pursuant to sections 81, 161b, 161i, 161o, 182 and 186 of the Atomic Energy Act of 1954, as amended, and the Commission's regulations in

10 CFR 2.202 and 10 CFR Part 30, IT IS HEREBY ORDERED, EFFECTIVE IMMEDIATELY, that:

- 4 -

A. Authorization for the receipt of pre-packaged radioactive waste at the Bethel Park facility is suspended.

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

V

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

the criteria set forth in 10 CFR 2.714(d).

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

- 5 -

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

In the absence of any request for hearing, 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

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Dames Lieberman, Director Office of Enforcement

Dated at Rockville, Maryland this 27thday of September 1996



UNITED STATES NUCLEAR REGULATORY COMMISSION REGION I 475 ALLENDALE RO '.O KING OF PRUSSIA. PENNSYLVANIA 19406-1415

September 13, 1995

EA No. 95-163

Mr. Steven J. McCool President Canspec Testing, Inc. 464 Lincoln Boulevard Middlesex, New Jersey 08846

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY - \$5,000 (NRC INSPECTION REPORT NO. 030-32380/95-001)

Dear Mr. McCool:

This refers to the NRC inspection conducted on July 19 and 25, 1995, and August 1, 1995, at your Middlesex, New Jersey facility, as well as at a temporary jobsite (BP Oil Refinery) in Marcus Hook, Pennsylvania, of activities authorized by NRC License No. 29-28659-01. The inspection report was sent to you on August 11, 1995. During the inspection, seven violations of NRC requirements were identified, three of which were repetitive of violations identified during two NRC inspections in 1994. On August 30, 1995, a predecisional enforcement conference was conducted in the Region I office with you to discuss the apparent violations, their causes, and your corrective actions. During the conference, another violation was identified involving your failure to provide complete and accurate information to the NRC in your written response, dated October 25, 1994, to a Notice of Violation sent to you on September 27, 1994, concerning one of the 1994 inspections. A copy of the enforcement conference report is enclosed.

The seven violations identified during the inspection are described in the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice). The violations involved the failures to (1) perform quarterly audits of radiographers and assistants; (2) properly secure licensed material (while in storage at your Middlesex, New Jersey facility) from unauthorized access or removal; (3) properly post a high radiation area created during the performance of radiography at the Marcus Hook jobsite; (4) calibrate alarm ratemeters at the required frequency; (5) calibrate survey meters at the required frequency; (6) calitrate pocket dosimeters at the required frequency; and (7) maintain training records for radiographers and radiographer's assistants. The eighth violation (identified during the conference) also is described in the enclosed Notice and in volved the submittal of inaccurate information to the NRC. Specifically, in you. October 25, 1994 response to four of the violations regarding maintenance of logs and records, you indicated that the records had been misfiled in a move of your offices to a new location, and that the paperwork subsequently was found and placed in the appropriate files. This statement was inaccurate. Records had not been found and placed in the file documenting training administered to an individual who was permitted to perform the duties of a radiographer.

Mr. Steven J. McCool

2

Given the nature and number of the violations, as well as the fact that three of the violations were repetitive of the violations identified during the two inspections at your facility in 1994, the NRC is concerned that there existed a significant lack of attention to, and control of, licensed activities by you as the President and Radiation Safety Officer (RSO) of the company. Your lack of control and attention is of concern, particularly given the fact that 13 violations were identified during the two NRC inspections in 1994, including 10 during the August 1994 inspection. In the September 27, 1994 letter transmitting the related Notice of Violation for that inspection, you were informed that additional attention to compliance with regulatory requirements was warranted. However, you did not pay adequate attention to the program, as you admitted during the enforcement conference. Furthermore, your October 25, 1994 response to the September 1994 Notice contained inaccurate information, as described The submittal of any inaccurate information to the NRC is a significant above. regulatory concern that can result in civil and/or criminal action against the licensee, as well as responsible individuals, depending on the circumstances surrounding such submittal. Therefore, you and your staff should be aware of the importance of providing complete and accurate information to the NRC. Failure to do so could result in action against individuals, in addition to your company.

The NRC license issued to Canspec Testing, Inc. entrusts responsibility for radiation safety to the RSO and licensee management; therefore, the NRC expects effective oversight of its licensed programs. Incumbent upon each NRC licensee is the responsibility of management in general, and the RSO in particular, to protect the public health and safety by ensuring that all requirements of the NRC license are met and any potential violations of NRC requirements are identified and corrected expeditiously. Given your lack of management attention towards licensed responsibilities, these violations are classified in the aggregate as a Severity Level III problem in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions" (Enforcement Policy), (NUREG: 60 FR 34381; June 30, 1995).

In accordance with the Enforcement Policy, a base civil penalty in the amount of \$5,000 is considered for a Severity Level III problem. Because your facility has not been the subject of escalated enforcement actions in the past, 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, which were described at the enforcement conference, included: (1) plans to increase the frequency of quarterly audits of radiographers and radiographer's assistants to 45-60 days; (2) issuance of a memorandum, from you to your staff communicating your expectations regarding compliance with requirements, and describing the disciplinary policy for those who do not comply; (3) plans to have a field radiographer ensure that other radiographers understand your expectations; and (4) plans to have only calibrated equipment used in the field. These corrective actions, however, do not form an adequate basis for providing credit because they were not implemented in a timely manner, specifically, you were not sure, at the conference, whether the memorandum (which was not sent until the day before the enforcement conference) had been received and evaluated by all of the radiographers; you were not sure whether the field radiographer had gone over these findings with the other radiographers; and although you are the RSO for the company, you indicated at the enforcement conference that you had not had a formal meeting with all of the radiographers at the time of the conference to implement these actions.

Mr. Steven J. McCool

3

Therefore, to emphasize the importance of (1) aggressive oversight of the radiation safety program by you as the President and RSO, so as to ensure that licensed activities are conducted safely and in accordance with requirements, and violations, when they exist, are identified and corrected promptly, and (2) the submittal of complete and accurate information to the NRC, I have been authorized, after consultation with the Director, Office of Enforcement, to issue the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice) in the base amount of \$5,000 for the Severity Level III problem.

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

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter, its enclosures, 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 or proprietary information so that it can be placed in the PDR without redaction.

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

Sincerely.

Pouran Mark

Thomas T. Martin Regional Administrator

Docket No. 030-32380 License No. 29-28659-01

Enclosures: 1. Notice of Violation and Proposed Imposition of Civil Penalty

2. Enforcement Conference Report

cc w/encls: Commonwealth of Pennsylvania State of New Jersey

#### ENCLOSURE 1

#### NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY

Canspec Testing, Inc. Middlesex, New Jersey Docket No. 030-32380 License No. 29-28659-01 EA 95-163

During an NRC inspection conducted on July 19 and 25, and August 1, 1995, violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (60 FR 34381; June 30, 1995), the Nuclear Regulatory Commission proposes to impose a civil penalty pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (Act), 42 U.S.C. 2282, and 10 CFR 2.205. The particular violations and associated civil penalty are set forth below:

A. 10 CFR 34.11(d)(1) requires, in part, that an applicant have an inspection program that requires the observation of the performance of each radiographer and radiographer's assistant during an actual radiographic operation at intervals not to exceed three months.

License Condition 18 incorporates the inspection program containing the requirements stated in 10 CFR 34.11(d)(1) as submitted in licensee's application dated May 14, 1991 (application), into License No. 29-28659-01.

Sections 3.3.2 and 3.3.4 of the application state that field personnel will be checked quarterly to insure that work being performed is within the limits of their qualifications.

Contrary to the above, the licensee had not observed the performance of a radiographer and an assistant radiographer involved in radiographic operations (to insure that work being performed is within the limits of their qualifications) at intervals not to exceed three months, as evidenced by the following:

- a radiographer was audited (performance observed) on October 3, 1994, and was not audited again until March 15, 1995, a period of time in excess of three morths.
- an assistant radiographer was audited (performance observed) on October 3, 1994, and was not audited again until February 23, 1995, a period of time in excess of three months. (IFS Code 01013)

This is a repetitive violation.

B. 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 20.1832 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, unrestricted area means an area, access to which is neither limited nor controlled by the licensee.

Contrary to the above, on July 25, 1995, the licensee did not secure from unauthorized removal or limit access to an Amersham 650 source changer containing 18 kilograms of depleted uranium, located in the licensee's garage/workshop area, an unrestricted area, and the licensee did not control and maintain constant surveillance of this licensed material. (IFS Code 01023)

C. 10 CFR 20.1902(b) requires that the licensee post each high radiation area with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, HIGH RADIATION AREA" OR "DANGER, HIGH RADIATION AREA."

Contrary to the above, on July 19, 1995, the licensee performed radiography at a field site at the BP Oil Refinery in Marcus Hook, Pennsylvania, which created a high radiation area in the area of the two platforms where radiography was being performed, and the high radiation area was not posted with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, HIGH RADIATION AREA" OR "DANGER, HIGH RADIATION AREA." (IFS Code 01033)

D. 10 CFR 34.33(f)(4) requires that alarm ratemeters be calibrated at periods not to exceed one year for correct response to radiation.

Contrary to the above, on July 19, 1995, licensee's assistant radiographers wore Xetec Model 317B alarm ratemeters which had not been calibrated since July 8, 1994, a period of time in excess of one year. (IFS Code 01043)

E. 10 CFR 34.24 requires, in part, that each survey instrument used to conduct physical radiation surveys be calibrated at intervals not to exceed three months and after each instrument servicing.

Contrary to the above,

- on June 8, 1995, a licensee employee conducted physical radiation surveys with a survey instrument (Serial Number 3369) which was last calibrated on February 17, 1995, an interval exceeding three months.
- on July 11, 1995, a licensee employee conducted physical radiation surveys with a survey instrument (Serial Number 2015) which was last calibrated on March 28, 1995, an interval exceeding three months.

 on August 15, 1994, a licensee radiographer conducted physical radiation surveys with a survey instrument (Serial Number 3369) which was last calibrated on April 4, 1994, an interval exceeding three months. (IFS Code 01053)

This is a repetitive violation.

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

Contrary to the above, on September 2, 1994, a licensee pocket dosimeter, serial number 1080515, was in use and had not been checked for correct response to radiation since August 20, 1993, a period in excess of one year. (IFS 01063)

G. 10 CFR 34.31(c) requires that records of training of radiographers and radiographer's assistants, including copies of written tests and dates of oral tests and field examinations, be maintained for three years.

Contrary to the above, as of August 1995, records of training (on Appendix A to 10 CFR Part 34) were not maintained for an individual who had worked as a radiographer since April 1994. (IFS Code 01073)

This is a repetitive violation.

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

Contrary to the above, in a letter, dated October 25, 1994 in response to a Notice of Violation issued by the NRC on September 27, 1994, the licensee stated, in its response to Violation B, involving the failure to maintain records documenting training administered to an individual who was permitted to perform the duties of a radiographer, that associated paperwork was misfiled in a move of its office to a new location, and the paperwork was found and placed in the appropriate file. This statement was inaccurate in that the box of records that was located subsequent to the NRC's September 27, 1994 letter did not contain this particular record. The statement was material because it had the capability to influence the NRC as to whether the violation had occurred. (IFS Code 01083)

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

Civil Penalty - \$5,000

A-26

3

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

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

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

In requesting mitigation of the proposed penalty, the factors addressed in Section 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, letter with payment of civil penalty, and Answer to a Notice of Violation) should be addressed to: Mr. James Lieberman, Director, Office c orcement, 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, 475 Allendale Road, King of Prussia, PA 19406.

5

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.

Dated at King of Prussia, Pennsylvania this 13th day of September 1995

NUREG-0940, PART III



#### UNITED STATES NUCLEAR REGULATORY COMMISSION WASHINGTON, D.C. 20665-0001

December 6, 1995

EA 95-163

Mr. Steven J. McCool President Canspec Materials Testing, Inc. 464 Lincoln Boulevard Middlesex, New Jersey 08846

SUBJECT: CIVIL PENALTY PROPOSED IN NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY DATED SEPTEMBER 13, 1995

Dear Mr. McCool:

With regard to the above captioned matter, enclosed is a Settlement Agreement which specifies the terms that have been discussed between yourself and John McGrath, Acting Chief, Nuclear Materials Safety Branch 3, Region I, Nuclear Regulatory Commission (NRC) or November 21, 1995. I have signed the enclosed Settlement Agreement.

In your two responses dated October 11, 1995, you admitted Violations A through D and F through H; denied Violation E; and requested that the proposed civil penalty be reduced if not dismissed. You also stated that if our decision was to impose the entire amount of the civil penalty, you requested that a payment plan be established. After consideration of your responses, we have concluded for the reasons given in the Appendix, which is attached to the enclosed Settlement Agreement, that Violation E occurred as stated and that reduction or dismissal of the civil penalty is not warranted. Therefore, a payment plan will be instituted as you reque ted.

If you agree to the terms of the Agreement, you should sign the enclosed Settlement Agreement on behalf of Canspec Materials Testing, Inc. in the space provided and date your signature. Please return the signed original document together with the \$1,000 initial payment, by January 1, 1996, to Mr. James Lieberman, Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, 11555 Rockville Pike, Rockville, Maryland 20852-2738. Please note that by accepting this agreement, you waive your right to a hearing to contest the civil penalty.

If you do not accept this agreement or have any question concerning this matter, please contact myself or Mr. Nader Mamish of my staff at (301) 415-2740.

We read with concern in your response that during your recent contact with the NRC, you had an occasion to see "eyes rolled and a face made as if to say this guy is an idiot." We appreciated your sharing this observation with the NRC. We have discussed your observation with the senior NRC official present at the enforcement conference; however, he did not observe the stated behavior.

Canspec Materials Testing, Inc. - 2 -

Please be assured that the NRC expects all of its staff members to conduct themselves in a professional manner.

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,

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James Lieberman, Director Office of Enforcement

Docket No. 030-32380 License No. 29-28659-01

Enclosure: As Stated

# UNITED STATES NUCLEAR REGULATORY COMMISSION

In the Matter of

CANSPEC MATERIALS TESTING, INC. Middlesex, New Jersey

Docket No. 030-32380 License No. 29-28659-01 EA 95-163

## SETTLEMENT AGREEMENT

1. On September 13, 1995, the Nuclear Regulatory Commission (NRC) issued to Canspec Materials Testing, Inc. (Licensee or CTI) a Notice of Violation and Proposed Imposition of Civil Penalty (Notice) in the amount of \$5,000 for violations involving: (1) failure to perform observations of a radiographer and assistant radiographer at the required frequency (this is a repetitive violation); (2) failure to secure licensed material stored in a controlled or unrestricted area from unauthorized removal or access; (3) failure to post a high radiation area with the required posting; (4) use of an alarm ratemeter which had not been calibrated at the required frequency; (5) conducting physical radiation surveys with survey instruments which had not been calibrated at the required frequency (this is a repetitive violation); (6) use of a pocket dosimeter which had not been checked for correct response to radiation at the required frequency; (7) failure to maintain records of training of radiographers and radiographer's assistants (this is a repetitive violation); and (8) failure to provide complete and accurate information to the NRC.

2. In an October 11, 1995 response to the Notice, CTI admitted the above violations except for Violation E of the Notice (No. 5 above), and requested that if the civil penalty is imposed in its entirety that a payment plan be instituted. The Licensee requested a payment schedule that would allow CTI to

remit \$1,000 on January 1, 1996, followed by payments of \$1,000 on the 1st day of February, March, April, and May of 1996.

- 2 -

3. The Licensee desires to resolve this matter without litigating it and therefore agrees to pay a civil penalty of \$5,000 with payment of the first \$1,000 on January 1, 1996, followed by payments of \$1,000 on the 1st day of February, March, April, and May of 1996. The Licensee and its president, Mr. Steven McCool, and the NRC staff conclude that this Settlement Agreement best serves the interests of the public, 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 \$5,000 civil penalty proposed by the NRC in its September 13, 1995 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 \$5,000 civil penalty. In addition, the Licensee hereby waives the right to request a hearing on the \$5,000 civil penalty or otherwise contest or seek review of this penalty before the NRC or in any court; and waives any right to contest the payment of the \$5,000 civil penalty should CTI 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.

- 3 -

U. S. NUCLEAR REGULATORY COMMISSION

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James Lieberman, Director Office of Enforcement

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CANSPEC MATERIALS TESTING, INC.

Steven J. McCool, President

Date

NUREG-0940, PART III

#### APPENDIX

#### EVALUATIONS AND CONCLUSION

On September 13, 1995, a Notice of Violation and Proposed Imposition of Civil Penalty (Notice) was issued for violations identified during an NRC inspection. Canspec Materials Testing, Inc. (Licensee or CTI) responded to the Notice on October 11, 1995. The Licensee admitted seven violations (violations A-D and F-H), denied one violation (violation E) and requested mitigation or dismissal of the civil penalty. The NRC's evaluation and conclusion regarding the licensee's requests are as follows:

# 1. Restatement of Violation E

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

Contrary to the above,

- on June 8, 1995, a licensee employee conducted physical radiation surveys with a survey instrument (Serial Number 3369) which was last calibrated on February 17, 1995, an interval exceeding three months.
- on July 11, 1995, a licensee employee conducted physical radiation surveys with a survey instrument (Serial Number 2015) which was last calibrated on March 28, 1995, an interval exceeding three months.
- on August 15, 1994, a licensee radiographer conducted physical radiation surveys with a survey instrument (Serial Number 3369) which was last calibrated on April 4, 1994, an interval exceeding three months.

This is a repetitive violation.

# 2. Summary of the Licensees Response to Violation E

The Licensee denied this violation, and stated that there was always a calibrated meter in use for surveys. The Licensee's president stated that he must have misunderstood a conversation he had with an NRC inspector regarding the use of survey instruments. The Licensee's president also stated that he was under the impression that as long as the survey meter used for compliance surveys was calibrated, a second meter could be used for information only.

Further, the Licensee's president stated that when an audit was performed in the field and the equipment was found to be out of calibration they only had to go to "our trailer" to obtain properly calibrated equipment. In addition, the Licensee stated that an NRC inspector allowed them to return to work because there was properly calibrated functional equipment on site for use. The Licensee also stated that the company had the appropriate equipment in place for use. Appendix

- 2 -

However, the workers did not take the time to check calibration dates before starting to work.

# 3. NRC Evaluation of the Licensees Response to Violation E

10 CFR 34.24 requires, in part, that each survey instrument used to conduct physical radiation surveys be calibrated at intervals not to exceed three months and after each instrument servicing. The inspection findings were based on a review of documentation of survey instrument use and calibration, maintained by the Licensee, which indicated instances where the survey instrument used to show compliance had not been calibrated at the required frequency. While the Licensee may have had in its possession survey instruments which were calibrated as required, the Licensee did not comply with the requirement as stated in 10 CFR 34.24. Specifically, survey meters used by the Licensee to perform physical radiation surveys to ensure compliance with 10 CFR 34.24 on the dates specified in the Notice had not been calibrated within the previous three months as required.

Having appropriately calibrated instruments on site or available for use does not demonstrate compliance with this requirement. It is the licensee's responsibility to assure that the instrument used is calibrated as required. Therefore, the NRC concludes that the Licensee has not provided an adequate basis for withdrawal of the violation.

On November 14, 1995, Mr. Frank Costello, Chief, Nuclear Materials Safety Branch 3, NRC, contacted the Licensee's president by telephone for clarification of the Licensee's statement, in its October 11, 1995 response, concerning an NRC inspector allowing the Licensee to return to work because properly calibrated functional equipment was on site. During the telephone conversation, the Licensee's president stated that the NRC inspector allowed the radiographers to return to work only after assuring that they were using calibrated equipment.

# 4. Summary of Licensee's Request for Mitigation

In its responses, the Licensee requested that the proposed civil penalty be reviewed for reduction if not dismissal. In June of 1995, Canspec was purchased by the current president. The president stated his contention that prior to this purchase, time was not spent where it should have been and now that he has assumed the position of president he will spend the time required to ensure that policy is followed "to the letter." The president stated that now he has greater control over the operation and will be able to spend the time necessary sorting out any problems with individuals and if they fail to conform, they will be replaced. The Licensee also stated its belief that the violations were not entirely the company's responsibility. Further, the president stated that the company had fulfilled the calibration requirements, yet the men made a mistake by not checking the calibration dates before starting to work.

#### Appendix

# 5. NRC Evaluation of Licensee's Request for Mitigation

The NRC determined that the violations, given their number, nature, and the fact that three were repetitive, were of significant regulatory concern and appeared to be indicative of the lack of management control over licensed activities. This was evidenced by the fact that 13 violations were identified during the two NRC inspections in 1994. Therefore, the violations were appropriately characterized at Severity Level III in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions" (Enforcement Policy), NUREG-1600 (60 FR 34381; June 30, 1995).

As to the president's statements concerning his increased control over the Licensee's operation, the NRC considers that such actions are part of the Licensee's corrective action and expects licensees to exercise adequate management control over licensed activities consistently to ensure the protection of the public and the environment. Regardless of who committed the violations, the Licensee is responsible for the acts of its employees and for assuring that it is in compliance with all applicable regulations.

Therefore, the NRC concludes that the Licensee has not provided an adequate basis for mitigation or withdrawal of the civil penalty.

#### 6. NRC Conclusion

The NRC has concluded that the violation occurred as stated and an adequate basis for mitigation of the civil penalty was not provided by the Licensee. Consequently, the proposed civil penalty in the amount of \$5,000 should either be paid in accordance with the enclosed settlement agreement or be imposed.



#### UNITED STATES NUCLEAR REGULATORY COMMISSION WASHINGTON, D.C. 20000-0001

February 2, 1996

EA 95-163

Mr. Steven J. McCool President Carspec Materials Testing, Inc. 464 Lincoln Boulevard Middlesex, New Jersey 08846

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

Dear Mr. McCool:

This refers to your two letters, both dated October 11, 1995, in response to the Notice of Violation and Proposed Imposition of Civil Penalty (Notice) sent to you by our letter dated September 13, 1995. Our letter and Notice describe eight violations identified during an NRC inspection on July 19 and 25, 1995.

To emphasize the significance of management attention toward licensed activities and the importance of providing complete and accurate information to the NRC, a civil penalty of \$5,000 was proposed.

In your October 11, 1995 responses, you admitted Violations A through D and F through H; denied Violation E; and requested that the proposed civil penalty be reduced if not dismissed. You also requested a payment plan be established, should the NRC decide to impose the entire amount of the civil penalty.

After consideration of your responses, we have concluded for the reasons given in the Appendix attached to the enclosed Order Imposing Civil Monetary Penalty (Order) that Violation E occurred as stated and that reduction or dismissal of the civil penalty is not warranted. Accordingly, we hereby serve the enclosed Order on Canspec Materials Testing, Inc. imposing a civil monetary penalty in the amount of \$5,000. As provided in Section IV of the enclosed Order, payment should be made within 30 days of the date of this Order, by check, draft, money order, or electronic transfer, payable to the Treasurer of the United States and mailed to Mr. James Lieberman, 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.

As to your request for payment over time, we note that on December 6, 1995, the NRC issued a Settlement Agreement (Settlement) to whose terms you had agreed during a telephone call on November 21, 1995, between yourself and John McGrath, Acting Chief, Nuclear Materials Safety Branch 3, NRC Region I. The letter forwarding the Settlement stated that if you agree to the terms of that Settlement, you should sign the Settlement on behalf of Canspec Materials Testing, Inc.; date your signature; and return the signed original document together with the \$1,000 initial payment, by January 1, 1996, to the NRC. Canspec Materials Testing, Inc. - 2 -

Otherwise, you were to contact Mr. James Lieberman, Director, Office of Enforcement, or Mr. Nader Mamish, Enforcement Specialist, at (301) 415-2740.

Because the NRC did not receive the signed Settlement and the initial installment of \$1,000, as agreed upon during the November 21, 1995 call, Mr. Francis M. Costello, Chief, Nuclear Materials Safety Branch 3, NRC Region I, called your office on January 11, 18, and 19, 1996, and left you messages to contact him. In addition, Mr. Mamish called you on January 23, 1996, and left you a message stating that if the NRC did not receive the signed Settlement with the initial installment of \$1,000, an order imposing the civil penalty would be issued. However, you did not return any of these telephone calls. As a result, the NRC concluded that you are not interested in settling this matter by payments of the civil penalty over time and notified you by a January 25, 1996 letter that an order imposing the civil penalty would be issued unless the NRC received a signed Settlement with the first installment.

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,

∮ames Lieberman, Directre Office of Enforcement

Docket No. 030-32380 License No. 29-28659-01

Enclosures: As Stated

NUREG-0940, PART III

# UNITED STATES NUCLEAR REGULATORY COMMISSION

In the Matter of CANSPEC MATERIALS TESTING, INC. Middlesex, New Jersey

Docket No. 030-32380 License No. 29-28659-01 EA 95-163

ORDER IMPOSING CIVIL MONETARY PENALTY

Canspec Materials Testing, Inc. (Licensee) is the holder of byproduct Materials License No. 29-28659-01 issued by the Nuclear Regulatory Commission (NRC or Commission) on August 12, 1991. The license authorizes the Licensee to possess and use byproduct material for industrial radiography and replacement of sources in accordance with the conditions specified therein.

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An inspection of the Licensee's activities was conducted on July 19 and 25, 1995. The results of this inspection indicated that the Licensee had not conducted its activities in full compliance with NRC requirements. A written Notice of Violation and Proposed Imposition of Civil Penalty (Nvice) was served upon the Licensee by letter dated September 13, 1995. The Notice states the nature of the violations, the provisions of the NRC's requirements that the Licensee had violated, and the amount of the civil penalty proposed for the violations.

The Licensee responded to the Notice in two letters, both dated October 11, 1995. In its responses, the Licensee admitted Violations A through D and F through H; denied Violation E; and requested that the proposed civil penalty be reduced if not dismissed.

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

- 2 -

III

#### IV

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

The Licensee pay a civil penalty in the amount of \$5,000 within 30 days of the date of this Order, by check, draft, money order, or electronic transfer, payable to the Treasurer of the United States and mailed to Mr. James Lieberman, Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, One White Flint North, 11555 Rockville Pike, Rockville, MD 20852-2738.

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The Licensie 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, D.C. 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 addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission Washington, D.C. 20555, with a copy to the Commission's Document Control Desk, Washington, D.C. 20555. Copies also shall be sent to the Assistant General Counsel for Hearings and Enforcement at the same address and to the Regional Administrator, NRC Region I, 475 Allendale Road, King of Prussia, Pennsylvania 19406-1415.

- 3 -

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 issues to be considered at such hearing shall be:

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

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

- 4 -

FOR THE NULLEAR REGULATORY COMMISSION

James Lieberman, Director Office of Enforcement

Dated at Rockville, Maryland this 2nd day of February 1996

#### APPENDIX

#### EVALUATIONS AND CONCLUSION

On September 13, 1995, a Notice of Violation and Proposed Imposition of Civil Penalty (Notice) was issued for violations identified during an NRC inspection. Canspec Materials Testing, Inc. (Licensee or CTI) responded to the Notice on October 11, 1995. The Licensee admitted seven violations (Violations A-D and F-H), denied one violation (Violation E) and requested mitigation or dismissal of the civil penalty. The NRC's evaluation and conclusion regarding the licensee's requests are as follows:

1. Restatement of Violation E

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

Contrary to the above.

- on June 8, 1995, a licensee employee conducted physical radiation surveys with a survey instrument (Serial Number 3369) which was last calibrated on February 17, 1995, an interval exceeding three months.
- on July 11, 1995, a licensee employee conducted physical radiation surveys with a survey instrument (Serial Number 2015) which was last calibrated on March 28, 1995, an interval exceeding three months.
- 3. on August 15, 1994, a licensee radiographer conducted physical radiation surveys with a survey instrument (Serial Number 3369) which was last calibrated on April 4, 1994, an interval exceeding three months.

This is a repetitive violation.

2. Summary of the Licensees Response to Violation E

The License denied this violation, and stated that there was always a calibrated meter in use for surveys. The Licensee's president stated that he must have misunderstood a conversation he had with an NRC inspector regarding the use of survey instruments. The Licensee's president also stated that he was under the impression that as long as the survey meter used for compliance surveys was calibrated, a second meter could be used for information only.

Further, the Licensee's president stated that when an audit was performed in the field and the equipment was found to be out of calibration they only had to go to "our trailer" to obtain properly calibrated equipment. In addition, the Licensee stated that an NRC inspector allowed them to return to work because there was properly calibrated functional equipment on site for use. The Licensee also stated that the company had the appropriate equipment in place for use. Appendix

- 2 -

However, the workers did not take the time to check calibration dates before starting to work.

# 3. NRC Evaluation of the Licensees Response to Violation E

10 CFR 34.24 requires, in part, that each survey instrument used to conduct physical radiation surveys be calibrated at intervals not to exceed three months and after each instrument servicing. The inspection findings were based on a review of documentation of survey instrument use and calibration, maintained by the Licensee, which indicated instances where the survey instrument used to show compliance had not been calibrated at the required frequency. While the Licensee may have had in its possession survey instruments which were calibrated as required, the Licensee did not comply with the requirement as stated in 10 CFR 34.24. Specifically, survey metars used by the Licensee to perform physical radiation surveys to ensure compliance with 10 CFR 34.24 on the dates specified in the Notice had not been calibrated within the previous three months as required.

Having appropriately calibrated instruments on site or available for use does not demonstrate compliance with this requirement. It is the licensee's responsibility to assure that the instrument used 's calibrated as required. Therefore, the NRC concludes that the Licensee has not provided an adequate basis for withdrawal of the violation.

On November 14, 1995, Mr. Frank Costello, Chief, Nuclear Materials Safety Branch 3, NRC, contacted the Licensee's president by telephone for clarification of the Licensee's statement, in its October 11, 1995 response, concerning an NRC inspector allowing the Licensee to return to work because properly calibrated functional equipment was on site. During the telephone conversation, the Licensee's president stated that the NRC inspector allowed the radiographers to return to work only after assuring that they were using calibrated equipment.

# 4. Summary of Licensee's Request for Mitigation

In its responses, the Licensee requested that the proposed civil penalty be reviewed for reduction if not dismissal. In June of 1995, Canspec was purchased by the current president. The president stated his contention that prior to this purchase, time was not spent where it should have been and now that he has assumed the position of president he will spend the time required to ensure that policy is followed "to the letter." The president stated that now he has greater control over the operation and will be able to spend the time necessary sorting out any problems with individuals and if they fail to conform, they will be replaced. The Licensee also stated its belief that the violations were not entirely the company's responsibility. Further, the president stated that the company had fulfilled the calibration requirements, yet the men made a mistake by not checking the calibration dates before starting to work.

#### Appendix

# 5. NRC Evaluation of Licensee's Request for Mitigation

The NRC determined that the violations, given their number, nature, and the fact that three were repetitive, were of significant regulatory concern and appeared to be indicative of the lack of management control over licensed activities. The lack of management control was evidenced by the fact that 13 violations were identified during the two NRC inspections in 1994. Therefore, the violations were appropriately characterized at Severity Level III in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions" (Enforcement Policy), NUREG-1600 (60 FR 34381; June 30, 1995).

As to the president's statements concerning his increased control over the Licensee's operation, the NPC considers that such actions are part of the Licensee's corrective action and expects licensees to exercise adequate management control over licensed activities consistently to ensure the protection of the public and the environment. Regardless of who committed the violations, the Licensee is responsible for the acts of its employees and for assuring that it is in compliance with all applicable regulations.

Therefore, the NRC concludes that the Licensee has not provided an adequate basis for mitigation or withdrawal of the civil penalty.

# 6. NRC Conclusion

The NRC has concluded that the violation occurred as stated and that an adequate basis for mitigation of the civil penalty was not provided by the Licenser. Consequently, the proposed civil penalty in the amount of \$5,000 should be imposed.



# UNITED STATES

REGIONIV

611 RYAN PLAZA DRIVE, SUITE 400 ARLINGTON, TEXAS 76011-8064 June 12, 1996

EA 96-056

Mr. Charles Myers Hospital Administrator Community Hospital 2000 Campbell Drive Torrington, Wyoming 82240

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY - \$2,500 (NRC Inspection Report No. 030-20277/95-01 and Investigation Report No. 4-95-049)

Dear Mr. Myers:

This refers to the routine, unannounced inspection and subsequent investigation conducted on September 11, 1995 through February 26, 1996. The inspection findings were discussed with you during a telephonic exit briefing on February 26, 1996, and were documented in the subject inspection report dated March 15, 1996. The inspection report identified three Severity Level IV violations, which were cited in the Notice of Violation which accompanied the report, and two apparent violations which were not cited at the time. As discussed in the cover letter to the inspection report, the apparent violations were being considered for escalated enforcement action, and we provided you with an opportunity to either respond to the apparent violations within 30 days or request a predecisional enforcement conference. You responded to the issues in the report by letter dated April 5, 1996, and you did not request a predecisional enforcement conference.

The first apparent violation identified in the subject report involved the failure to implement a Quality Management Program (QMP) that met the objectives that each administration of sodium iodide I-131 (I-131) in quantities greater than 30 microcuries was in accordance with the authorized users' directives, that written directives were prepared within 24 hours of an authorized user's ora? directive, and that any unintended deviation from an oral or written directive was identified and evaluated. The second apparent violation involved a failure to ensure that required records maintained by Community Hospita? were complete and accurate. This second apparent violation specifically involved a concern that one of your employees falsified required records related to the administration of sodium iodide I-131 to two patients. In order to obtain more information regarding this apparent violation, representatives from the NRC conducted a predecisional enforcement conference with the employee to discuss our concerns. The conference was transcribed and occurred on April 8, 1996.

Based on the information developed during the inspection, the investigation, the April 8 transcribed predecisional conference with the individual, and the

information that you provided in your April 5, 1996 response, the NRC has determined that violations of NRC requirements occurred. The circumstances surrounding the violations were described in detail in the subject inspection report. In brief, the issues involve two administrations of I-131 on September 6 and November 7, 1994. Authorized users requested that doses of 6 and 4 millicuries, respectively, be administered. However, NRC has concluded that the doses administered to the patients were approximately 30% and 40% greater respectively, and therefore, are categorized as misadministrations. This information was identified by NRC during its inspection, when the NRC inspector discovered a discrepancy between administration records and the information provided by the radiopharmaceutical manufacturer.

The hospital's assessment of the consequences of the misadministrations was documented in a letter to NRC dated December 22, 1995. The inspection report also documented the NRC's review of these misadministrations with a medical consultant. The NRC's consultant stated that there was no need for further review by a medical consultant because the risk resulting from the increased dosage of I-131 to patients who have had previous thyroidectomy and ablation of residual thyroid tissue would be negligible. Both NRC's consultant and the hospital's assessment noted that, although the dosages were higher than requested by the authorized user, the dosages were still within the range of doses commonly used in clinical practice.

However, although the actual consequences to the patients may have been negligible, this case is of significant regulatory concern in that the hospital did not implement a QMP which was effective in ensuming that radioactive material was administered in accordance with the authorized users' instructions and that deviations from the authorized users' instructions were not promptly identified and corrected. Furthermore, licensees are responsible for the actions of their employees. In this case, the NRC has concluded that the technologist who administered the higher-than-authorized dosages deliberately falsified dose administration records. Therefore, these violations 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 III problem.

In accordance with the Enforcement Policy, a base civil penalty in the amount of \$2,500 is considered for a Severity Level III problem. Because the violations involved willfulness, 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. Given that the issues were identified by an NRC inspector rather than your internal audits, no credit was given for the *Identification* factor. However, the NRC has determined that credit is warranted for the *Corrective Action* factor. Your corrective actions included the immediate suspension of nuclear medicine procedures involving the use of I-131, review of your policies and procedures, and disciplinary action against the technologist. Subsequently, you requested termination of your license, based on economic considerations. Community Hospital

Therefore, to emphasize the significance of a deliberate violation of NRC requirements and to emphasize the importance of licensee management responsibility for ensuring that licensed activities are conducted in accordance with applicable requirements, I have been authorized, after consultation with the Director, Office of Enforcement, to issue the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice) in the base amount of \$2,500 for the Severity Level III problem.

No response to the violations is required because you requested that your license be terminated. However, in the future, should you seek to obtain an NRC license, you will be required to provide a description of actions you plan to take to prevent recurrence of the violations.

In addition, the NRC is issuing a Notice of Violation to the technologist for his deliberate actions which caused the hospital to be in violation of NRC requirements. Section VIII of the Enforcement Policy states, in part, that "more serious violations, including those involving the integrity of an individual (e.g., lying to the NRC) concerning matters within the scope of the individual's responsibilities, will be considered for enforcement action against the individual as well as the facility licensee." The Commission's regulations at 10 CFR 30.10 provide, in part, that any licensee or any employee of a licensee may not engage in deliberate misconduct that causes a licensee to be in violation of any rule, regulation, or order, or any term, condition, or limitation of any license, issued by the Commission, and that any person who violates these requirements may be subject to enforcement action.

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,

Callan Regional Administrator

Docket No. 030-20277 License No. 49-23121-01

Enclosure: Notice of Violation and Proposed Imposition of Civil Penalty

cc w/Enclosure: State of Wyoming

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#### NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY

Community Hospital Torrington, Wyoming Docket No. 030-20277 License No. 49-23121-01 EA 96-056

During an NRC inspection and investigation conducted on September 11, 1995 through February 26, 1996, violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," NUREG-1600, the Nuclear Regulatory Commission proposes to impose a civil penalty pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (Act), 42 U.S.C. 2282, and 10 CFR 2.205. The particular violations and associated civil penalty are set forth below:

- A. 10 CFR 35.32(a) requires, in part, that the licensee establish and maintain a written quality management program to provide high confidence that byproduct material or radiation from byproduct material will be administered as directed by the authorized user.
  - Pursuant to 10 CFR 35.32(a)(1), the quality management program must include written policies and procedures to meet the objective that, prior to administration, a written directive is prepared for any administration of quantities greater than 30 microcuries of either sodium iodide I-125 or I-131.

10 CFR 35.2 defines a written directive as an order in writing for a specific patient, dated and signed by an authorized user prior to the administration of a radiopharmaceutical or radiation and containing certain information. For any administration of quantities greater than 30 microcuries of either sodium iodide I-125 or I-131, the written directive must include the dosage.

Contrary to the above, on September 9 and November 11, 1994, two written directives prepared for administrations of dosages in excess of 30 microcuries of sodium iodide I-131 were not signed by authorized users. (01013)

 Pursuant to 10 CFR 35.32(a)(4), the quality management program must include written policies and procedures to meet the specific objective that each administration is in accordance with a written directive, which is defined in 10 CFR 35.2.

The licensee's quality management program, submitted to NRC by letter dated January 20, 1992, and amended July 5, 1994, specifies that each administration will be in accordance with the written directive and that prior to administration, each dosage shall be confirmed by measurement in a dose calibrator by the person administering the radiopharmaceutical and the result compared to the prescribed dosage in the written directive.

Contrary to the above, a person who administered dosages of sodium iodide I-131 on September 9 and November 11, 1994, did not

- 2 -

adequately confirm the dosages in a dose calibrator and compare them with prescribed dosages. Specifically, on September 9, 1994, the administered dose was approximately 30% greater than that prescribed, and on November 11, 1994, the dose was approximately 40% greater than that prescribed. (01023)

3. Pursuant to 10 CFR 35.32(a)(5), the quality management program must include written policies and procedures to meet the specific objective that any unintended deviation from the written directive is identified and evaluated, and appropriate action is taken.

The licensee's quality management program, submitted to NRC by letters dated January 20, 1992, and amended July 5, 1994, states that any unintended deviation from the written directive will be identified and evaluated, and appropriate action will be taken by the radiation safety officer (RSO).

Contrary to the above, on September 9, 1994, a dose of sodium iodide 1-131 was administered which was approximately 30% greater than that prescribed in the applicable written directive, and on November 11, 1994, a dose of sodium iodide I-131 was administered which was approximately 40% greater than that prescribed in the applicable written directive, and as of September 11, 1995, the licensee had not identified and evaluated these unintended deviations from the written directives, and no action had been taken by the RSO. (01033)

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

10 CFR 35.32(d) requires that records of radiopharmaceutical dosages requiring written directives be retained for three years following the administration.

Contrary to the above, as of September 11, 1995, the licensee's records of radiopharmaceutical dosages requiring written directives which were administered on September 9 and November 11, 1994, were not complete and accurate in all material respects. Specifically, the dosage administered to a patient on September 9 was approximately 30% greater than that recorded in the applicable record and the dosage administered to a patient on November 11 was approximately 40% greater than that recorded in the applicable record. This is material because dose administration records are required to be maintained. (01043)

These violations represent a Severity Level III problem (Supplement VI). Civil Penalty - \$2,500.

The NRC has concluded that information regarding the reason for the violation, the corrective actions taken, and the date when full compliance was achieved is already adequately addressed on the docket in letter from Community

# Notice of Violation

- 3 -

Hospital (Licensee) dated April 5, 1996. However, the Licensee is required to submit a written statement or explanation pursuant to 10 CFR 2.201 if the description therein does not accurately reflect its corrective actions or its position. In that case, or if the Licensee chooses to respond, such response should be clearly marked as a "Reply to a Notice of Violation," and should be send to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555 with a copy to the Regional Administrator, Region IV, 611 Ryan Plaza Drive, Suite 400, Arlington, Texas 76011, within 30 days of the date of the letter transmitting this Notice of Violation (Notice).

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

In requesting mitigation of the proposed penalty, the factors addressed in Section VI.B.2 of 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, 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, ATTN: Enforcement Officer, U.S. Nuclear Regulatory Commission, Region IV, 611 Ryan Plaza Drive, Suite 400, Arlington, Texas 76011.

Because the response will be placed in the NRC Public Document Room (PDR), to the extent possible, it should not include any personal privacy, proprietary,

#### Notice of Violation

or safeguards information so that it can be placed in the PDR without redaction. However, if the Licensee finds it necessary to include such information, clearly indicate the specific information that the Licensee desires not to be placed in the PDR, and provide the legal basis to support the request for withholding the information from the public.

Dated at Arlington, Texas, this 12th day of June 1996 - 4 -



UNITED STATES

REGION IV

611 RYAN PLAZA DRIVE, SUITE 400 ARLINGTON, TEXAS 76011-8064

October 31, 1996

EA 96-232

CTI Alaska, Inc. ATTN: George E. Haugen 4831 Old Seward Highway Suite 107 Anchorage, Alaska 99503

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTIES -\$13,000 (NRC Inspection Report No. 030-17129/96-01)

Dear Mr. Haugen:

This refers to the inspection completed by the NRC on July 2. 1996. at your facility in Anchorage. Alaska. This was a special inspection which included a review of circumstances relating to the December 23. 1995. event involving an inadvertent exposure of a radiographer and potential malfunction of a radiographic exposure device. Your Radiation Safety Officer (RSO) informed the NRC of the event on December 28. 1995. and the NRC subsequently conducted the special inspection. The issues were discussed with you during an interim briefing on January 23. 1996. and a telephonic exit briefing on July 2. 1996. A predecisional enforcement conference was held with you in the NRC Region IV office in Arlington. Texas, on August 6. 1996.

Based on the information developed during the inspection, the information that you provided during the conference, and the information that you provided in your letters dated July 31. August 8, and September 6, 1996, 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 (Notice) and the circumstances surrounding them are described in detail in the subject inspection report.

The exposure event began during the night shift of December 23-24. 1995, when a safety latch inside the locking mechanism of an INC Model IR-100 exposure device failed to secure the source assembly in a fully shielded position after the source was retracted into the device. (Concerns about the radiographic device were addressed with the manufacturer.) Since the radiographer (the more senior of the two on the job) failed to conduct an adequate survey because the survey instrument was not initially operable, and failed to adequately check his alarm ratemeter prior to use. he was not aware that the source was not fully retracted. As a result, he received an excessive exposure, but not an overexposure. After recognizing that he was exposed to the source, the radiographer left the area and found that his pocket dosimeter was off-scale. Instead of stopping work and immediately notifying the CTI RSO or other appropriate personnel, the radiographer kept doing other work related to the job. At the end of the night shift, on the morning of December 24, the radiographers informed their supervisor of the event. When he found out the Radiation Safety Administrative Assistant (RSAA) was out of town, the supervisor did not try to reach other company officials. but instead waited until December 26. to notify the RSAA, who promptly notified the CTI RSO. It

NUREG-0940, PART III

wasn't until December 27 that the radiographer's film badge was sent to the badge supplier for processing.

The first four violations in the Notice are: (1) a radiographer's failure to adequately survey the radiographic device to determine that the sealed source had been returned to its shielded position (Violation I.A.1); (2) a radiographer's failure to check the operability of his alarm ratemeter prior to use at the start of the shift (Violation I.A.2); (3) radiography personnel failures to immediately notify the RSD or other designated managers about the potential malfunction of a radiographic exposure device and the otf-scale discharge of a pocket dosimeter (Violation I.A.3); and (4) CTI's failure to immediately send for processing a radiographer's film badge, after his pocket dosimeter discharged beyond its radige (Violation I.A.4).

Violations I.A.1 and I.A.2 are significant because they represent two breached safety barriers that are designed to prevent overexposures to radiographers and the public. Violations I.A.3 and I.A.4 are also significant because they resulted in a delay in CTI's notifications and response to the incident. In total, these represent a very significant regulatory concern. Therefore, these violations 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 civil penalty with a base value of \$8,000 is considered for a Severity Level II problem. 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 violations were essentially revealed through an event. In addition, CTI demonstrated a low degree of initiative in investigating the root cause of the violations. Specifically, at times during the inspection, information was developed as a result of the NRC's questioning. Based on the ease of discovery of the violations following the event, and CTI's low degree of initiative in identifying the root cause of the violations, the NRC has determined that no credit for Identification is warranted. However, the NRC has determined that credit for the Corrective Action factor is warranted. CTI's actions included, but were not limited to. disciplinary action against the involved radiographers. improved emphasis on reporting of incidents by employees and supervisors, posting safety memos regarding the incident, increased frequency of safety audits, additional training on the INC Model IR-100 exposure device. assignment of a new safety coordinator and a field operations manager to the BPX project, revised operating procedures and physical enhancements related to the use of the INC Model IR-100 exposure device, emphasized the consequences of noncompliance with NRC requirements, and increased audit frequency. Therefore, the civil penalty assessed for these violations is the base value of \$8,000

The next two violations identified in the Notice involved your employees' failure to post a high radiation area (Violation I.B.1) and to maintain accurate records in that the "Daily Radiation Job Sheet" indicated that a high

radiation area was posted when it had not been posted (Violation I.B.2). A radiographer told an NRC inspector that, although he knew that high radiation area signs were required, a high radiation area posting had not been used and that he had marked the CTI form to indicate that the posting was used so that he would not get in trouble.

These violations, which appear to be willful, are of significant regulatory concern because the conduct of licensed activities depends in large part on the integrity of the individuals conducting such activities. In this case, the radiographers' action were of particular concern because they are responsible to CTI for assuring compliance with the requirements of the Commission's regulations and the conditions of the license. Therefore, these violations are classified in accordance with the Enforcement Policy as a Severity Level III problem.

In accordance with the Enforcement Policy. a base civil penalty in the amount of \$5.000 is considered for a Severity Level III problem. Because the violations involve willfulness, 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. In this case, the NRC has determined that no credit for *Identification* is warranted, because the NRC inspector identified this violation. However, NRC has determined that credit for the *Corrective Action* factor is warranted based on the actions described above. Therefore, the civil penalty assessed for these violations is the base value of \$5,000.

To emphasize the importance of compliance with radiation safety procedures, the unacceptability of willful violations, and prompt identification of violations. I have been authorized, after consultation with the Director. Office of Enforcement, to issue the enclosed Notice in the amount of \$13,000 for the Severity Level II and Severity Level III problems described above.

The last violation described in the Notice involved the failure to complete and submit written reports in accordance with CTI's procedures. Specifically, CTI personnel did not complete and submit written reports to the RSO within 8 hours after two separate events involving potential malfunctioning INC Model IR-100 radiographic devices. The two events occurred on January 9, 1996, and the reports were not completed and submitted until February 9 and 15, 1996. This violation is classified in accordance with the Enforcement Policy as a Severity Level IV violation, and is cited in the enclosed Notice.

We have noted, with some concern. CTI's statements in its letter dated July 31 and September 6, 1996, regarding these violations, specifically attributing the root cause to complacency and indifference towards safety by two radiographers. You reiterated this at the August 3, 1996, predecisional enforcement conference. We note, however, that not all violations were related to the actions of two radiographers. A CTI supervisor failed to immediately notify the RSAA or other appropriate CTI manager, on December 24, 1995, and CTI management failed to promptly send the dosimeter for processing.

In addition, the violations in Section II of the notice, which occurred about 2 weeks after violations described in Section I. involved different employees but similar circumstances (i.e., lock mechanism problems on exposure devices for which required reports were not promptly completed and submitted).

Regarding the violations committed by the radiographers, we emphasized to you at the conference that we hold licensees responsible for the actions of their employees. All licensed artivities are carried out by employees and therefore, all violations are committed by employees. The licensee obtains the benefits of an employee's good performance and suffers the consequences of their poor performance. While we are concerned about the performance of your former employees, and in fact by separate correspondence plan to put them on notice that willful violations in the future may result in significant action against them, we do not intend to pursue any further the matters discussed in your letter dated September 6, 1996.

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

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

Sincerely.

Kur Regional Administrator

Docket No. 030-17129 License No. 50-19202-01

Enclosure: Notice of Violation and Proposed Imposition of Civil Penalties

cc (w/enclosure): Alaska Radiation Control Program Director

### NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTIES

CTI Alaska, Inc. Anchorage, Alaska

Docket No 030-17129 License No. 50-19202-01 EA 96-232

During an NRC inspection conducted on January 17 through July 2. 1996. violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions." NUREG-1600. the Nuclear Regulatory Commission proposes to impose civil penalties pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (Act). 42 U.S.C. 2282, and 10 CFR 2.205. The particular violation and associated civil penalties are set forth below:

# I. Violations Assessed a Civil Penalty

A. 1. 10 CFR 34.43(b) requires, in part, the licensee to ensure that a survey with a calibrated and operable radiation survey instrument is made after each radiographic exposure to determine that the sealed source has been returned to its shielded position.

Condition 17 of License 50-19202-01 requires, in part, that the licensee conduct its program in accordance with the statements, representations, and procedures contained in the letter, dated September 28, 1995, including the "Radiation Safety Program." Paragraph 1.2. Section 7.0. Part II of the "Radiation Safety Program" manual requires, in part, a radiation survey at the surface of an exposure device after completing each radiographic exposure by measuring the radiation levels and comparing them with the levels previously measured for the same source and exposure device. Paragraph 1.2 further states that if the levels do not correspond to previously measured levels, the source has not returned properly to a safe position.

Contrary to the above. on December 23. 1995. at the Endicott Island Project job site. a licensee radiographer did not perform an adequate survey with an operable radiation survey instrument after a radiographic exposure to determine that the sealed source had been returned to its shielded position. Specifically, using a malfunctioning survey meter, the radiographer failed to measure a radiation level exceeding 1 R/hr that was emitted near the surface of a Model IR-100 exposure device, and failed to compare the readings detected with those previously measured for the same source and device to evaluate whether the source had returned to its fully shielded and safe position. (01012)

10 CFR 34.33(f)(1) requires that each alarm ratemeter be checked to ensure that the alarm functions (sounds) prior to use at the start of each shift.

2

-2-

representations. and procedures contained in the letter dated September 28, 1995, with enclosures. Paragraph 3.5. Section 2.0. Part II of the "Radiation Safety Program." enclosed with the letter dated September 28, 1995, requires that each licensee radiographer check the operation of an alarm ratemeter before use during radiography by activating its battery and alarm tone test button, and requires that an alarm ratemeter not be used if either the LED battery light fails or the alarm fails to sound.

Contrary to the above, on approximately seven occasions during radiographic operations at the Endicott Island Project in December 1995, a licensee radiographer did not ensure that his alarm ratemeter functioned prior to its use at the start of each shift. Specifically, a Model RA-500 alarm ratemeter (S/N 5310) had been used without first activating the battery and alarm tone test button and thecking the ratemeter's response by observing if the installed LEU light failed and if the alarm failed to sound. (01022)

- Condition 17 of License 50-19202-01 requires, in part, that the licensee conduct its program in accordance with the statements, representations, and procedures contained in the letter dated September 28, 1995, with enclosures.
  - a. Paragraph 1.0. Section 13.0. Part II of the enclosure. "Radiation Safety Program." requires immediate notification of the radiation safety officer. or in his absence, the radiation safety manager or appropriate NRC or State authorities in the event of an emergency arising from malfunction of an exposure device.
  - b. Paragraph 1.2 of Section 13.0. Part II requires that if there is any question as to whether a given situation constitutes an emergency, emergency procedures must be followed.

Paragraph 1.5. Section 2.0. Part II of the same enclosure also requires radiography personnel to stop work and notify the radiographic supervisor and the radiation safety officer who will send in the film badge(s) for immediate processing if a radiographer's pocket dosimeter goes off-scale.

Contrary to the above, on the night of December 23, 1995, during radiography at the Endicott Island Project, two licensee radiographers and a supervisor failed to:

a. notify the radiation safety officer. the radiation safety manager. or appropriate NRC or State authorities immediately

following the apparent malfunction of a radiographic exposure device: and

-3-

- b. notify the radiation safety officer immediately following the off-scale discharge of a pocket dosimeter assigned to a radiographer. (The radiation safety officer was not notified until December 26, 1995, more than two days after the event.) (01032)
- 10 CFR 34.33(d) requires that if an individual's pocket dosimeter is discharged beyond its range, his film badge or TLD be immediately sent for processing.

Contrary to the above, on December 23, 1995, during radiography performed at the Endicott Island Project, a radiographer's pocket dosimeter discharged beyond its range and the film badge worn by the individual was not immediately sent for processing. (The film badge was not sent for processing until December 27, 1995.) (01042)

These violations represent a Severity Level II problem (Supplement VI). Civil Penalty - \$8,000.

B. 1. 10 CFR 34.42 requires, notwithstanding any provisions in 10 CFR 20.1903, that areas in which radiography is being performed be conspicuously posted, as required by 10 CFR 20.1902(a) and (b). 10 CFR 20.1902(b) requires that each high radiation area be conspicuously posted with a sign or signs bearing the radiation caution symbol and the words. "CAUTION, HIGH RADIATION AREA" OR "DANGER, HIGH RADIATION AREA."

Contrary to the above. on December 23. 1995. during radiography performed at the Endicott Island Project. the licensee did not post the high radiation area in which industrial radiography was being performed. (02013)

2. 10 CFR 30.9(a) requires, in part, that information required by license conditions to be maintained by the licensee be complete and accurate in all material respects. Condition 17 of License 50-19202-01 requires, in part, that the licensee conduct its program in accordance with the statements, representations, and procedures contained in the letter dated September 28, 1995, with enclosures. Paragraph 1.3, Section 6.0, Part I and paragraph 1.0, Section 1.1, Part II of the enclosure, "Radiation Safety Program" require that a radiographer complete a "Daily Radiation Job Sheet" with information that includes a check mark to indicate that high radiation area signs were posted, and that the licensee maintain the job sheet form records.

NUREG-0940, PART III

Contrary to the above, on December 23, 1995, the licensee failed to maintain an accurate record to indicate that a high radiation area was posted, as required by 10 CFR 34.42 and 10 CFR 20.1902(b). Specifically, a radiographer marked (checked) a "Daily Radiation Job Sheet" to indicate that a high radiation area was posted during industrial radiography when in fact the area was not posted. This record was material because, during an inspection, it could have influenced the NRC as to whether a violation had occurred. (02023)

These violations represent a Severity Level III problem (Supplement VI). Civil Penalty - \$5,000.

### II. Violation Not Assessed A Civil Penalty

Condition 17 of License 50-19202-01 requires, in part, that the licensee conduct its program in accordance with the statements, representations, and procedures contained in the letter dated September 28, 1995, with enclosures. The "Radiography Incident and Equipment Failure Report" form, enclosed with the September 28, 1995 letter requires licensee personnel to complete and submit (by facsimile) the report with attached information, as necessary, to the RSO within 8 hour after the incident/failure.

Contrary to the above, radiography personnel did not complete or submit the form or written report to the RSO following two radiography equipment incidents on January 9, 1996, each involving the apparent malfunction of a lock mechanism on a Model IR-100 exposure device. (03014)

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

Pursuant to the provisions of 10 CFR 2.201. CTI Alaska. 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 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.

-4-

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

-5-

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, letter with 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 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. 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.

Dated at Arlington. Texas. this 31st day of October 1996

NUREG-0940, PART III



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

August 5, 1996

EA 96-140

mr. Thomas Kregoski, President Diagnostic Reagents, Inc. 1727 Monroe Dearborn, MI 48124

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY -\$1,000 (NRC INVESTIGATION REPORT NO. 3-95-031)

Dear Mr. Kregoski:

This refers to the investigation conducted by the NRC Office of Investigations (OI) concerning the relocation of Diagnostic Reagents, Inc., and an alteration made to the license. By letter dated May 1, 1996, the synopsis of the OI report and a description of the apparent violations were mailed to Diagnostics Reagents, Inc. By letter dated June 1, 1996, Diagnostic Reagents, Inc., responded to the apparent violations and did not request a predecisional enforcement conference.

Based on the information obtained during the OI investigation and provided in a June 1, 1996 letter from Diagnostic Reagents, Inc., the NRC has determined that significant violations of NRC requirements occurred. The violations are cited in the enclosed Notice of Violation and Proposed Imposition of Civil Penaity and the circumstances surrounding them are described in the OI investigation report. The first violation concerned the possession and use of NRC-licensed materials at a location that was not authorized by Materials License No. 21-19345-OIG. The second violation pertained to an alteration on the license regarding the NRC-authorized location for the possession and use of licensed material (iodine-125 *in vitro* kits). The OI investigation concluded that the violations were deliberate.

The NRC considers the possession and use of NRC-licensed material at an unauthorized location to be a significant concern. The failure to notify the NRC and obtain authorization for such activities denies the NRC the opportunity to assure that activities are conducted in compliance with all NRC radiation safety requirements. Making an alteration on the license to show a different location where licensed materials are used is also a significant concern because the altered license was posted pursuant to 10 CFR 19.11 and because, by altering the license, Diagnostic Reagents, Inc., was able to receive licensed materials at an unauthorized location. In sworn testimony, Mr. Kregoski indicated that the license was altered because "[t]he manufacturers every so often ask you for a copy."

The incensee maintains in its June 1, 1996 letter that, because of pending fee issues, these violations were necessary under the circumstances in order to continue as a viable business. However, the licensee made no attempt to contact the NRC Region III Office to discuss the circumstances, or to arrange

for payments over time while the fee issues were resolved. Rather, the licensee proceeded to willfully violate the Commission's requirements. The NRC regulatory program is based on the carjor and integrity of each licensee and their employees; therefore, NRC cannot and will not condone willful violations. Accordingly, these violations are of significant regulatory concern and are categorized in the aggregate as a Severity Level III problem in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions" (Enforcement Policy), 10 CFR Part 2, Appendix C, which was in effect for most of the time the violations existed. The Enforcement Policy set forth in 10 CFR Part 2, Appendix C, was applied in this matter as

- 2 -

Therefore, to emphasize that willful violations are not acceptable, and violations must be identified and corrected as promptly as possible, and after consultation with the Director, Office of Enforcement, I have been authorized to issue the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice) in the amount of \$1,000 for the Severity Level III problem.

it resulted in more favorable treatment for the licensee than the application of the NRC's current Enforcement Policy, which is set forth in NUREG-1600.

In accordance with the Enforcement Policy, a base civil penalty in the amount of \$500 is considered for a Severity Level III problem. The base civil penalty was initially escalated 50 percent because the NRC identified the problem. The civil penalty was increased an additional 50 percent because prompt corrective action was not taken. The NRC recognizes that Amendment No. 4 to Materials License No. 21-19345-01G, issued on May 3, 1996, corrected the violation regarding the authorized location for the possession and use of licensed materials. However, the NRC identified during November 1994 that Diagnostic Reagents, Inc., had relocated. Diagnostic Reagents, Inc., did not write to the NRC about the move until February 1, 1995, and did not request the license be amended to list the new location until March 13, 1996. Furthermore, the June 1, 1996, letter from Diagnostic Reagents, Inc., did not specifically address corrective actions for the willful aspects of the problem. The licensee's past performance has been good; however, the NRC staff did not apply mitigation based on the licensee performance factor because the violations are willful. This exercise of discretion in cases involving willfulness is permitted under the Enforcement Policy, 10 CFR Part 2, Appendix C, in Section VII, and is intended to reflect the level of NRC's concern regarding willful violations and ensure that the enforcement action conveys the appropriate message to the licensee. The remaining civil penalty adjustment factors were considered and no further adjustment was necessary. On balance, the civil penalty was increased 100 percent. Diagnostic Reagents, Inc., should be aware that a substantially higher civil penalty could have been proposed had the violations been processed under the NRC's current Enforcement Policy (NUREG-1600).

Your letter of June 1, 1996, discursed the financial difficulties being encountered by Diagnostic Reagent, Inc. Your attention is directed to Section VI.B.1 of the current NRC Enforcement Policy (NUREG-1600, a copy of which was mailed to you on June 1, 1996) for the payment of a civil penalty over time. To use this option, Diagnostic Reagents, Inc., must demonstrate: Diagnostic Reagents, Inc.

- 3 -

(1) financial hardship; and (2) sufficient resources to safely conduct licensed activities and pay license fees. Application for payment of a civil penalty over time must be addressed to Mr. James Lieberman, Director, Office of Enforcement, U. S. Nuclear Regulatory Commission, Washington, DC 20555.

You are required to respond to this letter because your letter of June 1, 1996, did not address your specific actions to correct the willful aspects of the problem (i.e., to ensure that the NRC license is properly amended prior to making changes in ownership, location, or procedures required by license condition; to ensure that violations, once identified, are promptly corrected; and to prevent future willful violations). You should follow the instructions specified in the enclosed Notice when preparing your response. In your response, you should document the specific actions taken and any additional actions you plan to prevent recurrence. After reviewing your response to this Notice, including your proposed corrective actions and the results of future inspections, the NRC will determine whether further NRC enforcement action is necessary to ensure compliance with NRC regulatory requirements.

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

A. Bill Beach Regional Administrator

Docket No. 030-17466 License No. 21-19345-016

Enclosure: Notice of Violation and Proposed Imposition of Civil Penalty

NUREG-0940, PART III

#### NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY

Diagnostic Reagents, Inc. Dearborn, Michigan Docket No. 030-17466 License No. 21-19345-01G EA 96-140

During an NRC investigation conducted from August 22, 1995, to March 22, 1996, violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C, the Nuclear Regulatory Commission proposes to impose a civil penalty pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (Act), 42 U.S.C. 2282, and 10 CFR 2.205. The particular violations and associated civil penalty are set forth below:

A. 10 CFR 30.34(c) requires, in part, that each licensee confine its possession and use of byproduct materials to the location authorized by the license.

Condition No. 10 of Materials License No. 21-19345-01G requires that licensed material be used only at 1034 Monroc, Dearborn, Michigan.

Contrary to the above, from May 26, 1993, to May 3, 1996, the licensee possessed licensed material (iodine-125 *in vitro* kits) at 1727 Monroe, Dearborn, Michigan, a location not authorized by the license. (01013)

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

10 CFR 19.11(a) and (b) require, in part, that the licensee post current copies of the license, or that the licensee post a notice describing this dorument and where it may be examined.

Contrary to the above, information required by the Commission's regulations to be maintained by the licensee was not complete and accurate in all material respects. Specifically, sometime between May 1993 and August 1995, the licensee deliberately altered the NRCauthorized location for the possession and use of byproduct material (iodine-125 in vitro lits) as stated on License No. 21-19345-01G, Amendment No. 3, to show the address as 1727 Monroe, Dearborn, Michigan (instead of 1034 Monroe, Dearborn, Michigan, as approved by the NRC); and, as of August 1995, the licensee had posted a copy of the altered license pursuant to 10 CFR 19 11. This information is material because 10 CFR 19.11 requires that a copy of the NRC license be posted or available for examination. (0.023)

This is a Severity Level III problem (Supplements VI and VII). Civil Penalty \$1,000.

Pursuant to 10 CFR 2.201, Diagnostic Reagents, Inc. (Licensee) is hereby required to submit a written statement or explanation to the Director, Office

Notice of Violation and Proposed - 2 - Imposition of Civil Penalty

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

Within the same time as provided for the response required above under 10 CFR 2.201, the Licensee may pay the civil penalty by letter addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, with a check, draft, money order, or electronic transfer payable to the Treasurer of the United States in the amount of the civil penalty proposed above, or may protest imposition of the civil penalty in whole or in part, by a written answer addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission. Should the Licensee fail to answer within the time specified, an order imposing the civil penalty will be issued. Should the Licensee elect to file an answer in accordance with 10 CFR 2.205 protesting the civil penalty, in whole or in part, such answer should be clearly marked as an "Answer to a Notice of Violation" and may: (1) deny the violation listed in this Notice, in whole or in part, (2) demonstrate extendating 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.8.2 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 arv civil penalty due which subsequently has been determined in accordance which 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

Notice of Violation and Proposed - 3 -Imposition of Civil Penalty

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. 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.

Dated at Lisle, Illinois this 5th day of August 1996



#### UNITED STATES NUCLEAR REGULATORY COMMISSION WASHINGTON, D.C. 200001

November 4, 1996

EA 96-140

Diagnostic Reagents, Inc. ATTN: Mr. Thomas Kregoski, President 1727 Monroe Dearborn, Michigan 48124

Dear Mr. Kregoski:

SUBJECT: WITHDRAWAL OF PROPOSED CIVIL MONETARY PENALTY (NRC Investigation Report No. 3-95-031)

On August 5, 1996, the Nuclear Regulatory Commission issued a Notice of Violation and Proposed Imposition of Civil Penalty (Notice) in the amount of \$1,000 to Diagnostic Reagents, Inc. You answered the Notice by letter dated August 15, 1996. In your letter, you contested the violation and the amount of the civil penalty, and requested mitigation. Subsequently, by letters dated October 3 and 10, 1996, you requested that NRC Region III terminate your license. Concurrent with this letter, NRC is issuing an amendment terminating NRC License No. 21-19345-016.

We have reviewed your letter dated August 15, 1996, and we reaffirm our position that the violations are valid as cited and that the civil penalty was properly assessed. Notwithstanding the explanations and arguments for mitigation in your letter, you clearly knew that a license amendment was necessary before conducting licensed activities at a new address. However, you conducted licensed activities at your new address for a number of years without obtaining the necessary license amendment.

The NRC acknowledges that the appropriate application fee normally must accompany a license amendment request before it can be acted upon, and that any fee amounts remitted to NRC normally are applied to the licensee's oldest debt. This scheme assures that fees due to NRC are paid as required. The fact that you had not resolved an outstanding fee issue cannot be used as an excuse for proceeding in violation of an NRC requirement.

However, in light of the termination of your NRC license, the Notice of Violation issued August 5, 1996 is hereby modified to delete the civil penalty.

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

Sincerely. Amark

Dames Lieberman, Director Office of Enforcement



#### UNITED STATES NUCLEAR REGULATORY COMMISSION WASHINGTON, D.C. 20565-0001

March 29, 1996

EA 96-085

Mr. Himat J. Soni, President Eastern Testing and Inspection, Inc. 139 Crown Point Road Thorofare, New Jersey 08086

SUBJECT: ORDER SUSPENDING LICENSES (EFFECTIVE IMMEDIATELY)

Dear Mr. Soni:

The enclosed Order Suspending Licenses (Order) is being issued to Eastern Testing and Inspection, Inc. (ETI). The bases for this action are described in the enclosed Order, and include: (1) numerous violations, some willful, of NRC requirements, (2) failure to take appropriate actions to prevent violations from recurring, and (3) the poor enforcement history of ETI. In particular, ETI deliberately created inaccurate records, in violation of 10 CFR 30.9 and 30.10, and threatened a former employee with physical harm, based on the belief that the former employee had cooperated with an NRC investigation or inspection. Also, ETI deliberately utilized an employee, with no prior radiography experience, to perform radiography one day after he was hired, even though the individual had not received the required training, and ETI deliberately falsified ETI records representing that the employee was qualified to perform radiography.

The Order requires, pending further investigation, that: (1) all NRC-licensed material in your possession shall be placed in locked storage; (2) all activities under your licenses to use licensed material shall be suspended, except for transfer to an authorized recipient with specified prior notice to the NRC; (3) no NRC-licensed material may be received while the Order is in effect; and (4) all records related to licensed activities shall be maintained in their original form and must not be removed or altered in any way. Therefore, further action will be considered as appropriate.

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 this Order shall be subject to criminal prosecution as set forth in that section. Violation of this order also may subject the person to a civil monetary penalty.

Questions concerning this Order should be addressed to Mr. James Lieberman, Director, Office of Enforcement, who may be reached at (301) 415-2741.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter and the enclosure will be placed in the NRC's Public Document Room (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. However, if you find it necessary to include such

Eastern Testing and Inspection, Inc.

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.

- 2 -

Sincerely,

Kins- Makes-

James Lieberman, Director Office of Enforcement

Docket Nos: 030-05373; 030-32163 License Nos: 29-09814-01; 29-09814-02

Enclosure: As Stated

cc: w/encl State of New Jersey State of New York

NUREG-0940, PART III

### UNITED STATES MUCLEAR REGULATORY COMMISSION

In the Matter of

EASTERN TESTING & INSPECTION, INC. Thorofare, New Jersey Docket Nos. 030-05373; 030-32163 License Nos. 29-09814-01; 29-09814-02 EA 96-085

#### ORDER SUSPENDING LICENSES (EFFECTIVE IMMEDIATELY)

I

Eastern Testing & Inspection, Inc., (Licensee or ETI) is the holder of Byproduct Nuclear Material Licenses No. 29-09814-01 and No. 29-09814-02 issued by the Nuclear Regulatory Commission (NRC or Commission) pursuant to 10 CFR Part 30. License No. 29-09814-01 authorizes possession and use of iridium-192 and cobalt-60 sealed radiography sources for use in a compatible radiographic source exposure device. The license was last renewed on December 16, 1994 and is due to expire on December 31, 1999. License No. 29-09814-02 authorizes the use of portable gauges, was issued on May 23, 1991, and is due to expire on May 31, 1996.

#### II

The NRC Office of Investigations (SI) conducted an investigation of ETI and based on that investigation, it appears that with respect to License No. 29-09814-01:

(1) the ETI President. Mr. Himat Soni, deliberately caused the Licensee to create an inaccurate record in violation of 10 CFR 30.9 and 30.10, by signing an ETI radiographer's card, dated June 16, 1995, which certifies that an employee meets the applicable requirements of the SNT-TCI-IA and

is authorized to perform the duties of Radiographer Level I per ETI procedures, when the employee had received only a few hours of it truction and told Mr. Soni that the employee had not completed 40 hours of formal classroom training in radiation safety as specified by ETI Radiation Safety Procedures, Procedure No. RS-1, Rev. G, (March 14, 1994), incorporated by reference in Condition 17 of License No. 29-09814-01:

- 2 -

(2) the ETI Radiation Safety Officer (RSO), Mr. Joseph Badiali, deliberately caused the Licensee to create an inaccurate record of an employee's Radiation Safety Examination for Assistant Radiographer, dated June 20, 1995, in violation of 10 CFR 30.9 and 30.10, by providing the employee with answers to the examination;

(3) the ETI RSO deliberately caused the Licensee to create an inaccurate record of an employee's training, in violation of 10 CFR 30.9 and 30.10, by signing a document dated June 20, 1995, representing that he had given the employee an oral quiz as part of a practical examination, when the employee had not been given the oral quiz or a practical examination;

(4) ETI deliberately directed at least one unqualified and untrained employee, the employee referred to in subparagraphs (1)-(3) above, to perform radiography between June 15, 1995, and July 26, 1995, in violation of 10-CFR 34.31;

(5) ETI personnel did not complete utilization records on 97 occasions
 between January 1, 1994 and August 31, 1995, in violation of 10 CFR
 34.27; and

(6) on September 29, 1995, the President of ETI threatened a former employee with physical harm, based on the belief that the former employee may have cooperated with an NRC investigation and/or inspection of ETI.

- 3 -

In addition, on May 24, 1995, July 11 and 13, 1995, and August 1, 2, and 23, 1995, the NRC conducted an inspection at the ETI facility in Thorofare, New Jersey, and at a temporary jobsite in Deepwater, New Jersey. During the inspection, violations of NRC requirements were identified related to the radiography license (No. 29-09814-01). The violations involved:

(1) the provision of a few hours of instruction, rather than 40 hours of formal classroom instruction to an employee, who performed work as a radiographer's assistant between June 15, 1995 and July 26, 1995, in violation of 10 CFR 34.31(b) and ETI Radiation Safety Procedure No. RS-1, Revision 4, dated March 14, 1994, incorporated by reference in Condition 17 of License No. 29-09814-01;

(2) the failure to maintain records of audits of the radiation program content and implementation for 1994 and 1995, as required by 10 CFR
 20.2102(a)(2);

(3) the failure to "rezero" pocket dosimeters before the start of each shift on April 12, 1994, May 6, 1994, March 16, 1995, March 28, 1995, July 6, 1995, July 26, 1995, August 8, 1995, and August 23, 1995, as required by 10 CFR 34.33(a) and ETI Radiation Safety Procedures, Procedure No. ETI-1, Revision G, dated March 14, 1994, incorporated by reference in Condition 17 of License No. 29-09814-01;

(4) the failure on January 24 and 25, 1995, and August 31, 1995, to use

NUREG-0940, PART III

survey meters calibrated within three months and to maintain records of survey meter calibrations, as required by 10 CFR 34.24;

(5) the failure to complete dosimetry records for the period June 1995 through July 1995, as required by 10 CFR 20.2106(c), in that the names, social security numbers or birth dates of individuals were missing;
(6) the failure to complete utilization logs and return completed utilization logs to the Radiation Safety Officer, for the period June 1994 through August 1995, as required by ETI Radiation Safety Procedures, Procedure No. ETI-1, Revision G, dated March 14, 1994, incorporated by reference in Condition 17 of License No. 29-09814-01;
(7) the failure on August 23, 1995, to perform physical radiation surveys to ensure readings at roped-off boundaries do not exceed 2 millirem in an hour as required by ETI Radiation Safety Procedures, Procedures, Procedure No. ETI-1, Revision G, dated March 14, 1994, incorporated by reference in Condition 17 of License Mo. 29-09814-01;

(8) the failure on August 23, 1995, to perform a survey after each exposure to determine that the sealed source has been returned to the shielded position as required by 10 CFR 34.43(b);

(9) the failure on July 12, 1995, to complete a shipping paper prior to transporting licensed material outside the confines of the licensee's plant as required by 10 CFR 71.5(a) and 49 CFR 177.817(a);

(10) the failure on July 12, 1995, to identify the activity or transport index on the RADIOACTIVE label attached to a package containing licensed material transported outside the confines of the licensee's plant, as required by 10 CFR 71.5(a) and 49 CFR 172.403; and

NUREG-0940, PART III

(11) the failure on August 23, 1995, to block and brace packages containing licensed material transported outside the confines of the ETI facility, as required by 10 CFR 71.5(a) and 49 CFR 177.842(d).

- 5 -

The NRC staff performed a follow-up inspection of License No. 29-09814-01 on March 14, 1996, to determine the Licensee's compliance with NRC safety requirements. The staff concludes that the Licensee deliberately falsified documents of radiographer examinations, given during an annual eight hour refresher training course, in violation of 10 CFR 30.9 and 30.10. The responses to the 22 questions on the examination, dated January 16, 1996, were identical in the examination forms of the President of ETI and a radiographer. ETI Invoice No. 32478 and ETI Work Order No. 9512220007, however, document that on January 16, 1996, the radiographer was working at a jobsite in Brooklyn, New York. The work order states that the radiographer arrived at the Brooklyn jobsite at 6:00 a.m. and departed the Brooklyn jobsite at 2:00 p.m. The job-site is approximately a three-hour drive from the Licensee's facility, at which the RSO stated that the training had been given.

The Licensee has a poor enforcement history. Civil penalties have been issued to ETI twice since 1987 for violations of NRC requirements.<sup>1</sup> Some of the violations identified during the subject recent 1995 inspection were repetitive of violations that formed the basis for the \$7,500 civil penalty

<sup>&</sup>lt;sup>1</sup> On July 24, 1987, a Notice of Violation (EA 87-079) was issued citing 4 violations and a civil penalty of \$6500 was proposed, which was subsequently paid in full. On September 17, 1992, a Notice of Violation (EA 92-136) was issued citing 9 violations and a civil penalty of \$7500 was proposed, which was subsequently reduced to \$5000 in light of financial considerations.

issued on September 17, 1992.<sup>2</sup> The currently identified violation of directing an unqualified employee to perform radiography is repetitive of a 1994 violation.<sup>3</sup> Some of the violations listed in the 1992 action, and to which the licensee admitted, were found to be in careless disregard of NRC requirements, and thus willful.<sup>4</sup>

- 6 -

## III

Based on the above, the Licensee has violated numerous NRC requirements, some willfully, and has failed to take appropriate actions to prevent the recurrence of past violations. In particular, the Licensee deliberately created inaccurate records, in violation of 10 CFR 30.9 and 30.10, and

<sup>2</sup> The 1992 and 1995 inspections both found (1) violations of 10 CFR 34.43(b) for failure to survey the entire circumference of the radiographic exposure device, and (2) violations of 49 CFR 177.842(d), failure to block and brace the device in transport.

<sup>3</sup> On July 20, 1994, the NRC issued a Notice of Violation to the Licensee for permitting an individual to act as a radiographer's assistant without having successfully completed a practical field examination, in violation of 10 CFR 34.31(b). By letter dated August 26, 1994, the Licensee stated that its corrective action consisted of administering the practical field examination to all assistant radiographers and including the examination requirement in its training procedures.

<sup>4</sup> The letter transmitting EA 92-136 notes: "... the Radiation Safety Officer (RSO) at the facility was aware of the actions needed to ensure compliance with requirements, but did not take those necessary actions in a timely manner...with respect to [certain violations] ... the RSO indicated that he understood the need for action to comply with the requirements, but just did not get to completing those actions .... with respect to the violation involving the movement of a radiographic device in an unauthorized container, the RSO indicated that he understood the requirement for an approved container, but believed that the container fabricated for the transport was safe enough. These failures to ensure that the licensed activities were conducted in accordance with NRC requirements constitute careless disregard on the part of the RSO and therefore are considered willful within the context of the NRC enforcement policy."

threatened a former employee with physical harm, based on the belief that the former employee had cooperated with an NRC investigation or inspection. Also, the Licensee deliberately utilized an employee, with no prior radiography experience, to perform radiography one day after he was hired, even though the individual had not received the required training, and ETI deliberately falsified ETI records representing that the employee was qualified to perform radiography. The Commission must be able to rely on its Licensees to provide complete and accurate information and to otherwise comply with NRC requirements, and to refrain from conduct which could impede NRC inspections or investigations of safety concerns. The Licensee, however, through its President and its Radiation Safety Officer, Mr. Himat Soni and Mr. Joseph Badiali, respectively, has demonstrated an unwillingness to comply with NRC requirements. The actions of the Licensee and its senior officials have raised serious doubt as to whether the Licensee and its employees can be relied upon in the future to comply with NRC requirements and to maintain complete and accurate records of licensed activities.

- 7 -

Consequently, I lack the requisite reasonable assurance that the Licensee's current operations can be conducted under License Nos. 29-09814-01 and 29-09814-02 in compliance with the Commission's requirements and that the health and safety of the public, including the Licensee's employees, will be protected. Therefore, the public, health, safety and interest require that License Nos. 29-09814-01 and 29-09814-02 be suspended, pending further investigation. Furthermore, pursuant to 10 CFR 2.202, I find that the significance of the violations, and the willfulness of the Licensee's conduct, as described above, are such that the public health, safety, and interest

require that this Order be immediately effective.

IV

- 8 -

Accordingly, pursuant to sections 81, 161b, 161i, 161o, 182 and 186 of the Atomic Energy Act of 1954, 2s amended. and the Commission's regulations in 10 CFR 2.202 and 10 CFR Part 30, IT IS HEREBY ORDERED, EFFECTIVE IMMEDIATELY, THAT LICENSE Nos. 29-09814-01 and 29-09814-02 ARE SUSPENDED IN ACCORDANCE WITH THE FOLLOWING TERMS, PENDING FURTHER ORDER:

- A. All NRC-licensed material in the Licensee's possession shall be placed in locked storage.
- B. All activities under its licenses to use licensed material shall be suspended; however, licensed material may be transferred to an authorized recipient after providing written notice (telephonic facsimile is acceptable) to and receiving acknowledgement from the NRC, Region I, at least 72 hours prior to the transfer. The notice shall include the time, date, and location of the proposed transfer, identification of the materials to be transferred, and the name and license number of the recipient. All other requirements of the licenses remain in offect.
- C. No NRC-licensed material shall be received while this order is in effect.

D. All records related to licensed activities shall be maintained in their original form and must not be removed or altered in any way.

- 9 -

The Regional Administrator, Region I, may, in writing, relax or rescind this order upon demonstration by the Licensee of good cause.

V

In accordance with 10 CFR 2.202, the Licensee must, and any other person adversely affected by this Order may, submit an answer to this Order, 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 an extension of time must be made in writing to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, D.C., 20555, and include a statement of good cause for the extension. The answer may consent to this Order. Unless the answer consents to this Order, the answer shall, in writing and under oath or affirmation, specifically admit or deny each allegation or charge made in this order and set forth the matters of fact and law on which the Licensee or other person adversely affected relies and the reasons as to why the Order should not have been issued. Any answer or request for a hearing shall be submitted to the Secretary, U.S. Nuclear Regulatory Commission, ATTN: Chief, Docketing and Services Section, Washington, D.C. 20555. Copies of the hearing request also should be sent to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, to the Assistant General Counsel for Hearings and Enforcement at the same address, to the Regional

Administrator, NRC Region I, 475 Allendale Road, King of Prussia, Pennsylvania, 19406, and to the Licensee if the hearing request is by a person other than the Licensee. If a person other than the Licensee requests a hearing, that person shall set forth with particularity the manner in which the individual's interest is adversely affected by this Order and shall address the criteria set forth in 10 CFR 2.714(d).

- 10 -

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, or any other person adversely affected by this Order, may, in addition to demanding a hearing, at the time the answer is filed or sooner, move the presiding officer to set aside the immediate effectiveness of the Order on the ground that the Order, including the need for immediate effectiveness, is not based on adequate evidence but on mere suspicion, unfounded allegations, or error.

In the absence of any request for hearing, or a 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

## NUREG-0940, PART III

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

James Lieberman, Director

Office of Enforcement

Dated at Rockville, Maryland this 29th day of March 1996

June 6, 1996

# UNITED STATES OF AMERICA NUCLEAR REGULATORY COMMISSION

# BEFORE THE ATOMIC SAFETY AND LICENSING BOARD

In the Matter of	)		
EASTERN TESTING AND INSPECTION	)	Docket No. 030-05373 License No. 29-09814-01	
(Byproduct Material License Nos. 29-09814-01 & 29-09814-02)	)	Docket No. 030-32163 License No. 29-09814-02	
	1	FA No 96-085	

## SETTLEMENT AGREEMENT

### INTRODUCTION

On March 29, 1996, the staff of the Nuclear Regulatory Commission (Staff) issued an Order Suspending Licenses (Effective Immediately) (Order) to Eastern Testing & Inspection, Inc. (Licensee or ETI). 61 Fed. Reg. 15836 (April 9, 1996). The Licensee is the holder of Byproduct Nuclear Material Licenses Nos. 29-09814-01 and 29-09814-02. Order at 1; 61 Fed. Reg. at 15836. License No. 29-09814-01 authorizes the possession and use of iridium-192 and cobalt-60 sealed radiography sources for use in a compatible radiographic source exposure device. License No. 29-09814-02 authorizes the use of americium-241 and cesium-137 sealed sources in portable gauging devices. The Order alleged numerous violations, including some deliberate violations of NRC requirements, which were identified as the result of NRC inspections and an investigation conducted by the NRC's Office of Investigations (OI). The Order provided that: A) all NRC-licensed material in the Licensee's possession must be placed in locked storage; B) all activities under the licenses must be suspended; C) no NRC-licensed material may be received while the Order is in effect; and D) all records related to licensed activities must be maintained in their original form and not be removed or altered in any way. Order at 8-9, 61 Fed. Reg. at 15838.

- 2 -

By letter dated April 1, 1996, the Licensee requested that the immediate effectiveness of the order be set aside. On April 10, 1996, an Atomic Safety and Licensing Board was established to preside over the proceeding. *Eastern Testing and Inspection, Inc.; Establishment of Atomic Safety and Licensing Board*, 61 Fed. Reg. 16654 (April 16, 1996). On May 10, 1996, following oral argument, the Board denied the Licensee's request. "Memorandum and Order (Denying Licensee Motion to Set Aside Immediate Effectiveness)," LBP-96-9, May 10, 1996.

On April 16, 1996, the Licensee requested a hearing on the Order. "Eastern Testing and Inspection, Inc.'s Demand for a Hearing on Order Suspending Licenses." On May 2, 1996, the Licensee submitted its answer to the Order (Answer). "Eastern Testing and Inspection, Inc.'s Answer to Order Suspending Licenses (Effective Immediately)." In its Answer, the Licensee admitted certain of the allegations in the Order and denied the remainder. Specifically, the Licensee denied any deliberate misconduct by its President and Radiation Safety Officer (RSO) as alleged in the Order.

The Staff and the Licensee agree that it is in their respective interests and in the public interest to settle this enforcement action without further litigation and agree to the following terms and conditions:

1. Prior to resumption of NRC-licensed activities:

a) In addition to implementing the corrective actions identified in its Answer dated May 2, 1996 to the March 29, 1996 Order, ETI agrees to submit to the NRC for approval, the name of an experienced outside independent auditor who also can qualify as the Corporate Radiation Safety Officer. The NRC staff will review and approve the auditor based on the auditor's qualifications. Upon NRC approval of the auditor, ETI will retain that individual.

- 3 -

b) The auditor will (1) review the qualifications of all employees who perform NRC-licensed activities for ETI, (2) conduct or supervise any additional training needed, and (3) test, in the area of radiation safety, each employee who performs NRC-licensed activities to assure that the employee is qualified, consistent with the training provisions of 10 C.F.R. Part 34 and the license, to act as a radiographer, radiographer's assistant, or gauge operator. The auditor will certify to the NRC completion of this step before each individual may resume performance of NRC-licensed activities.

c) The independent auditor will certify to the NRC that he or she has read and understands the concerns of the NRC expressed in the Order of March 29, 1996, the Inspection Reports issued April 22, 1996, the terms and conditions of this Settlement Agreement, the applicable NRC regulations, and ETT's license requirements, and understands that he or she may be held personally accountable for any violations of NRC regulations or ETI licenses pursuant to 10 C.F.R. § 30.10.

2. The auditor will make findings and recommendations based upon his or her own discretion and professional judgment in any area of ETI licensed operations,

including, but not limited to: ETI management oversight, procedures, radiographer turining, testing, and qualifications, recordkeeping, field operations and audits.

- 4 -

 The suditor has the authority and obligation under this Settlement Agreement to:

 a) stop work on any operation that is unsafe or which either violates ETI's licenses, applicable NRC regulations, or the provisions of this Settlement Agreement;

b) make required reports to the NRC and report to NRC any concerns relating to safety or compliance with NRC requirements, ETI's licenses, or this Settlement Agreement, if ETI is not taking prompt and appropriate corrective action as required; and

c) report to the NRC any interference by ETI management or employees with his or her duties and obligations pursuant to this Settlement Agreement or the proper conduct of NRC-licensed activities by any ETI employee.

4. The auditor shall implement the following audit program:

a) Phase One: The auditor will submit an audit plan for NRC approval within 30 days of approval of this agreement by the Atomic Safety and Licensing Board, describing the audit scope and methodology, including but not limited to performing a check on equipment and storage practices, including radiation-production devices and monitoring devices, qualifications of staff, training, field audits of radiographers' performance, and reviewing selected ETI records to verify compliance with ETI's radiation safety program. Within 30 days of approval of the audit plan, the auditor will commence the audit. The auditor thereafter will prepare a report on these activities, which he or she will provide to the NRC Staff and to ETI in a timely manner, but within

30 days of the completion of the audit. Within 30 days of receipt of the auditor's report, or at some other mutually agreeable time, ETI will notify the NRC Staff in writing concerning the status of any corrective actions as a result of the auditor's findings, including an explanation of and justification for any recommendations by the auditor that will not be addressed in ETI's corrective actions.

- 5 -

b) Phase Two: Within three months after completion of Phase One activities and at quarterly intervals thereafter, the auditor will perform unannounced field audits of radiographic operations and each radiographer or radiographer's assistant, at various ETI job sites consistent with the NRC-approved audit plan. Within 30 days of completion of these audits, the auditor will report his or her findings to ETI and the NRC Staff. Within thirty days following receipt of the auditor's report, or at some other mutually agreeable time, ETI will notify the NRC Staff in writing concerning the status of any corrective actions as a result of the auditor's findings.

5. The auditor will act as the "Corporate Radiation Safety Officer," on NRC license 29-09814-01, with the following duties and obligations:

 a) be responsible, at all times, for the training, qualification, and testing of all individuals performing NRC-licensed activities, including, but not limited to, radiographers and radiographer's assistants;

b) will certify to the NRC Staff that he or she has personally attended any and all training sessions and that the required subject matter was adequately covered, that any tests given at the training session were appropriately monitored and graded, that the individuals attending the training were present during the entire time of training, and that

the individuals who attended the training were appropriately trained for his or her duties in accordance with NRC regulations and license requirements;

- 6 -

c) will verify and certify to the NRC, on a quarterly basis, that all utilization logs are accurate and complete; and

 not take direction on any compliance issue or radiation safety matter from any officer or employee of ETI.

6. In addition to the Corporate Radiation Safety Officer, prior to the commencement of NRC-licensed activities, ETI will propose an assistant Radiation Safety Officer, who must also be approved by the NRC Staff. The assistant Radiation Safety Officer shall:

a) be responsible for the day-to-day performance of the duties of a radiation
 safety officer as described in ETI's License No. 29-09814-01 procedures;

b) have the authority to stop work on any operations that are unsafe and or which will violate ETI's licenses, NRC regulations, or this Settlement Agreement;

 c) report to the NRC any interference by ETI management or employees with his or her duties and obligations pursuant to this Settlement Agreement or the proper conduct of NRC-licensed activities by any ETI employee;

d) report directly to the Corporate Radiation Safety Officer; and

e) not take direction on any compliance issue or radiation safety matter from any supervisor at ETI other than the Corporate Radiation Safety Officer.

7. ETI also agrees to inform all employees, including radiographers and radiographer's assistants, of the terms and conditions of this Settlement Agreement, the

terms and conditions of ETI's licenses, and the applicable NRC Regulations. ETI specifically agrees to inform, in writing, its employees of the requirements of 10 C.F.R § 34.44, "Supervision of radiographer's assistants" and to require employees to certify that they have read these requirements and provide to the NRC Staff each employee's certification.

- 7 -

8. ETI agrees to ensure the cooperation of its officers and employees with the auditor, the Corporate Radiation Safety Officer, and the assistant Radiation Safety Officer, and will provide these individuals upon request with access to records kept in the ordinary course of ETI's business and in accordance with NRC requirements.

9. To ensure his or her independence from ETI, the auditor will not be an employee of ETI and will have no financial interest in ETI. Except as provided in this Settlement Agreement, nothing in this Settlement Agreement will be construed to provide the auditor with any legal authority to bind ETI with respect to any matter relating to ETI's NRC-licensed activities, and further, the auditor will not represent ETI's interest to the NRC or other authority.

10. ETI will also propose and obtain approval of a new Radiation Safety Officer for License No. 29-09814-02 prior to conducting activities under that license. The new Radiation Safety Officer may be the same individual named on License No. 29-09814-01 as the assistant Radiation Safety Officer.

11. Upon the resumption of NRC-licensed activities, ETI will, at the start of each work week, provide, in writing, the NRC Region I Staff and the auditor, with its work schedule for the week. The notification shall include the name of the customer, the

schedule of work hours and location of the work. If there are any changes to this schedule, ETI will make its best effort to inform NRC Region I staff and the auditor at least 24 hours in advance, if possible. These submissions may be made by facsimile. Notification to the NRC shall be made to Frank Costello, Region I, 610-337-5275; FAX: 610-337-5269.

- 8 -

12. ETI agrees that its President, Himat J. Soni and the current Radiation Safety Officer named on License No. 29-09814-01, Joseph Badiali, will not be involved in the supervision of NRC-licensed activities or ETI's radiation safety program. However, Messrs. Soni and Badiali may perform the duties of radiographer and supervise radiographers' assistants as part of those duties. In addition, Messrs. Soni and Badiali may be involved in other business activities of ETI, including marketing, record keeping and technical training exclusive of radiation safety.

13. For good cause shown, the Staff may, in writing, extend the time to complete any action set forth in any provision of this Settlement Agreement. No earlier than one year from the date this Settlement Agreement is approved by the Atomic Safety and Licensing Board, ETI may request that the NRC Regional Administrator, Region I, rescind any of the provisions of this Settlement Agreement upon a demonstration of good cause. The decision as to good cause is in the sole discretion of the NRC Regional Administrator, Region I.

14. The NRC Staff agrees to withdraw the Order dated March 29, 1996. ETI agrees that a failure on its part to comply with the terms of this Settlement Agreement will constitute a material breach of this Agreement, and that any such breach may result

in the revocation or suspension of the license, effective immediately, if the NRC Staff, in its sole discretion, determines such action to be appropriate, and may result in further enforcement or other action as the NRC Staff may determine, in its sole discretion, to be appropriate.

15. ETI agrees to withdraw its demand for a hearing dated April 16, 1996. The Staif expects that good faith implementation of this Settlement Agreement should resolve the concerns stated in the March 29, 1996 Order. Nothing in this Settlement Agreement precludes the NRC Staff from taking additional regulatory action if warranted. The Staff and ETI agree and understand that this Settlement Agreement is only binding on the NRC and ETI and only relates to NRC's March 29, 1996 Order. This Settlement Agreement shall not be relied upon by any person or other entity as proof or evidence of any of the matters set forth in the Order.

16. This Settlement Agreement shall be binding upon the legal representatives, successors and assigns of each of the parties hereto.

17. The Staff and ETI shall jointly move the Atomic Safety and Licensing Board designated in the above-captioned proceeding for an order approving this Settlement Agreement and terminating this proceeding.

- 9 -

In Witness Whereof, the parties have caused this Settleman: Agroement to be executed

by their authorized representatives.

# FOR BASTERN TESTING AND INSPECTION

2.

Himat J. Soni Prosiden: Essern Testing and Inspection

iger

Daniel F. Stenger Robert E. Helfrich Counsel for Eastern Testing and Inspection, Inc.

Dated at Rockvilla, Maryland this \_\_\_\_\_ day of June, 1996

HUN THE NEC STAFF

aven Manen L. Zubles

Stimerel G. Bachmann 1. Junisel für NRC Staff



UNITED STATES NUCLEAR REGULATORY COMMISSION WASHINGTON, D.C. 20056-0001

October 21, 1996

EA 96-154

Dr. José L. Fernández 160 Ponce de León Avenue Puerta de Tierra San Juan, Puerto Rico 00901

SUBJECT: ORDER MODIFYING NRC MATERIALS LICENSE NO. 52-25114-01 (EFFECTIVE IMMEDIATELY)

Dear Dr. Fernández:

The enclosed immediately effective Order Modifying License (Order) is being issued to you as the result of your failure to identify medical misadministrations and to notify the affected patients. Since February 9, 1996, the Nuclear Regulatory Commission (NRC) has requested that you identify all medical misadministrations which have occurred under your NRC license and that you complete the required notifications to the involved patients and the NRC. NRC regulations in Title 10 of the Code of Federal Regulations Part 35.21 (10 CFR 35.21) and 10 CFR 35.33, require that you identify and investigate misadministrations and notify the affected patients. You have repeatedly failed to adequately comply with those requirements and provide NRC with reliable and complete information.

The enclosed Order requires you, among other things, to: (1) within 30 days of the Order, submit for NRC approval the credentials of an independent Health Physicist/Radiation Physicist Consultant with expertise in therapy dosimetry calculations who is prepared to assist you in responding to this Order; (2) following the NRC's approval, ensure that the consultant reviews all patient radiation dose administrations to identify any medical misadministrations and assess the completeness and accuracy of your misadministration records; (3) submit an updated, final report to the NRC of all misadministrations; (4) notify individuals who received misadministrations; (5) maintain the strontium-90 sources in locked, safe storage until the sources are transferred to an authorized recipient; and (6) transfer the sources to an authorized recipient within 90 days of this Order.

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 this Order, once effective, shall be subject to criminal prosecution as set forth in that section. Violation of this Order may also subject the licensee to a civil monetary penalty of up to \$100,000. In addition, issuance of this Order does not preclude the NRC from taking further enforcement action for the violations described in this Order. You should be aware that, in determining whether to take enforcement action for the violations described in this Order, the NRC will consider, among other things, your compliance with the provisions of the Order. In your letter of August 20, 1996, you requested NRC's assistance in obtaining a list of consultants located in Puerto Rico. NRC employees are generally prohibited from providing advice or recommendations to licensees; however, given your stated continued inability to obtain a consultant, the need to expedite the identification of misadministrations, and the absence of professional organizations in Puerto Rico that could assist you in locating a consultant, Region II representatives provided you a list for information purposes of individuals and institutions who might be able to provide the services and/or information required by the Order during a meeting with you on September 27, 1996. At your request, another copy of the list was provided to you by facsimile on October 3, 1996. No representations or recommendations are made or offered concerning the completeness of the list which is also enclosed with the Order or the individuals and institutions identified on the list, nor has any assessment been made concerning each individual's qualifications or ability to provide assistance. You remain under an obligation to assure yourself and the NRC that any consultant you hire meets the provisions of this Order.

Finally, following your completion of the requirements of this Order, the NRC will address the termination of your license as you requested in your August 20, 1996 letter, and whether further escalated enforcement is appropriate.

Questions concerning this Order should be addressed to Mr. James Lieberman, Director, Office of Enforcement, who may be reached 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. quino

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

Docket No. 030-31873 License No. 52-25114-01

Enclosures: 1. Consultants/Institutions List 2. Order Modifying License

cc w/encl 2 only: Commonwealth of Puerto Rico Tribunal Examinador de Médicos de Puerto Rico [Puerto Rico Board of Medical Examiners] ATTN: Dr. Humberto Vázquez President P.O. Box 13969 San Juan, Puerto Rico 00908

NUREG-0940, PART III

Encl. 1

# Potential Consultants in Puerto Rico

Alison De Hoyos	(787) 265-5130, (787) 265-4160	
Santiago Gómez	(787) 751-0042	
Ricardo González	(787) 759-1255 u-2181812, (787) 754-38 (787) 767-0382	31
Pedro J. Montes García	(787) 763-4149, (787) 754-0315	
Samuel Muñoz	(787) 754-0315	
Heidi Pabón Pérez	787) 758-7575 x-3255	
María M. Palacios de Lozano	(787) 758 -7575 x-5413	
José D. Pacheco	(787) 764-4215	
Carmelo Pérez	(787) 802-2472 x-7074	
José V. Pérez Bobonis	(787) 766-3062	
Cecilia Ramirez	(787) 765-2212	
Miria Roque Palacios	(787) 754-0315	
Shakil Shafique	(787) 767-2251	
Roberto J. Torres	(787) 265-5833	
Heriberto Torres	(787) 758-2525 x-1450, x-1439	
Daniel Torres Ortiz	(787) 834-8686 x-2770	

No representations or recommendations are made or offered concerning the completeness of this list, the individuals and/or institutions identified on this list, nor has any accessment been made concerning their qualification or ability to provide assistance.

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## - 2 -

## Additional Sources of Information

American Academy of Health Physics, Secretariat 8000 West Park Drive McLean, Virginia 22102 Telephone: 703-790-1745

American Association of Physicists in Medicine 1 Physics Ellipse College Park, Maryland Telephone: 301-209-3100

Society of Nuclear Medicine/American College of Nuclear Physicians Government Relations 1101 Connecticut Avenue, NW Washington, DC 20036 Telephone: 202-429-5120

American College of Medical Physicists 1891 Preston White Drive Reston, Virginia 22091 Telephone: 703-648-8966

No representations or recommendations are made or offered concerning the completeness of this list. the individuals and/or institutions identified on this list. nor has any assessment been made concerning their gualification or ability to provide assistance.

Encl. 2

#### UNITED STATES NUCLEAR REGULATORY COMMISSION

In the Matter of

José L. Fernández, M.D. San Juan, Puerto Rico Docket No. 030-31873 License No. 52-25114-01 EA 96-154

# ORDER MODIFYING LICENSE (EFFECTIVE IMMEDIATELY)

José L. Fernández, M.D. (Licensee) is the holder of Byproduct Nuclear Material License No. 52-25114-01 (License) issued by the Nuclear Regulatory Commission (NRC or Commission) pursuant to 10 CFR Part 35. The License authorized the possession and use of a total of two strontium-90 sources not to exceed 150 millicuries for the treatment of superficial eye conditions on humans at medical facilities located at 160 Ponce de León Avenue, Puerta de Tierra, Sam Juan, Puerto Rico and at La Palma Building, Suite 1-A, Peral-De Diego Street, Mayagüez, Puerto Rico. The License, originally issued to the Licensee on March 22, 1991, was amended on January 14, 1994, and expired on February 28, 1996. Pursuant to 10 CFR 30.36(c), the Licensee is authorized to possess but not use licensed material.

II

A routine, unannounced inspection of the Licensee's activities at the Mayaguez, Puerto Rico, facility was performed on October 18, 1995. During the inspection, an issue regarding the validity of the calibration of one of the Licensee's strontium-90 eye applicators and the possibility of multiple misadministrations was identified. The Licensee was unable to provide adequate documentation of source strength (i.e., a calibration from the National Institute of Standards and Technology or the source manufacturer).

A Confirmatory Action Letter (CAL) was issued on October 19, 1995, which confirmed the Licensee's agreement to discontinue any use of the strontium-90 eye applicator and place it in storage until: (1) a Quality Management Program (QMP) was submitted to the NRC, and (2) NRC approved resumption of operations. Subsequently, a calibration of the source located at the Mayagüez office was performed by the source manufacturer, which indicated that the source delivered approximately 53 centigrays per second, rather than the 24 centigrays per second that was assumed by the Licensee and used in treatments. The Licensee and the source manufacturer notified the NRC of the source dose rate on February 8, 1996.

- 2 -

Based on the fact that there was an error in the radiation dose rate and that this error caused patients to receive doses in amounts greater than that intended by the physician, the NRC issued a second CAL to the Licensee on February 9, 1996, to confirm that the Licensee would: (1) review, within 30 days, all patient radiation dose administrations performed at the Mayaguez office to identify any medical misadministrations; (2) comply with the notification and reporting requirements of 10 CFR 35.33 (within the time frame specified in the regulations) for each misadministration identified; and (3) maintain the strontium-90 sources in safe storage and refrain from using them until authorized by the NRC.

The Licensee notified time NRC, via the NRC Operations Center, on March 1, 1996, that 71 patients had received misadministrations. In a letter received on March 15, 1996, the Licensee notified the NRC, in accordance with 10 CFR 35.33, that all patients determined to have received a

misadministration had been notified in writing by March 8, 1996. However, the written notification to the NRC failed to indicate whether the patients were notified within 24 hours of discovery, as required by 10 CFR 35.33(a)(3) and, if not, why not, and whether records of the misadministrations were retained by the Licensee as required by NRC requirements.

- 3 -

To verify the status of the Licensee's actions to identify misadministrations and to complete patient notifications, the NRC conducted a second inspection at the Licensee's Mayagüez facility on April 8-10, 1996. During the inspection, the NRC determined, based on its review of Licensee records, that the Licensee had failed to: (1) identify 16 additional misadministrations that occurred since October 1994, (2) notify, within 24-hours of discovery as required by 10 CFR 35.33(a)(3), three individuals of their misadministrations, (3) provide written reports of misadministrations to three individuals within the 15 days required by 10 CFR 35.33(a)(4), and (4) retain complete misadministration records as required by 10 CFR 35.33(b) in that only 67 records were documented instead of the 71 originally identified by the Licensee (the four records were misplaced by the Licensee after the misadministrations were identified).

In addition, during the October 1995 inspection, the Licensee informed the NRC that he had purchased the Mayagüez facility including one of the strontium-90 eye applicators in October 1994. Therefore, during the April 1996 inspection, the scope of the review was specifically confined to the period between October 1994 and October 1995. However, the NRC determined that the initial date of operation (i.e., start of the possession and use of byproduct material

at the Mayaguez facility) was not October 1994, as originally related by the Licensee. The Licensee actually took possession of the byproduct material in January 1994, prior to the change in ownership in October 1994 and following receipt of the NRC's authorization to work under the Mayaguez license (amended on January 14, 1994). The NRC also determined that, during the period between January and October 1994, the Licensee's byproduct material had been used by an unauthorized user on at least two occasions, contrary to the requirements of 10 CFR 35.11. Moreover, the Licensee further identified 17 additional misadministrations that occurred during this period.

- 4 -

Subsequently, in a June 13, 1996 letter to the Licensee, the NRC documented the results of a June 11, 1996 telephone call in which Dr. Fernández agreed to hire an independent Health Physicist/Radiation Physicist consultant with expertise in therapy dosimetry calculations to perform a review of the Licensee's patient administration records to identify all misadministrations, to assess the completeness and accuracy of misadministration records, to determine if any unauthorized uses of byproduct materials had occurred, and to assist the Licensee in submitting a report to the NRC on the results of these reviews. On July 10, 1996, the Licensee replied to the NRC's June 13, 1996 letter explaining Licensee difficulties in obtaining an independent consultant to complete the agreed-upon actions.

During a third inspection on August 7 and 9, 1996, the NRC determined that certain of the patients, who received misadministrations and should have been notified of the misadministration verbally and in writing, stated that they had not received such notification. In addition, during this inspection the

NRC identified seven additional misadministrations at the San Juan facility resulting from the failure to correct source strength to account for radioactive decay. These misadministrations appear to involve underdosing patients.

- 5 -

By letter dated August 7, 1996, the NRC again requested the Licensee to provide to the NRC the name of a consultant and his credentials, and the Licensee's schedule for the completion of requested activities. The NRC also offered the Licensee the opportunity to participate in a predecisional enforcement conference. On August 20, 1996, the Licensee replied to the NRC's August 7, 1996 letter reiterating the Licensee's inability to obtain a consultant, stating the intention to terminate the License, and declining the invitation to participate in a predecisional enforcement conference.

As a result of the October 18, 1995, the April 8-10, 1996, and August 7 and 9, 1996 inspections, numerous violations were identified. The violations include the failure of the Licensee to: (1) establish and maintain a QMP, which included assurance that the radiation dose delivered was correct (i.e, the calibration of the applicator was correct), as required by 10 CFR 35.32 (the use of an inaccurate dose rate resulted in at least 104 misadministrations during the period January 1994 through October 1995); (2) maintain the security of byproduct material as required by 10 CFR 20.1801; (3) perform quarterly physical invergetories of byproduct material as required by 10 CFR 35.59(g); (4) test sealed sources for leakage at intervals not to exceed six months as required by 10 CFR 35.59(b); (5) notify individuals of a misadministration within 24-hours of discovery as required by 10 CFR

35.33(a)(3); (6) provide written reports to individuals within 15 days of discovery of a misadministration as required by 10 CFR 35.33(a)(4); (7) maintain misadministration records as required by 10 CFR 35.33(b); and (8) amend his license prior to permitting an individual to work as an authorized user as required by 10 CFR 35.11.

- 6 -

Representatives from NRC Region II met with the Licensee on September 27, 1996, and again the Licensee informed the staff that it intended to obtain a consultant to review its activities. At that meeting, NRC provided the Licensee with a list of consultants in Puerto Rico that might be considered. On October 3, 1996, the Licensee called the NRC to request that the NRC provide another copy of the consultant's list because it had lost the one provided on September 27, 1996. At that time the Licensee stated that it planned to review the records, with the assistance of a consultant.

III

Based on the above, the Licensee has demonstrated a significant lack of control and attention to licensed activities. Specifically, the Licensee has failed to use accurate radiation dose rates for the strontium-90 eye applicators which resulted in numerous misadministrations and has repeatedly failed to fully evaluate and identify the number of misadministrations. This raises a significant commern as the patients, depending on the doses received, may develop complications, and without appropriate follow-up actions, these complications may go unrecognized and serious consequences may occur.

NUREG-0940, PART III

Furthermore, the Licensee has failed to: (1) establish and maintain a QMP as required by 10 CFR 35.32; (2) maintain the security of byproduct material as required by 10 CFR 20.1801; (3) perform quarterly physical inventories of byproduct material as required by 10 CFR 35.59(g); (4) test sealed sources for leakage at intervals not to exceed six months as required by 10 CFR 35.59(b); (5) notify individuals of a misadministration within 24-hours of discovery as required by 10 CFR 35.33(a)(3); (6) provide written reports to individuals within 15 days of discovery of a misadministration as required by 10 CFR 35.33(a)(4); (7) maintain misadministration records as required by 10 CFR 35.33(b); and (8) amend his license prior to permitting an individual to work as an authorized user as required by 10 CFR 35.11.

- 7 -

The Licensee has failed to honor its commitment to obtain a qualified consultant to review its patient records to assure as required by the Commission's regulations that all misadministrations are identified and proper patient notifications have been made. As a result, given the Licensee's past performance, the NRC does not have adequate assurance that all misadminstrations have been identified, properly evaluated, and the involved patients properly notified.

It is imperative that licensees conduct activities in accordance with NRC requirements and with the requisite sensitivity and attention to detail, especially with respect to the amount of radiation delivered to individuals. In addition, the Commission must be able to rely on its licensees to provide complete and accurate information.

Consequently, I have concluded that the Licensee has failed to comply with a number of significant NRC requirements and that the actions Ordered in Section IV of this Order are required to protect the public health and safety. Given the number of misadministrations identified to date, the number of violations committed to date by the Licensee, the potential consequences to patients if not identified, notified, and monitored, the difficulty in locating patients over time, and the lack of meeting license requirements and commitments. I have concluded, pursuant to 10 CFR 2.202, that the public health and safety requires that this Order be immediately effective.

- 8 -

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Accordingly, pursuant to Sections 81, 161b, 161i, 161o, 182 and 186 of the Atomic Energy Act of 1954, as amended, and the Commission's regulations in 10 CFR 2.202 and 10 CFR Parts 30 and 35, IT IS HEREBY ORDERED, EFFECTIVE IMMEDIATELY, THAT LICENSE NO. 52-25144-01 IS MODIFIED AS FOLLOWS:

- A. Within 30 days of the date of this Order, the Licensee shall submit to the Regional Administrator, NRC, Region II, for approval, the credentials of an independent Health Physicist/Radiation Physicist Consultant with expertise in therapy dosimetry calculations.
- B. The Licensee shal<sup>®</sup> ensure that, within 45 days of acceptance of the consultant by the NRC, the Consultant:

- Performs, independent of the Licensee, a review of all patient radiation doses administered by the Licensee at the Mayagüez facility to identify all medical misadministrations that occurred between January 1994 and October 1995 and assure that the dose records are complete and accurate.
- 2. Reviews the Licensee's misadministration records to verify completeness and accuracy in reference to the requirements of 10 CFR 35.33. To the extent possible, incomplete records shall be appropriately corrected. Where records of individuals may not be accurately reconstructed, the consultant shall assume that the individual has received a misadministration based on 53 centigrays per second, rather than the 24 centigrays per second that was assumed by the Licensee and used in treatments.
- Reviews the Licensee's radiation dose administration records to determine if any additional unauthorized uses of byproduct material occurred between January 1994 and October 1995.
- 4. Reviews the Licensee's misadministration notification records to identify any misadministrations where notification was not provided to: (a) the NRC as required by 10 CFR Part 35.33(a)(2); and (b) all maffected patients and referring physicians as required by 10 CFR 35.33(a)(3) and (4).

NUREG-0940, PART III

- Assists the Licensee in the review and submission to the NRC of an updated/revised report pursuant to 10 CFR 35.33(a)(2).
- C. Within 60 days of acceptance of the consultant by the NRC, the Licensee shall:
  - Submit an updated, final report to the NRC, Regional Administrator. Region II, of all misadministrations, pursuant to 10 CFR 35.33(a)(2), including a listing of any additional unauthorized uses of byproduct material that occurred between January 1994 and October 1995.
  - Notify the referring physician and individuals who received misadministrations, including those individuals whose records may not be accurately reconstructed, of the misadministrations, pursuant to 10 CFR 35.33(a)(3).
- D. The Licensee shall not receive or use any licensed material and shall maintain the strontium-90 sources in locked, safe storage until the material is transferred to an authorized recipient.
- E. The Licensee shall, within 90 days of this Order, transfer all strontium-90 sources in its possession to an authorized recipient and provide to the Regional Administrator, Region II, a completed Form-314.

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

- 11 -

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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 include a statement of good cause for the extension. The answer may consent to this Order. Unless the answer consents to this Order, the answer shall, in writing and under oath or affirmation, specifically admit or deny each allegation or charge made in this Order and set forth the matters of fact and law on which the Licensee or other person adversely affected relies and the reasons as to why the Order should not have been issued. Any answer or request for a hearing shall be submitted to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, with a copy to the Commission's Document Control Desk, Washington, D.C. 20555. Copies also shall be sent to the Assistant General Counsel for Hearings and Enforcement, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, to the Regional Administrator, NRC Region II, 101 Marietta St., NW, Suite 2900, Atlanta, GA 30323-0199, 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 ac 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.

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.

## NUREG-0940, PART III

A-108

- 12 -

AN ANSWER OR A REQUEST FOR HEARING SHALL NOT STAY THE IMMEDIATE EFFECTIVENESS OF THIS ORDER.

- 13 -

FOR THE NUCLEAR REGULATORY COMMISSION

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

Dated at Rockville, Maryland this <sup>21st</sup> day of October 1996

NUREG-0940, PART III



#### UNITED STATES

#### NUCLEAR REGULATORY COMMISSION

REGIONIV

611 RYAN PLAZA DRIVE, SUITE 400 ARLINGTON, TEXAS 76011 8064

June 6, 1996

EA 96-093

Mr. Jim Ham, President Gamma Tech Industries, Inc. 3645 Dalbergia Street San Diego, California 92113-3912

SUBJECT: NOTICE OF VIOLATION & PROPOSED IMPOSITION OF CIVIL PENALTY -\$1,500 (NRC INSPECTION REPORT 999-90004/95-09; INVESTIGATION REPORT 4-95-042)

Dear Mr. Ham:

This is in reference to the predecisional enforcement conference conducted on April 25, 1996, in San Diego, California. Enclosure 1 is a list of conference attendees. The conference was conducted to discuss apparent violations of NRC requirements identified during an NRC inspection and investigation of Gamma Tech Industries, Inc.'s (Gamma Tech) activities in NRC jurisdiction. The apparent violations, which were summarized in a March 28, 1996, letter to you, included: 1) conducting radiography in exclusive federal jurisdiction without an NRC license'; 2) deliberately causing the above violation; and 3) providing inaccurate information to the NRC during a telephone interview.

With respect to the first two apparent violations, you admitted during the investigation and at the conference that Gamma Tech had knowingly conducted radiography on U.S. Navy ships, an area which is under exclusive federal jurisdiction, without obtaining the necessary autho. Lation from the NRC. You indicated at the conference that the reasons for this violation were that Gamma Tech was struggling financially; that other companies also appeared to be in noncompliance in the past; and that the NRC had not (until late 1995) made an issue of this requirement not being met by radiographers in the San Diego area.

With respect to the third apparent violation, you acknowledged that you may have provided inaccurate information to an NRC inspector in response to a question about when Gamma Tech had last conducted radiography on U.S. Navy ships, but explained that you provided this response without first checking your records and that you did not intend to mislead the NRC. Furthermore, you indicated that you made records of this work available to the NRC during the investigation.

Although Gamma Tech Industries, Inc., is licensed by the state of California, the license is limited to "areas not under exclusive federal jurisdiction."

Gamma Tech Industries, Inc.

Based on the information developed during the inspection and investigation and the information that you 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 involves Gamma Tech's intentional failure to obtain an NRC license before using byproduct material to perform industrial radiography in an area of exclusive federal jurisdiction. As an alternative to obtaining an NRC license, Gamma Tech had the option, as permitted by NRC practice, to file an NRC Form 241, "Report of Proposed Activities in Non-Agreement States," and pay the required fees prior to conducting those licensed activities.

Gamma Tech stated during the conference that it places a premium on conducting its activities safely and in accordance with all safety requirements. The NRC's inspection of Gamma Tech's records and interviews of Gamma Tech personnel did not find any evidence of significant safety violations. Nonetheless, the failure to obtain NRC authorization is a matter of significant regulatory concern because it denies the NRC the opportunity to assure through inspections that radiography activities are being conducted in compliance with all NRC radiation safety requirements. In addition, deliberate violations of NRC requirements, even those that are administrative in nature, raise questions about attitudes toward compliance in general. Therefore, this violation has been classified in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions (Enforcement Policy)," NUREG-1600, at Severity Level III.

Gamma Tech stated at the conference that it discontinued attempts to file a Form 241 with the NRC and discontinued conducting radiography in NRC jurisdiction after August 1995. These actions were apparently taken because of the belief that an NRC inspector had told Gamma Tech's chief inspector, Mr. Mahaffey, not to bother filing because of the ongoing NRC investigation. Even though the inspector's recollection differs from Gamma Tech's regarding this discussion, the NRC accepts Gamma Tech's statement that it was intent on coming into compliance in late 1995 and has since taken additional steps to familiarize itself with NRC requirements.<sup>3</sup> Gamma Tech also was assured following the conference that there were no restrictions on its applying for an NRC license or, as permitted by NRC practice, filing a Form 241 in order to conduct radiography in ARC jurisdiction.

The base civil penalty for a Severity Level III violation is \$5,000. In accordance with the Enforcement Policy, the NRC normally considers only three factors -- previous enforcement history, identification of the violation and corrective action -- in determining whether a Severity Level III violation

<sup>2</sup> The reciprocity fee assessed radiographers, which was established in 1991, was \$600 in 1991; \$640 in 1992; \$700 in 1993 and 1994, and \$1,100 as of July 20, 1995.

"NRC requirements are not necessarily identical to those of an Agreement State; licensees are required to comply with all applicable NRC requirements when working in areas under exclusive federal jurisdiction. Gamma Tech Industries, Inc.

- 3 -

should result in a base penalty, two times a base penalty or no penalty. The NRC also may exercise discretion and assess either a larger or smaller penalty based on the circumstances involved, including whether the violation was committed willfully. The normal assessment process in this case would have resulted in at least the base penalty being assessed. However, the NRC has decided to exercise its discretion, in accordance with VII.B.6 of the Enforcement Policy, to assess a smaller civil penalty based on the circumstances of this case. The circumstances that the NRC took into account include the fact that Gamma Tech is a small business, the absence of significant safety violations, and the fact that Gamma Tech's willful violation after it was placed on notice by the NRC resulted in a savings of fees to Gamma Tech on the order of the amount of the civil penalty that is proposed herein.

Notwithstanding Gamma Tech's corrective actions noted above, to emphasize the significance of making a deliberate decision to violate an NRC requirement and the importance of complying with all NRC requirements in the future, I have been authorized, after consultation with the Director, Office of Enforcement, and the Deputy Executive Director for Nuclear Materials Safety, Safeguards and Operations Support, to issue the enclosed Notice of Violation and Proposed Imposition of Civil Penalty in the amount of \$1,500 for this Severity Level III violation.

The NRC has decided not to take any individual enforcement action based on deliberate misconduct. You are now on notice that deliberate violations may subject individuals to civil and criminal sanctions pursuant to 10 CFR 30.10. In addition, the NRC has decided not to issue a violation based on inaccurate information being given to an NRC inspector. With regard to the latter, the NRC has taken into account that this information was provided during a telephone interview and was provided without first checking Gamma Tech's records. The NRC notes, however, that its expectation is that a licensee inform the NRC if it is not sure of an answer and if any information in a communication was in error.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. In your response, you should document the specific actions taken and any additional actions you plan to prevent recurrence. You should also document steps you have taken or plan to take to assure that you are complying with all NRC requirements for any work conducted in areas of exclusive federal jurisdiction. After reviewing your response to this Notice, including your proposed corrective actions and the results of future inspections, the NRC will determine whether further NRC enforcement action is necessary to ensure compliance with NRC regulatory requirements.

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

Gamma Tech Industries, Inc.

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.

- 4 -

Sincerely,

Callan Regional Administrator

Docket No. 999-90004 License No. CA 5364-80

Enclosures:

- 1. Predecisional Enforcement Conference Attendees
- Notice of Violation and Proposed Imposition of Civil Penalty

cc w/Enclosures: California Radiation Control Program

### Attendees

Predecisional Enforcement Conference

April 25, 1996

San Diego, California

Gamma Tech Industries, Inc.

Jim Ham, President and Radiation Safety Officer Tony Mahaffey, Chief Inspector

Nuclear Regulatory Commission, Region IV

Linda Howell, Chief, Nuclear Materials Inspection & Fuel Cycle/Decommissioning Branch, Division of Nuclear Materials Safety Gary Sanborn, Enforcement Officer, Office of the Regional Administrator

## NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY

Gamma Tech Industries, Inc. San Diego, California

Docket No. 999-90004 License No. CA 5364-80 EA 96-093

During an NRC inspection and investigation conducted August 15, 1995, through February 28, 1996, a violation of NRC requirements was identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," NUREG-1600, the Nuclear Regulatory Commission proposes to impose a civil penalty pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (Act), 42 U.S.C. 2282, and 10 CFR 2.205. The particular violation and associated civil penalty are set forth below:

10 CFR 30.3 requires in relevant part, that no person shall possess or use byproduct material except as authorized by a specific or general license issued by the NRC unless exempt as provided in Part 30 or Part 150.

Contrary to the above, on multiple instances during calendar years 1992, 1993, 1994 and 1995, Gamma Tech Industries, Inc., a licensee of the state of California, used byproduct material to perform industrial radiography on U.S. Navy ships, an area in exclusive federal jurisdiction, without either a specific or general license issued by the NRC. (01013)

This is a Severity Level III violation (Supplement VI). Civil Penalty - \$1,500

Pursuant to the provisions of 10 CFR 2.201, Gamma Tech Industries. Inc., is hereby required to submit a written statement or explanation to the Director. Office of Enforcement, U.S. Nuclear Regulatory Commission, within 30 days of the date of 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 license should not be modified, suspended, or revoked or why such other action as may be proper should not be taken. Consideration may be given to extending the response time for good cause shown. Under the authority of Section 182 of the Act. 42 U.S.C. 2232, this response shall be submitted under oath or affirmation.

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

- 2 -

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, letter with payment of civil penalty, 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, ATTN: Enforcement Officer, 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. 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.

Dated at Arlington, Texas. this 6th day of June 1996

NUREG-0940, PART III



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

October 4, 1996

EA 96-256 and EA 96-377

Wayne Weinfurter President GCME, Inc. 3471 Packerland Drive DePere, WI 54115

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY -\$5,000 AND DEMAND FOR INFORMATION (NRC Inspection Report No. 030-31195/96001(DNMS))

Dear Mr. Weinfurter:

This refers to the routine safety inscection conducted at GCME, Inc., from June 27 to July 22, 1996, during which several violations of NRC requirements were identified. A copy of the inspection report was sent to GCME, Inc., on August 12, 1996, and a predecisional enforcement conference was held in the NRC Region III office, Lisle, Illinois, on August 29, 1996.

Based on the information developed curing the inspection and the information provided at the conference by you and the GCME Radiation Protection Officer (RPO), the NRC has determined that significant violations of NRC requirements have occurred. The violations are cited in the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice), and the circumstances surrounding the violations are described in detail in the inspection report. Additional examples of the failure to monitor the user of a nuclear gauge with a film badge and the failure to secure or maintain surveillance of NRClicensed material in an unrestricted area were identified during the predecisional enforcement conference. Specifically, the RPO stated that he permitted a new employee to operate a nuclear gauge without the employee having a film badge during training sessions while under the RPO's direct supervision in June 1996. During other discussions with the RPO at the conference, he stated that he routinely left a nuclear gauge unsecured or unattended while working at construction sites. These issues are included in the enclosed Notice as additional examples of the violations previously described in the inspection report.

The NRC is particularly concerned about your repetitive failure to ensure that your employees are wearing film badges while using NRC-licensed material. Specifically, during an inspection of GCME, Inc., on October 10, 1989, the NRC identified that an employee had not worn a film badge while using NRC-licensed material on August 15, 1989. This violation of NRC requirements was cited at Severity Level IV on November 6, 1989. ICME, Inc., responded to that violation in a letter dated November 6, 1989, and stated that ". . . film badges have been received and are worn every time (sic) machine is used . . . " The next NRC inspection was conducted on January 10, 1995, with a subsequent investigation by the NRC Office of Investigations (OI). That

GCME, Inc.

investigation and inspection found that GCME, Inc., had not provided film badges to any of the authorized users of NRC-licensed materials from October 1990 through the summer of 1991 and from the end of 1992 to July 3, 1993. The 1990 to 1993 violations were considered to represent careless disregard of NRC requirements and were categorized at Severity Level III. By letter, dated October 5, 1995, GCME, Inc., described its corrective action to ensure that film badges were distributed to employees. Since the current inspection and confeience found more examples of the same violation, it is apparent that GCME, Inc., has not taken effective corrective action to prevent the recurrence of this violation. Furthermore, the failure by employees of GCME, Inc., to properly secure or maintain surveillance of NRC-licensed material in an unrestricted area is also of concern because inadequate controls could lead to the inadvertent release of radioactive material to the public domain.

- 2 -

In the aggregate, the violations are of significant regulatory concern because they are indicative of a breakdown in the control of NRC-licensed activities that collectively represent a potentially significant lack of attention or carelessness toward licensed responsibilities. Incumbent upon each company licensed by the NRC to use byproduct material in a commercial enterprise is the responsibility to protect public health and safety, including its employees, by ensuring that the rules, regulations and license conditions are followed at <u>all</u> times. That has not been the case at GCME, Inc. Therefore, the violations are collectively 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 \$2,500 is considered for a Severity Level III problem. Because your facility has been the subject of an escalated enforcement action 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. Credit was not given for the Identification factor because the NRC identified the violations. Credit was not warranted for the Corrective Action factor because GCME, Inc., had not determined the root cause of the problem or developed corrective actions prior to the August 29, 1996 conference even though GCME. Inc., was informed of the potential violations during the inspection exit meeting on June 27, 1996, and during several follow-up telephone conversations from July 3 to July 24, 1996. Additionally, a copy of NRC Information Notice 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action," was provided to GCME, Inc., on August 12, 1996. Furthermore, it was not until the August 29, 1996 predecisional enforcement conference that GCME, Inc., with NRC prompting, proposed corrective actions.

EA 95-154, issued on November 16, 1995, represented a Severity Level III violation for failing to ensure that authorized users were provided with film badges for use in conjunction with the operation of a moisture/density gauge. A civil monetary penalty was not proposed for this Severity Level III violation.

GCME, Inc.

Therefore, to emphasize the need to immediately identify violations, to assure that the root cause of each violation is fully identified and understood, to ensure that corrective actions are prompt and comprehensive to avoid repetition of a violation, and in recognition of the previous escalated enforcement action involving GCME, Inc., I am issuing the enclosed Notice in the amount of \$5,000 for the Severity Level III problem. You should be aware that the issuance of this Notice constitutes an escalated enforcement action that may subject GCME, Inc., to increased inspection effort.

Since this problem demonstrates a lack of regard for, and adherence to, procedures and a lack of management control and supervision over licensed activities, it raises a question as to whether GCME, Inc., will in the future be able to effectively manage the NRC-licensed radiation safety program. Therefore, a Demand for Information is also enclosed. The Demand for Information seeks further information to determine: (1) whether the NRC can have reasonable assurance that in the future GCME, Inc., will conduct its activities in accordance with the Commission's requirements; and (2) whether your license should be modified, suspended or revoked, or other enforcement action taken to ensure compliance with NRC regulatory requirements. Failure to comply with the provisions of this Demand for Information may result in additional enforcement action.

Questions concerning the Demand for Information should be addressed to Mr. James Lieberman, Director, Office of Enforcement, who can be reached at telephone number (301) 415-2741.

You are required to respond to this letter and should follow the instructions specified in the enclosures when preparing your responses.

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

GCME, Inc.

response, please provide the level of protection described in 10 CFR 73.21.

1

Sincerely,

James Lieberman, Director Office of Enforcement

Docket No. 030-31195 License No. 48-23409-01

Enclosures: 1. Notice of Violation and Proposed Imposition of Civil Penalty 2. Demand for Information

-

NUREG-0940, PART III

# NOTICE OF VIOLATION

AND

PROPOSED MPOSITION OF CIVIL PEHALTY

GCME, Inc. DePere, Wisconsin

Docket No. 030-31195 License No. 48-23409-01 EA 96-256

During an NRC inspection conducted from June 27 to July 22, 1996, violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," NUREG-1600 (60 FR 34381; June 30, 1995), the Nuclear Regulatory Commission proposes to impose a civil penalty pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (Act), 42 U.S.C. 2282, and 10 CFR 2.205. The particular violations and associated civil penalty are set forth below:

A. Condition 18 of NRC Materials License No. 48-23409-01, requires that licensed material be possessed and used in accordance with the statements, representations and procedures contained in an application dated August 7, 1995, and the enclosure to the application.

Item 10.1 of the enclosure to the application, "Radiation Safety Program: Personnel Monitoring Program," requires, in part, that all gauge users be monitored with a film badge.

Contrary to the above, on June 27, 1996, a gauge user was not monitored with a film badge while using a moisture/density gauge containing NRClicensed material (nominally 10 millicuries (0.37 GBq) of cesium-137 and nominally 50 millicuries (1.9 GBq) of americium-241). (01013)

(This is a repeat violation.)

B. 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 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, unrestricted area means an area, access to which is neither limited nor controlled by the licensee.

Contrary to the above, the licensee did not secure from unauthorized removal or limit access to moisture/density gauges containing NRClicensed material (nominally 10 millicuries (0.37 GBq) of cesium-137 and nominally 40-50 millicuries (1.9 GBq) of americium-241) located in unrestricted areas and that were not in storage, nor did the licensee control and maintain constant surveillance of this licensed material. Specifically,

 On June 27, 1996, a gauge technician returned to the licensee's facility, parked the truck in the licensee's front parking lot, an unrestricted area, and entered the licensee's office. A gauge containing NRC-licensed material was in the rear of the truck, the gauge was not secured within the truck, the rear hatch of the pickup truck was missing, and the technician did not maintain constant surveillance of the gauge containing licensed material.

2. As of the August 29, 1996 predecisional enforcement conference, the licensee's Radiation Protection Officer stated that he routinely left gauges unattended or uncontrolled at various temporary job sites. As a regular practice, he would walk away from a gauge that was not secured, often with his back to the device, in order to perform other tasks; therefore, the gauge containing NRC-licensed material was not controlled or under constant surveillance. (01023)

C. Condition 11.A. of NRC Materials License No. 48-23409-01 requires, in part, that licensed material shall be used by, or under the supervision and in the physical presence of, individuals who have successfully completed the device manufacturer's training program for gauge users, and have been designated by the licensee's Radiation Protection Officer.

Contrary to the above, on June 27, 1996, a Campbell Pacific Nuclear moisture/density gauge containing NRC-licensed material (nominally 10 millicuries (0.37 GBq) of cesium-137 and nominally 50 millicuries (1.9 GBq) of americium-241) war used by an individual who had not successfully completed the device manufacturer's training program for gauge users and who had not been under the supervision and in the physical presence of an individual who had successfully completed the device manufacturer's training program. Furthermore, the individual had not been designated by the licensee's Radiation Protection Officer to use licensed material. (01033)

- D. 10 CFR 71.5(a) requires that a licensee who transports licensed material outside of the confines of its plant or other place of use, or who delivers licensed material to a carrier for transport, comply with the applicable requirements of the regulations appropriate to the mode of transport of the Department of Transportation (DOT) in 49 CFR Parts 170 through 189.
  - 49 CFR 177.842 requires, in part, that packages of radioactive materials be so blocked and braced that they cannot change position during conditions normally incident to transportation.

Contrary to the above, on June 27, 1996, the licensee transported a package containing nominally 10 millicuries (0.37 GBq) of cesium-137 and nominally 50 millicuries (1.9 GBq) of americium-241 outside the confines of its plant, and the package was not blocked and braced such that it could not change position during conditions normally incident to transportation. Specifically, a gauge user did not use the equipment provided by the licensee to block and brace the moisture/density gauge during transport. (01043)

NUREG-0940, PART III

# Notice of Violation

2. 49 CFR 173.475(a) requires, in part, that before each shipment of any radioactive materials package, the shipper shall ensure by examination or appropriate tests, that the packaging is proper for the contents to be shipped.

Contrary to the above, on June 27. 1996, the licensee offered for transportation nominally 10 millicuries (0.37 GBq) of cesium-137 and nominally 40 millicuries (1.5 GBq) of americium-241 (special form) and the licensee did not ensure by examination or appropriate tests, that the packaging was proper for the contents to be shipped. Specifically, a gauge user did not transport the moisture/density gauge in a Type A transport container in that the gauge was not transported in its transport container. (01053)

This is a Severity Level III problem (Supplements IV, V, and VI). Civil Penalty - \$5,000

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

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

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 repl, by specific reference (e.g., citing page and paragraph numbers) to avoid repetition. The attention of the Licensee is directed to the other provisions of 10 CFR 2.205, regarding the procedure for imposing a civil penalty.

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

The response noted above (Reply to Notice of Violation, letter with payment of civil penalty, and Answer to a Notice of Violation) should be addressed to: 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 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 i clude 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 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 Rockville, Maryland this 4th day of October 1996

NUREG-0940, PART III

# UNITED STATES NUCLEAR REGULATORY COMMISSION

In the Matter of

GCME, Inc. DePere, Wisconsin Docket No. 030-31195 License No. 48-23409-01 EA 96-377

DEMAND FOR INFORMATION

GCME, Inc. (Licensee) holds Byproduct Materials License No. 48-23409-01, issued by the Nuclear Regulatory Commission (NRC or Commission) pursuant to 10 CFR Part 30. The license was initially issued on July 27, 1989, was renewed in its entirety on November 2, 1995, and will expire on November 30, 2000. The license authorizes the Licensee to use sealed sources of cesium-137 and americium-241 in mointure/density gauges of several manufacturers at 3741 Packerland Drive, DePere, Wisconsin, and at temporary job sites anywhere in the United States that the U. S. Nuclear Regulatory Commission maintains jurisdiction for regulating the use of licensed material.

II

A routine safety inspection was conducted at the Licensee's facility on June 27, 1996, during which significant violations of NRC requirements were identified. The inspection continued through July 22, 1996. On August 29, 1996, a predecisional enforcement conference was held with the Licensee. The Licensee was represented at the conference by the president of GCME, Inc., and its Radiation Protection Officer (RPO). The inspection and information provided by the Licensee's representatives at the conference established the violations cited in the Notice of Violation and Proposed Imposition of Civil Penalty issued on October 4th, 1996. Specifically:

A. On June 27, 1996, the Licensee permitted an individual to use a moisture/density gauge containing NRC-licensed material (nominally 10 millicuries (0.37 GBq) of cesium-137 and nominally 40-50 millicuries (1.9 GBq) of americium-241) and the individual was not provided with a film badge as required by License Condition No. 18.

- 2 -

- B. On June 27, 1996, and on several other occasions the Licensee failed to secure NRC-licensed materials from unauthorized removal or access when licensed materials (nominally 10 millicuries (0.37 GBq) of cesium-137 and nominally 40-50 millicuries (1.9 GBq) of americium-241) were in unrestricted areas<sup>1</sup> as required by 10 CFR 20.1801 and 20.1802.
- C. On June 27, 1996, a Campbell Facific Nuclear moisture/density gauge containing NRC-licensed material (nominally 10 millicuries (0.37 GBq) of cesium-137 and nominally 50 millicuries (1.9 GBq) of americium-241) was used by an individual who had not successfully completed the device manufacturer's training program for gauge users and had not been authorized by the RPO to use a gauge as required by License Condition 11.A.
- D. On June 27, 1996, the Licensee transported a package containing nominally 10 millicuries (0.37 GBq) of cesium-13? and nominally 50 millicuries (1.9 GBq) of americium-241 and the package was not blocked and braced such that it could not channe position during

As defined in 10 CFR 20.1003, <u>unrestricted area</u> means an area, access to which is neither limited nor controlled by the licensee.

conditions normally incident to transportation as required by 10 CFR 71.5(a) and 49 CFR 177.842.

- 3 -

E. On June 27, 1996, the Licensee offered for transportation nominally 10 millicuries (0.37 GBq) of cesium-137 and nominally 40 millicuries (1.5 GBq) of americium-241 (special form) which was not blocked or braced as required by 10 CFR 71.5(a) and 49 CFR 177.842, and was not properly packaged as required by 10 CFR 71.5(a) and 49 CFR 173.475(a).

The violation for the Licensee's failure to provide a film badge to a technician using a moisture/density gauge was also cited during NRC inspections of GCME in 1989 and in 1995. The initial inspection of GCME, Inc., on October 10, 1989, found that an emoloyee had not worn a film badge while using NRC-licensed material on August 15, 1989. This violation was cited at Severity Level IV on November 6, 1989. The second inspection of GCME, Inc., was conducted on January 10, 1995, with a subsequent investigation by the NRC Office of Investigations (OI). That investigation and inspection found that GCME, Inc., had not provided film badges to any of the authorized users of NRC-licensed materials from October 1990 through the summer of 1991 and from the end of 1992 to July 3, 1993. The violations from 1990 to 1993 were considered to be the result of careless disregard of NRC requirements and were categorized at Severity Level III. The fact that each of the three NRC inspections of the Licensee found that GCME, Inc., was in violation of the same requirement shows that the Licensee has been unable to achieve effective, comprehensive corrective action and is indicative of ineffective or insufficient management oversight of the radiation safety program at GCME. Inc.

Furthermore, as of the August 29, 1996 productional enforcement conference, the Licensee had not conducted a root cause analysis or proposed corrective actions for the current violations. Additionally, information provided at the conference by the Licensee representatives indicated that the Licensee placed a premium on production over compliance with NRC requirements. Also at the conference, it appeared that Licensee managers, in particular the RPO, were unfamiliar with the specific requirements of the NRC license and the rules and regulations of the Commission.

- 4 -

These circumstances demonstrate a lack of regard for, and adherence to, procedures and a lack of management control and supervision over licensed activities, and raise a question as to whether the Licensee will in the future be able to effectively manage the NRC-licensed radiation safety program. Therefore, further information is needed to determine whether the Commission can have reasonable assurance that in the future the Licensee will conduct its activities in accordance with the Commission's requirements.

III

Accordingly, pursuant to sections 161c, 161o, 182 and 186 of the Atomic Energy Act of 1954, as amended, and the Commission's regulations in 10 CFR 2.204 and 10 CFR 30.32(b), in order for the Commission to determine whether License No. 48-23409-01 should be modified, suspended or revoked, or other enforcement action taken to ensure compliance with N°C regulatory requirements, the Licensee is required to submit to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, within 30 days of the

date of this Demand For Information, the following information. In writing and under oath or affirmation:

- 5 -

- A. Provide written assurance that all nuclear gauge users, including the Radiation Protection Officer, have been, and will be in the future, trained on and fully understand the conditions of the NRC license and the rules and regulations of the Commission applicable to the NRClicensed program at GCME, Inc. Describe your basis for reaching this conclusion.
- B. Describe the steps taken to ensure that sufficient management resources are available to properly oversee the NRC-licensed program.
- C. Fully describe the audit program required by the "Duties and Responsibilities of the Radiation Safety Officer" that are enclosures to the August 7, 1995 application and are incorporated into License Condition No. 18.A. The description should include the written policies, procedures, and schedules used to implement the audit program, including the type and frequency of the audits, the qualifications of the person or persons performing the audits, and whether the audits will be performed by GCME, Inc. employees or by an external source. Written audit reports shall be retained by GCME, Inc., as required by the same license condition.

- 6 -
- D Describe how GCMF Inc. will ensure that radiation safety considerations are given top priority despite business scheduling and other operational pressures.
- E. Describe why you have confidence that your corrective actions will be long lasting.
- F. In light of the inspection history, explain why the NRC: (1) should conclude that you are able to, or willing to, comply with the Commission's requirements; and (2) should not suspend and revoke GCME, Inc.'s License No. 48-23409-01 to possess and use licensed material.

Copies also shall be sent to the Assistant General Counsel for Hearings and Enforcement at the same address, and to the Regional Administrator, NRC Region III, 801 Warrenville Road, Lisle, IL 60532-4351.

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

FOR THE NUCLEAR REGULATORY COMMISSION

Ann

Dames Lieberman, Director Office of Enforcement

Dated at Rockville, Maryland this y/h day of October 1996



#### UNITED STATES NUCLEAR REGULATORY COMMISSION WASHINGTON, D.C. 2055-0001

HINGTON, D.C. 2055-0001

September 13, 1996

EA 96-302

GRD Steel Corporation ATTN: Mr. Pradip K. Ghosh and Mr. KPS Ahluwalia Post Office Box 111 Monongahela, Pennsylvania 15093

SUBJECT: ORDER SUSPENDING LICENSE (IMMEDIATELY EFFECTIVE), AND REQUIRING TRANSFER OF LICENSED MATERIAL, AND DEMAND FOR INFORMATION

The enclosed Order Suspending License (Immediately Effective) (Order), and Requiring Transfer of Licensed Material, and the Demand for Information are being issued as a result of NRC inspections and investigations that have identified that there has been a foreclosure on the facility which houses two licensed gauges for which you are the licensee, and that, consequently, the Monongahela Industrial Development Association (MIDA), controls access to this facility and is in possession of licensed material without an NRC license.

The enclosed Order requires GRD Steel to suspend all licensed activities with the exception of transferring the two licensed gauges to an authorized recipient in cooperation with MIDA.

You are required to provide an Answer to the Order and to respond to the Demand for Information, which requires you to provide information to assist the NRC in determining whether your license should be revoked, or whether the NRC can have confidence that future activities will be carried out in compliance with all requirements.

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 this Order shall be subject to criminal prosecution as set forth in that section. Violation of this order may also subject the person to civil monetary penalty.

Based on the information set forth in Sections II and III of the enclosed Order, the Commission requires further information from the Licensee in order to determine whether the Commission can have reasonable assurance that in the future the Licensee will conduct its activities in accordance with the Commissions requirements. Accordingly, pursuant to sections 161c, 161o, 182 and 186 of the Atomic Energy Act of 1954, as amended, and the Commission's regulations in 10 CFR 2.204 and 10 CFR 30.32(b), in order for the Commission to determine whether License No. 37-30147-01 should be revoked, or other GRL Steel Corporation

- 2 -

enforcement action taken to ensure compliance with NRC regulatory requirements, the Licensee is required to submit to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, D.C., 20555, within 20 days of the date of this Order and Demand for Information, the following information, in writing and under oath or affirmation:

- A. State the reasons why, in light of the violations discussed in Sections II and III of the enclosed Order, NRC License No. 37-30147-01 should not be revoked.
- B. In light of the information set forth in Section II of the Order, provide an explanation of the relationship between Commercial Steel and GRD Steel Corporation including, but not limited to, any public disclosure statements, articles of incorporation, proxy statements, and agreements between Commercial Steel and GRD Steel, and provide a list of the names and addresses of all former and current officers, Board of directors, and stockholders of GRD Steel Corporation; and state whether any such officers or directors are currently or have previously been officers or directors of Commercial Steel.

Copies of this letter also shall be sent to the Assistant General Counsel for Hearings and Enforcement at the same address, and to the Regional Administrator, NRC Region I, 475 Allendale Road, King of Prussia, Pennsylvania 19406-1415. After reviewing your response, the NRC will determine whether further action is necessary to ensure compliance with regulatory requirements.

Questions concerning this Order should be addressed to Mr. James Lieberman, Director, Office of Enforcement, who may be reached at (301) 415-274?.

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). To the extent possible, your response should not include any personal, privacy, proprietary, or safeguards information so that it can be placed int eh 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 bases for your claim of withholding (e.g., explain why the disclosure of GRD Steel Corporation

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.

- 3 -

Sincerely,

nmm

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

Docket No. 030-33534 License No. 37-30147-01

Enclosure: As Stated

cc w/encl: Commonwealth of Pennsylvania Commercial Steel - Somi Ahluwalia, President Virindar Bubbar, Chief Executive Officer Girish Soni, Vice-President MIDA - Lue Ann Pawlick, General Manager

## UNITED STATES NUCLEAR REGULATORY COMMISSION

In the Matter of GRD STEEL CORPORATION (GRD)

EA 96-302

# ORDER SUSPENDING LICENSE (IMMEDIATELY EFFECTIVE) AND REQUIRING TRANSFER OF LICENSED MATERIAL

GRD Steel Corporation, (Licensee) is the holder of NRC License No. 37-30147-01 issued by the Nuclear Regulatory Commission (NRC or Commission) on February 6, 1995 pursuant to 10 CFR Part 30. License No. 37-30147-01 authorizes the possession and use of up to 10 millicuries of cobalt-60 in sealed sources (with a maximum activity per source of 3.3 millicuries). The license is due to expire on February 28, 2005. GRD was engaged in the manufacturing of carbon steel.

II

On December 22, 1995, the NRC issued a Notice of Violation to GRD for two violations of NRC requirements. GRD responded to the Notice of Violation on December 29, 1995. Since the NRC had questions concerning the adequacy of the GRD response regarding locking of the sources, the NRC Region I staff contacted GRD's Radiation Safety Officer (RSO) (Mr. Mauro Coruzzi) on March 28, 1996, by telephone. The RSO indicated that GRD's operations had ceased and he was no longer working for GRD; the employment of all GRD employees was either terminated or transferred to another steel company (Commercial Steel Corporation (Commercial Steel)); and the owner of the building that housed the GRD operation was the Monongahela Industrial Development Association (MIDA) which now held title to GRD's Mid Mound Center facility and to both gauges as a result of its purchase at a sheriff's foreclosure sale of the property of GRD, and which was controlling access to the building via the posting of guards. MIDA is not licensed by the NRC to possess radioactive material.

- 2 -

On April 10, 1996, Region I contacted Mr. Coruzzi by telephone because GRD had not made a formal declaration of bankruptcy or requested the NRC to assent to a change of ownership. The RSO indicated that GRD was not in bankruptcy nor had there been a change of ownership. However, he did indicate that MIDA had taken control of the facility because of GRD's apparent abandonment of the facility. He also indicated that the two gauges located at the facility, each containing approximately 3.3 millicuries of cobalt-60, were locked and not in use, nor could the gauges be accessed by unauthorized personnel because he was the only person in possession of the key used to unlock the gauges.

During the April 10, 1996 conversation, Region I requested that GRD promptly document the information received verbally from the RSO. Since such documentation was not promptly received by the NRC, the NRC sent GRD a letter, dated April 23, 1996, advising the company to notify the NRC if it decided to change ownership, terminate licensed activities, or declare bankruptcy. GRD did not reply to that letter. As a result, on June 18, 1996, Mr. Coruzzi was again contacted by telephone by NRC, Region I. At that time, Mr. Coruzzi informed the NRC that the GRD President, Mr. Pradip K. Ghosh, was working for Commercial Steel, Glassport, Pennsylvania.

NUREG-0940, PART III

Shortly thereafter, on June 19, 1996, NRC Region I telephoned Mr. Ghosh, because of NRC concerns that 1) the gauges were in the possession of MIDA, and that GRD had transferred material to MIDA, an unlicensed entity, in violation of the requirements of 10 CFR 30.3 and 10 CFR 30.41, and 2) there might have been a transfer of control of the license without first obtaining the Commission's consent in writing as required by 10 CFR 30.34(b). During that conversation, Mr. Ghosh made a number of commitments to the NRC, including the commitment to contact APGEE/Berthold, the manufacturer of the gauges, by July 15, 1996, to arrange for return of the gauges to the manufacturer. Mr. Ghosh also committed to provide a completed Certificate of Disposition (NRC Form 314) to the NRC, and request that its license be terminated, by July 31, 1996. The NRC issued a Confirmatory Action Letter (CAL) to confirm these commitments on June 20, 1996. A copy of this CAL was also sent to MIDA.

- 3 -

On June 24, 1996, GRD sent the NRC Region I office a facsimile which stated that it was not correct to state that GRD had sold the property to MIDA and therefore it was not correct to conclude that GRD had transferred the license. GRD also stated that it did not want to terminate the license, and that it was working to gain additional financial backing in order to restart the operation, and requested that the gauges be kept in place to facilitate restarting the operation.

On June 26, 1996, Supplement 1 to the CAL was issued to GRD and a copy was sent to MIDA. The CAL replaced the statement that GRD would request

termination of its license by July 31, 1996, with the statement that GRD would maintain its license until a final determination was made with regard to the future of the company.

- 4 -

On August 6, 1996, NRC Region I learned that the facility had been broken into approximately two to three weeks earlier. Subsequently on August 6, 1996, NRC Region I telephoned Ms. Lue Ann Pawlick, the General Manager of MIDA, about the apparent break-in at the facility. The General Manager described the materials taken from the facility, and indicated that the gauges were not affected by the break-in, all materials had been recovered, the perpetrators had been apprehended, and additional local police patrols and daily walk-throughs by a local president of the steel workers union were being performed.

On August 6, 1996, NRC Region I attempted to contact the President of GRD. At that time, the NRC learned that the President would be out of the country until early September and could not be reached.

On August 12, 1996, the NRC issued a Confirmatory Order to MIDA to assure that MIDA maintains control of the NRC-licensed gauges and that the gauges will remain locked at all times; that MIDA request additional patrols from the local police in the area, until such time as the gauges are transferred to an authorized recipient; that MIDA perform daily walk-throughs of the plant to ensure that the gauges had not been tampered with; that MIDA either obtain a license from the NRC to possess the material or to transfer the material to a specific NRC or Agreement State licensee authorized to possess such material,

and, in the absence of obtaining a license from the NRC to possess the gauges, transfer the gauges within 90 days from the date of this Order, either back to the manufacturer, or to another authorized recipient; and that MIDA inform the NRC by August 19, 1996 under oath or affirmation regarding the specific actions MIDA will take to comply with these conditions.

- 5 -

The NRC has also received information from the Pennsylvania Corporation Bureau that indicated that there was some similarity in corporate officers of GRD Steel and Commercial Steel. The NRC has determined that the President and Radiation Safety Officer (RSO) of GRD Steel are currently employed by Commercial Steel, and that telephone calls to GRD are answered by Commercial Steel, and that the address of both companies is the same.

III

Based on the above, it appears that GRD Steel, its employees, including the President and the Radiation Safety Officer, have willfully permitted the licensed gauges to be transferred to MIDA, an entity known by GRD not to have an NRC license to possess radioactive material. GRD Steel, as the licensee, remains responsible for assuring that the licensed material is possessed and controlled by a licensee of the Commission or an Agreement State and, therefore, is jointly and severally responsible with MIDA for the proper transfer of that licensed material now possessed by MIDA. Further, the actions of GRD Steel, including the failure to reply to NRC inquiries and to reply completely to the Notice of Violation issued in December 1995 in a

NUREG-0940, PART III

timely manner, indicate that GRD Steel is not able to conduct its program in accordance with all NRC requirements.

- 6 -

Consequently, I lack the requisite reasonable assurance that the Licensee's activities can be conducted under License No. 37-30147-01 in compliance with the Commission's requirements and that the health and safety of the public, including the Licensee's employees, will be protected. Therefore, public health, safety, and interest require that License No. 37-30147-01 be suspended. Furthermore, pursuant to 10 CFR 2.202, I find that the significance of the violation described above is such that public health, safety, and interest require that this Order be immediately effective.

IV

Accordingly, pursuant to sections 81, 161b, 161i, 161o, 182 and 186 of the Atomic Energy Act of 1954, as amended, and the Commission's regulations in 10 CFR 2.202 and 10 CFR Part 30, IT IS HEREBY ORDERED, EFFECTIVE IMMEDIATELY, THAT:

A. GRD's authority under License No. 37-30147-01 to receive. possess, and use radioactive material is suspended. GRD may only possess material for the purpose of transferring it to an authorized recipient under credition B below;

NUREG-0940, PART III

B. GRD will transfer, in cooperation with MIDA, all NRC-regulated material to an authorized recipient within 60 days of receipt of this Order. If GRD believes it does not have sufficient funds to complete the transfer, it must provide, within 30 days of this Order, evidence supporting such a claim by submitting to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, in writing under an oath or affirmation:

- 7 -

 an estimate of the cost of the transfer and the basis for the estimate, including the license number and identity of the entity that would perform the transfer;

 written statements from at least two banks stating that GRD could not qualify for a loan to pay for the transfer;

copies of the Federal income tax return for the years ending
 1994 and 1995 for GRD Steel Corporation and its officers;

 copies of profit and loss statements from GRD Steel Corporation for these same years;

C. GRD shall notify NRC Region I at least two working days prior to the date of the transfer so that NRC may, if it elects, observe the transfer of the storial to an authorized recipient;

NUREG-0940, PART III

D. GRD, within seven days following the completion of the transfer, shall provide to the Regional Administrator, Region I:

- 8 -

1) confirmation in writing (NRC Form 314) that the radioactive material has been transferred; and

2) a copy of the certification from the authorized recipient that the material has been received.

E. The provisions of Section IV of this Order do not relieve MIDA of any requirement imposed by the Confirmatory Order dated August 12, 1996, identified in Section II of this Order.

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

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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 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 include a statement of good cause for the extension. The answer may consent to this Order. Unless the answer consents

to this Order, the answer shall, in writing and under oath or affirmation, specifically admit or deny each allegation or charge made in this order and set for the matters of fact and law on which the Licensee or other person adversely affected relies and the reasons as to why the Order should not have been issued. Any answer or request for a hearing shall be submitted to the Secretary, U.S. Nuclear Regulatory Commission, ATTN: Chief, Docketing and Service Section, Washington, D.C. 20555. Copies also shall be sent to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, to the Assistant General Counsel for Hearings and Enforcement at the same address, to the Regional Administrator, NRC Region I, 475 Allendale Road, King of Prussia, Pennsylvania, 19406-1415, and to the Licensee. If such a person requests a hearing, that person shall set forth with particularity the manner in which his interest is adversely affected by this Order and shall address the criteria set forth in 10 CFR 2.714(d).

If a hearing is requested by 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, 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.

NUREG-0940, PART III

- 9 -

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

KUNO nmn Hugh/L. Thompson/ Jr. For

Deputy Executive Director for Nuclear Materials Safety, Safeguards, and Operations Support

Dated at Rockville, Maryland this 3<sup>th</sup>day of September 1996

NUREG-0940, PART III



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

August 22, 1996

EA 96-234

Mr. John Driscoll, President HNU Systems, Inc. 160 Charlemont Street Newton Highlands, Massachusetts 02161-9987

SUBJECT: CONFIRMATORY ORDER MODIFYING LICENSE (EFFECTIVE IMMEDIATELY)

Dear Mr. Driscoll:

The enclosed Confirmatory Order Modifying License (which is immediately effective upon issuance) is being issued to you to confirm commitments that you made to the NRC in: (1) a June 18, 1996 letter in response to an NRC Demand for Information sent to you on June 7, 1996; (2) a telephone call on July 18, 1996; and (3) a written consent signed by you on August 7, 1996.

Questions concerning this Confirmatory Order should be addressed to Mr. James Lieberman, Director, Office of Enforcement, who can be reached at (301) 415-2741.

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

Sincerely,

Gray, Acting Pirector Enforcement of

Docket Nos. 030-31621; and 030-31622 License Nos. 20-27938-03G; 20-27938-02

Enclosure: Confirmatory Order

cc w/encl: Commonwealth of Massachusetts

# UNITED STATES NUCLEAR REGULATORY COMMISSION

In the Matter of

HNU Systems, Inc. Newton Highlands, Massachusetts Docket Nos. 030-31621 030-31622 License Nos. 20-27938-036 20-27938-02 EA 96-234

# CONFIRMATORY ORDER MODIFYING LICENSE (EFFECTIVE IMMEDIATELY)

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HNU Systems, Inc. (Licensee or HNU), is the holder of Byproduct Materials License Nos. 20-27938-03G and 20-27938-02 (Licenses) issued by the Nuclear Regulatory Commission (NRC or Commission) pursuant to 10 CFR Part 30. The Licenses authorize the distribution, possession, and use of sealed sources in devices generally licensed, not to exceed 100 millicuries per source and 1,000 millicuries per foil, in accordance with the conditions specified therein. The Licenses were due to expire on March 31, 1996. However, on February 29, 1996, the Licensee filed a renewal application and, in accordance with 10 CFR 30.36(a), the Licenses are under a timely renewal.

# II

As a result of a June 1995 inspection, a Confirmatory Action Letter (CAL) was issued on June 15, 1995 and a Notice of Violation (NOV) was issued on July 27, 1995 to HNU for numerous vio?ations characterized in the aggregate as a Severity Level III problem. The violations included the failure to: (1) notify the NRC that the Radiation Safety Officer (RSO) listed on the Licenses had been laid off and had not been replaced; (2) conduct a physical inventory of radioactive materials; (3) conduct leak tests of sealed sources at the required six month intervals; (4) calibrate survey instruments at the required

six month intervals; (5) perform monthly surveys; (6) monitor exposures of individuals to radiation and radioactive material; (7) review the radiation protection program content and implementation at least annually; (8) report to the NRC any transfers of generally licensed devices; (9) maintain radiation safety record notebooks; and (10) provide training to Licensee staff.

- 2 -

Subsequently, the NRC conducted a follow-up inspection from December 8, 1995, to April 23, 1996, to review the Licensee's implementation of the corrective actions taken in response to the June 1995 CAL and July 1995 NOV. Based on this inspection, the NRC identified several repetitive violations and determined that the Licensee had not implemented adequately the corrective actions in response to the Notice and CAL.

Therefore, the Commission required further information from HNU in order to determine whether the Commission can have reasonable assurance that in the future, should HNU be permitted by the NRC to continue to perform licensed activities under the Licenses, it will conduct the activities in accordance with NRC requirements, and whether further enforcement action is warranted against HNU. Accordingly, the NRC issued a Demand for Information (DFI) to the Licensee on June 7, 1996, which required the Licensee to submit, among other things to the NRC, within 30 days of the date of the DFI, in writing and under oath or affirmation:

 a statement as to whether the Licensee will apply sufficient resources to manage an effective radiation safety program; and

NUREG-0940, PART III

1110

 a statement as to why the Licenses should not be revoked in light of the financial concerns and the repetitive violations.

- 3 -

In a letter, dated June 18, 1996, the Licensee responded to the DFI and indicated that it would: (1) commit the necessary resources to permit the RSO (who works part-time) to work up to 20 hours per week until full compliance with the radiation safety program requirement was achieved, which it stated could be dore in 4 months, after which it believes that it can maintain compliance by the RSO working 10-12 hours per week; (2) designate an assistant RSO from a qualified member of the staff; (3) complete, by August 1, 1996, a Radiation Safety Refresher Course, including testing, for employees dealing with instruments containing sealed sources; (4) conduct an annual audit of the radiation safety program, and update quarterly reports of source transfers by October 1, 1996; (5) perform wipes of all sources taken from storage; (6) calibrate a second survey meter by July 15, 1996, to ensure one calibrated survey meter is available at all times; (7) continue its search for a missing 50 mCi Fe-55 source; (8) provide locked files for radiation safety records; (9) have an outside auditor conduct an audit of the organization after the program is brought into full compliance; and (10) meet the specified payment schedule that it negotiated with the NRC Fees Branch for the payment of fees.

In a followup call with the Licensee on July 18, 1996, the Licensee agreed that: (1) the RSO would work at least 20 hours per week, rather than 10-12 hours per week, until this condition was relaxed by the NRC; (2) it would have an outside auditor complete an audit of the organization by December 1, 1996; and (3) it would meet the other commitments made in its June 18, 1996 letter.

On August 7, 1996, the Licensee consented to issuing this Order with the commitments, as described in Section III below. The Licensee further agreed in its August 7, 1996 letter that this Order is to be effective upon issuance and that it has waived its right for a hearing. Implementation of these commitments will provide enhanced assurance that sufficient resources will be applied to the radiation safety program, and that the program will be conducted safely and in accordance with NRC requirements.

- 4 -

Therefore, I find that the Licensee's commitments as set forth in its June 18, 1996, and August 7, 1996 letters are acceptable and necessary, and conclude that with these commitments, the public health and safety are reasonably assured. In view of the foregoing, I have determined that the public health and safety require that the Licensee's commitments be confirmed by this Order. Based on the above and on the Licensee's consent, the Order is immediately effective upon issuance.

# III

Accordingly, pursuant to sections 81, 161b, 161i, 161o, 182, and 186 of the Atomic Energy Act of 1954, as amended, and the Commissions's regulations in 10 CFR 2.202 and 10 CFR Part 30, IT IS HEREBY ORDERED, EFFECTIVE IMMEDIATELY UPON ISSUANCE, THAT LICENSE NOS. 20-27938-03G and 20-27938-02, ARE MODIFIED AS FOLLOWS:

 The Licensee's Radiation Safety Officer will work a minimum of 20 hours per week until this commitment is relaxed by the NRC;

NUREG-0940, PART III

2. An assistant RSO will be designated within 15 days of the date of the Order, and the Licensee will provide written notification to NRC Region I of the individual designated as assistant RSO and the individual's qualifications within 30 days of the date of the Order;

- 5 -

- A radiation safety refresher course, including testing, will be given by October 1, 1996 to all employees working with instruments containing sealed sources.
- 6. The required annual audit of the radiation safety program, and all previously submitted quarterly reports of source transfers, will be completed by October 1, 1996, and submitted to NRC Region I by November 1, 1996;
- 5. Wipes will be performed of all sources taken from storage; in determining compliance with License Condition 12, appropriate actions will be taken if contamination greater than 0.005 Uci is identified, and appropriate wipe tests and source disposition records will be maintained, effective immediately;
- At least one calibrated survey meter will be available at all times;
- Radiation Safety Records will be placed in locked files within 15 days of the date of the issuance of this Confirmatory Order;
- An experienced outside independent auditor will conduct and complete an

audit of the Licensee's adherence to the requirements of its NRC Licenses by December 1, 1996. The Licensee shall submit the name and qualifications of the outside auditor to the NRC for approval by October 1, 1996, and the outside auditor shall provide the audit results simultaneously to both HNU and the NRC; and

- 6 -

9. The Licensee will notify Mr. Francis Costello, Chief, Nuclear Materials Safety Branch 3, NRC Region I, if it does not adhere to the specified payment schedule that it negotiated with the NRC Fees Branch for the payment of fees, as noted in the Conditional Order Extending Time, dated June 24, 1996. If the payment schedule is not met, notification will be made within 10 business days from the missed payment due date.

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

IV

Any person adversely affected by this Confirmatory Order, other than the Licensee, may request a hearing within 20 days of its issuance. 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 include a statement of good cause for extension. Any request for a hearing shall be submitted to the Secretary, U.S. Nuclear Regulatory Commission, ATTN: Chief, Docketing and Service Section.

Washington, D.C. 20555. Copies also shall be sent to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, to the Assistant General Counsel for Hearings and Enforcement at the same address, to the Regional Administrator, NRC Region I, 475 Allendale Road, King of Prussia, Pennsylvania, 19406, and to the Licensee. If such a person requests a hearing, that person shall set forth with particularity the manner in which his interest is adversely affected by this Order and shall address the criteria set forth in 10 CFR 2.714(d).

- 7 -

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

Pursuant to 10 CFR 2.202(c)(2)(i), any person other than the Licensee, 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.

This Order is immediately effective upon issuance. 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 III 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 III 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 EFFECTIVENESS OF THIS ORDER.

- 8 -

FOR THE NUCLEAR REGULATORY COMMISSION

Director of Enf

Dated at Rockville, Maryland this 22cd day of August, 1996 UNITED STATES



#### NUCLEAR REGULATORY COMMISSION

REGION IV

611 RYAN PLAZA DRIVE, SUITE 400 ARLINGTON, TEXAS 76011 8064

June 6, 1996

EA 96-065

Mr. Samuel Boykin, President Industrial Marine Testing Labs, Inc. 3167 Commercial Street San Diego, California 92113

SUBJECT: NOTICE OF VIOLATION & PROPOSED IMPOSITION OF CIVIL PENALTY -\$1,500 (NRC INSPECTION REPORT 150-00004/95-10; INVESTIGATION REPORT 4-95-028)

Dear Mr. Boykin:

This is in reference to the predecisional enforcement conference conducted on April 25, 1996, in San Diego, California. Enclosure I is a list of conference attendees. The conference was conducted to discuss an apparent violation of NRC requirements identified during an NRC inspection and investigation of Industrial Marine Testing Labs, Inc. (Industrial Marine) activities in NRC jurisdiction. The apparent violation, which was summarized in a March 18, 1996, letter to you, involved knowingly conducting radiography in exclusive federal jurisdiction without an NRC license<sup>1</sup>.

You admitted during the investigation and at the conference that Industrial Marine had knowingly conducted radiography on U.S. Navy ships, an area which is under exclusive federal jurisdiction, without obtaining the necessary authorization from the NRC. You indicated at the conference that the primary reasons for this violation were that Industrial Marine was struggling financially; that other companies also appeared to he in noncompliance in the past; that the requirement had not come up even though you were working for an arm of the federal government; and that based on your own experience you didn't believe the NRC considered it an important matter.

Based on the information developed during the inspection and investigation and the information that you 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 involves Industrial Marine's intentional failure to obtain an NRC license before using byproduct material to perform radiography in an area of exclusive federal jurisdiction. As an alternative to obtaining

Although Industrial Marine Testing Labs, Inc., is licensed by the state of California, the license is limited to "areas not under exclusive federal jurisdiction."

Industrial Marine Testing Labs, Inc.

an NRC license, you had the option, as permitted by NRC practice, of filing an NRC Form 241, "Report of Proposed Activities in Non-Agreement States," and paying the required fees<sup>2</sup>.

- 2 -

Industrial Marine stated during the conference that, despite financial problems, it places a premium on conducting its activities safely and in accordance with all safety requirements. The NRC's inspection of Industrial Marine's records and interviews of Industrial Marine personnel did not find any evidence of significant safety violations. Nonetheless, the failure to obtain NRC authorization is a matter of significant regulatory concern to the NRC because it denies the NRC the opportunity to assure through field inspections that radiography activities are being conducted in compliance with all NRC radiation safety requirements. In addition, deliberate violations of NRC requirements, even those that are administrative in nature, raise questions about attitudes toward compliance with the "General Statement of Policy and Procedure for NRC Enforcement Actions (Enforcement Policy)," NUREG-1600, at Severity Level III.

The base civil penalty for a Severity Level III violation is \$5,000. In accordance with the Enforcement Policy, the NRC normally considers only three factors -- previous enforcement history, identification of the violation and corrective action -- in determining whether a Severity Level III violation should result in a base penalty, two times a base penalty or no penalty. The NRC also may exercise discretion and assess either a larger or smaller penalty based on the circumstances involved, including whether the violation was committed willfully. The normal assessment process in this case would have resulted in at least the base penalty being assessed. However, the NRC has decided to exercise its discretion, in accordance with VII.B.6 of the Enforcement Policy, to assess a smaller civil penalty based on the circumstances of this case. The circumstances that the NRC took into account include the fact that Industrial Marine is a small business, the absence of significant safety violations, and that you were put on specific notice by the NRC on November 22, 1993 and you continued to conduct activities, and the fact that monies were saved by being in noncompliance. We also note that Industrial Marine filed an NRC Form 241 in late 1995 and paid the accompanying fee and did the same for calendar year 1986. Industrial Marine also stated at the conference that it has since taken additional steps to familiarize itself with NRC requirements."

<sup>2</sup> The reciprocity fee assessed radiographers, which was established in 1991, was \$600 in 1991; \$640 in 1992; \$700 in 1993 and 1994, and \$1,100 as of July 20, 1995.

<sup>3</sup> NRC requirements are not necessarily identical to those of an Agreement State; licensees are required to comply with all applicable NRC requirements when working in areas under exclusive federal jurisdiction.

Industrial Marine Testing Labs, Inc.

Notwithstanding Industrial Marine's corrective actions noted above, to emphasize the significance of making a deliberate decision to violate an NRC requirement and the importance of complying with all NRC requirements in the future. I have been authorized, after consultation with the Director, Office of Enforcement, and the Deputy Executive Director for Nuclear Materials Safety. Safeguards and Operations Support, to issue the enclosed Notice of Violation and Proposed Imposition of Civil Penalty in the amount of \$1,500 for this Severity Level III violation.

- 3 -

As to your statement regarding your competitors doing work for the Navy without having an NRC license, as a result of the NRC's investigations of state licensees who worked for the Navy, the Navy is now assuring that such companies have NRC licenses before allowing work to be done.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. In your response, you should document the specific actions taken and any additional actions you plan to prevent recurrence. You should also document steps you have taken or plan to take to assure that you are complying with all NRC requirements for any work conducted in areas of exclusive federal jurisdiction. After reviewing your response to this Notice, including your proposed corrective actions and the results of future inspections, the NRC will determine whether further NRC enforcement action is necessary to ensure compliance with NRC regulatory requirements.

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

feel Ul Callan Regtonal Administrator

Docket No. 150-00004 License No. CA 2799-90

Enclosures:

- 1. Predecisional Enforcement Conference Attendees
- Notice of Violation and Proposed Imposition of Civil Penalty

cc w/Enclosures: California Radiation Control Program

#### Attendees

Predecisional Enforcement Conference

# April 25, 1996

# San Diego, California

Industrial Marine Testing Labs, Inc.

Samuel Boykin, President and Radiation Safety Officer

Nuclear Regulatory Commission, Region IV

Linda Howell, Chief, Nuclear Materials Inspection & Fuel Cycle/Decommissioning Branch, Division of Nuclear Materials Safety Gary Sanborn, Enforcement Officer, Office of the Regional Administrator

## NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY

Industrial Marine Testing Labs, Inc. San Diego, California Docket No. 150-00004 License No. CA 2799-90 EA 96-065

During an NRC inspection and investigation conducted June 13, 1995, through February 15, 1996, a violation of NRC requirements was identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," NUREG-1600, the Nuclear Regulatory Commission proposes to impose a civil penalty pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (Act), 42 U.S.C. 2282, and 10 CFR 2.205. The particular violation and associated civil penalty are set forth below:

10 CFR 30.3 requires in relevant part, that no person shall possess or use byproduct material except as authorized by a specific or general license issued by the NRC unless exempt as provided in Part 30 or Part 150.

Contrary to the above, on multiple instances during calendar years 1993, 1994 and 1995, Industrial Marine Testing Labs, Inc., a licensee of the state of California, used byproduct material to perform industrial radiography on U.S. Navy ships, an area in exclusive federal jurisdiction, without either a specific or general license issued by the NRC. (01013)

This is a Severity Level III violation (Supplement VI). Civil Penalty - \$1,500

Pursuant to the provisions of 10 CFR 2.201, Industrial Marine Testing Labs, Inc., is hereby required to submit a written statement or explanation to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, within 30 days of the date of 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 license should not be modified, suspended, or revoked or why such other action as may be proper should not be taken. Consideration may be given to extending the response time for good cause shown. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, this response shall be submitted under oath or affirmation.

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

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

In requesting mitigation of the proposed penalty, the factors addressed in Section VI.B.2 of 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 decermined 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: 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, ATTN: Enforcement Officer, 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. 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.

Dated at Arlington, Texas, this 6th day of June 1996



# UNITED STATES

July 31, 1996

EA 96-065

Mr. Samuel Boykin, President Industrial Marine Testing Laboratories, Inc. 3167 Commercial Street San Diego, California 92113

SUBJECT: ORDER IMPOSING CIVIL MONETARY PENALTY - \$1,500

Dear Mr. Boykin:

This refers to your letter dated July 1, 1996, in response to the Notice of Violation and Proposed Laposition of Civil Penalty (Notice) sent to you by our letter dated June 6, 1996. Our letter and Notice described one Severity Level III violation involving your deliberate failure to obtain an NRC license prior to conducting radiography in areas of exclusive federal jurisdiction. To emphasize the significance of making a deliberate decision to violate an NRC requirement and the importance of complying with all NRC requirements in the future, a civil penalty of \$1,500 was proposed. The NRC exercised discretion, in accordance with VII.B.6 of the NRC Enforcement Policy, to assess a reduced civil penalty based on the circumstances described in our June 6 letter.

In your July 1 letter, you acknowledged that Industrial Marine Testing Laboratories, Inc. (Industrial Marine), knowingly conducted radiography in exclusive federal jurisdiction without an NRC license or the filing of an NRC Form 241. By separate letter dated July 1, 1996, you also requested further reduction of the civil penalty because paying the \$1,500 penalty would hurt the company financially. You also acknowledged that the NRC had considered the size of the company in arriving at the reduced, \$1,500 proposed civil penalty.

After consideration of your response, we have concluded for the reasons given in the Appendix attached to the enclosed Order Imposing Civil Monetary Penalty that the civil penalty should not be mitigated any further. Accordingly, we hereby serve the enclosed Order on Industrial Marine Testing Laboratories, Inc., imposing a civil monetary penalty in the amount of \$1,500.

The NRC's Enforcement Policy provides, "... it is not the NRC's intention that the economic impact of a civil penalty be so severe that it puts a licensee out of business (orders, rather than civil penalties, are used when the intent is to suspend or terminate licensed activities) or adversely affects a licensee's ability to safely conduct licensed activities." Therefore, in view of your statement concerning your financial hardship, we are prepared to permit you to pay this civil penalty over time. If you make arrangements to pay in installments, interest will be assessed and there may be other administrative charges. If you wish to pay in installments, you are to inform Mr. James Lieberman, Director, Office of Enforcement, within 15 days of the date of this letter, and arrange the terms and conditions of payment.

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

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

Sincerely,

R. Gray. Acting Director e of Er. forcement

Docket No. 150-00004 License No. CA 2799-80

Enclosure: As Stated

cc w/encl: State of California

# UNITED STATES NUCLEAR REGULATORY COMMISSION

In the Matter of ) Industrial Marine Testing Laboratories, Inc. ) Docket No. 150-00004 San Diego, California ) License No. CA 2799-80 EA 96-065

ORDER THPOSING CIVIL MONETARY PENALTY

Industrial Marine Testing Laboratories, Inc. (Industrial Marine or Licensee) is the holder of Radioactive Materials License No. CA 2799-80 issued by the state of California, an Agreement State, on December 27, 1993. The license authorizes the Licensee to possess and use sealed radioactive sources in conducting industrial radiography at specific locations in San Diego, California and at temporary jobsites in areas not under exclusive federal jurisdiction throughout the state of California in accordance with the conditions specified therein. Pursuant to NRC practice, the Licensee may conduct the same activities in areas under NRC jurisdiction provided that the NRC is notified and the provisions of 10 CFR 150.20 are followed. Otherwise, an NRC license is required for such activities in accordance with the requirements of 10 CFR 30.3.

II

An inspection and investigation of the Licensee's activities was conducted during June 13, 1995, through February 15, 1996. The results of the inspection and investigation indicated that the Licensee had not conducted its activities in full compliance with NRC requirements. A written Notice of Violation and Proposed Imposition of Civil Penalty (Notice) was served upon the Licensee by letter dated June 5, 1996. The Notice stated the nature of

the violation, the provision of the NRC's requirements that the Licensee had violated, and the amount of the civil penalty proposed for the violation.

-2-

The Licensee responded to the Notice in a letter dated July 1, 1996. In its response, the Licensee admitted the violation but requested further mitigation of the civil penalty, asserting that imposition of the civil penalty would hurt Industrial Marine financially.

#### III

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

IV

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

The Licensee pay a civil penalty in the amount of \$1,500 within 30 days of the date of this Order, by check, draft, money order, or electronic transfer, payable to the Treasurer of the United States and mailed to Mr. James Lieberman, Director, Office of Enforcement, U.S. Nuclear

Regulatory Commission, One White Flint North, 11555 Rockville Pike, Rockville, MD 20852-2738.

V

-3-

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, D.C. 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 addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission Washington, D.C. 20555, with a copy to the Commission's Document Control Desk, Washington, D.C. 20555. Copies also shall be sent to the Assistant General Counsel for Hearings and Enforcement at the same address and to the Regional Administrator, NRC Region IV, 611 Ryan Plaza Drive, Suite 400, Arlington, Texas 76011.

If a hearing is requested, the Commission will issue an Order designating the time and place of the hearing. If the Licensee fails to request a hearing within 30 days of the date of this Order (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 issues to be considered at such hearing shall be:

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

FOR THE NUCLEAR REGULATORY COMMISSION

Acting Director Gray, R. of

Dated at Rockville, Maryland this 3/57 day of July 1996

#### APPENDIX

## EVALUATION AND CONCLUSION

On June 6, 1996, a Notice of Violation and Proposed Imposition of Civil Penalty (Notice) was issued for a violation identified during an NRC inspection and investigation. Industrial Marine Testing Laboratories, Inc. (Industrial Marine or Licensee) responded to the Notice on July 1, 1996. The licensee admitted the violation but requested mitigation on grounds that the imposition of the civil penalty would hurt the company financially. The NRC's evaluation and conclusion regarding the licensee's requests are as follows:

## Summary of Licensee's Request for Mitigation

In its July 1, 1996, "Answer to a Notice of Violation," the Licensee stated that it is a very small business and that although the NRC has already taken that into consideration, the imposition of the proposed civil penalty in the amount of \$1,500 would hurt the company financially. The Licensee did not want to imply that the NRC was being unfair in arriving at the amount, but noted that it was financial duress that helped to create the problem.

## NRC Evaluation of Licensee's Request for Mitigation

The base civil penalty for the uncontested Severity Level III violation is \$5,000. However, considering the circumstances, including the fact that Industrial Marine is a small business, the NRC exercised discretion and reduced the civil penalty to \$1,500. The reduced civil penalty is roughly equivalent to the fees the Licensee would have paid to remain in compliance.

In cases such as this, an NRC enforcement action is used as a deterrent to emphasize the importance of compliance with requirements. In this regard, further reduction of the penalty would do little to emphasize the importance of compliance with the involved requirements.

However, NRC's Enforcement Policy also provides, "... it is not the NRC's intention that the economic impact of a civil penalty be so severe that it puts a licensee out of business (orders, rather than civil penalties, are used when the intent is to suspend or terminate licensed activities) or adversely affects a licensee's ability to safely conduct licensed activities."

Therefore, to balance these considerations and to be responsive to the potential financial hardship to the licensee, rather than mitigating the civil penalty the licensee should be permitted to pay it in monthly installments.

#### NRC Conclusion

The NRC has concluded that the violation occurred as stated and that Industrial Marine did not provide an adequate basis for further reduction of the civil penalty. Consequently, the proposed civil penalty in the amount of \$1,500 should be imposed. However, to be responsive to the potential for further financial hardship, the NRC should permit Industrial Marine to pay the civil penalty in monthly installments.



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

August 12, 1996

EA 96-288

Middle Monongahela Industrial Development Association, Inc (MIDA) ATTN: Ms. Lue Anne Pawlick Post Office Box 491 Donora Industrial Park Donora, Pennsylvania 15033

SUBJECT: CONFIRMATORY ORDER

Dear Ms. Pawlick:

Attached is a Confirmatory Order which requires that you adhere to several commitments that you made to Mr. Charles W. Hehl and other members of the NRC Region I staff during a telephone conversation on Friday, August 9, 1996 regarding the vacated GRD Steel Corporation (GRD) facility at Mid Mound Center, Route 136, East Monongahela, Pennsylvania. The basis for this action is described in the enclosed Order. The Order requires that you: (1) assure that you maintain control of the NRC-licensed gauges possessed at Mid Mound Center, Route 135, East Monongahela, Pennsylvania and that the gauges will remain locked at all times; (2) request additional patrols from the local police in the area, until such time as the gauges are transferred to an authorized recipient; (3) perform daily walk-throughs of the plant to ensure that the gauges had not been tampered with; (4) in the absence of obtaining a license from the NRC to possess the gauges within 90 days from the date of this Order, transfer the gauges either back to the manufacturer, or to another authorized recipient; and (5) by August 19, 1996 inform the NRC under oath or affirmation regarding the specific actions MIDA will take to comply with conditions 1, 2, and 3 above.

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 this Order shall be subject to criminal prosecution as set forth in that section. Violation of this order also may subject the person to a civil monetary penalty. Failure to comply with the provisions of this Confirmatory Order may result in further enforcement action. Questions concerning this Order should be addressed to Mr. James Lieberman, Director, Office of Enforcement, who may be reached at (301) 415-2741.

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

the public.

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

Sincerely,

ame

James Lieberman, Director Office of Enforcement

Docket No. 99990001 Non-Licensee

Enclosure: As Stated

cc w/encl: Commonwealth of Pennsylvania

P. K. Ghosh, President GRD Steel Corporation P. O. Box 111 Monongahela, PA 15063

## UNITED STATES NUCLEAR REGULATORY COMMISSION

In the Matter of

Middle Monongahela Industrial Development Association, Inc (MIDA) Non-License EA 96-288

CONFIRMATORY ORDER

I

Middle Monongahela Industrial Development Association, Inc. (MIDA) is a non-profit organization that exists in Monongahela County, PA for the purpose of encouraging businesses to locate in that geographical area. One of the business entities that existed in the area was GRD Steel Corporation (GRD), a company engaged in the manufacturing of carbon steel. GRD was located at the Mid Mound Center, Route 136, East Monongahela, Pennsylvania. GRD is a licensee of the NRC, specifically, the holder of NRC License No. 37-30147-01 issued by the Nuclear Regulatory Commission (NRC or Commission) on February 6, 1995 pursuant to 10 CFR Part 30. License No. 37-30147-01 authorizes the possession and use of up to 10 millicuries of Cobalt-60 in sealed sources (with a maximum activity per source of 3.3 millicuries).

II

GRD possessed two gauges each containing approximately 3.3 millicuries of Cobalt-60, a radioactive material, at its Mid Mound Center facility. GRD has ceased operations (the steel mill had been shut down). As a result of its purchase at a sheriff foreclosure sale of property of GRD at the Mid Mound Center, MIDA now: (1) holds the title to both GRD's gauges and GRD's Mid Mound Center facility in East Monongahela; and (2) is in possession of the two gauges each containing Cobalt-60, a highly radioactive byproduct material.

In order to receive or possess byproduct material, an NRC license is required by the Atomic Energy Act of 1954, as amended, and the Commission's regulations in 10 CFR 30.3. MIDA does not have a license to receive or possesses this byproduct material.

- 2 -

It does appear that MIDA has taken some action to maintain security of the gauges because the gauges have been maintained with their shutters locked in the closed position. However, the NRC was recently informed that the building where the gauges are possessed has been subject to at least one break-in. The gauges were not stolen or damaged. Since the break-in, the NRC understands that the perpetrators have been apprehended, that local police patrols are occurring, and daily walk-throughs by a local president of the steel union are being conducted.

## III

These gauges contain radioactive material which, if not properly handled or secured, could cause a member of the public to receive a significant radiation exposure. The NRC must be able to ensure that radioactive byproduct material subject to NRC regulation only be possessed by persons having an NRC license authorizing such possession, and that security of the radioactive material is maintained at all times to ensure that it is not lost or stolen. MIDA has not met these conditions. Therefore, on August 9, 1996, Mr. Charles W. Hehl and other members of the NRC Region I office contacted Ms. Lue Anne Pawlick of MIDA during which MIDA committed to implement the terms in Section IV of this Order and agreed to waive their rights to a hearing.

I find that MIDA's commitments described in Section IV are acceptable and necessary and conclude that with these commitments the public health and safety are reasonably assured. In view of the foregoing, I have determined that the public health and safety require that these commitments be confirmed by this Order. MIDA has agreed to this action. Pursuant to 10 CFR 2.202, I have also determined, based on the Licensee's consent and on the significance of these matters, described above, that the public health and safety require that this Order be immediately effective.

- 3 -

IV

Accordingly, pursuant to Sections 81, 161b, 161i, 161o, 182 and 186 of the Atomic Energy Act of 1954, as amended, and the Commission's regulations in 10 CFR 2.202 and 10 CFR Part 30, IT IS HEREBY ORDERED, EFFECTIVE IMMEDIATELY, THAT MIDA:

- assures that it will maintain control of the NRC-licensed gauges
  possessed at Mid Mound Center, Route 136, East Monongahela, Pennsylvania
  and that the facility and gauges will remain locked at all times;
- requests additional patrols from the local police in the area, until such time as the gauges are transferred to an authorized recipient;
- performs daily walk-throughs of the facility to ensure that the gauges have not been tampered with;

4. shall either obtain a license from the NRC to possess the material or transfer the material to a specific NRC or Agreement State licensee authorized to possess such material; in the absence of obtaining a license from the NRC to possess the gauges within 90 days from the date of this Order, transfers the gauges either back to the manufacturer, or to another authorized recipient

- 4 -

 by August 19, 1996 inform the NRC under oath or affirmation regarding the specific actions MIDA will take to comply with conditions 1, 2, and 3 above.

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

V

MIDA has agreed to waive its right to a hearing. Any person adversely affected by this Confirmatory Order, other than MIDA, may request a hearing within 20 days of its issuance. Any request for a hearing shall be submitted to the Secretary, U.S. Nuclear Regulatory Commission, ATTN: Chief, Docketing and Service Section, Washington, D.C. 20555. Copies also shall be sent to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, to the Assistant General Counsel for Hearings and Enforcement at the same address, to the Regional Administrator, NRC Region 1, 475 Allendale Road, King of Prussia, Pennsylvania, and to the Licensee. If

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

- 5 -

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

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

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

FOR THE NUCLEAR REGULATORY COMMISSION

Amer Lieben

James Lieberman, Director

Dated at Rockville, Maryland this 12thday of August 1996



#### UNITED STATES NUCLEAR REGULATORY COMMISSION WASHINGTON, D.C. 20666-0001

July 16, 1996

EA 94-029

NDT Services, Inc. ATTN: Mr. Thomas Crossland, Owner Rio Cañas Industrial Park, Suite 370 Road No. 175, Km. 0.02, Corner Road No. 1 Caguas, Puerto Rico 00726-4952

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTIES -\$15,000 (NRC Inspection Report No. 52-19438-01/93-02 and Investigation Report No. 2-93-072)

Dear Mr. Crossland:

This letter refers to a special inspection conducted by this office on December 16-17, 1993, and an investigation conducted by the Nuclear Regulatory Commission (NRC) Office of Investigations (OI) completed on December 21, 1995. During these reviews, the NRC examined the facts and circumstances surrounding a radiography event involving NDT Services, Inc. (NDTS) which occurred at the Sun Oil Company refinery in Yabucoa, Puerto Rico on September 4, 1993. NDTS was informed of the inspection findings during an exit meeting conducted on December 17, 1993, followed by the inspection report, dated February 4, 1994, and by letter, dated February 16, 1996, which forwarded the synopsis of the OI investigation report for this case. The letter also provided NDTS an opportunity to attend a predecisional enforcement conference to discuss the apparent violations, their cause, and the corrective actions to preclude recurrence. A closed, transcribed conference was conducted with NDTS on March 4, 1996, at the Region II office in Atlanta, Georgia. The report summarizing the conference was sent to you by letter dated April 1, 1996.

Based on the information developed during the inspection and the investigation as well as the information you provided during the conference, the NRC has determined that violations of NRC requirements occurred for the reasons described below. These violations are cited in the enclosed Notice of Violation and Proposed Imposition of Civil Penalties (Notice) and the circumstances surrounding them are described in the subject inspection and investigation reports as well as our February 16, 1996 correspondence. Violations A and B in Part I of the Notice directly resulted from the misconduct of your former President and former Radiation Safety Officer (RSO), who deliberately disregarded regulatory requirements, falsified documents required by the NDTS license, and provided inaccurate and incomplete information to the NRC in violation of 10 CFR 30.10, "Deliberate Misconduct."

Violation A in Part I of the Notice involves the failure of NDTS, through the deliberate actions of the former RSO and the former President, to utilize personnel who were trained and qualified as radiographers in accordance with the requirements of 10 CFR 34.31(a). The radiographers, whose services were obtained through a third-party contractor, were not qualified to perform

radiography under the NDTS license in that they had not been trained on NDTS radiography equipment or emergency and operating procedures prior to performing radiographic operations at the Sun Oil Company refinery on September 4, 1993. This contributed to the improper connection of the guide tube of the radiographic device such that the source could not be retracted into the shielded position following radiography, causing an evacuation of the Sun Oil refinery for several hours.

- 2 -

At the predecisional enforcement conference, NDTS expressed its position that the company was not responsible for the training of the contract radiographers because the owner of NDTS had intended to fully contract out the subject radiography work under National Inspection Consultants' (NIC's) license and therefore NDTS was not responsible for the training of these radiographers. The owner stated that he had expected the contractor to provide two fully qualified radiographers who would perform radiography activities under the contractor's license and contractor's RSO. In addition, NDTS provided copies of invoices indicating the amount of the payment made to the contractor contending that a full overhead was paid consistent with an independent contractor and the work to be done under NIC's license. The owner also stated that the former RSO was working at another site and the former President was not sufficiently knowledgeable to be aware of the training requirements under the work agreement.

While it may have been the owner's intent to fully contract out the work under NIC's license, based on all the evidence available in this case, the NKC concludes the work performed on September 4, 1993, was performed using NDTS licensed material under the provisions of the NDTS license. This conclusion is based on: (1) the former RSO's admission that he did not provide the training and did not administer a proficiency test to the two contract radiographers although he knew that training and passing this test was required prior to performing radiography under the NDTS license; (2) information obtained from NIC which indicate that the rate paid by NDTS for NIC's was neither reflective of the rate of an independent contractor nor consistent with the work to be done under NIC's license; (3) information obtained during the May 1996 interviews with the former NDTS RSO and Plesident and a representative of NIC that all three believed that the work performed at the Sun Oil Refinery was conducted under the NDTS license; (4) the fact that NDTS licensed material was utilized to perform the radiography on September 4. 1993, without any documented transfer of the material to the contractor; (5) the fact that no written contract or other documentation was provided outlining the scope and conditions of work; (6) the fact that NIC did not file for reciprocity to work in areas under NRC jurisdiction; (7) the incident reports submitted by NDTS indicating its responsibility for the September 4. 1993, activities; and (8) the NDTS owner's admission that he was not directly involved in the contract negotiation, the use of the material, or the conditions of the use during the September 4, 1993 timeframe.

Violation P in Part I of the Notice involves the failure of your former RSO to provide complete and accurate information to the NRC during the course of the inspection. Specifically, on December 16, 1993, the former RSO provided an NRC inspector with written certification of the qualifications of the two

- 3 -

contract radiographers, dated September 3, 1993, which was falsified following the September 4, 1993 event. In addition, during the inspection, the former RSO orally represented to an NRC inspector that he demonstrated the safe use of the NDTS radiography equipment prior to allowing two contract radiographers to operate the equipment on September 3, 1993, when he knew that he had not conducted such a demonstration. Subsequently, the former NDTS RSO admitted to NRC investigators that he falsely signed the letters designating the two contractor radiographers to perform the duties of radiographer Level II under the NDTS license and that he knew that such falsification constituted a violation of NRC regulations. Although not cited in the enclosed Notice, the NRC obtained information which indicated that subsequent to the September 4, 1993 event, the former NDTS President attempted to generate a false training record for the radiographers when he requested them to sign documents indicating that they had been trained, when in fact, they had not been.

Although no overexposure resulted from the source disconnect event, Violations A and B in Part I of the Notice are of very significant regulatory concern because of the potential adverse consequences of unqualified personnel handling radioactive sources that emit significant amounts of radiation. It was only through the common-sense actions and general knowledge of the radiographers involved in the event, who took the necessary actions to initially secure the source and surrounding area until the former RSO arrived and successfully retracted the source, that prevented this event from becoming more serious. In addition, the deliberate disregard for NRC requirements and the submittal of false information to the NRC, particularly by your former RSO, is unacceptable and a very serious matter. NRC regulatory programs rely substantially on licensees and their employees to conduct activities in accordance with regulations and to communicate fully and truthfully with the NRC.

As a result of the aforementioned activities, the former NDTS President and former NDTS RSO were found to have violated 10 CFR 30.10 and Orders are being issued to them prohibiting them from engaging in any licensed activities for a period of five years. We recognize that these two individuals are no longer employed by your company. Nevertheless, you, as an NRC licensee, are responsible for the acts of your employees, especially your management representatives. Therefore, in accordance with the "General Statement of Policy and Procedures for NRC Enforcement Actions" (Enforcement Policy), NUREG-1600, Viclations A and B in Part I of the Notice have been categorized in the aggregate as a Severity Level I problem.

In accordance with the Enforcement Policy, a base civil penalty in the amount of \$10,000 is considered for Violations I.A and I.B, a Severity Level I problem. 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. In this case, the NRC has concluded that it is not appropriate to give credit for *Identification* because the violations were identified by the NRC as a result of our inspection and investigative efforts. In considering *Corrective Action*, the NRC recognizes that: (1) the former RSO was relieved of his responsibilities and a new RSO was designated; (2) the former President and former RSO involved in this case

no longer work for NDTS; (3) following the September 4, 1993 incident you retained an outside firm to audit your radiation safety program, identify problems, and develop corrective actions; and (4) subsequent rcutine inspections of your program conducted on October 1994, June 1995, and May 1996 have noted significant improvement in the area of regulatory compliance with no similar violations identified. In view of these facts, the NRC concluded that credit is warranted for *Corrective Action*; and therefore, the base civil penalty of \$10,000 is appropriate.

Violation C in Part I of the Notice involves the failure of the two radiographers to wear alarming ratemeters during radiographic and source retrieval activities on September 4, 1993, in accordance with 10 CFR 34.33(a). Although alarm ratemeters were available from NDTS at the Sun Oil Company work site, the former NDTS RSO did not ensure that this equipment was provided to or used by the radiographers on September 4, 1993. The root causes of this violation were the lack of RSO oversight of the activities of the radiographers and the failure to train the radiographers in this particular requirement of the NDTS license. A contributing factor was the failure of the contract radiographers to recognize the need for such equipment because, in September 1993, alarming ratemeters were not required by the State of Florida, the licensing and regulatory entity with jurisdiction over the radiographers' principal employer. The NRC places a high emphasis on the use of alarm ratemeters because they provide a real-time indication of radiation levels and aid in the prompt recognition of unanticipated, radiological incidents, such as the source disconnect event on September 4, 1993. Therefore, in accordance with the Enforcement Policy, Violation C in Part I of the Notice has been categorized as a Severity Level III violation.

In accordance with the Enforcement Policy, a base civil penalty of \$5,000 is considered for a Severity Level III violation. Because your facility had not been the subject of escalated enforcement action within the last two inspections conducted prior to the December 16-17, 1993, inspection, the NRC considered whether credit was warranted for the factor of Corrective Action in accordance with the civil penalty assessment process described previously. Based on the corrective actions outlined above for Violations A and B in Part I of the Notice, the NRC determined that credit for Corrective Action was warranted, and a civil penalty would therefore, not normally be proposed. However, in considering the circumstances surrounding this particular violation, its importance to safety, previously expressed NRC concerns related to NDTS' failure to properly use alarm ratemeters', and the fact that prior corrective actions were ineffective to prevent this violation, the NRC is exercising discretion in accordance with Section VI.B.2.d of the Enforcement Policy and is assessing a base civil penalty of \$5,000 for this Severity Level III violation.

In a September 21, 1992 Notice of Violation, NDTS was cited for failure to wear alarming ratemeters while conducting radiography. In the letter accompanying this Notice of Violation, the NRC stated, in part, that "Future violations of this type will be considered at Severity Level III and possible civil penalty."

- 5 -

Violation A in Part II of the Notice involves your failure to perform adequate surveys to evaluate the extent of the radiological hazard present during source disconnect and retrieval activities. Specifically, on September 4, 1993, your former RSO conducted source retrieval activities without properly assessing the hazard and planning his actions prior to entry into the radiation field, even though his survey meter was reading off-scale and his alarming ratemeter was alarming at a pre-set level of 500 millirem per hour. The lack of planning and disregard for the survey instrumentation indications had a substantial potential for resulting in an overexposure. In addition, following the event, you failed to adequately evaluate and assign the extremity and whole body exposure of the former RSO resulting from the source retrieval activities. A calculated exposure, which was within NRC limits, was subsequently determined by the NRC through event recreation and evaluation of the thermoluminescent dosimeter results you obtained. Therefore, in accordance with the Enforcement Policy, Violation A in Part II of the Notice has been categorized as a Severity Level III violation.

For Violation A in Part II of the Notice, the NRC considered whether credit was warranted for the factor of *Corrective Action* in determining the appropriate civil penalty for this violation. Based on the corrective actions previously delineated, NRC determined that credit was warranted; and, therefore, no civil penalty will be assessed for this violation. However, you should be aware that any similar violations in the future could result in further enforcement action and civil penalties.

In summary, to emphasize the importance of compliance with NRC requirements and the necessity for complete and accurate information, and in recognition of your corrective actions, I have been authorized, after consultation with the Director, Office of Enforcement, the Deputy Executive Director for Nuclear Materials Safety, Safeguards and Operations Support, and the Commission, to issue the enclosed Notice in the total amount of \$15,000 for the violations discussed above.

The Severity Level IV violations described in Part II of the Notice involved the failure of NDTS procedures to include the elements required by 10 CFR 34.32 for responding to a source disconnect event; the failure to determine prior occupational exposure of the two radiographers before allowing them to conduct radiography; and the transport of radiography source packages during the period 1989 through December 1993 without an NRC approved quality assurance plan. Regarding the last violation, we noted that subsequent to the December 16-17, 1993 inspection you submitted and obtained approval of your quality assurance plan. The root cause of these violations was the lack of management oversight by your former RSO and former President.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. In your response, you should document the specific actions taken and any additional actions you plan to prevent recurrence. Your response should also include the steps you have taken to strengthen the RSO's oversight of your license. After

reviewing your response to this Notice, including your proposed corrective actions and the results of future inspections, the NRC will determine whether further NRC enforcement action is necessary to ensure compliance with NRC regulatory requirements.

- 6 -

In accordance with 10 CFR 2.790 of the NRC \* "Rules of Practice," a copy of this letter, its enclosures, 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 sanguards information so that it can be placed in the PDR without redaction.

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

Sincerely,

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

Docket No. 030-17711 License No. 52-19438-01

Enclosures: 1. Notice of Violation and Proposed Imposition of Civil Penalties 2. Order to former NDTS RSO

3. Order to former NDTS President

cc w/encl: Mr. David Vaughn, Radiation Safety Officer NDT Services, Inc. Rio Cañas Industrial Park, Suite 370 Road No. 175, Km. 0.02, Corner Road No. 1 Caguas, PR 00726-4952

Mr. John Shea, President Puerto Rico Sun Oil Company P. O. box 186 Yabucoa, PR 00767

Commonwealth of Puerto Rico

NUREG-0940, PART III

### NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTIES

NDT Services, Inc. Caguas, Puerto Rico Docket No. 030-17711 License No. 52-19438-01 EA 94-029

During an NRC inspection conducted on December 16-17, 1993, and an Office of Investigations investigation completed on December 21, 1995, violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," NUREG-1600, the Nuclear Regulatory Commission proposes to impose civil penalties pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (Act), 42 U.S.C. 2282, and 10 CFR 2.205. The particular violations and associated civil penalties are set forth below:

- I. Violations Assessed a Civil Penalty
  - A. 10 CFR 34.31(a) requires that the licensee not permit any individual to act as a radiographer until such individual: has received copies of and instruction in the NRC license under which the radiographer will perform radiography, and the licensee's operating and emergency procedures; has demonstrated competence to use the licensee's radiographic exposure devices, sealed sources, related handling tools, and survey instruments; and has demonstrated understanding of the instructions in this paragraph by successful completion of a written test and field examination on the subjects covered.

Contrary to the above, on September 4, 1993, NDTS permitted two individuals to act as radiographers without giving these individuals any instruction in the NDTS license or the NDTS operating and emergency procedures, and did not have these individuals demonstrate competence on the use of NDTS radiographic exposure devices, sealed sources, related handling tools, and survey instruments. Correspondingly, no written tests or field examinations were completed. (01011)

B. 10 CFR 30.9(a) requires that information provided to, or required to be maintained by, the NRC be complete and accurate in all material respects.

Condition 12 of the NDTS license requires that records of designated radiographers and their qualifications be maintained.

Contrary to the above, the licensee maintained required information and submitted information to the Commission that was not complete and accurate in all material respects. These inaccuracies were material to the NRC's review of the training requirements for two individuals performing radiographic operations on September 4, 1993. Specifically, on December 16, 1993:

#### Notice of Violation

- 1. the former NDTS Radiation Safety Officer provided false documentation to an NRC inspector which indicated that the qualifications of two contract radiographers were based on records received from the radiographers' principal employer and on the experience demonstrated by the radiographers to the former Radiation Safety Officer. In fact, the former RSO knew that there were no contemporaneous supporting records from the radiographers' principal employer and the radiographers did not demonstrate the level of their experience to the former Radiation Safety Officer; and
- the former NDTS Radiation Safety Officer orally represented to an NRC inspector that he demonstrated the safe use of the NDTS radiography equipment prior to allowing two new radiographers to operate this equipment on September 3, 1993, when in fact he knew that he had not conducted such a demonstration. (01021)

This is a Severity Level I Problem (Supplements VI and VII) Civil Penalty - \$10,000

C. 10 CFR 34.33(a) requires, in part, that the licensee not permit any individual to act as a radiographer unless, at all times during radiographic operations, the individual wears an alarming ratemeter.

Contrary to the above, on September 4, 1993, two individuals acting as contract radiographers for the licensee failed to wear alarming ratemeters during radiographic operations including source exposure (and disconnect) activities. (02013)

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

# II. Violations Not Assessed a Civil Penalty

A. 10 CFR 20.201(b) [effective until January 1, 1994] required the licensee to 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 and the potential radiological hazards that could be present.

Contrary to the above, the licensee failed to perform adequate surveys to evaluate the extent of radiation levels and the potential radiological hazards present as follows:

 On September 4, 1993, during an event involving a disconnect of an Iridium-192 source, a former NDTS Radiation Safety Officer, knowing that his survey meter was reading offscale and his ratemeter was alarming at 500 millirem per hour

NUREG-0940, PART III

during his first approach to the event area, failed to adequately evaluate the radiation hazards before his whole body and extremities were exposed.

2. From September 4 until December 17, 1993, NDTS had not evaluated the unmonitored extremity exposure of the former NDTS Radiation Safety Officer described above in order to assign a dose, and the assignment of his whole body dose was not adjusted based on the shielding of his film badge by his knee joint which occurred when he performed the source reconnect in a crouched position. (03013)

This is Severity Level III Violation (Supplement IV)

B. 10 CFR 34.32 requires, in part, that a licensee maintain a copy of current operating and emergency procedures, including instructions in the handling and use of licensed sealed sources and radiographic exposure devices, to prevent a likelihood of persons exceeding 10 CFR Part 20 limits, methods and occasions for conducting surveys, instructions for the use of monitoring equipment, and procedures for minimizing exposure in the event of an accident.

Contrary to the above, from September 4 until December 17, 1993, NDTS emergency procedures did not include the methods and occasions for conducting surveys, instructions for the use of monitoring equipment, and procedures for minimizing exposure in the event of an incident. (04014)

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

C. 10 CFR 20.102(a) [effective until January 1, 1994] required that a licensee determine the prior occupational exposure of individuals that were likely to have received, or would receive, in excess of 25 percent of one or more of the quarterly dose limits specified in 10 CFR 20.101(a).

Contrary to the above, NDTS did not determine the prior occupational exposure of two contract radiographers to ensure that they would not exceed the limits in 10 CFR 20.101(a) prior to allowing them to perform radiography on September 4, 1993. (05014)

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

D. 10 CFR 71.12(b) requires that NDTS have an approved quality assurance program in order to transport licensed material under the provisions of 10 CFR 71.12(a). Contrary to the above, NDTS transported radiography source packages during the period 1989 to December 17, 1993, without an approved quality assurance program. Specifically, the licensee's quality assurance program expired in 1989. (06014)

This is a repeat Severity Level IV Violation (Supplement VI).

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

In requesting mitigation of the proposed penalties, the factors addressed in Section 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

Notice of Violation

- 5 -

incorporate parts of the 10 CFR 2.201 reply by specific reference (e.g., citing page and paragraph numbers) to avoid repetition. The attention of the Licensee is directed to the other provisions of 10 CFR 2.205, regarding the procedure for imposing a civil penalty.

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

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

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.

Dated at Rockville, Maryland this 16th day of July 1996

NUREG-0940, PART III



UNITED STATES NUCLEAR REGULATORY COMMISSION REGION II 101 MARIETTA STREET, N.W., SUITE 2900 ATLANTA, GEORGIA 33323-0199

August 21, 1996

EA 96-213

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

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY -\$12,500 (NRC Inspection Report No. 70-143/96-05)

This letter refers to the special inspection conducted by the Nuclear Regulatory Commission's (NRC) Augmented Inspection Team (AIT) during the beriod April 3 through 11, 1996, at your Erain. Tennessee facility. The inspection reviewed the facts and circumstances surrounding a fire in the incinerator and 300 Complex ventilation system on April 2, 1996. The results of the AIT inspection were formally transmitted to you by letter dated May 21. 1996: and by letter dated June 24, 1996, you were informed of the apparent violations resulting from the inspection. A closed, predecisional enforcement conference was conducted at your facility in Erwin. Tennessee, on July 12, 1996, to discuss the apparent violations, the root causes, and your corrective actions to preclude recurrence. A letter summarizing the conference was sent to you on July 29, 1996.

Based on the information developed during the inspection and the information you 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 (Notice) and the circumstances surrounding them are described in detail in the subject inspection report.

Violation A in the enclosed Notice involved your failure to implement and maintain a configuration control and management system for the Building 302 incinerator which was used to handle uranium. Violations B.1 and B.2 involved your failure to institute adequate procedures for the safe operation of the incinerator and multiple examples in which your staff failed to follow procedures. Of particular concern was your failure to verify the operability of the quench tank spray nozzles prior to operation of the incinerator because such verification contributes to assuring the effectiveness of the incinerator exhaust cooling. Tolation C in the enclosed Notice involved your failure to identify the incinerator as safety-related which is juiled in failure to implement a preventative maintenance and surveillance program for components essential to safety. Finally, Violation D involved your failure to implement an adequate training program for personnel operating the incinerator equipment. The root cause of the violations appears to be a lack of attention in ensuring that safety systems and controls remain in place and that changes which might affect them are controlled and reviewed. Collectively, the violations represent a significant regulatory concern because they are indicative of a significant lack of attention toward licensed responsibilities. Specifically, multiple processes and barriers to preventing unsafe operation of the Building 302 incinerator failed including equipment. procedures, and personnel which culminated in the April 2. 1996, fire. A further example of your lack of attention is the fact that corrective actions in response to a similar fire in 1983 were not effective in preventing the April 1996 fire and were not fully implemented. Therefore, the violations in the Notice are 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. a base civil penalty in the amount of \$12,500 is considered for a Severity Level III problem. Because your facility has not been the subject of escalated enforcement actions within the last two years, 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 immediate actions included a prompt and effective response to mitigate the fire in the incinerator and 300 Complex ventilation system and establishment of an investigation team to review the event. At the conference, you stated that additional corrective actions implemented and/or planned included: (1) review of other operational activities (decommissioning and waste water treatment) and associated procedures to determine whether similar deficiencies existed: (2) issuance of a notice to all employees regarding expectations for procedural adherence and conduct of follow-up meetings with each employee: (3) enhancements to the training program: (4) performance of a hazards review and incorporation of lessons learned into the readiness review program for the near-term activities in the 200 Complex: and (5) development of a Performance Management Program intended to provide an audit and quality oversight function for site activities including configuration control and procedural adherence. In addition, you stated that a hazards analysis and implementation of corrective actions have not yet been completed for the incinerator itself: however, such activities would be performed prior to any restart of the equipment. Although many of your corrective actions are not implemented because your operations are inactive, your investigation team and management did identify the root causes of the violations. In view of these actions, the NRC concluded that credit is warranted for the factor of Corrective Action.

The application of the Enforcement Policy as described above would normally result in no civil penalty. However, the violations represent particularly poor performance in several aspects of your safety program. Not only did the violations contribute to the April 2, 1996 fire with the potential release of uranium outside controlled areas, but the consequences of the fire, both potential and actual, would have been mitigated had you effectively implemented corrective actions following the 1983 fire.

The NRC recognizes that work with uranium at the site has been limited since 1993 and the off site impact of the uranium released as a result of the fire was minimal: however, adequate controls for the licensed activities you were conducting should have been implemented and in effect, and they were not. Therefore, the NRC is exercising discretion by assessing a base civil penalty

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in accordance with Sections VI.B.2.d and VII.A.1 of the Enforcement Policy to reflect NRC's concern regarding the violations. In reaching the decision to exercise discretion, the NRC did consider your comments made during the predecisional enforcement conference regarding the civil penalty assessment process and mitigation of enforcement sanctions in this case. However, to emphasize the importance of effective management and control of equipment and systems important to safety. I have been authorized, after consultation with the Director. Office of Enforcement, to issue the enclosed Notice in the base amount of \$12,500 for the Severity Level III problem.

- 3 -

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

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

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

Sincerely ula For Stewart D. Ebnetep Regional Administrator

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

Enclosure: Notice of Violation and Proposed Imposition of Civil Penalty

cc w/encl: (See Page 4)

# - 4 -

cc w/encl: Andrew M. Maxin Vice President Safety and Regulatory Management Nuclear Fuel Services. Inc. P. O. Box 337. MS 123 Erwin. TN 37650

Michael H. Mobley. Director Division of Radiological Health 3rd Floor. L and C Annex 401 Church Street Nashville. TN 37243-1532

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# NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY

Nuclear Fuel Services. Inc. Erwin. Tennessee Docket No. 70-143 License No. SNM-124 EA 96-213

As a result of an NRC inspection conducted on April 3 through 11. 1996. violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedures for NRC Enforcement Actions." NUREG-1600. the Nuclear Regulatory Commission proposes to impose a civil penalty pursuant to Section 234 of the Atomic Energy Act of 1954. as amended (Act). 42 U.S.C. 2282. and 10 CFR 2.205. The particular violations and associated civil penalty are set forth below:

A. License Condition 10 of Special Nuclear Materials (SNM) License No. 124 requires the licensee to comply with all listed conditions in the following three sections: Safety Conditions. Safeguards Conditions, and Transportation Conditions.

Safety Condition S-30 requires the licensee to develop, implement, and maintain a configuration control system including a proces: ind instrument document description system on or before December 31, 1993.

Contrary to the above. as of April 2. 1996, the licensee failed to implement and maintain an adequate configuration control and management system for the Building 302 incinerator which was used to incinerate licensed materials. Specifically, as-built descriptions and drawings, including piping and instrument drawings (P&IDs) of the incinerator system were not maintained to ensure control of the configuration of the system, as evidenced by the following:

- The P&ID 302-F0011-D. "302 Incinerator P&ID." dated February 2. 1994. did not reflect the actual. installed features of the Building 302 incinerator system in that there was instrumentation installed in the system which was not shown on the diagram. including certain temperature elements for measuring temperatures in the process streams and displayed on specific instruments; and
- The licensee did not maintain any drawings, wiring diagrams or logic diagrams for the instrumentation or control circuits, including alarms for the Building 302 incinerator system. (01013)
- B. License Condition 10 of Materials License No. SNM-124 requires the Licensee to comply with all listed conditions in the following three sections: Safety Conditions. Safeguards Conditions, and Transportation Conditions.

Safety Condition S-12 requires, in part, that the licensee, on or before September 6, 1993, establish and implement written procedures for the control of equipment to maintain personnel and nuclear criticality safety and to avoid unauthorized operation of equipment. Notice of Violation and Proposed - 2 -Imposition of Civil Penalty

Safety Condition S-1 requires the licensee to comply with the statements, representations, and conditions in Chapters 1 through 8 of the application dated August 15, 1989, and supplements thereto.

Chapter 2. Section 2.7 of the application, requires that SNM operations and safety function activities be conducted in accordance with written procedures. Operating and safety procedures are defined in Sections 1.7.4 and 1.7.5, respectively.

Standard Operating Procedure (SOP) 266. Section L. Incinerator. Revision 11. dated June 5. 1992. which is written and approved as set forth in Section 1.7.4. specifies the actions to be performed during loading. operation. and unloading of the Building 302 incinerator and the operation of the incinerator scrubber system.

- Contrary to the above, from September 6, 1993, until April 2, 1996, SOP 266, a written procedure for the control of equipment, was inadequate to maintain personnel safety or avoid unauthorized operation of equipment, as evidenced by the following:
  - a. SOP 266 required inspection of the pre-quench tank spray nozzles prior to each run. However, the procedure did not provide specific instruction to assure the spray nozzles functioned as designed or as authorized for safety.
  - b. SOP 166 required inspection of the pre-quench tank spray nozzles prior to each run only after instructing the operator to start the scrubber pump and maintain the scrubber line pressure. This would result in the operator disassembling part of the system for the inspection while it was under pressure which would be dangerous for the operator. Therefore, the procedure was not adequate to maintain personnel safety.
  - c. Except for the scrubber system startup. SOP 266 did not contain a specific set of instructions or check-lists to tell the operator how system valves should be aligned to start-up. run or shutdown the systems: and, therefore, was not adequate to avoid unauthorized operation of equipment or maintain safety as designed.
  - d. Section L.8.3 of SOP 266 specified temperature set points for the Underfire Air Controller of 1700 degrees Fahrenheit (°F) and 1600°F for the Afterfire Burner Fuel Controller. However, Section L.7.2 of SOP 266 stated that the Underfire Air dampers closed at temperatures above 1600°, and Section L.9.4 stated that the Afterfire Burner was designed to throttle back at temperatures above 1400°F; thus providing conflicting instructions to the operator regarding instrument set points, which would not avoid unauthorized operation. (01023)

Notice of Violation and Proposed - 3 -Imposition of Civil Penalty

- Contrary to condition S-1 and Chapter 2 of the license application, on April 2, 1996, the licensee failed to follow safety procedures written for SNM operations, as evidenced by the following:
  - a. Section L.1.1 of SOP 266 required that the incinerator be continually manned while it was in operation (during the burning of material). but the operator assigned to perform manning activities was assigned other tasks one of which required him to go to the other side of the 300 Complex to sample the scrubber:
  - b. Sections L.2.3 and L.2.4 of SOP 266 required that certain valves be opened and closed to place the scrubber water filters on line, but, the incinerator system was started with the filters by-passed:
  - c. Section L.2.10 of SOP 266 required the pre-quench spray nozzles to be inspected, but the inspection was not performed;
  - d. Section L.2.11 of SOP 266 required three independent tests be performed to verify that there was flow of the scrubber solution to the upper two pre-quench nozzles, to the venturi nozzles, and the flow of city water to the lower pre-quench nozzle, but the independent tests were not performed:
  - e. Section L.7.1.B of SOP 266 required the incinerator water sprays to be checked by activating the "high temperature" and "water spray" controllers to provide a full bed water spray, but the check was not performed:
  - f. Section L.8.15 of SOP 266 required the Afterfire Burner temperature to reach 1400°F before ignition of the Overfire Burner, but the operator started the Overfire Burner when the Afterfire Burner temperature was 500°F. (01033)
- C. Safety Condition S-12 of Material License SNM-124 requires, in part, that on or before September 6, 1993, the licensee establish and implement written procedures for the following: (1) maintenance of safety-related equipment expected to require recurring maintenance: (2) post-maintenance testing and inspection of equipment to verify and document its functional acceptability: (3) calibration and testing of safety-related equipment and instrumentation, such as interlocks, alarm devices, and in-line monitors; and (4) preventative maintenance of equipment and instrumentation.

Procedure NFS-HS-GH-43. Safety-Related Equipment Control Program. Revision 1. dated December 19. 1994. defines safety-related equipment. establishes a system for identification of safety-related equipment. establishes requirements for maintenance (including preventive Notice of Violation and Proposed - 4 -Imposition of Civil Penalty

maintenance). calibration. and functional verification of the performance of safety-related equipment. and training of personnel who perform maintenance on safety-related equipment. Safety-related equipment is defined as "... that equipment whose primary purpose is to protect personnel from injury during plant operations. This equipment may be used as a barrier or to provide an indication of when a process is approaching a potentially hazardous condition."

Contrary to the above, as of April 2, 1996, the licensee failed to adequately establish and implement written procedures for the items in Safety Condition S-12 for the Building 302 incinerator and related components which were safety related. Specifically, the licensee's maintenance and surveillance program did not include components of the incinerator system and related equipment that met the definition in Procedure NFS- HS-GH-43, as evidenced by the following:

- Safety-related components of the incinerator system, such as thermocouples, temperature and pressure indicators, and high temperature alarms, all of which were designed to protect personnel from injury and to provide an indication of when a process was approaching a potentially hazardous condition, were not included in the maintenance and surveillance program;
- The licensee did not perform preventative maintenance on key components of the incinerator system such as the spray nozzles. system vacuum damper valve. alarms. scrubber system filters. or solenoid valves:
- 3. There was no implemented preventative maintenance program to functionally verify the performance of the incinerator ductwork in that inspections were not performed to verify that the ductwork was not damaged or that there was no material buildup inside the ducting; and
- 4. Adequate calibration and testing of safety-related equipment and instrumentation was not performed in that the calibration involved only the sensor (thermocouple) and the read-out (meter) and did not involve the entire instrument loop. As a result, some of the instrumentation was not working as designed on April 2, 1996. (01043)
- D. Safety Condition S-1 of Materials License No. SNM-124 requires the licensee to comply with the statements. representations. and conditions in Chapters 1 through 8 of the application dated August 15, 1989, and supplements thereto.

Chapter 2. Section 2.6 of the application. requires that the licensee's work training program for operating personnel will provide the desired knowledge and/or skill for operating procedures. safety controls specific to a particular work assignment, and refresher training when changes are made.

Notice of Violation and Proposed - 5 - Imposition of Civil Penalty

Contrary to the above, on April 2, 1996. training on incinerator operations was demonstrated to be inadequate in that it did not provide the desired level of knowledge and/or skill to personnel. Specifically, an operator lacked an understanding of which portions of the procedure were requirements and which were recommendations and incorrectly understood that certain operational steps were optional, as evidenced by the following:

- During system startup, the scrubber water filters were routinely placed in the by-pass mode instead of on-line as required by procedure: and
- 2. The pre-quench spray nozzles were not inspected as required, but were assumed to be operating by operator observation that the lights on the panel that indicated the flow switches were sensing flow to the nozzles. (1053)

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

Within the same time as provided for the response required above under 10 CFR 2.201. the Licensee may pay the civil penalty by letter addressed to the Director. Office of Enforcement. U.S. Nuclear Regulatory Commission, with a check, draft, money order, or electronic transfer payable to the Treasurer of the United States in the amount of the civil penalty proposed above, or the cumulative amount of the civil penalties if more than one civil penalty is proposed, or may protest imposition of the civil penalty in whole or in part. by a written answer addressed to the Director. Office of Enforcement, U.S. Nuclear Regulatory Commission Should the Licensee fail to answer within the time specified, an order imposing the civil penalty will be issued. Should the Licensee elect to file an answer in accordance with 10 CFR 2.205 protesting the civil penalty, in whole or in part, such answer should be clearly marked as an "Answer to a Notice of Violation" and may: (1) deny the Notice of Violation and Proposed - 6 - Imposition of Civil Penalty

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.

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 ratter 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 II.

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.

Dated at Atlanta. Georgia this 21st day of August 1996

NUREG-0940, PART III



## UNITED STATES NUCLEAR REGULATORY COMMISSION WASHINGTON, D.G. 2000-0000

September 13, 1996

EA 96-349

Roy Sadovsky, D.V.M. Post Office Box 20243 Floral Park, New York 11002

SUBJECT: ORDER SUSPENDING LICENSE (EFFECTIVE IMMEDIATELY) AND DEMAND FOR INFORMATION (NRC Inspection No. 030-31085/96-001)

Dear Dr. Sadovsky:

The enclosed Order Suspending License (Effective Immediately) and Demand for Information (DFI) are being issued due to your apparent willful use of licensed material at a location not authorized by your license and your failure to comply with numerous additional NRC requirements. The Order, which is effective on the date issued, requires that: (1) all NRC-licensed material in your possession shall be placed in locked storage; (2) you suspend all activities under your license to use, receive, or transfer licensed material; and (3) all records related to licensed activities must be maintained in their original form and must not be removed or altered in any way.

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 this Order shall be subject to criminal prosecution as set forth in that section. Violation of this Order may also subject you to civil monetary penalties.

You are required to provide an answer to the Order and to respond to the DFI, which requires you to provide information to the NRC to determine whether your license should be revoked, or whether the NRC can have confidence that future licensed activities will be carried out in compliance with all requirements. Specifically, the DFI requires that you submit information, in writing and under oath or affirmation, as to: (1) why your license should not be revoked, or in the alternative not renewed; (2) all locations where licensed material has been used since February 1992, and the date thereof; and (3) the identity of all persons who have assisted with treatments or cared for treated horses and an estimate of the radiation exposure received by each such person.

Questions concerning this Order should be addressed to Mr. James Lieberman, Director, Office of Enforcement, who may be reached at (301) 415-2741.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter and the enclosure will be placed in the NRC's Public Document Room (PDR). To the extent possible, your response should not include any personal privacy, and proprietary 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

Roy Sadovsky, D.V.M.

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 bases for your claim of withholding (e.g., explain why the disclosure of the 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).

Sincerely,

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Hugh U. Thompson, Jr Deputy Executive Director For Nuclear Materials Safety, Safeguards and Operations Support

Docket No. 030-31085 License No. 31-28369-01

Enclosure: As Stated

NUREG-0940, PART III

# UNITED STATES NUCLEAR REGULATORY COMMISSION

In the Matter of

ROY SADOVSKY, D.V.M. Floral Park, New York Docket No. 30-31085 License No. 31-28369-01 EA 96-349

ORDER SUSPENDING LICENSE (EFFECTIVE IMMEDIATELY) AND DEMAND FOR INFORMATION

1

Roy Sadovsky, D.V.M., (Licensee) is the holder of Byproduct Nuclear Material License No. 31-28369-01 (License) issued by the Nuclear Regulatory Commission (NRC or Commission) pursuant to 10 CFR Part 30. The License authorizes possession and use of licensed material (i.e., gold-198 seeds) for implantation in horses for the treatment of leg injuries and diseases in accordance with the conditions specified therein. Condition 10 of the License requires that licensed material be used only at the Meadowlands Race Track in East Rutherford, New Jersey, or Showplace Farm and Gaitway Farm in Millstone Township, New Jersey. The License, originally issued on December 22, 1989, was amended on January 10, 1992, and expired on January 31, 1995. The Licensee filed an application for renewal on January 24, 1995.

II

On December 4 and 5, 1991, the NRC conducted an inspection at the Hyatt Hotel in New Brunswick, New Jersey, and at the Gaitway Farm in Millstone Township, New Jersey. During the inspection, the inspector determined that the Licensee had used licensed material at a location not authorized by the License. Specifically, the Licensee had used licensed material consisting of gold-198 seeds at White Birch Farm in Allentown, New Jersey, an unauthorized location.

In response to a Notice of Violation issued on January 23, 1992, the Licensee stated that he had not realized that the License did not allow work at White Birch Farm, and that "full compliance to avoid further violations will commence immediately and [my] procedures will be limited to the 3 sites allowed by [my] license." The letter was signed by Roy Sadovsky, D.V.M.

- 2 -

On August 26, and September 5, 1996, the NRC conducted an inspection at the Licensee's office in Elmont, New York, and at the Gaitway Farm in Millstone Township, New Jersey. During the inspection, the NRC inspector determined that the Licensee had continued to conduct licensed activities at a location not authorized by Condition 10 of the License. Specifically, the inspector determined, through review of records and interview of the Licensee, that gold-198 seeds were used at White Birch Farm in Allentown, New Jersey, a location not listed on the License, on at least five occasions in 1996, five occasions in 1995, and one occasion in 1994. These violations were apparently willful, in that, the Licensee had been put on notice in 1992 that the License limited use of licensed material to only the locations authorized on the License, and was aware that this material was being used at Allentown, New Jersey, a location not authorized on the NRC license.

Although the NRC investigation and inspection into this matter is ongoing, based on information developed to date, it appears that the Licensee violated additional NRC requirements by: (1) failing to secure from unauthorized removal or access licensed materials (approximately 120 millicuries of gold-198 that were stored in the Licensee's unlocked, open vehicle on September 5, 1996), as required by 10 CFR 20.1801 and 20.1802;

(2) transporting licensed material without complying with the applicable requirements of the U.S. Department of Transportation regulations, as required by 10 CFR 71.5, including failure to use a Type A package as required by 49 CFR 173.415, failure to apply the radioactive material yellow II label required by 49 CFR 172.403, and failure to describe the material on the shipping paper as required by 49 CFR 172.200; (3) failing, in at least one instance in March 1996, to provide individual monitoring devices to personnel who assist in the Licensee's use of licensed material and to ensure the use of those devices by such personnel, as required by Condition 15 of the License (incorporating Item 10 of the application dated March 20, 1989); and (4) conducting operations with gold-198 licensed material, so as to cause dose rates in an unrestricted area to exceed 2 millirem in any one hour, as prohibited by 10 CFR 20.1301(a)(2).

- 3 -

#### III

Based on the above, it appears that the Licensee has willfully violated NRC requirements. Moreover, these violations are of significant concern in that they have the potential to impact the public health and safety. In particular, the radiation level from the quantity of gold-198 which the Licensee typically uses is approximately 2.5 rem per hour at 10 centimeters, and, when implanted in horses, the legs of the treated horses produce radiation levels at more than 200 millirem per hour at a distance of 30 centimeters.

NUREG-0940, PART III

Given the high radiation levels emitted by this licensed material, the Licensee's storage of this licensed material in an unsecured vehicle, transport of this material without proper packaging, fail\_re to affix proper labels which would have required a radioactive material yellow level II label, and failure to include shipping papers which accurately described the nature of this licensed material are of serious concern to the NRC. Moreover, given the high radiation levels associated with these sources, the failure to provide and to ensure the use of individual monitoring by a worker raises a question as to whether workers were exposed to radiation levels in excess of NRC requirements.

- 4 -

The NRC must be able to rely on the Licensee to comply with NRC requirements. It is important that licensed material be used in accordance with the applicable requirements. It appears that the Licensee has failed to comply with numerous Commission requirements and has also failed to take the necessary action to correct a violation of NRC requirements as described in a letter from the Licensee received by the NRC on February 7, 1992. While the NRC's investigation and inspection is continuing, given the safety significance of the identified violations and the apparent willful nature of one violation, the Licensee's actions raise serious doubt as to whether the Licensee is able or willing to comply with NRC requirements and whether the public health and safety will be protected.

Consequently, I lack the requisite reasonable assurance that the Licensee's current operations can be conducted under License No. 31-28369-01 in compliance with the Commission's requirements and that the health and safety

of the public will be protected. Therefore, the public health, safety and interest require that License No. 31-28369-01 be suspended pending the completion of the NRC's investigation and inspection, and further order. Furthermore, pursuant to 10 CFR 2.202, I find that the significance of the violations above is such that the public health, safety, and interest require that this Order be immediately effective.

- 5 -

IV

Accordingly, pursuant to sections 81, 161b, 161i, 161o, 182 and 186 of the Atomic Energy Act of 1954, as amended, and the Commission's regulations in 10 CFR 2.202 and 10 CFR Part 30, IT IS HEREBY ORDERED, EFFECTIVE IMMEDIATELY, THAT LICENSE NO. 31-28369-01 IS SUSPENDED AS FOLLOWS:

Pending further investigation, inspection, and Order by the NRC:

- A. All NRC-licensed material in the Licensee's possession shall immediately be placed in locked storage.
- B. The Licensee shall suspend all activities under the License to use, receive, or transfer licensed material. All other requirements of the License remain in effect.
- C. All records related to licensed activities must be maintained in their original form and must not be removed or altered in any way.

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

- 6 -

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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, and include a statement of good cause for the extension. The answer may consent to this Order. Unless the answer consents to this Order, the answer shall, in writing and under oath or affirmation, specifically admit or deny each allegation or charge made in this Order and shall set forth the matters of fact and law on which the Licensee or other person adversely affected relies and the reasons why the 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 Section, Washington, DC 20555. Copies also shall be sent to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission. Washington, DC 20555, to the Assistant General Counsel for Hearings and Enforcement at the same address, to the Regional Administrator. NRC Region I. 475 Allendale Road, King of Prussia, Pennsylvania 19406-1415, 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).

- 7 -

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, or any other person adversely affected by this Order, may, in addition to demanding a hearing, at the same time the answer is filed or sconer, 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 Part IV of this Order 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.

NUREG-0940, PART III

In addition, pursuant to sections 161c, 161o, 182 and 186 of the Atomic Energy Act if 1954, as amended, and the Commission's requirements in 10 CFR 2.204 and 10 CFR 30.32(b), in order for the Commission to determine whether License No. 31-28369-01 should be further modified, suspended, or revoked, or other enforcement action taken to ensure compliance with NRC regulatory requirements, the Licensee is required to submit to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, within 20 days of the date of this Order and Demand For Information, a response in writing and under oath or affirmation:

- 8 -

VI

- A. Explaining why the License should not be revoked, or in the alternative not renewed, in light of the NRC findings described herein;
- B. Describing all locations where licensed material has been used since February 1992, and the date thereof; and
- C. Providing the identity and, if known, addresses and telephone numbers of all persons who have assisted with treatments or cared for treated horses, and whether such persons wore individual personnel dosimetry:
  - If such dosimetry was used, provide the dosimetry records of those persons;

NUREG-0940, PART III

 If no such dosimetry was used, an estimate of the radiation exposure received by each such person during each year since the License was issued.

Copies also shall be sent to the Assistant General Counsel for Hearings and Enforcement at the same address, and to the Regional Administrator, NRC Region 1. 475 Allendale Road, King of Prussia, Pennsylvania 19406.

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

FOR THE NUCLEAR REGULATORY COMMISSION

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

Dated at Rockville, Maryland this 13th day of September 1996 - 9 -

NUREG-0940, PART III



UNITED STATES NUCLEAR REGULATORY COMMISSION REGION I 475 ALLENDALE ROAD KING OF PRUSSIA, PENNSYLVANIA 19405-1415

July 25, 1996

EA 96-104

Mr. Robert Funari, President and CEO Syncor International Corporation 20001 Prairie Street Chatsworth, California 91311

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY -\$2,500 (NRC Inspection 030-33224 (Formerly 030-15134)/96-001)

Dear Mr. Funari:

This letter refers to the NRC inspection conducted on February 26-27. 1996, at your facility in Pittsburgh. Pennsylvania. of activities authorized by NKC License No. 37-18467-01MD (which has now been replaced by License No. 04-26507-01MD). The inspection report was sent to you on April 10, 1996. During the inspection, the inspectors reviewed the circumstances associated with an event that occurred at your facility in August 1995 involving the contamination of one of your workers. Based on the NRC review of this event, a deliberate violation of NRC requirements has been identified. On April 22. 1996, a predecisional enforcement conference was conducted by the NRC Region I office with Mr. Jack Coffey and other members of the Syncor staff, to discuss the apparent violation, its causes, and your corrective actions. A copy of the enforcement conference report was forwarded to you on May 3, 1996.

The violation, which is described in the enclosed Notice of Violation and Proposed Imposition of Civil Penalty, involved the use of radioactive material in a manner not authorized by the license. Specifically, an individual worker's lock and locker at the facility were deliberately contaminated with technetium-99m, which led to contamination of the worker after he returned to the facility following delivery of radiopharmaceuticals to various destinations. The individual had gone to his locker upon returning from the deliveries, and then proceeded to the restricted area. Upon exiting the restricted area, the individual performed a survey and identified that he was contaminated. Surveys also determined that his lock and locker were contaminated and that the delivery vehicle was not contaminated. After the individual reported this finding to his management, you subsequently performed an investigation, but were unable to determine who was responsible for the contamination.

After reviewing all available information about this event, we have concluded that the violation most likely was deliberate because of the amount of contamination that was concentrated on the lock, and the fact that the only other contamination at the facility correlated with the activities of the contaminated individual after his visit to the locker. Moreover, there was a lack of a more credible explanation for the contamination of the lock. Given the deliberate nature of the violation, and the resultant contamination of an individual worker, the violation is of significant concern to the NRC.

# Syncor International Corporation

It is noteworthy that your company was cited in November 1994 for a deliberate violation in which a worker at your Kansas City facility deliberately used licensed material in a manner not authorized by the license. In that case, the individual sprayed byproduct material on two butterflies in the unrestricted area outside of the Kansas City facility. Although you viewed that event as significant and terminated the responsible individual's employment, you did not take any corporate-wide action at the time to inform managers and employees at your other facilities about the event a recurrence at your other facilities. You were in the process of seeking consolidation of your NRC licenses at the time. Especially under those circumstances, NRC would have expected specific corporate-wide action to highlight the unacceptability of deliberate misuse of licensed material.

The staff at all of your facilities must recognize that the licenses issued to Syncor International Corporation entrust responsibility for radiation safety not only to the Radiation Safety Officer (RSO) and licensee management, but also to each individual employee. The NRC expects, in addition to effective oversight of licensed programs by Syncor management and radiation safety staff, that each employee fully understands and implements the conditions of the license. Incumbent upon each NRC licensee and each licensee employee is the responsibility to protect the public health and safety by ensuring that all requirements of the NRC license are met and any potential violations of NRC requirements are identified and corrected expeditiously. Deliberately circumventing such requirements is a serious offense that will not be tolerated by the NRC. Such acts can result in civil action against the individual by the NRC, including prohibition from any involvement in NRClicensed activities, and may result in criminal prosecution by the Department of Justice. Given the deliberate nature of the violation in this case, the violation is classified at Severity Level III 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 \$2,500 is considered for a Severity Level III violation. Although your facility has not been the subject of escalated enforcement actions in the past two years or two inspections, given the deliberate nature of the violation, 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 event was identified by your staff and subsequently investigated, the NRC has determined that credit is warranted for your identification. Your corrective actions, which were described at the enforcement conference, included: (1) issuance of a memorandum, dated April 18, 1996, to all your employees regarding deliberate violations: (2) the prompt decontamination of the individual and control of the spread of contamination within the facility; (3) conduct of the investigation described in your records dated August 24 and 29, 1995, and November 29, 1995: (4) admonitions to the staff at the Pittsburgh pharmacy regarding adherence to requirements: and (5) distribution of a memorandum to all Syncor employees stating that deliberate misuse of any hazardous material is grounds for termination. Based on these actions, the NRC has determined that credit for your corrective action is also appropriate. Therefore, based

Syncor International Corporation 3

on the credit provided for identification and corrective action, a civil penalty normally would not be issued for this violation.

However, the Enforcement Policy provides that discretion may be exercised to assess a civil penalty notwithstanding the normal civil penalty assessment factors for cases involving willfulness. The willful action of a Syncor employee in causing radioactive contamination that could expose another individual cannot be tolerated by the NRC. Moreover, as noted above, this violation represents the second occurrence of deliberate misuse of licensed material within Syncor International Corporation. Therefore, a significant sanction is warranted to emphasize to the licensee and its employees that such actions are not acceptable. Based on these concerns, the NRC has determined that it is appropriate to exercise enforcement discretion, as permitted in Section VII.A.1 of the Enforcement Policy, to propose a base civil penalty of \$2,500.

Therefore, to emphasize: (1) the significance of deliberate violations, and (2) the importance of aggressive action to prevent deliberate misuse of licensed material. I have been authorized, after consultation with the Director, Office of Enforcement, and the Commission, to issue the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice) in the amount of \$2,500 for this 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. In your response, you should document the specific actions you have taken and any additional actions you plan to take to prevent recurrence. You also should describe your plans for ensuring that notice of significant occurrences at any of your facilities is disseminated promptly to employees at all of your facilities. Such dissemination is particularly important given the consolidation of all of your licensed activities under a single NRC license issued by the NRC Region IV office. After reviewing your response to this Notice, including your proposed corrective actions and the results of future inspections, the NRC will determine whether further NRC enforcement action is necessary to ensure compliance with NRC regulatory requirements.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter, its enclosure, and your response will be placed in the NRC Public Document Room (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. If 10 CFR 2.790 material is included in your response, the response must place brackets around the proprietary material. In addition, a nonproprietary version, leaving the brackets intact but deleting the material within the brackets, must be submitted to be placed in the PDR.

Syncor International Corporation

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

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Sincerely, 1/1 lles

Thomas T. Martin Regional Administrator

Docket No. 030-33224 (Formerly 030-15134) License No. 04-26507-01MD (Formerly 37-18467-01MD)

Enclosure: Notice of Violation and Proposed Imposition of Civil Penalty

cc w/encl: Commonwealth of Pennsylvania State of California

# NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY

Syncor International Corporation Pittsburgh, Pennsylvania Docket No. 030-33224 (Formerly 030-15134) License No. 04-26507-01MD (Formerly 37-18467-01MD) EA 96-104

During an NRC inspection conducted on February 26 - 27. 1996. a violation of NRC requirements was identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions." NUREG-1600. the Nuclear Regulatory Commission proposes to impose a civil penalty pursuant to Section 234 of the Atomic Energy Act of 1954. as amended (Act). 42 U.S.C. 2282. and 10 CFR 2.205. The particular violation and associated civil penalty are set forth below:

10 CFR 30.34(c) requires, in part, that each licensee shall confine his possession and use of byproduct material to the locations and purposes authorized in the license. Condition 9.F. of License No. 37-18467-01MD authorized the use of technetium-99m, a byproduct material, for dispensing and/or distribution of prepared radiopharmaceuticals to authorized recipients and for processing with reagent kits in preparing radiopharmaceuticals.

Contrary to the above, on August 10, 1995, the licensee did not confine its possession and use of byproduct material to the locations and purposes authorized by the license. Specifically, an unidentified licensee employee (or employees) deliberately used technetium-99m to contaminate a lock and locker located in the garage, an unrestricted area, and consequently to contaminate an individual worker at the facility, which are uses not authorized by the license.

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

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

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

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

# Notice of Violation

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 by bracketing such 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 addition, a nonproprietary version much be submitted with the information in brackets redacted to be placed in the PDR.

Dated at King of Prussia, Pennsylvania this 25th day of July 1996

3



UNITED STATES

475 ALLENDALE ROAD KING OF PRUSSIA, PENNSYLVANIA 19406-1415

December 15, 1995

EA 95-152

Leon Malmud, M.D. Vice President, Health Sciences Center Temple University 3401 N. Broad Street Philadelphia, PA 19140

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY -\$8,000 (U.S. Department of Labor Case No. 94-ERA-25)

Dear Dr. Malmud:

This letter refers to the results of an administrative proceeding conducted by the U.S. Department of Labor (DOL), consisting of an investigation and hearing, regarding a complaint filed March 30, 1994, by a former employee of Temple University (TU). In this case, a DOL Administrative Law Judge (ALJ) issued a Recommended Decision and Order on July 10, 1995, finding that TU discriminated against the employee because he engaged in protected activities, in violation of Section 211 of the Energy Reorganization Act of 1974, as amended.

On August 14, 1995, the Secretary of Labor (SOL) issued a Preliminary Order and Remand. The SOL ordered reinstatement of the complainant; reinstatement of his health, pension, and insurance benefits; expunging of negative statements from his personnel file; and posting of the Preliminary Order and Remand. The SOL remanded the case to the ALJ for a recommended calculation of back pay and lost benefits with interest. Once the ALJ's supplemental recommended decision is issued, the SOL will issue a supplemental preliminary order.

On October 3, 1995, a transcribed predecisional enforcement conference was held with you, Mr. James White, Executive Vice President of TU, and other members of your staff, to discuss this matter, the apparent violation, its cause and your corrective actions. Based on the ALJ's decision, and after considering the information that you provided during the conference, the NRC has concluded that a violation of the Commission's regulations has occurred.

The enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice), sets forth a violation of 10 CFR 30.7, "Employee Protection." The circumstances surrounding the violation are described in detail in the ALJ's Recommended Decision and Order. Specifically, according to the ALJ decision, the employee had raised safety concerns regarding compliance with 10 CFR

Temple University

2

Part 20, i.e., visitors to patients receiving radiopharmaceuticals for therapy; the employee's protected activity was followed several hours later by the personnel officer's threat and warning of dismissal; and the actual decision to terminate occurred 14 days after the initial threat.

10 CFR 30.7 prohibits discrimination by a Commission licensee 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. Protected activities are 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, but are not limited to, ar employee providing the Commission or his or her employer information about alleged violations of either the Atomic Energy Act or the Energy Reorganization Act. Since the discriminatory actions in this case involved the Associate Vice President of Environmental Health and Safety, this violation has been categorized in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions" (Enforcement Policy), NUREG-1600 (60 FR 34381; June 30, 1995) at Severity Level II.

In accordance with the Enforcement Policy, a base civil penalty in the amount of \$4,000 is considered for a Severity Level II violation. Because the violation is categorized at Severity Level II, 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. No credit is warranted for identification since you did not identify the violation. In fact, an internal investigation conducted by TU determined that discrimination had not occurred, which is contrary to the ALJ's findings. In accordance with the Enforcement Policy, Section VI.B.2.c, credit is not warranted for your corrective action because it did not provide a remedy for the particular discrimination at issue.

Therefore, to emphasize the importance of continuously assuring a work environment that is free of any harassment, intimidation, or discrimination against those who raise safety concerns, I have been authorized, after consultation with the Director, Office of Enforcement, to issue the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice) in the amount of \$8,000, twice the base civil penalty for this Severity Level II violation in accordance with the civil penalty assessment process set forth in 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. Since the NRC enforcement action in this case is being proposed prior to a final SOL decision on this matter, you may delay payment of, or response to, the proposed civil penalty, as well as certain portions of the response, as described in the enclosed Notice, until 30 days after the SOL decision, at which time you may also supplement your earlier responses. In the response

# Temple University

required by this letter and Notice, you should document the specific actions taken and any additional actions you plan to prevent recurrence of violations of this type, and any actions that you have taken or planned to minimize any chilling effect arising from this incident that might inhibit or prevent your employees from raising safety concerns to either your own organization or the NRC. After reviewing your response to this Notice, including your proposed corrective actions and the results of future inspections, the NRC will determine whether further NRC enforcement action is necessary to ensure compliance with NRC regulatory requirements.

Under separate cover, you will receive a copy of an NRC letter to your former Associate Vice President of Environmental Health and Safety regarding this matter.

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

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

Sincerely,

Genes Man

Thomas T. Martin Regional Administrator

Docket No. 030-02963 License No. 37-00697-31

Enclosure: Notice of Violation and Proposed Imposition of Civil Penalty

cc: Commonwealth of Pennsylvania

NUREG-0940, PART III

3

#### NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY

Temple University Philadelphia, Pennsylvania

Docket No. 030-02963 License No. 37-00697-31 EA 95-152

Based on results of investigations and hearings conducted by the U.S. Department of Labor (DOL) (DOL case 94-ERA-25) and the resulting decision by DOL Administrative Law Judge (ALJ), dated July 10, 1995, a violation of NRC requirements was identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (60 FR 34381; June 30, 1995), NUREG-1600, the Nuclear Regulatory Commission proposes to impose a civil penalty pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (Act), 42 U.S.C. 2282, and 10 CFR 2.205. The particular violation and associated civil penalty are set forth below:

10 CFR 30.7(a), in nart, prohibits discrimination by a Commission licensee 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 are 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.

10 CFR 30.7(a)(1)(i) provides that protected activities include, but are not limited to, an employee providing the Commission or his or her employer information about alleged violations of either the Atomic Energy Act or the Energy Reorganization Act named in 10 CFR 30.7(a) or possible violations of requirements imposed under either of those statutes.

Contrary to the above, on January 31, 1994, the licensee discriminated against an employee for engaging in protected activities. Specifically, a DOL Administrative Law Judge, in his decision dated July 10, 1995 (94-ERA-25), found that an employee was terminated from his position after he raised safety concerns to the Commission and his employer. (01012)

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

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

#### Notice of Violation

taken to avoid further violations, and (5) the date when full compliance will be achieved. At your election, responses to items (1) and (2) may be deferred until 30 days after the decision by the Secretary of Labor. Your response may 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. 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 30 days of the final decision of the Secretary of the Department of Labor in this case, the Licensee may pay the civil penalty by letter addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, with a check, draft, money order, or electronic transfer payable to the Treasurer of the United States in the amount of the civil penalty proposed above, or may protest imposition of the civil penalty in whole or in part, by a written answer addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission. Should the Licensee fail to answer within 30 days after the Secretary of Labor's final decision, 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 234c of the Act, 42 U.S.C. 2282c.

2

Notice of Violation

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 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. However, if you find it necessary to include such information, you should clearl, 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.

Dated at King of Prussia, Pennsylvania this 15th day of December 1995

3



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

October 31, 1995

EA 95-101

Testco, Inc. ATTN: James L. Shelton President and Radiation Safety Officer Post Office Box 18511 Greensboro, North Carolina 27417

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY -\$5,000 (NRC Inspection Report No. 150-00032/94-01 and Investigation No. 2-92-027R)

Dear Mr. Shelton:

This letter refers to a special inspection conducted by Mr. Jeffrey Mumper of this office on August 31 and September 6, 1994, and an investigation conducted by the Nuclear Regulatory Commission (NRC) Office of Investigations (OI) completed on April 25, 1995. During the inspection and investigation, the NRC examined the facts and circumstances surrounding Testco, Inc.'s (Testco's) use of radioactive material for the performance of radiographic operations in the Commonwealth of Virginia without notifying the NRC as required by 10 CFR 150.20(b)(1). You were informed of the preliminary inspection findings during the exit meeting conducted on August 31, 1994, and the synopsis of the OI investigation which was sent to you by letter dated June 27, 1995. The latter correspondence also provided you an opportunity to attend a predecisional enforcement conference to discuss the apparent violations, their cause, and your corrective action to preclude recurrence. A transcribed conference was conducted on July 27, 1995, in Greensboro, North Carolina. The report summarizing the conference was sent to you by letter dated September 5, 1995.

Based on the information developed during the inspection and investigation as well as the information that you 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). The violation involved your use of radioactive materials in areas under NRC jurisdiction without obtaining a specific NRC license or filing Form-241, "Report of Proposed Activities in Non-Agreement States", as required pursuant to the general NRC license in 10 CFR 150.20. The NRC identified at least 11 instances when your company performed licensed activities in Virginia during the period January 1992 through January 1994 without notifying the NRC.

In addition, on numerous occasions you performed work at military installations in areas of exclusive federal jurisdiction within Agreement States during the period 1990 through 1994 without filing a Form-241. Although these examples are not being cited, you are now on notice that 10 CFR 30.3 requires that such work be performed under a specific or general

In accordance with the Enforcement Policy, the NRC considered the issuance of a civil penalty in the amount of \$10,000. No credit was determined to be warranted for *Identification* based on NRC's identification of the uncorrected

responsible for the acts of its employees. It is essential that the NRC be able to maintain the highest trust in individuals working with licensed material and that licensees appropriately manage their programs to ensure that personnel fully understand the importance of complying with regulatory requirements. The willful nature of the violation brings into question the integrity of the RSO and his commitment to assuring that radiographic operations are conducted safely and in accordance with applicable State and NRC requirements. In addition, the violation denied the NRC the opportunity to inspect Testco's activities in non-Agreement States thereby impeding the NRC's ability to perform its statutory responsibility of verifying that licensed activities are performed in accordance with NRC requirements. Therefore, this violation has been categorized at Severity Level III in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions" (Enforcement Policy), NUREG-1600 (60 FR 34381; June 30,

# Testco, as an entity licensed to possess and use radioactive material, is

As a result of the aforementioned activities, an Order is being issued on this date prohibiting the President/RSO (Mr. James L. Shelton) from controlling or engaging in NRC-licensed activities for a period of three years. Based on the Order, for the period of time that the prohibition is in effect, Testco cannot conduct licensed activities in areas under NRC jurisdiction as long as Mr. Shelton remains as President or RSO, or maintains any position that would allow him to have any control over the NRC-licensed activity including, but not limited to, assigning, supervising, directing, or assisting licensed

Based on the information gathered in this case, the NRC concluded that the violation resulted directly from the deliberate misconduct of the President/ Radiation Safety Officer (RSO), who willfully disregarded regulatory requirements by conducting licensed work in areas under NRC jurisdiction without filing appropriate documentation or taking steps to ensure that appropriate documentation was filed with the NRC. In addition to the investigative findings, this determination is also based partly on statements made by the RSO at the conference indicating that he was knowledgeable of the requirements of 10 CFR 150.20, he became aware of the failure to submit the Form-241's, and he failed to take any corrective action for the violations. The RSO did not take corrective action to assure that Form-241's were filed until the NRC inspection focused on the Form-241 issue in August 1994.

NRC license. Future such failures to comply with the requirements of 10 CFR 30.3 and 10 CFR 150.20 may be considered willful and may result in additional enforcement sanctions. In the future, if Testco does work on Federal property, even though the property may be located in an Agreement State. Testco should get a written determination from the Federal agency controlling the property in order to clarify whether the location of work is an area of

Testco, Inc.

Testco, Inc.

violation during the August 1994 inspection and the conclusion that the violation was willful. At the predecisional enforcement conference, you stated that your corrective actions subsequent to NRC identification of the violation included: (1) development of a listing of authorized sites which designates work locations that require a Form-241; (2) verification by the RSO that the required forms have been filed; and (3) plans to apply for an NRC license which would relieve the company from the obligation to file for reciprocity when performing work in NRC jurisdictions. Although Testco appears to have submitted NRC Form-241's subsequent to identification of the violation by NRC, the NRC has determined that you should not be given credit for the factor of *Corrective Action*. This determination is based on the RSO's own admission of his failure to take corrective action prior to NRC involvement. Credit for corrective action to restore compliance upon learning of the violation. Therefore, the normal application of the Enforcement Policy would result in a civil penalty of \$10,000.

However, after considering the size of Testco and the effect that the Order against the President/RSO will have on Testco's operations, the NRC has decided to assess the base civil penalty of \$5,000. Therefore, to emphasize the importance of strict adherence to all regulatory requirements and that deliberate failures to comply with NRC regulations cannot be tolerated. I am issuing the enclosed Notice of Violation and Proposed Imposition of Civil Penalty in the amount of \$5,000.

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

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

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

Testco, Inc.

If you have any questions regarding this letter, please contact Mr. Charles M. Hosey, Chief, Nuclear Materials Inspection Section at (404) 331-5614.

Sincerely,

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

Docket No. 150-00032 General License (10 CFR 150.20)

Enclosure: Notice of Violation

cc w/encl: State of North Carolina

#### NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY

Testco, Inc. Greensboro, North Carolina

Docket No. 150-00032 License No. (General License) EA 95-101

During an NRC inspection conducted on August 31 and September 6, 1994, and an Office of Investigations (OI) investigation concluded on April 25, 1995, a violation of NRC requirements was identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," NUREG-1600 (60 FR 34381; June 30, 1995), the Nuclear Regulatory Commission proposes to impose a civil penalty pursuant to section 234 of the Atomic Energy Act of 1954, as amended (Act), 42 U.S.C. 2282, and 10 CFR 2.205. The particular violation and associated civil penalty is set forth below:

10 CFR 30.3 requires in relevant part, that no person shall possess or use byproduct material except as authorized by a specific or general license issued by the NRC.

10 CFR 150.20(a) provides in part that any person who holds a specific license from an Agreement State is granted an NRC general license to conduct the same activity in non-Agreement States subject to the provisions of 10 CFR 150.20(b).

10 CFR 150.20(b)(1) requires, in part, that any person engaging in activities in non-Agreement States shall, at least 3 days before engaging in such activity, file four copies of Form-241, "Report of Proposed Activities in Non-Agreement States," with the Regional Administrator of the appropriate NRC regional office.

Contrary to the above, between January 7, 1992 and January 22, 1994, Testco, Inc. performed radiography using Iridium-192 in Virginia, a non-Agreement State, at the following locations on the indicated dates without a specific license issued by the NRC and without filing any copies of Form-241 with the NRC:

- Yorktown, on or about January 7 and 13, 1992; Goochland, on or about March 20, 1992; 1.
- 2.
- 3.
- Lynchburg, on or about March 24, 1992; Yorktown, on or about September 9 and 11, 1992; 4.
- Franklin, on or about February 4, 1993; 5.
- Boydton, on or about April 12, 1993; 6.
- Craney Island, on or about August 13 and 27, 1993; and 7.
- 8. Hillsville, on or about January 22, 1994

This is a Severity Level III violation (Supplements VI and VII). Civil Penalty - \$5,000

Pursuant to the provisions of 10 CFR 2.201, Testco, Inc. is hereby required to submit a written statement or explanation to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, within 30 days of the date of

# Notice of Violation

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.

2

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

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

NUREG-0940, PART III

Notice of Violation

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 II, 101 Marietta Street, Atlanta, GA 30323.

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.

Dated at Rockville, Maryland this 3154 day of October 1995



#### UNITED STATES NUCLEAR REGULATORY COMMISSION WASHINGTON, D.C. 20060-0001

March 19, 1996

EA 95-101

Mr. James L. Shelton President and Radiation Safety Officer TESTCO, Inc.
P. O. Box 18511 Greensboro, North Carolina 27417

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

Dear Mr. Shelton:

This refers to your letters dated December 20 and 21, 1995 ("Reply"), in response to the Notice of Violation and Proposed Imposition of Civil Penalty ("Notice") sent to you by our letter dated October 31, 1995. Our letter and Notice described a violation of NRC requirements that was identified during an NRC inspection conducted on August 31 and September 6, 1994 and an investigation conducted by the NRC Office of Investigations (OI) that was completed on April 25, 1995.

To emphasize the importance of strict adherence to all regulatory requirements and that deliberate failures to comply with NRC regulations cannot be tolerated, a civil penalty of \$5,000 was proposed.

In your Reply, you denied the violation and requested a hearing on the matter. As the basis for your denial, you contend that prior to October 3, 1994, which you describe as the date of "the issue of NRC Manual Chapter 1220," the NRC did not have a tracking method in place for processing NRC Form-241s; and that TESTCO, Inc. had located copies of NRC Form-241s filed prior to that time.

By letter dated December 28, 1995, the NRC responded to your request for a hearing, indicating that a request for a hearing on this issue was premature and requesting that you provide to Mr. James Lieberman, Director, NRC Office of Enforcement, at the address specified, any additional documentation you had to show that you filed Form-241s and paid the appropriate fees for the dates and locations of work stated in the Notice. Specifically, NRC indicated that even if your documentation was incomplete, you should still provide whatever documentation you had to support your position. During a telephone conference held January 31, 1996, as confirmed by NRC letter dated February 1, 1996, an extension was granted giving you until February 7, 1996, to provide the NRC Office of Enforcement any documents that you had in your possession or control which might rebut the October 31, 1995 Notice, such as any NRC Form-241s and any checks for reciprocity fees regarding work performed in Virginia from January 1992 to January 1994. As further discussed in the enclosure, you did submit some information in a facsimile communication on March 5, 1996, but did not provide documentation addressing the dates and locations of work stated in the Notice, as NRC had requested. Therefore, as of the date of this letter,

TESTLO, Inc.

TESTCO, Inc., has not provided the documentation that TESTCO, Inc. referenced in its Reply.

After consideration of your responses, we have concluded, for the reasons given in the Appendix to the enclosed Order Imposing Civil Monetary Penalty that the violation occurred as stated and that an insufficient basis was provided to warrant rescinding the violation and associated civil penalty. Accordingly, we hereby serve the enclosed Order on TESTCC, Inc. imposing a civil monetary penalty in the amount of \$5,000. As provided in Section IV of the enclosed Order, payment should be made within 30 days of the date of this Order, by check, draft, money order, or electronic transfer, payable to the Treasurer of the United States and mailed to Mr. James Lieberman, 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 enclosure will be placed in the NRC's Public Document Room.

Sincerely,

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James Lieberman, Director Office of Enforcement

Docket No. 150-00032 General license (10 CFR 150.20)

Enclosure: Order Imposing Monetary Civil Penalty

cc w/encl: State of North Carolina

NUREG-0940, PART III

# UNITED STATES NUCLEAR REGULATORY COMMISSION

In the Matter of

TESTCO, INC. Greensboro, North Carolina Docket No. 150-00032 License No. (General License) EA 95-101

ORDER IMPOSING CIVIL MONETARY PENALTY

TESTCO, Inc. (TESTCO or Licensee), located in Greensboro, North Carolina, holds Byproduct Materials License No. 041-0894-1 issued by the State of North Carolina under an agreement with the Nuclear Regulatory Commission (NRC or Commission) pursuant to subsection 274b of the Atomic Energy Act of 1954, as amended. The license permits the possession and use of byproduct material for industrial radiography activities in accordance with the conditions specified therein.

II

On September 9, 1992, while conducting an inspection of another NRC licensee, an NRC inspector obtained information which indicated that TESTCO had performed radiographic activities in areas under NRC jurisdiction. A review of NRC records revealed that TESTCO did not possess an NRC specific license pursuant to 10 CFR 30.3, nor had TESTCO notified the NRC of its activities by filing an NRC Form-241 as required by 10 CFR 150.20(b)(1).

The requirement that an Agreement State licensee must file Form-241 before conducting a licensed activity in a non-Agreement State allows NRC to be informed of the location and duration of the activity and permits NRC to

inspect licensed activities as appropriate. Since August 9, 1991, NRC has required a fee for the filing of Form-241.

2

Between November 16, 1992 and April 25, 1995, an investigation was conducted by the NRC Office of Investigations (OI) to determine whether TESTCO performed radiography in non-Agreement States and deliberately withheld notification from the NRC by failing to file Form-241s. In addition, an inspection of the Licensee's performance of activities in areas of NRC jurisdiction was conducted on August 31 and September 6, 1994. The results of the inspection and investigation indicated that the Licensee had not conducted its activities in full compliance with NRC requirements. Specifically, OI concluded that TESTCO, Inc., while a State of North Carolina radioactive materials licensee. performed radiographic services in Virginia, a non-Agreement State, and its Radiation Safety Officer deliberately withheld notification to the NRC by his failure to file the required NRC Form-241s regarding those activities. A written Notice of Violation and Proposed Imposition of Civil Penalty ("Notice") was served upon the Licensee by letter dated October 31, 1995. Th Notice stated the nature of the violation, the provisions of the NRC's requirements the Licensee had violated, and the amount of the civil penalty proposed for the violation.

The Licensee responded to the Notice in letters dated December 20 and 21, 1995 ("Reply"). In its Reply, the Licensee denied the violation and requested a hearing. As the basis for the Licensee's denial, the Licensee contended that prior to October 3, 1994, which the Licensee described as the date of "the issue of NRC Manual Chapter 1220," the NRC did not have a tracking method in

NUREG-0940, PART III

place for processing NRC Form-241s and that TESTCO had located copies of NRC Form-241s filed prior to that time.

3

By letter dated December 28, 1995, NRC responded to the Licensee's request for a hearing, indicating that a request for a hearing on this issue was premature and requesting that TESTCO provide to Mr. James Lieberman, Director, NRC Office of Enforcement, at the address specified, any additional documentation that was relevant to the case by January 27, 1996. The NRC letter further advised that even if the documentation was incomplete, TESTCO should still provide whatever documentation it had to support its position. During a telephone conference held on January 31, 1996, as confirmed by letter dated February 1, 1996, NRC granted an extension giving TESTCO until February 7, 1996, to provide to the NRC Office of Enforcement any documents that it had in its possession or control which might rebut the October 31, 1995 Notice, including any NRC Form-241s and any checks for reciprocity fees regarding work performed in Virginia from January 1992 to January 1994. As further discussed in the Appendix to this Order, TESTCO did submit some information in a facsimile communication on March 5, 1996, but did not provide documentation addressing the dates and locations of work stated in the Notice, as NRC had requested. As of the date of this Order, TESTCO has not provided the documentation (copies of Form-241) that TESTCO claimed it had located in its Reply denying the violation.

NUREG-0940, PART III

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

4

111

#### IV

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

The Licensee pay a civil penalty in the amount of \$5,000 within 30 days of the date of this Order, by check, draft, money order, or electronic transfer, payable to the Treasurer of the United States and mailed to Mr. James Lieberman, Director, Office of Enforcement, U. S. Nuclear Regulatory Commission, One White Flint North, 11555 Rockville Pike, Rockville, MD 20852-2738.

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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, D. C. 20555, and include a statement of good cause for the extension. A request for hearing should be clearly marked as a "Request for an Enforcement Hearing" and shall be addressed to the Director, Office of Enforcement, U. S. Nuclear Regulatory Commission, Washington, D. C. 20555, with a copy to the Commission's Document Control Desk, Washington, D. C. 20555. Copies also shall be sent to the Assistant General Counsel for Hearings and Enforcement at the same address and to the Regional Administrator, NRC Region II, 101 Marietta Street, Suite 2900, Atlanta, Georgia 30323.

5

If a hearing is requested, the Commission will issue an Order designating the time and place of 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 issues to be considered at such hearing shall be:

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

6

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

FOR THE NUCLEAR REGULATORY COMMISSION

Dames Lieberman, Director

Office of Enforcement

Dated at Rockville, Maryland this 19th day of March 1996

#### APPENDIX

#### EVALUATION AND CONCLUSION

On October 31, 1995, a Notice of Violation and Proposed Imposition of Civil Penalty ("Notice") was issued for a violation identified during an NRC inspection and investigation. TESTCO, Inc. (the Licensee) responded to the Notice in letters dated December 20 and 21, 1995 ("Reply"). The Licensee denied the violation. The NRC's evaluation and conclusion regarding the Licensee's denial are as follows:

#### Restatement of Violation

10 CFR 30.3 requires in relevant part, that no person shall possess or use byproduct material except as authorized by a specific or general license issued by the NRC.

10 CFR 150.20(a) provides in part that any person who holds a specific license from an Agreement State is granted an NRC general license to conduct the same activity in non-Agreement States subject to the provisions of 10 CFR 150.20(b).

10 CFR 150.20(b)(1) requires, in part, that any person engaging in activities in non-Agreement States shall, at least 3 days before engaging in such activity, file four copies of Form-241, "Report of Proposed Activities in Non-Agreement States," with the Regional Administrator of the appropriate NRC regional office.

Contrary to the above, between January 7, 1992 and January 22, 1994, TESTCO, Inc. performed radiography using Iridium-192 in Virginia, a non-Agreement State, at the following locations on the indicated dates without a specific license issued by the NRC and without filing any copies of Form-241 with the NRC :

- 1. Yorktown, on or about January 7 and 13, 1992;
- 2.
- 3.
- Goochland, on or about March 20, 1992; Lynchburg, on or about March 24, 1992; Yorktown, on or about September 9 and 11, 1992; Franklin, on or about February 4, 1993; 4.
- 5.
- 6.
- Boydton, on or about April 12, 1993; Craney Island, on or about August 13 and 27, 1993; and 7.
- Hillsville, on or about January 22, 1994 8.

This is a Severity Level III violation (Supplements VI and VII). Civil Penalty - \$5,000

### Summary of Licensee's Response to Violation

In its Reply, the Licensee denied that the violation occurred as stated and requested a hearing on the matter. The Licensee claimed as the basis for its denial that before October 3, 1994, which the Licensee describes as the date of "the issue of NRC Manual Chapter 1220," the NRC did not have a tracking method in place for processing NRC Form-241s and revisions. In addition, the

Licensee stated that it had located TESTCO, Inc.'s copies of NRC Form-241s which were filed prior to October 3, 1994.

## NRC Evaluation of Licensee's Response

By letter dated December 28, 1995, the NRC responded to the Licensee's request for hearing. The NRC informed TESTCO, Inc. that a hearing in this matter was premature in that a civil penalty only had been proposed and not yet imposed by Order. Further, the NRC requested that the Licensee provide to Mr. James Lieberman, Director NRC Office of Enforcement, at the address specified, by January 27, 1996, any additional documentation that it had to show that it had filed Form-241s and paid the appropriate fees for the dates and locations of work stated in the Notice. In the letter, the NRC indicated that even if the documentation was incomplete, the Licensee should still provide whatever documentation it had to support its position. During a telephone conference on January 31, 1996, and as confirmed by NRC letter dated February 1, 1996, an extension was granted giving the Licensee until February 7, 1996 to provide to the NRC Office of Enforcement any documents that it may have in its possession or control which might rebut the October 31, 1995 Notice, such as any NRC Form-241s and any checks for reciprocity fees regarding work performed in Virginia from January 1992 to January 1994.

Since the February 7, 1996 NRC letter, the NRC has received two additional communications from the Licensee and/or its attorneys:

(1) In a February 13, 1996 letter concerning settlement, addressed to Mr. James Lieberman, Director of NRC's Office of Enforcement, the Licensee and its attorneys contended that the civil penalty amount should not have been determined in accordance with the NRC Enforcement Policy that became effective June 30, 1995 (NUREG 1600), because the violations occurred before that date. However, the NRC staff chose to use the newer Enforcement Policy because by doing so, the civil penalty amount was reduced, thus producing a result that was advantageous to the Licensee.

(2) In a March 5, 1996 facsimile communication to Mr. David Collins of the NRC Region II Office, Mr. J. L. Shelton, the Licensee's president, included some documentation concerning work performed in the Fall of 1994, but that documentation is not relevant to the dates and locations of work that are set forth in the Notice. In the facsimile, Mr. Shelton also made an assertion that a listing of dates and locations of work performed by TESTCO, Inc. in NRC

<sup>&</sup>lt;sup>1</sup>Under the current Enforcement Policy (NUREG-1600), the civil penalty was calculated by increasing the base civil penalty of \$5,000 by 100% to \$10,000, considering the factors of Identification and Corrective Action, and in view of the willful nature of the violation. Then, after consulting with the Commission, the NRC staff applied enforcement discretion, based in part on the small size of the Licensse, to reduce the amount of the civil penalty from \$10,000 to \$5,000. Under the Enforcement Policy in effect at the time that the violation was occurring (10 CFR Part 2, Appendix C), the base civil penalty of \$5,000 could have been increased by 300% to \$20,000, considering the factors of Identification, Corrective Action, Multiple Occurrences, and Prior Notice, and in view of the willful nature of the violation.

jurisdictions, compiled by NRC's Office of Investigations (OI), "appears to have locations. . . that Testco, Inc., or J. L. Shelton has never worked at." Thus, while the Licensee did submit some additional information, the Licensee has not provided the documentation, as requested by NRC, that the Licensee claimed it had located in its Reply denying the violation (*i.e.*, copies of Form-241 relevant to the dates and locations of work that are set forth in the Notice). The Licensee also has not provided any other documentation that specifically addresses the dates and locations of work stated in the Notice. The NRC believes that the listing of dates and locations of work performed in NRC jurisdictions, as set forth in the Notice, is reliable because it is based on documentary evidence, including work records and invoices.

In its Reply, the Licensee questioned the reliability of NRC's findings due to what the Licensee claims was the lack of an NRC Form-241 tracking system prior to October 3, 1994. However, NRC Manual Chapter 1220, "Processing of NRC Form-241, 'Report of Proposed Activities in Non-Agreement States,' and Inspection of Agreement State Licensees Operating Under 10 CFR 150.20," has been in effect since March 1988. The October 3, 1994 date that the Licensee relies on is merely the date that a revision of Manual Chapter 1220 was effected.

Beginning in March 1988, in accordance with Manual Chapter 1220, each Region was required to maintain records of NRC Form-241 activities including the reports received, the reciprocity activities conducted, inspections performed, and noncompliances identified. Hardcopy information was, and continues to be, retained in the NRC Regio. II Docket Files, the repositor; for official records related to NRC Region II materials licensing and inspection activities. Moreover, from January 1991 through January 1994, the NRC Region II Office did have in place a method to track the filing of Form-241s by a log maintained on a computer. Prior to that time, Region II tracked the filing of Form-241s manually by using a log book. After that time, an NRC agency-wide computerized system was used to document and track the filing of Form-241s.

Further, at the predecisional enforcement conference held with TESTCO, Inc. on July 27, 1995, the Licensee indicated it had additional information to support its contention that NRC Form-241s were filed. Since that time, no such information has been provided.

In the absence of additional documentation from ISTCO, Inc., as was requested, to support its position and refute the facts disclosed by NRC, the NRC concludes that the violation occurred as stated.

#### NRC Conclusion

The NRC has concluded that this violation occurred as stated and no adequate basis for withdrawal of the violation or mitigation of the civil penalty has been provided by the Licensee. Consequently, the proposed civil penalty in the amount of \$5,000 should be imposed.

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UNITED STATES OF AMERICA NUCLEAR REGULATORY COMMISSION 56 OCT -1 P2:25 ATOMIC SAFETY AND LICENSING BOARD C CE OF SECRETARY Before Administrative Judges (ETING & SERVICE BRANCH Charles Bechhoefer, Chairman Dr. Frank F. Hooper Dr. Charles N. Kelber

In the Matter of

Docket No. IA 95-055

JAMES L. SHELTON

(Order Prohibiting Involvement in NRC-Licensed Activities (Effective Immediately)) ASLBP No. 96-712-01-EA

SERVED OCT - 1 1996

In the Matter of

TESTCO, INC.

(Order Imposing Civil Monetary ASLBE Penalty)

(General License) EA 95-101

Docket No. 150-00032-EA EA 95-10J ASLBP No. 96-719-04-EA

October 1, 1996

## MEMORANDUM AND ORDER (Approving Settlement Agreement)

These two enforcement proceedings involve, respectively, an immediately effective enforcement order seeking to bar Mr. James L. Shelton (a radiographer) from participating in certain NRC-licensed activities for a period of three years (measured from October 31, 1995) and a proposed civil penalty of \$5,000.00 against the firm of which Mr. Shelton serves as President. Atomic Safety and Licensing Boards, consisting of the same Administrative

NUREG-0940, PART III

Judges, were established for each proceeding. Those Boards issued Notices of Hearing for each proceeding. 61 Fed. Reg. 2848 (January 29, 1996)(Shelton proceeding); 61 Fed. Reg. 43268 (August 21, 1996)(Testco proceeding). The proceedings have been consolidated. Prehearing Conference Order, dated August 15, 1996 (unpublished); see also 61 Fed. Reg. 43268.

- 2 -

On September 17, 1996, the NRC Staff advised the Atomic Safety and Licensing Boards that it had reached a settlement with both Testco and Mr. Shelton. Under the agreement, Mr. Shelton (1) is prohibited from engaging in certain licensed activities until October 31, 1996; (2) must submit certain forms and pay certain fees prior to conducting such licensed activities during the period November 1,1996 through December 31, 1998; (3) until October 31, 1998, must provide certain notifications to NRC prior to conducting those licensed activities; and (4) must pay a civil penalty of \$1,000, in two installments due no later than October 31, 1996. A copy of the agreement is attached hereto.

Pursuant to 10 C.F.R. § 2.203, settlement agreements such as have been agreed to here are subject to Licensing Board approval, "according due weight to the position of the [NRC] staff." By motion dated September 17, 1996 (delivery of which to one of the Board members was delayed until the week of September 23-27, 1996), the Staff moved that we approve the agreement, which itself recites the Staff's position that the agreement "best serves the interests of

the public and the parties," as well as the Atomic Energy Act and NRC requirements, and that we terminate the proceedings.

- 3 -

Absent any contrary information, and according due weight to the Staff's position, we hereby <u>appprove</u> the Settlement Agreement submitted to us and <u>terminate</u> the proceedings.

Pursuant to 10 C.F.R. § 2.764, this Order is effective immediately but is subject to Commission review under 10 C.F.R. § 2.786.

It is so Ordered.

The Atomic Safety and Licensing Boards

Charles Bechhoefer, Chairman

ADMINISTRATIVE JUDGE

Hooper in CB

Dr. Frank F. Hooper ADMINISTRATIVE JUDGE

Dr. Charles N. Kelber ADMINISTRATIVE JUDGE

Rockville, Maryland October 1, 1996

## UNITED STATES NUCLEAR REGULATORY COMMISSION

## BEFORE THE OFFICE OF ENFORCEMENT

In the Matter of

TESTCO, INC. AND JAMES L. SHELTON Greensboro, North Carolina

) Docket No. 150-00032 ) General License (10 CFR 150.20) ) EA 95-101 and IA 95-055

## SETTLEMENT AGREEMENT

On October 31, 1995, the NRC issued a written Notice of Violation and Proposed Imposition of Civil Penalty - \$5,000 (Notice) to Testco, Inc. (Licensee or TESTCO), and an Order Prohibiting Involvement in NRC-Licensed Activities (Effective Immediately) to Mr. James Shelton. The Notice and the Order stated the provisions of the NRC's requirements the Licensee had violated and the amount of the civil penalty proposed for the violation.

As a result of the Licensee's failure to adequately respond to the Notice, the NRC issued on March 19, 1996, an Order Imposing Civil Monetary Penalty -\$5,000. By a letter dated July 20, 1996, the Licensee requested a hearing concerning this matter before the Atomic Safety and Licensing Board, and the Board subsequently granted the request.

In telephone discussions on September 5 and 9, 1996, between Mr. James Shelton, President of TESTCO, and Mr. James Lieberman, Director, Office of Enforcement, Mr. Shelton indicated that TESTCO desires to settle this matter without further ligitation, as noted below. 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 of 1954, as amended, and the NRC's requirements.

Therefore, pursuant to Section 81, Subsections (b) and (o) of Section 161, and Section 234 of the Atomic Energy Act of 1954, as amended (42 U.S.C. § § 2111, 2201(b), 2201(o), and 2282), and 10 C.F.R. § 2.203, the October 31, 1995, and March 19, 1996 Orders are hereby modified as follows:

2

- Mr. Shelton is prohibited from engaging in licensed activities in areas under NRC jurisdiction until October 31, 1996. For purposes of this Settlement Agreement (Settlement), areas under NRC jurisdiction are areas in non-Agreement States, offshore waters, or any areas under exclusive Federal jurisdiction.
- 2. Prior to conducting licensed activities in NRC jurisdiction after November 1, 1996, the Licensee is required to submit an NRC Form 241 that covers the remainder of calendar year 1996 (i.e., until December 31, 1996). The Licensee is also required to submit a NRC Form 241 prior to conducting licensed activities in calendar year 1997 and calendar year 1998. These submittals would be in accordance with 10 CFR 150.20(b); however, the Licensee should be aware that if it performs work in areas under NRC jurisdiction for more than 180 days in any calendar year, the Licensee is required to apply for a specific NRC license. Fees are required to be submitted upon each filing of NRC Form 241 and before commencing work. However, a separate fee is not required for the weekly notification under Paragraph 3 below.

NUREG-0940, PART III

3. Until October 31, 1998, following submittals of the yearly NRC Form 241 under Paragraph 2 above, Mr. James Shelton, on behalf of Testco, Inc., shall notify NRC Region II, by 9:00 a.m. EST Monday (or Tuesday, if Monday is a Federal holiday) of each week, whether the Licensee plans to perform radiography work in areas under NRC jurisdiction. Notification shall be made to the Chief, Materials Licensing/Inspection, Branch 1, by facsimile at (404) 331-7437 using the attached form, and receipt shall be verified by calling (404) 331-5624.

3

- A. If radiography work is planned, the Licensee shall provide the location of the field sites under NRC jurisdiction where the work is planned that week, as well as the specific date(s) and time(s). Inasmuch as the Licensee is required to submit to the NRC written notification on a weekly basis, the provisions of 10 CFR 150.20(b)(1) requiring that additional NRC Form 241s be filed for the remainder of each calendar year prior to engaging in licensed activities are waived; the Licensee is not required to comply with the three day notification requirement as long as it is making the weekly notifications to NRC Region II.
- B. If unplanned radiography work arises after the weekly notification, the new work cannot be performed unless the NRC has been provided a 24-hour written notification. Telephone notification is not acceptable.

NUREG-0940, PART III

- C. Notification is required to include work on Federal property in Agreement States, unless the Licensee has a written statement from the Federal agency where work is planned that the area is not under exclusive Federal jurisdiction.
- 4. The Licensee agrees to pay a civil penalty of \$1,000. The Licensee shall pay \$500 within two weeks of the date of this Settlement and \$500 no later than October 31, 1996. If the \$1,000 Penalty is not paid in full by October 31, 1996, TESTCO agrees to pay the full penalty described in the October 31, 1995 Notice (\$5,000) by November 30, 1996, and waives its right for a hearing concerning the civil penalty imposed by the March 19, 1996 Order.
- 5. The Licensee and Mr. Shelton agree to withdraw their respective requests for hearing in Docket Nos. EA 95-101 and IA 95-055 (now consolidated before an Atomic Safety and Licensing Board) in consideration of the modification of the October 31, 1995 and March 19, 1996 Orders, as provided under Paragraphs 1 through 4 above.
- If this Settlement is violated, the October 31, 1995 and the March 19, 1996 Orders shall be reinstated, and Mr. Shelton and the Licensee agree not to contest the reinstatement these Orders.

NUREG-0940, PART III

7. The staff, Mr. Shelton, and TESTLO shall jointly move the Atomic Safety and Licensing Board designated in the above-captioned proceedings for orders approving this Settlement and terminating the proceedings.

ş

James Shelton, as an Individual

09113196 Date

TESTCO, INC.

James Shelton,

09/13/96 Date

U. S. NUCLEAR REGULATORY COMMISSION

per han James Lieberman, Director

Office of Enforcement

9/16/91

Fax To: Chief, Materials Licensing/Inspection, Branch 1

From: James Shelton, President, Testco

Subject: Notification of Work in Areas Under NRC Jurisdiction For the Week of \_/\_/\_

- 1. Is radiography work planned in non-Agreement States or offshore waters? Yes/No
  - If the answer to Question 1 is yes, thip to 3. Α.
  - 8. If the answer to Question 1 is no, and the work planned is not on a Federal property, skip to 6.
  - С. If the answer to Question 1 is no, and the work planned is on a Federal property, go to 2.
- 2. Is there a written statement from the Federal agency stating that the area is not under exclusive Federal jurisdiction? Ves/No
  - If the answer to Question 2 is no, proceed to 3. A.
- If the answer to Question 2 is yes, skip to 6. 8. Work Location Address (Street 3. Date and Time 4. Name and phone 5. of Planned Work Number of Firm Address, City, and State)

I. THE UNDERSIGNED. HEREBY CERTIFY THAT: 6.

A. 8.

- All the information in this form is true and complete. I have read and understand the provisions of the general license in 10 CFR 150.20, and understand that I am required to comply with these provisions as well as all byproduct, source, or special nuclear material which I possess and use in areas under MRC jurisdiction under the general license for which this form is filed with the Muclear Regulatory Commission.
- C.
- I understand that activities, including storage, conducted in areas under MRC jurisdiction under the general license in 10 CFR 150.20 are limited to 180 days in a calender year. I understand that I may be inspected by the MRC at the above listed work site locations and at the licensee home office address for activities performed in areas under MRC jurisdiction. I was also every that I am responsible for any fees associated with any ٥. inspections.
- I understand that conduct of any activities not described above, including conduct of activities on dates or locations different from those described above or without NRC suthorization, may subject as to enforcement action, including civil or criminal penalties. Ε.

Certifying Officer, Name and Title

Signature

Date

NUREG-0940, PART III

## UNITED STATES OF AMERICA NUCLEAR REGULATORY COMMISSION

In the Matter of

JAMES L. SHELTON AND TESTCO, INC.

Docket No.(s) IA-95-055/150-00032-EA

## CERTIFICATE OF SERVICE

I hereby certify that copies of the foregoing LB M&O (APPROVING SETTLEMENT) have been served upon the following persons by U.S. mail, first class, except as otherwise noted and in accordance with the requirements of 10 CFR Sec. 2.712.

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

Administrative Judge Charles N. Kelber Atomic Safety and Licensing Board Mail Stop T-3 F 23 U.S. Nuclear Regulatory Commission Washington, DC 20555

John T. Hull, Esq. Mitzi A. Young, Esq. Office of the General Counsel Mail Stop 0-15 B 18 U.S. Nuclear Regulatory Commission Washington, DC 20555

Dated at Rockville, Md. this 1 day of October 1996 Administrative Judge Charles Bechhoefer, Chairman Atomic Safety and Licensing Board Mail Stop T-3 F 23 U.S. Nuclear Regulatory Commission Washington, DC 20555

Administrative Judge Frank F. Hooper 26993 McLaughlin Boulevard Bonita Springs, FL 33923

James L. Shelton Pres. & Radiation Safety Officer Testco, Inc. P.O. Box 18511 Greensboro, NC 27417

Wens Office of the Secretary of the Commission

NUREG-0940, PART III



#### UNITED STATES NUCLEAR REGULATORY COMMISSION REGION 7.1

801 WARRENVI' LE ROAD LISLE, ILLINOIS 60532-4351

June 18, 1996

EA 96-041

Mr. Gene Bacon, Plant Manager The Dial Corporation 110 West First Street London, Ohio 43140

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY -\$2,500 (NRC INSPECTION REPORT NO. 999-90003/95025(DNMS))

Dear Mr. Balon:

This refers to the special safety inspection conducted from January 22 to February 21, 1996, to review the circumstances surrounding the loss of an NDC Systems Model No. 103 gauge containing radioactive material and possessed under an NRC General License. On November 3, 1995, The Dial Corporation (Dial) informed the NRC that the gauge was last seen during 1992 and only the detector panel (the non-radioactive portion) could be located in October 1995. The details of the incident are discussed in NRC Inspection Report No. 999-90003/95025(DNMS), dated March 12, 1996. By letter dated April 9, 1996, Dial responded to the apparent violation described in the inspection report and did not request a predecisional enforcement conference.

Based on the information developed during the inspection and the information that Dial provided in response to the inspection report, the NRC has determined that a significant violation of NRC requirements occurred. The violation involves the failure to properly transfer or dispose of generally licensed material in accordance with 10 CFR 31.5(c)(8) and is cited in the enclosed Notice of Violation and Proposed Imposition of Civil Penalty.

We recognize that, as noted above, on November 3, 1995, Dial informed the NRC that the source for a gauge was missing. However, you had not initiated action to locate the source associated with the detector panel. Further, it is not clear that absent our inquiry you would have notified us as required by 10 CFR 20.2201 and 10 CFR 31.5.

Incumbent upon each company possessing byproduct material is the responsibility to protect the public health and safety by ensuring that radioactive materials are controlled at all times. This violation is of significant regulatory concern because Dial does not know the circumstances surrounding the loss, the ultimate disposition of the material, or the possibility of any individual exposures to radiation. Furthermore, the failure to effectively control material is a significant safety concern because it can lead to the inadvertent release of radioactive material to the public domain. The violation represents a failure to control access to

I the gauge contained a nominal 200 millicurie (7.4 GBq) sealed source of Americium-241

The Dial Corporation

licensed materials for radiation purposes and 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 \$2,500 is considered for a Severity Level III violation. The NRC recognizes that application of the civil penalty assessment process would not result in a civil penalty in this case. Nevertheless, the NRC is exercising discretion in accordance with Section VII.A.1(g) of the Enforcement Policy and is proposing a civil penalty of \$2,500. Discretion is being exercised because licensed material was not controlled and is currently missing.

Therefore, to emphasize the need to strictly control licensed material. I have been authorized, after consultation with the Director, Office of Enforcement, and the Deputy Executive Director for Nuclear Materials Safety, Safeguards, and Operations Support, to issue the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice) in the base amount of \$2,500 for the Severity Level III violation.

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. 999-90003/95025 and a letter dated April 9, 1996, from Dial. Therefore, you are not required to provide any additional statement or explanation pursuant to 10 CFR 2.201 unless the description already provided does not accurately reflect your corrective actions or your position. You are required to respond to the proposed civil penalty pursuant to 10 CFR 2.205 and for that response, you should follow the directions 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). 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,

Hubert J. Miller ✤ Regional Administrator

Docket No. 999-90003 General License

Enclosure Notice or Violation and Proposed Imposition of Civil Penalty

#### NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY

The Dial Corporation London, Ohio

Docket No. 999-90003 General License EA 96-041

During an NRC inspection conducted from January 22 to February 21, 1996, a violation of NRC requirements was identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," NUREG-1600, the Nuclear Regulatory Commission proposes to impose a civil penalty pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (Act). 42 U.S.C. 2282, and 10 CFR 2.205. The particular violation and associated civil penalty is set forth below:

10 CFR 31.5(c)(8) requires, in part, that any person who acquires, receives, possesses, uses or transfers byproduct material in a device pursuant to a general license shall, except as provided in 10 CFR 31.5(c)(9), transfer or dispose of the device containing byproduct material only by transfer to persons holding a specific license pursuant to 10 CFR Parts 30 and 32 or from an Agreement State to receive the device.

Contrary to the above, during the approximate period 1992 to October 1995, the licensee disposed of an NDC Systems gauge containing an americium-241 sealed source of nominally 200 millicuries and this disposal was not made to a person holding a specific license pursuant to 10 CFR Parts 30 and 32 or from an Agreement State to receive the device and the exceptions in 10 CFR 31.5(c)(9) did not apply. (01013)

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

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. 999-90003/95025(DNMS) and a letter dated April, 1996, from The Dial Corporation (Licensee). However, you are required to submit a written statement or explanation pursuant to 10 CFR 2.201 if the description 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, NRC Region III, 801 Warrenville Road, Lisle, Illinois 60532-4351, within 30 days of the date of the letter transmitting this Notice of Violation. Under the authority of Section 182 of the Act, 42 U. S. Code 2232, the response shall be submitted under oath or affirmation.

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

2

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

In requesting mitigation of the proposed penalty, the factors addressed in Section VI.B.2 of 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, 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, 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. 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.

Dated at Lisle, Illinois this 18th day of June 1996



# UNITED STATES NUCLEAR REGULATORY COMMISSION

VASHINGTON, D.C. 20555-0001

October 31, 1996

EA 96-041

Mr. Gene Bacon Plant Manager The Dial Corporation 110 West First Street London, Ohio 43140

SUBJECT: ORDER IMPOSING CIVIL MONETARY PENALTY - \$2,500 (NRC Inspection Report No. 999-90003/95025(DNMS))

Dear Mr. Bacon:

This refers to letters from The Dial Corporation (Dial) dated July 16, 1996, in response to the Notice of Violation and Proposed Imposition of Civil Penalty (Notice) sent to you by our letter dated June 18, 1996. It also refers to an April 9, 1996 letter from Dial in response to the inspection report which was forwarded to Dial on March 12, 1996. Our letters and Notice described a violation' identified during a special safety inspection conducted from January 22 to February 21, 1996.

To emphasize the need to strictly control licensed material, a civil penalty of \$2,500 was proposed.

In your April 9, 1996 response, Dial admits the violation. In the letters of July 16, 1996, Dial alleged errors in the NRC cover letter for the Notice as to its efforts to locate the source and reporting its loss and requested mitigation of the proposed civil penalty. Dial's reasons for requesting mitigation of the civil penalty are that Dial began an immediate search for the source and notified the NRC once it became known to Dial that the source was missing. Dial contended that there were extenuating and special circumstances associated with the loss of the americium-241 source that the NRC should consider, that a civil penalty would have no deterrent effect, and the NRC enforcement program and goals would not be served by imposing a penalty. Dial claimed it was unaware of the existence of the generally licensed device from the time that Dial purchased the facility in 1985 until the loss of the source was discovered in October 1995. Dial also suggested that if the NRC must impose a civil penalty, \$730 was a reasonable amount based on estimated disposal costs.

After consideration of your responses, we have concluded, for the reasons given in the Appendix attached to the enclosed Order Imposing Civil Monetary Penalty that the civil penalty assessment is warranted. The NRC recognizes that the civil penalty assessment would ordinarily result in no civil penalty in this case; however, the NRC is exercising discretion to impose a base civil

<sup>&#</sup>x27; The improper disposal or transfer of a nominal 200 millicurie (7.4 GBq) americium-241 source.

The Dial Corporation

- 2 -

penalty in accordance with the Enforcement Policy. This exercise of discretion reflects the NRC's added concern for the potential safety consequences associated with the type of radioactive material that Dial failed to control and which may exist in the public domain.

Historically, uncontrolled radioactive material has resulted in radiation exposure to members of the general public, contamination in scrap yards and foundries as a result of smelting activities, and environmental contamination. In order to emphasize the importance of adequate oversight and control of radioactive material, we hereby serve the enclosed Order on The Dial Corporation imposing a civil monetary penalty in the amount of \$2,500. As provided in Section IV of the enclosed Order, payment should be made within 30 days of the date of this Order, by check, draft, money order, or electronic transfer, payable to the Treasurer of the United States and mailed to Mr. James Lieberman, Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, One White Flint North, 11555 Rockville Pike, Rockville, MD 20852-2738.

We note that the Dial facility at London, Ohio, no longer possesses NRClicensed material. Furthermore, the July 16, 1996, "Answer to a Notice of Violation" from Dial states that Dial does not plan to obtain any NRC-licensed material in the future. Therefore, we do not have any questions regarding your corrective actions to these concerns.

Should you have any questions concerning this matter, please contact me at (301) 415-2741.

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

Sincerely.

lan - hich

James Lieberman, Director Office of Enforcement

Docket No. 999-90003 General License

Enclosure: As Stated

cc w/encl: William A. Arbitman Associate General Counsel The Dial Corporation

## UNITED STATES NUCLEAR REGULATORY COMMISSION

In the Matter of

THE DIAL CORPORATION London, Ohio

Docket No. 999-90003 General License London Ohio EA 96-041

## ORDER IMPOSING CIVIL MONETARY PENALTY

The Dial Corporation (Licensee) was authorized to use licensed materials by the Nuclear Regulatory Commission (NRC or Commission) pursuant to the general license provisions in 10 CFR Part 31. The Licensee possessed and used generally licensed industrial gauging devices containing nuclear materials, principally strontium-90 and americium-241.

II

An inspection of the Licensee's activities was conducted from January 22 to February 21, 1996. The results of this inspection indicated that the Licensee had not conducted its activities in full compliance with NRC requirements. The inspection report was sent to Dial by letter dated March 12, 1996, and by letter, dated April 9, 1996, Dial responded to the apparent violation described in the inspection report. A written Notice of Violation and Proposed Imposition of Civil Penalty (Notice) was served upon the Licensee by letter dated June 18, 1996. The Notice states the nature of the violation, the provision of the NRC's requirements that the Licensee had violated, and the amount of the civil penalty proposed for the violation.

In its April 9, 1996 response to the inspection report, Dial admitted the violation had occurred. The Licensee responded to the Notice in a Reply to a

Notice of Violation and an Answer to a Notice of Violation, both dated July 16, 1996. In the July 16, 1996 letters, the Licensee requested mitigation of the proposed civil penalty and alleged that the cover letter for the Notice was incorrect as to the Licensee's efforts to locate the source and report its loss. The NRC's responses to those allegations are contained in the Appendix to this Order.

- 2 -

## III

Historically, uncontrolled radioactive material has resulted in radiation exposure to members of the general public, contamination in scrap yards and foundries as a result of smelting activities, and environmental contamination. In order to emphasize the importance of adequate oversight and control of radioactive material, and 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 penalty proposed for the violation designated in the Notice should be imposed.

IV

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

The Licensee pay a civil penalty in the amount of \$2,500 within 30 days of the date of this Order, by check, draft, money order, or electronic transfer, payable to the Treasurer of the United States and mailed to Mr. James Lieberman, Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, One White Flint North, 11555 Rockville Pike, Rockville, MD 20852-2738.

- 3 -

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, D.C. 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 addressed to the Director, Office of Enforcement, U.S. Nur'ear Regulatory Commission Washington, D.C. 20555, with a copy to the Commission's Document Control Desk, Washington, D.C. 20555. Copies also shall be sent to the Assistant General Counsel for Hearings and Enforcement at the same address and to the Regional Administrator, NRC Region III, 801 Warrenville Road, Lisle, IL 60532-4351.

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.

- 4 -

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

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

FOR THE NUCLEAR REGULATORY COMMISSION

Dames Lieberman, Director Office of Enforcement

Dated at Rockville, Maryland this 31st day of October 1996

#### APPENDIX

#### EVALUATION AND CONCLUSION

On June 18, 1996, a Notice of Violation and Proposed Imposition of Civil Penalty (Notice) was issued for a violation identified during an NRC inspection. The Dial Corporation (Licensee) responded to the inspection findings in a letter dated April 9, 1996. (The inspection report was mailed to the Licensee on March 12, 1996.) The Licensee replied to the Notice on July 16, 1996. In its April 9, 1996 letter, the Licensee admitted the violation. In the July 16, 1996 correspondence, the Licensee requested that the civil penalty be fully mitigated or reduced to \$730. The NRC's evaluation and conclusion regarding the licensee's requests are as follows:

#### Restatement of Violation

10 CFR 31.5(c)(8) requires, in part, that any person who acquires, receives, possesses, uses or transfers byproduct material in a device pursuant to a general license shall, except as provided in 10 CFR 31.5(c)(9), transfer or dispose of the device containing byproduct material only by transfer to persons holding a specific license pursuant to 10 CFR Parts 30 and 32 or from an Agreement State to receive the device.

Contrary to the above, during the approximate period 1992 to October 1995, the licensee disposed of an NDC Systems gauge containing an americium-241 sealed source of nominally 200 millicuries and this disposal was not made to a person holding a specific license pursuant to 10 CFR Parts 30 and 32 or from an Agreement State to receive the device and the exceptions in 10 CFR 31.5(c)(9) did not apply. (01013)

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

NRC Evaluation of Licensee's Letter Dated July 16, 1996, "Reply to a Notice of Violation"

As discussed in the NRC's June 18, 1996 letter transmitting the Notice, the NRC informed the Licensee that the application of the civil penalty assessment process resulted in no monetary penalty being assessed. That letter also informed the Licensee that notwithstanding the civil penalty assessment process, a penalty was proposed under the enforcement discretion provisions in Section VII.A.1(g) of the NRC Enforcement Policy. This discretionary factor permits the proposal of a civil penalty when NRC-licensed material is lost, unless the licensee identifies and reports the loss to the NRC. The June 18, 1996 letter also indicated that discretion was being exercised because licensed material was not controlled and was currently missing.

In its July 16, 1996 letter, "Reply to a Notice of Violation," the Licensee indicates that it found part of the gauging device on October 25, 1995, initiated a prompt search for the americium-241 source on that same day, and reported the loss to the NRC on November 3, 1995 during a discussion with an NRC Inspector. However, during a November 2, 1995 discussion between the Licensee's Materiais Manager and the NRC Inspector, the NRC was not informed Appendix

that the Licensee had discovered the loss on October 25, 1995. Furthermore, during a November 3, 1995 discussion, it was only as the result of a direct question from the NRC Inspector about other NRC-licensed materials in the possession of the Licensee that the Materials Manager told the Inspector that the americium-241 source was missing. Since the inspector was not specifically informed that Dial had discovered the loss on October 25, 1995, the Inspector concluded that Dial had discovered the loss on November 3, 1995.

- 2 -

As to reporting, the Licensee contends that a report was made within the 30 day period permitted by 10 CFR 20.2201(a)(ii). However, 10 CFR 20.2201(a)(ii) is not the applicable requirement. Rather, 10 CFR 20.2201(a)(i) is applicable and requires that a licensee must <u>immediately</u> notify the NRC of any stolen, lost or missing material in a quantity of 1,000 times the limit specified in 10 CFR Part 20, Appendix C. The limit specified by 10 CFR Part 20, Appendix C, for americium-241 is 0.001 microcuries. In this case, the missing americium-241 source was nominally 200 millicuries which greatly exceeds the requirement for making an immediate report to the NRC. Therefore, the Licensee was required to notify the NRC <u>immediately</u> upon discovery that the americium-241 source was missing.

In view of this, the NRC staff has reconsidered the application of discretion under the enforcement discretion provisions in Section VII.A.1(g) of the NRC Enforcement Policy (NUREG-1600). Although not properly reported as required, the licensee did inform the NRC of the loss. Nonetheless, this case is particularly significant. The Licensee admits that a nominal 200 millicurie americium-241 source is missing from its London, Ohio facility. The Licensee does not know the circumstances of the loss, the ultimate disposition of the material, or the possibility of any individual exposures to radiation. With the source and its probe intact and the source shutter closed, the likelihood of significant radiation exposure to Dial staff or to members of the public is minimal. However, if the source is ruptured, or otherwise not intact, (e.g., the probe is shredded cr meited down with scrap materials) significant facility and environmental contamination may occur with resultant internal and external personnel radiation exposure. As a member of the group of transuranic elements, with alpha particle emissions, a physical half life of 458 years and an effective half-life in bone of about 140 years, unsealed and uncontrolled americium-241 is a significant internal radiation exposure hazard. Moreover, the fundamental cause of this incident was that the licensee possessed radioactive material and was not aware of it and did not control it.

In the view of the NRC staff, it is important to provide a strong message to licensees that it is not acceptable to possess radioactive material without appropriate controls. Given the quantity of licensed material that was lost, a civil penalty is warranted. Accordingly, pursuant to Section VII.A.1. of the Enforcement Policy, the NRC is exercising discretion by assessing a civil penalty to reflect the significance of not maintaining awareness of possession and not controlling the material.

## Summary of Licensee's Request for Mitigation

The Dial Corporation (Dial) requests that the proposed civil penalty be mitigated for extenuating circumstances and as a Violation Involving Special Circumstances under NUREG-1600, Section VII.B.6. Dial indicates in its July 16, 1996, "Answer to a Notice of Violation," that the loss of the source was an inadvertent, one-time occurrence, that the loss occurred as long ago as 1992, and the loss was of limited safety significance.

Dial also contends that it was unaware of the presence of the device from the time of the asset transfer (from Purex) which occurred in 1985 until the October 25, 1995 call from OSHA. Therefore, it could not be expected to have prevented the violation.

Dial contends further that since it has no intention of possessing any licensed material in the future, a civil penalty can have no deterrent effect, and that the NRC enforcement program or goals are not served by imposing a penalty.

Finally, Dial took exception to the amount of the proposed civil penalty, contending that the amount of the penalty exceeded the \$730 that Dial estimated would be the cost to dispose of an americium-241 source.

## NRC Evaluation of Licensee's Request for Mitigation

The NRC has reviewed the Licensee's request to mitigate the civil penalty pursuant to Section VII.B.6 of NUREG-1600, "Violations Involving Special Circumstances." As previously noted, the loss of the americium-241 source has potential radiation safety consequences for Dial employees and the general public. The NRC has not identified any other extenuating or special circumstances in the NRC Enforcement Policy or in Dial's response that warrants mitigation of the civil penalty.

The Licensee contends that from the time the London, Ohio, facility was purchased in 1985 from The Purex Corporation, it was unaware that it possessed licensed material until it was contacted by the Occupational Safety and Health Administration (OSHA), on October 25, 1995, and could not have been reasonably expected to prevent the violation. This contention is not supported by the evidence. On May 21, 1991, NDC Systems, the manufacturer of the americium-241 gauge, repaired the device and on May 24, 1991, returned it to Dial at the London, Ohio, facility. Furthermore, NDC analyzed a leak test sample from the americium-241 source and provided Dial with a Leak Test Certificate, dated October 10, 1991. Therefore, it is reasonable to conclude that Dial was or should have been aware of the americium-241 gauge before OSHA contacted the London, Ohio, facility about radioactive materials on October 25, 1995.

The NRC disagrees with the Licensee's contention that a civil penalty can have no deterrent effect and that the NRC's enforcement program and goals are not served by imposing a civil penalty. A civil penalty imposed for lost or missing radioactive sources emphasizes the importance the NRC places on the control of licensed material. It encourages compliance in all licensees in a manner that deters future violations.

The Licensee stated that if a civil penalty must be imposed, a civil penalty of \$730 would be realistic because it is the amount that Dial estimates it would cost for proper disposal of the americium-241 source. The Licensee based its estimate of \$730 for disposal on the cost of disposing of two, nominally 25 millicurie (925 MBq) sources of strontium-90. The Licensee did not consider the added cost for disposing of a transuranic (americium-241). The staff contacted both the device manufacturer and an NRC-licensed waste disposal broker. The manufacturer indicated that it would cost about \$500 to have a device containing americium-241 returned for refurbishment. The waste broker estimated that it would cost approximately \$5,000 to take the americium-241 source for disposal. Consideration was therefore given to increasing the civil penalty to reflect the cost of disposal. However, in consideration of your intent not to possess radioactive material in the future, the civil penalty was not increased.

## NRC Conclusion

The NRC has concluded that this violation occurred as stated and has potential safety consequences. Consequently, the proposed civil penalty in the amount of \$2,500 should be imposed. The NRC has also reconsidered the application of the enforcement discretion provisions in Section VII.A.1.(g) of the NRC Enforcement Policy. A \$2,500 civil penalty is in accordance with the discretion authorized in Section VII.A.1. of the NRC Enforcement Policy.



# UNITED STATES

REGIONIV

611 RYAN PLAZA DRIVE, SUITE 400 ARLINGTON, TEXAS 76011-8064

June 17, 1996

EA 96-049

Joseph J. Ferretti, Ph.D. Senior Vice President and Provost University of Oklahoma Health Sciences Center P.O. Box 26901 Oklahoma City, Oklahoma 73190

SUBJECT: NOTICE OF VIOLATION & PROPOSED IMPOSITION OF \$2,500 CIVIL PENALTY (NRC Inspection Report No. 030-12750/95-01 and Investigation Report No. 4-95-057)

Dear Dr. Ferretti:

This is in reference to the University of Oklahoma's May 13, 1996 written response to an apparent violation identified in the NRC's April 9, 1996 letter and enclosed inspection report. As stated in the NRC's April 9 letter, the inspection and a subsequent investigation identified an apparent violation involving a failure to secure licensed radioactive material in the public domain. Specifically, on September 26, 1995, an NRC inspector observed a driver employed by the University of Oklahoma leave radiopharmaceuticals unattended in an unlocked vehicle during a delivery to Mercy Health Center. This incident was brought to the attention of the university by the NRC on the same date.

In your reply to the apparent violation, you did not deny that a violation had occurred, described the reasons for the violation from the university's perspective, and described your corrective actions. Your corrective actions consisted of: issuing verbal and written reprimands to the driver, instructing all delivery personnel in the requirements and methods to secure material, establishing a requirement to prevent the dispatch of a delivery vehicle lacking proper security, establishing a schedule of disciplinary actions for violations of security requirements, and notifying all radioactive materials users through a campus safety newsletter of the significance of failing to secure radioactive material that is left unattended in an area where members of the public have access. The director of the nuclear pharmacy also informed all delivery personnel that customer service, although important, is subordinate to the requirement to comply with all NRC requirements and the conditions of the license.

Based on the information developed during the inspection and investigation and the information that you provided in your response to the inspection report, the NRC has determined that the September 26, 1995 incident did violate NRC requirements. The violation is cited in the enclosed Notice of Violation and Proposed Imposition of Civil Penalty; the circumstances surrounding it were described in detail in the subject inspection report. Although the incident in question resulted in material being left unattended for only a brief period of time, the NRC's inspection and investigation found that the involved driver made a decision to leave the material unattended despite being aware of requirements to secure such material, and that he left material unattended on other occasions, including deliveries performed earlier on the same day. As an NRC licensee, you are responsible for ensuring that licensed material is protected from loss into the public domain, where it could be subject to theft or tampering. 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.

-2-

In accordance with Section VI.B.2 of the Enforcement Policy, a civil penalty is considered for a Severity Level III violation. The base value for such a penalty in this case is \$2,500. Because this violation was found by the NRC to have been committed willfully, the NRC considered whether credit was warranted for *Identification* and *Corrective Action* in accordance with the civil penalty assessment process in the Enforcement Policy. As discussed at a sviolation was discovered by an NRC inspector; thus, credit for contification is not warranted. Based on the corrective actions that you described in your letter, which are summarized above, credit for corrective actions is warranted. This results in the assessment of a penalty at the base value.

Therefore, to emphasize the significance of failing to secure radioactive material left unattended in the public domain, as well as the importance of identifying such problems, and to further emphasize the importance of ensuring that your employees are complying with all NRC requirements, I have been authorized, after consultation with the Director, Office of Enforcement, to issue the enclosed Notice of Violation and Proposed Imposition of Civil Penal\*y (Notice) in the base amount of \$2,500 for the Severity Level III violation discussed above. Based on the disciplinary actions you have already taken against the driver who caused this violation, the NRC is not pursuing enforcement action against him.

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

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter, its enclosure, and your response will be placed in the NRC Public Document Room (PDR). To the extent possible, your response should not include

University of Oklahoma

any personal privacy, proprietary, or safeguards information so that it can be placed in the PDR without redaction.

-3-

Sincerely,

L. J. Callan Regional Administrator

Docket No.030-12750 License No. 35-03176-04MD

Enclosure: Notice of Violation and Proposed Imposition of Civil Penalty

cc w/Enclosure: State of Oklahoma

#### NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY

University of Oklahoma Health Sciences Center Docket No. 030-12750 Oklahoma City, Oklahoma

License No. 35-03176-04MD EA 96-049

During an NRC inspection and investigation conducted September 25, 1995 to February 28, 1996, a violation of NRC requirements was identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," NUREG-1600, the Nuclear Regulatory Commission proposes to impose a civil penalty pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (Act), 42 U.S.C. 2282, and 10 CFR 2.205. The particular violation and associated civil penalty are set forth below:

10 CFR 20.1801 requires, in part, that the licensee secure from unauthorized removal 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. An unrestricted area means an area to which access is neither limited nor controlled by the licensee.

Contrary to the above, on September 26, 1995, a licensee employee did not secure from unauthorized removal or maintain constant surveillance of licensed material, i.e., radiopharmaceuticals, that was in an unrestricted area. Specifically, an NRC inspector observed a driver employed by the University of Oklahoma leave radiopharmaceuticals unattended in an unlocked vehicle during a delivery to Mercy Health Center, Oklahoma City. (01013)

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

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

Notice of Violation

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

In requesting mitigation of the proposed penalty, the factors addressed in Section VI.B.2 of 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, 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, ATTN: Enforcement Officer, 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. 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.

Dated at Arlington, Texas, this 17th day of June 1996

NUREG-0940, PART III

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

2



UNITED STATES NUCLEAR REGULATORY COMMISSION REGION I

475 ALLENDALE ROAD KING OF PRUSSIA, PENNSYLVANIA 19406-1415

July 12, 1996

EA 96-186

Gary Candia, Ph.D. Vice President of Professional Services and Quality Assurance Abington Memorial Hospital 1200 Old York Road Abington, Pennsylvania 19001

SUBJECT: NOTICE OF VIOLATION (NRC INSPECTION REPORT NO. 030-02948/96-001)

Dear Dr. Candia:

This letter refers to the NRC inspection conducted on May 15-16, 1996, at your facility in Abington, Pennsylvania. The purpose of this inspection was to determine whether activities authorized by your license were conducted safely and in accordance with NRC requirements, and to review the circumstances surrounding an incident in which a brachytherapy sealed source was found by your staff lying on the floor of your radiation waste storage area (a restricted area) on May 13, 1996. At the conclusion of the inspection, the findings were discussed with you and other members of your staff. During the inspection, two apparent violations of NRC requirements were identified, as described in the NRC inspection report, a copy of which was sent to you on June 18, 1996. On July 10, 1996, a predecisional enforcement conference was conducted with you and other members of your staff to discuss the apparent violations, their causes, and your corrective actions. A copy of the Enforcement Conference Report is enclosed.

Based on the information developed during the inspection, information provided in a letter dated June 13, 1996, from your Radiation Safety Officer (RSO), and information provided during the conference, one violation of NRC requirements is being cited in the enclosed Notice of Violation (Notice), and the circumstances surrounding it are described in detail in the subject inspection report. The violation described in the enclosed Notice involves the failure to conduct, for a period of time (possibly up to 20 years), a quarterly physical inventory of a particular brachytherapy source in your possession. NRC regulations require that a licensee in possession of brachytherapy sources conduct a quarterly physical inventory of all such sources in its possession.

The NRC is concerned that your inventory procedure did not account for a brachytherapy source which contained 16.75 millicuries of cesium-137. The source had been purchased in 1976 according to records obtained after discovery of the source on the floor of your waste storage area. Your records of quarterly inventories performed from the date of purchase of the source until May 13, 1996, when the source was discovered, did not include this particular source. In addition, the exact location of the source from 1976 until 1996 was not known with certainty. The NRC also is concerned because this event had the potential to cause exposure to patients, staff and the public. As such, given the number

Abington Memorial Hospital

of years that the source was excluded from your inventories, this violation constitutes a significant regulatory concern and is categorized at Severity Level III in accordance with the "General Statement of Policy and Procedures for NRC Enforcement Actions," (Enforcement Policy) NUREG-1600. The violation demonstrates the importance of increased attention to this aspect of your radiation safety program to ensure that regulatory requirements are understood and followed, and your activities are conducted safely and in accordance with those requirements.

In accordance with the Enforment Policy, a base civil penalty in the amount of \$2,500 is considered for the Severity Level III violation. Because your facility has not been the ject of escalated enforcement in the past 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 was warranted because your corrective actions were considered both prompt and comprehensive in response to the discovery of the source in the waste storage area, as well as in response to the inspection findings. Your corrective actions, which were described in your presentation during the conference, included, but were not limited to: (1) performing a complete inventory of all brachytherapy sources in your possession; (2) color coding all brachytherapy sources in your possession; (3) obtaining source certificates for all brachytherapy sources in your possession; and (4) creating a "Code of Ethics" for the RSO and physicist which requires the RSO and physicist, upon terminating their employment with Abington Memorial Hospital, to turn over all required documentation to the hospital in order to assure that required documentation such as source certificates and inventories are retained by the hospital.

Therefore, to encourage prompt and comprehensive correction of violations, and in recognition of the absence of previous escalated enforcement action at your facility, I have been authorized not to propose a civil penalty in this case. However, any similar violations in the future could result in more significant escalated enforcement action, including issuance of a civil penalty.

The apparent violation concerning the failure to secure the source, is not being cited because the facts do not support a violation of a regulatory requirement. At the conference, you indicated that the waste disposal room, where the source was located, was secured by two doors that were locked and under your control.

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

### Abington Memorial Hospital

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter, its enclosure, and any additional 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. If redactions are required, a proprietary version containing brackets placed around the proprietary, privacy, and/or safeguards information should be submitted. In addition, a nonproprietary version with the information in the brackets redacted should be submitted to be placed in the PDR.

3

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

Sincerely,

Thomas T. Martin Regional Administrator

Docket No. 030-02948 License No. 37-00432-02

Enclosures: 1. Notice of Violation 2. Enforcement Conference Report

cc w/encls: Ramanik Patel, Radiation Safety Officer Commonwealth of Pennsylvania

NUREG-0940, PART III

## ENCLOSURE 1

#### NOTICE OF VIOLATION

Abington Memorial Hospital Abington, Pennsylvania Docket No. 030-02948 License No. 37-00432-02 EA 96-186

During an NRC inspection conducted on May 15-16, 1996, 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 35.59(g) requires, in part, that a licensee in possession of a sealed source or brachytherapy source shall conduct a quarterly physical inventory of all such sources in its possession.

Contrary to the above, from 1976 until May 13, 1996, the licensee did not conduct a quarterly physical inventory of a specific brachytherapy source in its possession. Specifically, the licensee did not account for a 16.75 millicurie cesium-137 brachytherapy source, 3M Serial No. 10-135, in its quarterly physical inventories. (01013)

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

Pursuant to the provisions of 10 CFR 2.201, Abington Memorial Hospital is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555, with a copy to the Regional Administrator, Region I, within 30 days of the date of the letter transmitting this Notice of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each violation: (1) the reason for the violation, or, if contested, the basis for disputing the violation, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken to avoid further violations, and (4) the date when full compliance will be achieved. 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 Demand for Information may be issued as to why the license should not be modified, suspended, or revoked, or why such other action as may be proper should not be taken. Where good cause is shown, consideration will be given to extending the response time.

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

# Enclosure 1

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.

Dated at King of Prussia, Pennsylvania this 12th day of July 1996



UNITED STATES NUCLEAR REGULATORY COMMISSION REGION II 101 MARIETTA STREET, N.W., SUITE 2900 ATLANTA, GEORGIA 30323-0199

October 2. 1996

EA 96-314

Anderson Columbia Construction. Inc. ATTN: Mr. T. H. McRae President Post Office Box 1386 Lake City. Florida 32056-1386

SUBJECT: NOTICE OF VIOLATION (NRC Inspection Report No. 999-90002/96-04)

Dear Mr. McRae:

This refers to the inspection conducted on August 8, 1996, at Plant No. 5 in Bagdad. Florida. The purpose of the inspection was to review the facts and circumstances surrounding your use of byproduct material at Eglin Air Force Base. Florida without an NRC license. The results of the inspection were formally transmitted to you by letter dated September 4, 1996. That letter also provided you the opportunity to respond to the apparent violation or request a predecisional enforcement conference. In letters dated September 6 and 10, 1996, you declined to participate in a predecisional enforcement conference. admitted the apparent violation, and submitted a response to the NRC which included an explanation of the root cause of the apparent violation and your corrective actions to preclude recurrence, as requested in our letter dated September 4, 1996. 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 written 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 involved Anderson Columbia Construction. Inc.'s use of a moisture density gauge at locations within NRC's jurisdiction without first obtaining a specific or general NRC license. in accordance with 10 CFR 30.3. Specifically, in June 1996, you took possession of a moisture density gauge from Okaloosa Asphalt. Inc. and used it to perform testing activities at the Eglin Air Force Base in areas of exclusive Federal jurisdiction. At the time you possessed and used the gauge, you did not possess an NRC specific or general license. In addition, although not directly related to the violation, you also did not possess a radioactive materials license from the State of Florida at the time you performed the work at Eglin Air Force Base; however. the individual who used the gauge was appropriately trained and appeared to have conducted the operations safely. The NRC has concluded that based on the information available the failure to obtain the appropriate license was not intentional on the part of Anderson Columbia Construction. Inc., and your staff was unaware of the licensing requirements in this regard.

Anderson Columbia Construction. Inc.

11

2

This violation is of significant regulatory concern because it denied the NRC an opportunity to inspect Anderson Columbia Constructions. Inc.'s use of byproduct material in areas of exclusive Federal jurisdiction. thereby impeding the NRC's ability to perform its statutory responsibility of verifying that by-product material is used in accordance with NRC requirements. The NRC relies on licensees and their employees to fully understand and comply with NRC requirements prior to performing licensed activities. Therefore, this violation is classified in accordance with the "General Statement of Policy and Procedures 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 \$2,500 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. In your September 6, 1996, response, you stated that your corrective actions included: (1) application for and receipt of a State of Florida Radioactive Materials license (No. 2708-1); (2) submission of a request for the appropriate forms to apply for NRC reciprocity in the State of Florida from NRC Region II; (3) informing all management and supervisory personnel within Anderson Columbia Construction. Inc. of the violation and the proper steps to avoid recurrence: and (4) directing your Radiation Safety Officer (RSO) to contact the appropriate Federal RSO in the event that future work is performed on a military base or other Federal property. In addition, on September 9, 1996, you filed the appropriate forms with the NRC and paid the fee for conducting further licensed activities in areas of exclusive Federal jurisdiction. Based on the above, the NRC determined that your corrective actions were prompt and comprehensive, and credit was warranted for this factor.

Therefore. to encourage prompt and comprehensive correction of violations. I have been authorized, after consultation with the Office of Enforcement, not to propose a civil penalty in this case. Notwithstanding this decision, we would expect that, in the future. Anderson Columbia Construction, Inc. would obtain written assessments from, or document assessments by. Federal authorities as to whether a proposed work site is in an area of exclusive Federal jurisdiction. Absent such documentation showing that Federal authorities assessed the work site as not being in an area of exclusive Federal jurisdiction, additional enforcement action including assessment of a civil penalty may be taken for failure to seek the required authorization to perform licensed activities in areas of exclusive Federal jurisdiction.

Please note that the violation described in the enclosed Notice does not address work performed at Hurlburt Field. Inclusion of this worksite as part of the apparent violation described in our September 4. 1996. Letter to you was in error. Particularly, you did not perform licensed activities at the facility, and Hurlburt Field is not an area of exclusive Federal jurisdiction.

The NRC has concluded that information regarding the reason for the violation. the corrective actions taken and planned to correct the violation and prevent

Anderson Columbia Construction. Inc.

recurrence, and the date when full compliance was achieved is already adequately addressed on the docket in your letter dated September 6, 1996. 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 any response you may choose to provide will be placed in the NRC Public Document Room (PDR).

Sincerely.

linte awar Stewart D. Ebneter Regional Administrator

Docket No. 999-90002

Enclosure: Notice of Violation

cc w/encl: State of Florida

B-8

Anderson Columbia Construction. Inc. Lake City, Florida Docket No. 999-90002 EA 96-314

During an NRC inspection conducted on August 8. 1996. 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 30.3 requires, in relevant part, that no person shall possess or use by-product material except as authorized by a specific or general license issued by the NRC.

Contrary to the above, between June 17 and 29. 1996. Anderson Columbia Construction. Inc., used millicurie quantities of Cesium-137 and Americium-241 to perform moisture density activities at Eglin Air Force Base. Florida in areas of exclusive Federal jurisdiction, without either a specific or general license issued by the NRC. (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 your letter dated September 6, 1996. 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, 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.

Dated at Atlanta, Georgia this 2nd day of October 1996



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

November 7, 1996

EA 96-247

David J. Moylan, III, M.D. Medical Director and Radiation Safety Officer EquiMed, Inc. 800 Mahoning Street, Suite E Lehighton, Pennsylvania 18235

# SUBJECT: NOTICE OF VIOLATION (NRC Inspection Report No. 030-33333/96-001)

Dear Dr. Moylan:

This letter refers to the NRC inspection conducted on June 24 and 25, 1996, at your facility in Lehighton, Pennsylvania, and to an exit meeting conducted by telephone, with you on September 23, 1998. The inspection was conducted to determine whether activities authorized by the license were conducted safely and in accordance with NRC requirements. During the inspection, apparent violations of NRC requirements were identified, and were described in the NRC inspection report transmitted with our letter dated September 27, 1998.

In the September 27, 1996 letter, the NRC provided you with an opportunity to either respond in writing to the apparent violations addressed in the inspection report or request a predecisional enforcement conference, within 21 days of the letter. You responded to the apparent violations in a letter to the NRC dated October 11, 1996.

Based on the information developed during the inspection and the information you provided in your October 11, 1996 response, the NRC has determined that violations of NRC requirements occurred. These violations are cited in the enclosed Notice of Violation (Notice) and circumstances surrounding them are described in detail in the subject inspection report. The first violation involves your failure to follow your Quality Management Program (QMP) which caused two patient misadministrations to occur. The misadministrations occurred on December 31, 1995 while two patients were being treated using the High Dose Hate Remote Afterloader (HDR). Prior to the treatments, the transfer of data from the treatment planning computer had not been adequately checked by the person entering the data into the control not been adequately checked by the person entering the data. As a result, an error in the data entry for source positions had not been identified. You concluded that each patient received 312 rads, instead of the prescribed dose of 500 rads and a mean dose to an additional 5 centimeters length (that was not intended to be treated) was 312 rads.

Given that this violation of your QMP Program contributed to two therapeutic misadministrations, this violation has been categorized at Severity Level III in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions" (Enforcement Policy), NUREG-1600.

#### EquiMed, Inc.

In accordance with the Enforcement Policy, a base civil penalty in the amount of \$2,500 is considered for a Severity Level III violation. Because EquiMed, Inc. 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 action is warranted because your actions were both prompt and comprehensive. These actions, which were noted in your October 11, 1996 letter included, but were not limited to: (1) initiating a new requirement for all HDR treatments requiring the authorized user and authorized physicist to remove the pre-treatment print-out from the treatment console, review the parameters input to the computer, and initial the print-out before initiating the treatment; and (2) reviewing the OMP in detail to identify other potential weaknesses in the program. The OMP will be rewritten, after the review is completed, to conform to current standards and to incorporate the necessary changes identified in the review.

Therefore, to emphasize prompt identification and comprehensive correction of violations when they exist, 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.

The second violation involves your failure to notify the NRC no later than the next working day after the discovery of the misadministrations, and to submit a written report to the NRC and the patient within 15 days after discovery of the misadministrations. These misadministrations were both discovered on January 5, 1996. You did not notify the NRC until July 3, 1996, of either misadministration. In addition, the written report was not submitted until July 12, 1996. While this violation has been categorized in accordance with the Enforcement Policy at Severity Level IV, the NRC is concerned that it did not become aware of the misadministrations until the June inspection because of your failure to report the misadministration as required. Any similar violations of reporting requirements in the future could result in escalated enforcement action.

The NRC has concluded that the information regarding the reason for the violation, the corrective actions taken and planned to correct the violation and prevent recurrence, and the date of compliance are already addressed adequately on the docket in Inspection Report 030-33333/96-001, dated September 27, 1996, and your letters dated July 12, 1996, and October 11, 1996. 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, 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. 20556 with a copy to the Regional Administrator, Region I, within 30 days of the date of the letter transmitting this Notice. EquiMed, Inc.

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

Sincerely,

Muller

Hubert J. Miller Regional Administrator

Docket No. 030-33333 License No. 37-30086-01

Enclosure: Notice of Violation

cc w/encl: Commonwealth of Pennsylvania

## ENCLOSURE

## NOTICE OF VIOLATION

EquiMed, Incorporated Lehighton, Pennsylvania Docket No. 030-33333 License No. 37-30086-01 EA 96-247

During an NRC inspection conducted on June 24 and 25, 1996, 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 35.32(a) requires, in part, that the licensee establish and maintain a written quality management program to provide high confidence that byproduct material or radiation from byproduct material will be administered as directed by the authorized user.

The licensee's Quality Management Program (QMP) for the administration of high dose rate (HDR) brachytherapy was submitted to NRC by a letter dated

September 15, 1994, and requires, in part, that prior to treating the patient with the HDR, the transfer of data from the treatment planning computer (e.g., channel number, source positions, and treatment times) be checked by the parson entering the data in the control console, and verified by the authorized user.

Contrary to the above, on December 31, 1995, prior to the HDR treatment of two patients, the transfer of data from the treatment planning computer (i.e., channel number, source positions, and treatment times) was not adequately checked by the person entering the data in the control console and verified by the authorizer user. Specifically, the check did not identify an error in the data entry for source positions, in that, the stepping distance entered was 10 millimeters instead of the computer generated stepping distance of 5 millimeters. Consequently, two patients were administered 312 rads to 5 additional centimeters of tissue which was not prescribed to receive such a dose. (01013)

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

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 the misadministration. 10 CFR 35.33(a)(2) and (a)(4) require, in part, that a written report be submitted to the NRC and to the patient within 15 days after discovery of the misadministration.

Contrary the above, although the two misadministrations occurred on December 31, 1995, the licensee did not notify, by telephone, the NRC Operations Center by the next working day after the discovery of the misadministrations and did not submit a written report to the NRC and to the patient, within 15 days after discovery of the misadministrations. Specifically, the misadministrations were discovered on January 5, 1996, and the telephone notification to the NRC Operations Center was not made until July 3, 1996, and the required, written report was not submitted until July 12, 1996. (02014)

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

## Enclosure

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 was adequately addressed in your letters dated July 12, 1996, and October 11, 1996. 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, D.C. 20555 with a copy to the Regional Administrator, Region I, within 30 days of the date of the letter transmitting this Notice of Violation (Notice).

Dated at King of Prussia, Pennsylvania this 7thday of November 1996 September 3, 1996

EA 96-254

Mr. Jim Anderson Vice President of Operations Evart Products 631 West Seventh Street Evart, MI 49631-9468

SUBJECT: NOTICE OF VIOLATION (NRC INSPECTION REPORT NO. 999-90003/9606(DNMS))

Dear Mr. Anderson:

This refers to the special safety inspection conducted from June 27 to July 11, 1996, to review the circumstances surrounding the loss on January 20-21, 1996, of three NRD Model No. P-210 static elimination devices possessed by Evart Products under an NRC General License. Each device contained nominally 10 millicuries of polonium-210. On March 29, 1996, Evart Products notified the NRC of the loss. The inspection report was mailed to Evart Products on August 2, 1996, and a predecisional enforcement conference was held on August 9, 1996.

Based on the information developed during the inspection and the information provided by Evart Products during the conference, the NRC has determined that significant violations of NRC requirements occurred. The first violation involves the failure to properly transfer or dispose of generally licensed material in accordance with 10 CFR 31.5(c)(8). The second violation pertains to the failure to notify the NRC within 30 days of the discovery that licensed material was lost, stolen, or missing. The violations are cited in the enclosed Notice of Violation.

Incumbent upon each company possessing byproduct material is the responsibility to protect the public health and safety by ensuring that radioactive materials are controlled at all times. The NRC recognizes that only a small quantity of material was lost. Nevertheless, the loss of any NRC-licensed material is a significant regulatory concern because it can lead to the inadvertent release of radioactive material to the public domain and the possibility of unnecessary exposure of individuals to radiation. While we recognize that Evart has had several organizational changes over the past several years, the company previously lost three similar devices since 1991. The multiple losses indicate that effective corrective actions were not implemented by Evart Products after the earlier losses. The violations represent a continued failure to control access to licensed materials for radiation purposes and the failure to notify the NRC within the specified time. The violations are categorized in the aggregate and in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions" (Enforcement Policy), NUREG-1600, as a Severity Level III problem. Evart Products

In accordance with the Enforcement Policy, a base civil penalty in the amount of \$2,500 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 V.B.2 of the Enforcement Policy. Credit for the *Corrective Action* factor was warranted because of the timely and thorough actions taken, including, but not limited to: accounting for the devices on a shift-to-shift basis; storing the devices in a locked container whenever the facility was not operating; training supervisors about the control of licensed materials; and developing a safety manual that will include a discussion on radiation safety.

Therefore, to encourage prompt comprehensive correction of violations and in recognition of the absence of previous escalated enforcement action, I have decided not to propose a civil penalty in this case. However, significant violations in the future could result in a civil penalty.

Furthermore, any theft of NRC-licensed material could be referred to the U.S. Department of Justice for investigation and prosecution. Therefore, we request that this letter and the enclosed Notice be posted throughout your facility or published in your employee newsletter to ensure the widest dissemination of this enforcement action to your employees.

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

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

/s/ W. L. Axelson (for)

A. Bill Beach Regional Administrator

Docket No. 999-90003 General License

Enclosure: Notice of Violation

NUREG-0940, PART III

B-16

### NOTICE OF VIOLATION

Evart Products Evart, Michigan Docket No. 999-90003 General License EA 96-254

During an NRC inspection conducted from June 27 to July 11, 1996, 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 31.5(c)(8) requires, in part, that any person who acquires, receives, possesses, uses or transfers byproduct material in a device pursuant to a general license shall, except as provided in 10 CFR 31.5(c)(9), transfer or dispose of the device containing byproduct material only by transfer to persons holding a specific license pursuant to 10 CFR Parts 30 and 32 or from an Agreement State to receive the device.

Contrary to the above, on the weekend of January 20-21, 1996, the licensee lost three NRD Model P-2051 air ionizing strice elimination devices (Serial Nos. 77599, 79152 and 79156), each Jevice contained a polonium-210 sealed source of nominally 10 millicuries, and this transfer was not made to a person holding a specific license pursuant to 10 CFR Parts 30 and 32 or from an Agreement State to receive the device, and the exceptions in 10 CFR 31.5(c)(9) did not apply. (01013)

(This is a repeat violation.)

B. 10 CFR 31.5(c)(2) requires, in part, that a licensee comply with the requirements of 10 CFR 20.2201 for reporting the theft or loss of licensed material.

10 CFR 20.2201(a)(ii) requires, in part, a licensee report by telephone to the NRC within 30 days after the occurrence of any lost, stolen, or missing licensed material becomes known to the licensee, and the licensed material in a quantity greater than 10 times the quantity specified in Appendix C to 10 CFR Part 20. The quantity specified in 10 CFR Part 20, Appendix C, 0.1 microcurie.

Contrary to the above, on the night of January 21-22, 1996, the licensee learned that three air ionizing static elimination devices, containing NRC-licensed material (polonium-210), were missing. Each device contained nominally 10 millicuries of polonium-210, which is greater than the 0.1 microcurie quantity specified in 10 CFR Part 20, Appendix C, and the licensee did not report the loss to the NRC until March 29, 1996, which is a period greater than 30 days. (01023)

This is a Severity Level III problem (Supplements IV and VI).

Pursuant to the provisions of 10 CFR 2.201, Evart Products (Licensee) is hereby required to submit a written statement or explanation to the U. S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555, with a copy to the Regional Administrator, Region III. Notice of Violation

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.

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. 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.

Dated at Lisle, Illinois this 3rd day of September 1996



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

July 3, 1996

EA 96-189

Mr. Tim Nebel Senior Vice President, Operations Geisinger Medical Center 100 North Academy Avenue Danville, Pennsylvania 17822-2408

SUBJECT: NOTICE OF VIOLATION (NRC INSPECTION REPORT NO. 030-02984/96-001)

Dear Mr. Nebel:

This letter refers to the NRC inspection conducted April 17 - May 22, 1996, at your facilities in Danville, Pennsylvania, of activities authorized by NRC License No. 37-01421-01. During the inspection, apparent violations of NRC requirements were identified. A copy of the NRC inspection report was sent to you on June 17, 1996. On June 26, 1996, a transcribed predecisional enforcement conference was conducted with you and other members of your staff to discuss the apparent violations, their causes, and your corrective actions. A copy of the Enforcement Conference Report is enclosed.

Based on the information developed during the inspection, information provided in a facsimile, dated May 3, 1996, from your Radiation Safety Officer, and information provided during the conference, three violations of NRC requirements are being cited, as described in the enclosed Notice of Violation. The violations involve: (1) two examples of failure to maintain complete and accurate information concerning the amount of radioactive material in a particular container, as well as whether a survey had been done prior to disposal of certain waste; (2) two examples of failure to perform required radiological surveys at the facility; and (3) failure to follow required procedures for ordering iodine-131 (I-131). The fourth apparent violation described in the inspection report is being withdrawn for the reasons described in the enforcement conference report.

The NRC recognizes that all of the violations were identified by your staff, and were documented at your facility. The NRC also recognizes that appropriate disciplinary action was taken. Nonetheless, the NRC is particularly concerned with the failure to maintain accurate records of certain activities at the facility, since the NRC must be able to rely on its licensees and their employees to maintain records that are complete and accurate in all material respects. The NRC also is concerned that conditions existed that warranted the performance of radiological surveys, yet the responsible nuclear medicine technologists did not perform the required surveys.

# Geisinger Medical Center

2

Your facility was issued a \$1,250 civil penalty on June 20, 1994 for other violations of NRC requirements. Given that past history, as well as the significance of maintaining records that were inaccurate, and not performing required surveys, these two recent violations demonstrate a breakdown in the control of licensed activities at your facility which collectively represent a potentially significant lack of attention or carelessness toward licensed responsibilities. Therefore, the two violations have been categorized in the aggregate at Severity Level III in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions" (Enforcement Policy), NUREG-1600. The two violations are described in Section I of the enclosed Notice. The third violation being cited is classified at Severity Level IV and is described in Section II of the enclosed Notice.

In accordance with the Enforcement Policy, a base civil penalty in the amount of \$2,500 is considered for the Severity Level III violation. Because your facility has been the subject of escalated enforcement in the past 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. Credit was warranted for identification because you identified the violations. Credit also is warranted for corrective action because your actions were both prompt and comprehensive. Your corrective actions, which were described in your presentation during the conference, included, but were not limited to: (1) immediate removal from the nuclear medicine department of those individuals responsible for the inaccurate records, once the inaccuracies were identified; (2) establishment of a new disciplinary program which includes investigation of incidents to determine culpability of the individual(s) involved, referral to the Employee Assistance Program of any individual found culpable, and certain actions for negligence and failure to follow procedures, including suspension and/or termination; (3) revision of the decay-in-storage form to minimize chances of misreviewing data; (4) retention of a new Chairman of Radiology; and (5) establishment of a multi-disciplinary investigation team to review incidents at the facility.

Therefore, to encourage continued identification and prompt and comprehensive correction of violations, I have been authorized not to propose a civil penalty in this case. However, any similar violations in the future could result in more significant escalated enforcement action, including issuance of a civil penalty.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. In your response, you should document the specific actions taken and any additional actions you plan to prevent recurrence. In addition, you should further emphasize to your staff the importance of ensuring that all records of activities at your facilities are complete and accurate in all material respects. After reviewing your response to this Notice, including your proposed corrective actions and the results of future inspections, the NRC will determine whether further NRC enforcement action is necessary to ensure compliance with NRC regulatory requirements.

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

3

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

Sincerely, Mh /m alhon 1

Thomas T. Martin Regional Administrator

Docket No. 030-02984 License No. 37-01421-01

Enclosures: 1. Notice of Violation 2. Enforcement Conference Report

cc w/encls: Ms. C. Anderko, Radiation Protection Officer Commonwealth of Pennsylvania

# ENCLOSURE 1

## NOTICE OF VIOLATION

Geisinger Medical Center Danville, Pennsylvania

Docket No. 030-02984 License No. 37-01421-01 EA 96-189

During an NRC inspection conducted April 17 - May 22, 1996, 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. VIOLATIONS FOR INACCURATE RECORDS AND LACK OF ADEQUATE SURVEYS
  - A. 10 CFR 30.9(a) requires, in part, that information required by the Commission's regulations to be maintained by the licensee shall be complete and accurate in all material respects.

Contrary to the above, certain information required by the Commission's regulations to be maintained by the licensee was not complete and accurate in all material respects. Specifically,

- on January 28, 1993, a container label required to be maintained in accordance with 10 CFR 20.1904 was not accurate in that the label, which was completed by a nuclear medicine technologist, indicated that the container held 350 millicuries (mCi) of technetium-99m (Tc-99m) when, in fact, the container actually held less than 50 mCi of Tc-99m. This was material because it was required to be maintained.
- 2. on January 18, 1996, a waste disposal log required to be maintained in accordance with 10 CFR 35.92(b) [as a record of a disposal made pursuant to 10 CFR 30.92(a)] was not accurate in that the log indicated that a radiation survey of iodine-131 (I-131) and Tc-99m waste had been performed prior to disposal, and radiation measurements were recorded at background; however, the licensee concluded that this survey was never performed because the waste contained millicurie quantities of I-131 and Tc-99m, including a straw used in the administration of an I-131 therapy dose, and it was not possible for radiation levels of this waste to be at background. This was material because it was required to be maintained. (01013)
- B. 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.

NUREG-0940, PART III

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, the licensee did not make surveys to assure compliance with 10 CFR 20.1201, which limits radiation exposure to occupational workers. Specifically:

- 1. on January 28, 1993, although a nuclear medicine technologist observed that a vial (known to contain 350 mCi of Tc-99m) that had been placed in a water bath was found in a dry pot on direct heat, a survey was not conducted to determine whether the integrity of the vial had been compromised and radioactive material released.
- 2. on March 8, 1996, although a nuclear medicine technologist suspected that a spill of radioactive material had occurred in the Cardiac Stress Laboratory, a survey was not conducted by the technologist before leaving the work area to verify his suspicion that a spill of greater than 20 microcuries had occurred and that the licensee's emergency procedures needed to be implemented. (01023)

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

II. OTHER VIOLATION OF NRC REQUIREMENTS

Condition 28 of License No. 37-01421-01 requires, in part, that the licensee conduct its program in accordance with statements, representations, and procedures contained in a letter, including enclosures, dated September 10, 1993.

Item No. 1 of Attachment No. 5 of the September 10, 1993 letter, <u>Control</u> of <u>Procurement and Use</u>, requires that for medical use, only authorized personnel listed on the NRC License, or authorized persons working under the direct supervision of an authorized user listed on the license, may prescribe and have radioisotopes ordered for diagnosis and therapy.

Contrary to the above, on September 28, 1995, 7 millicuries of I-131 was ordered for therapy by an individual who was neither an authorized user listed on the NRC license, nor an authorized person working under the direct supervision of an authorized user listed on the license. (02014)

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

Enclosure 1

Pursuant to the provisions of 10 CFR 2.201, Geisinger Medical Center is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 2055, with a copy to the Regional Administrator, Region I, within 30 days of the date of the letter transmitting this Notice of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each violation: (1) the reason for the violation, or, if contested, the basis for disputing the violation, (2) the corrective steps that have been taken and the results achieved. (3) the corrective steps that will be taken to avoid further violations, and (4) the date when full compliance will be achieved. 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.

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. 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.

Dated at King of Prussia, Pennsylvania this 3rd day of July 1996

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3



UNITED STATES NUCLEAR REGULATORY COMMISSION REGION III

301 WARRENVILLE ROAD LISLE, ILLINOIS 60532-4351

November 1, 1996

EA 96-233

Mr. Jan Freeman Operations Director Lucent Technologies, Inc. 777 N. Blue Parkway Lee's Summit, MO 64086

SUBJECT: NOTICE OF VIOLATION (NRC INSPECTION REPORT NO. 030-05097/96001(DNMS)

Dear Mr. Freeman:

This refers to the inspection conducted on May 21, 1996, with continuing NRC review through June 5, 1996, at the Lucent Technologies, Inc., facility in Lee's Summit, Missouri (formerly AT&T Microelectronics). The purpose of the inspection was to determine whether "Tracerflo" devices remaining at the Lee's Summit facility following termination of NRC License No. 24-0601: 02 were contaminated with licensable radioactive material. The inspection also included a review of the actions taken to terminate the license. The subject inspection report was sent to Lucent Technologies, Inc. by letter dated July 30, 1996.

Based on the information developed during the inspection and the information that you provided in your response to the subject inspection report dated September 6, 1996, 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 are described in detail in the subject inspection report. In summary the violations are: (a) AT&T Microelectronic's (AT&TM) provided the NRC with incomplete and inaccurate information on a Form 314 and (b) AT&TM/Lucent Technologies, Inc. retained NRC licensed material on its premises for more than two years after the NRC license had been terminated.

These violations are of regulatory significance because when an NRC Form 314, "Certificate of Disposition of Materials," is submitted, the submitting party attests that all licensed materials have been properly disposed of and that all licensed activities have ceased. In AT&TM's case, all licensed material had not been disposed of at the time of request for license termination. Specifically, two 55 gallon drums containing components contaminated with krypton-85 were stored at the Lee's Summit facility at the time of the 1993 termination request. The drums containing contaminated equipment remained on the premises until they were shipped for disposal to the Barnwell waste facility in December 1995. During the May 1996 onsite inspection, krypton-85 was found in a spare gas storage tank in quantities significant enough to require an NRC license. This occurred because the former licensee's technical consultant failed to accurately characterize the degree of residual contamination remaining on or in the equipment. If the Form 314 information had been complete and accurate when reviewed by the NRC staff, it would have been likely that substantial further inquiry such as a formal request for information or additional inspection effort would have occurred. Therefore, these violations are considered to be a significant regulatory concern and 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 III problem.

2

In accordance with the Enforcement Policy, a base civil penalty in the amount of \$2500 is considered for a Severity Level III problem. Because your facility has not been the subject of escalated enforcement actions within the last 2 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 was warranted because as of August 29, 1996, Lucent Technologies, Inc. shipped all remaining licensed materials for disposal.

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.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice ...en 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).

Sincerely,

A. Bill Beach Regional Administrator

Docket No. 030-05097 License No. 24-06015-02 (Terminated)

Enclosure: Notice of Violation

#### NOTICE OF VIOLATION

Lucent Technologies, Inc. Lee's Summit, Missouri Docket No. 030-05097 License No. 24-06015-02 EA 96-233

During an NRC inspection conducted on May 21, 1996, with continuing NRC review through June 5, 1996, 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 30.9(a) requires, in part, that information provided to the Commission by a licensee, or information required by the Commission's regulations to be maintained by the licensee, shall be complete and accurate in all material respects.

Contrary to the above, the licensee did not provide to the Commission information that was complete and accurate in all material respects. Specifically, the NRC Form 314 (Certificate of Disposition) signed by the licensee on December 20, 1993, requesting termination of License No. 24-06015-02, failed to identify the krypton-85 contaminated equipment which remained in AT&T Microelectronic's possession until 1996. The incomplete and inaccurate information was material to the NRC because the NRC granted license termination based on the information provided. (01013)

B. 10 CFR 30.3 requires, in part, that except for persons exempted, no person shall possess or use byproduct material except as authorized by a specific or general license issued pursuant to Title 10, Chapter 1, Code of Federal Regulations.

Contrary to the above, between February 4, 1994, and August 1996, AT&T Microelectronics/Lucent Technologies, Inc. possessed krypton-85 in quantities requiring a specific or general license without a valid license and was not exempted from possessing a license. (01023)

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

Pursuant to the provisions of 10 CFR 2.201, Lucent Technologies, Inc. is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555, with a copy to the Regional Administrator, Region III, within 30 days of the date of the letter transmitting this Notice of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each violation: (1) the reason for the violation, or, if contested, the basis for disputing the violation, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken to avoid further violations, and (4) the date when full compliance will be achieved. 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.

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 <u>must</u> 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 1st day of November 1996



UNITED STATES NUCLEAR REGULATORY COMMISSION REGION 1 475 ALLENDALE ROAD KING OF PRUSSIA, PENNSYLVANIA 19406-1415

December 20, 1996

EA 96-396

Mr. Lawrence A. Tanner, President New Britain General Hospital 100 Grand Street New Britain, Connecticut 06050

SUBJECT: NOTICE OF VIOLATION (NRC Office of Investigations Report No. 1-96-013)

Dear Mr. Tanner:

This refers to the investigation conducted by the NRC Office of Investigations (OI) on April 12, 1996, at the New Britain General Hospital in New Britain, Connecticut. The OI Synopsis was sent to you with our letter, dated November 5, 1996. On November 18, 1996, a Predecisional Enforcement Conference was conducted with you to discuss the apparent violation, its cause, and your corrective actions to prevent recurrence. A copy of the Predecisional Enforcement Conference Report will be sent to you by separate correspondence.

Based on the information developed during the investigation, and the information provided during the conference, the NRC has determined that a violation of NRC requirements occurred. This violation is cited in the enclosed Notice of Violation (Notice). The violation involves your failure to comply with 10 CFR 30.9 in that your former Chief Nuclear Medicine Technologist (CNMT) made false entries into the New Britain General Hospital dose calibrator constancy record.

The dose calibrator constancy record was inaccurate in that the indicated readings recorded by the CNMT for the barium and cesium settings for November 29, 1995, were approximately 5% lower than they should have been. These recorded readings on that day were essentially the same as those recorded on the day prior to that date; however, based on a dose calibrator accuracy test performed by the Radiation Safety Officer (RSO) on November 28, 1995, the settings had been increased by 5% on that date. Therefore, the test results recorded by the former CNMT on November 29, 1995, should have been approximately 5% higher than the test results on the day before. Based on the OI investigation, the NRC concluded that the constancy test was not conducted on November 29, 1995, and the record was falsified. This discrepancy was identified by the RSO on November 30, 1995, and brought to the attention of hospital management and subsequentity the NRC.

Falsifying records required to be maintained by the Commission's requirements is of significant regulatory concern because the conduct of licensed activities in accordance with the Commission's requirements depends in large part on the integrity of individuals conducting licensed activities. Since this violation was caused by a first line supervisor, the violation is classified at Severity Level III in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions" (Enforcement Policy), NUREG-1600.

#### New Britain General Hospital

In accordance with the Enforcement Policy, a base civil penalty in the amount of \$2,500 is considered for a Severity Level III violation or problem. 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 because you identified the violation. Your corrective actions, which were described at the enforcement conference, included: (1) initially removing the CNMT from some NRC-licensed activities and requiring supervision for some NRC-licensed activities; (2) subsequently terminating the employment of the CNMT; and (3) conducting one-on-one meetings with members of the Nuclear Medicine Department, during March 1996, in order to obtain an understanding of their view of this falsification event. Thus, credit for your corrective action is warranted.

Therefore, to encourage identification and 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. Please note that a Notice of Violation is also being issued on this date to the Former CNMT (copy enclosed).

At the conference, the RSO indicated that he has not been able to locate copies of documents which have been incorporated into, and are therefore part of, your NRC license. Additionally, the RSO stated that his reviews of the licensed program were based on his general understanding of NRC requirements and guidance, not the site-specific NRC license for your facility. This is of concern to the NRC as it raises questions regarding the adequacy of these reviews. Copies of these documents were sent to you and your RSO by separate correspondence. Upon receipt of this material, you should immediately review the documents to ensure that your program is conducted in accordance with the license conditions and Commission's regulations. These documents contain required procedures which are to be followed by the hospital and are required to be maintained by the hospital in accordance with 10 CFR Part 35.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. As noted above, the NRC recognizes your efforts in taking corrective action with respect to the CNMT and informing the NRC. Nonetheless, you should further emphasize to all Nuclear Medicine Department staff at your facility the importance of complying with all applicable Commission regulations and required procedures and that deliberately violating the Commission's regulations and required procedures will not be tolerated. Therefore, in your response, please describe the actions you have taken or plan to take to emphasize to your staff the importance of maintaining complete and accurate records and the unacceptability of deliberate misconduct. 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 any response will be placed in the NRC Public Document Room.

Sincerely, William Mm Hr

Hubert J. Miller Regional Administrator

New Britain General Hospital

3

Docket No. 030-01250 License No. 06-02388-01

Enclosure: Notice of Violation

cc w/encl: State of Connecticut

#### ENCLOSURE

# NOTICE OF VIOLATION

New Britain General Hospital New Britain, Connecticut

Docket No. 030-01250 License No. 06-02388-01 EA 96-396

During an NRC investigation by the NRC Office of Investigations (OI), for which the synopsis of the report was sent to the licensee on November 5, 1996, 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 30.9(a) states, in part, that information required by the Commission's regulations to be maintained by the licensee shall be complete and accurate in all material respects.

10 CFR 35.50 requires, in part, that each licensee shall check each dose calibrator for constancy with a dedicated check source at the beginning of each day of use and that the licensee retain a record of each check required by 10 CFR 35.50 for three years unless directed otherwise.

Contrary to the above, on November 29, 1995, information required by the Commission's regulations to be maintained by the licensee, was not complete and accurate in all material respects. Specifically, the then Chief Nuclear Medicine Technologist, a first line supervisor, made inaccurate entries into the licensee's dose calibrator constancy record on that date. The readings reported for the barium and cesium settings on November 29, 1996, by the then CNMT were approximately 5% lower than they should have been. This conclusion is based on the results obtained on November 28, 1995, by the Radiation Safety Officer (RSO) when he performed an accuracy test of the dose calibrator and the fact that the RSO adjusted the dose calibrator settings on November 28, 1995, to increase the readings for the barium and cesium settings by 5%. This record was material since it was required to be maintained by NRC regulations. (01013)

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

Pursuant to the provisions of 10 CFR 2.201, New Britain General Hospital (Licensee) is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington D.C. 20555 with a copy to the Regional Administrator, Region I, within 30 days of the date of the letter transmitting this Notice of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each alleged violation: (1) the 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

#### Enclosure

modified, suspended, or revoked or why such other action as may be proper should not be taken. Where good cause is shown, consideration will be given to extending the response time.

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

Because your response will be placed in the NRC Public Document Room (PDR), to the extent possible, it should not include any personal privacy, or proprietary 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).

Dated at King of Prussia, Pennsylvania this 20th day of December 1996



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

November 13, 1996

EA 96-398

Ms. Mary Schneider Administrative Director, Radiology New England Medical Center 171 Harrison Avenue Boston, Massachusetts 02111

### SUBJECT: NOTICE OF VIOLATION (NRC Inspection Report No. 030-01868/96-002)

#### Dear Ms. Schneider:

This letter refers to the NRC inspection conducted on September 24 and 25, 1996, at your facility in Boston, Massachusetts. The purpose of this inspection was to determine whether activities authorized by your license were conducted safely and in accordance with NRC requirements, and to review the circumstances surrounding the receipt of a package containing NRC licensed radioactive material by your staff and transportation of this package by taxi to the Department of Veterans Affairs Medical Center (DVAMC) also located in Boston, Massachusetts. During the inspection, apparent violations of NRC requirements were identified, and were described in the NRC inspection report transmitted with our letter dated October 23, 1996. On November 7, 1996, a Predecisional Enforcement Conference was held with you and other members of your staff to discuss the incident, apparent causes, and corrective actions to prevent recurrence. A copy of the Predecisional Enforcement Conference Report will be sent to you by separate correspondence at a later date.

Based on the information developed during the inspection, and the information 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 first violation involves your failure to comply with 49 CFR 173.441(a) in that, you failed to assure that a package of radioactive material for shipment was prepared such that the radiation level did not exceed 200 millirem per hour at any point on the external surface of the package. Compliance with 49 CFR 173.44(a) is required by NRC regulations in 10 CFR 71.5(a). Specifically, on September 23, 1996, your medical physicist transported in the trunk of a taxi a package containing 44 millicuries of iridium-192 (15 seeds in a ribbon) to the DVAMC in Boston, and upon arrival of that package at the DVAMC, a survey of the package by the DVAMC staff indicated that the radiation level at the bottom of the package was 400 millirem per hour. The second violation involves your failure to perform, at NEMC prior to the transfer to the DVAMC, an adequate survey of the package as required by 10 CFR 20.1501 to assure compliance with exposure limits for members of the public in 10 CFR 20.1302. Although no exposure above 0.002 rem in one hour to a member of the public had occurred, it was fortuitous that the package was always handled in the upright position with the high exposure rates (400 mR/hr at contact and 40 mR/hr at one meter) emanating from the bottom of the package towards the ground and the bottom of the taxi cab trunk.

New England Medical Center

2

The NRC is particularly concerned with your failure to perform an adequate survey prior to transporting the package, because such failures have the potential to cause unnecessary exposure to members of your staff, the staff at the receiving facility, and members of the public while the package is in transport. Since these violations involved radiation levels in excess the NRC limit (although less than five times the limit), the violations are classified in the aggregate at Severity Level III 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 \$2,500 is considered for a Severity Level III violation or problem. Because New England Medical Center 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 action is warranted because your actions were both prompt and comprehensive. These actions included, but were not limited to: (1) creating a revised survey form for packages containing radioactive material; and (2) providing extensive training, to all staff who receive and ship packages containing radioactive material, in the procedure for surveying packages and use of the revised survey form.

Therefore, to emphasize prompt identification and comprehensive correction of violations when they exist, 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.

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 any response will be placed in the NRC Public Document Room (PDR).

Sincerely.

Hubert J. Miller Regional Administrator

Docket No. 030-01868 License No. 20-03857-06

Enclosure: Notice of Violation

cc w/encls: Commonwealth of Massachusetts

# ENCI OSURE

# NOTICE OF VIOLATION

New England Medical Center Boston, Massachusetts Docket No. 030-01868 License No. 20-03857-06 EA 96-398

During an NRC inspection conducted on September 24 and 25, 1996, violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," the violations are listed below:

A. 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 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 200 millirem per hour at any point on the external surface of the package.

Contrary to the above, on September 23, 1996, a package offered for transportation was not prepared for shipment such that radiation levels did not exceed 200 millirem per hour on the external surface of the package. Specifically, the licensee shipped a package containing 44 millicuries of iridium-192 by common carrier vehicle (not designated as exclusive use) and the radiation level measured at a point on the external surface of the package was approximately 400 millirem per hour. (01013)

B. 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.

10 CFR 20.1302 requires, in part, that if an individual were continuously present in unrestricted areas, the dose from external sources would not exceed 0.002 rem in an hour.

NUREG-0940, PART III

#### Enclosure

2

Contrary to the above, as of September 23, 1996, the licensee did not make surveys to assure compliance with 10 CFR 20.1302, Dose limits for individual members of the public. Specifically, the licensee failed to adequately survey a package which was transported in a taxi cab from the New England Medical Center to the Department of Veterans Affairs Medical Center. Fortuitously, no exposures of personnel of greater than .002 rem in one hour had occurred. (01023)

These violations represent a Severity Level III problem (Supplements IV and V).

Pursuant to the provisions of 10 CFR 2.201, New England Medical Center is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555, with a copy to the Regional Administrator, Region I, within 30 days of the date of the letter transmitting this Notice of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each violation: (1) the reason for the violation, or if contested, the basis for disputing the violation, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken to avoid further violations and (4) the date when full compliance will be achieved. 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 Demand for Information may be issued as to why the license should not be modified, suspended, or revoked, or why such other action as may be proper should not be taken. Where good cause is shown, consideration will be given to extending the response time.

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

Because your response will be placed in the NRC Public Document Room (PDR), to the extent possible, it should not include any personal privacy, or proprietary 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 disclosure of the information will create an unwarranted invasion of personal privacy or provide the confidential commercial or financial information).

Dated at King of Prussia, Pennsylvania this 13thday of November 1996



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

September 25, 1996

EA 96-298

Gary Niblock President Niblock Excavating, Inc. 906 Maple Street P.O. Box 211 Bristol, IN 46507

SUBJECT: NOTICE OF VIOLATION (NRC Inspection Report No. 030-31686/96001(DNMS))

CLOSURE OF CONFIRMATORY ACTION LETTER NO. RIII-96-007

Dear Mr. Niblock:

This refers to the routine safety inspection conducted at Niblock Excavating, Inc. from June 19, 1996 to August 15, 1996, during which several violations of NRC requirements were identified. A copy of the inspection report was sent to Niblock Excavating, Inc. on August 22, 1996, and a predecisional enforcement conference was held by telephone on September 17, 1996.

Based on the information developed during the inspection and the information that you and the Radiation Protection Officer (RPO) provided during the conference, the NRC has determined that significant 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 root cause of these violations stems from the apparent lack of knowledge and oversight of the radiation safety program by licensee management.

Incumbent upon each entity licensed by the NRC to use byproduct material in a commercial enterprise is the responsibility to protect public health and safety, by ensuring that the rules, regulations and license conditions that have been developed to control radioactive materials are followed at all times. This has not been the case at Niblock Excavating, Inc. Five apparent violations pertaining to the use and control of licensed materials were identified during this inspection. Of particular concern was the use of nuclear gauges by City of Goshen employees without adequate supervision and oversight by Niblock many meet or Radiation Protection Officer. A Confirmatory Action Let was issued on June 25, 1996, to confirm your immediate actions for a lessing the issues of control and use of licensed material as well as training and instruction for management and authorized users regarding the program requirements. Collectively the apparent violations are indicative of a breakdown in the control and oversight of

licensed activities and represent a potentially significant lack of attention or carelessness toward licensed responsibilities. Therefore, these violations 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 III problem.

In accordance with the Enforcement Policy, a base civil penalty in the amount of \$2500 is considered for a Severity Level III problem. Because your facility has not been the subject of escalated enforcement actions, 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 was warranted for the following corrective actions: management received instruction regarding program requirements; a new RPO was appointed and approved by the NRC; the RPO designated specific individuals as authorized users and provided them with extensive instruction of the program requirements; the RPO will conduct periodic field audits to assure that the licensed material is being used in accordance with the license; and leak tests and inventories have been performed and procedures are in place to assure that they will continue to be performed in the future.

Therefore, to encourage prompt and comprehensive correction of violations and in recognition of the absence of previous escalated enforcement action, I have decided 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.

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.

We acknowledge your letters dated July 22, 1996 and August 14, 1996, in response to the Confirmatory Action Letter (CAL) dated June 25, 1996. Your response indicates that you have completed all actions described in the CAL. We will evaluate the effectiveness of your corrective actions during a future inspection.

NUREG-0940, PART III

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,

sh fa 0 A. Bill Beach

Regional Administrator

Docket No. 030-31686 License No. 13-26181-01

Enclosure: Notice of Violation

3

#### NOTICE OF VIOLATION

Niblock Excavating, Inc. Bristol, Indiana Docket No. 030-31686 License No. 13-26181-01 EA 96-298

During an NRC inspection conducted at Niblock Excavating, Inc. from June 19, 1996 to August 15, 1996, 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. Condition 10 of License No. 1326181-01 requires, in part, that licensed materials shall be used only at the licensee's facilities located at 806 Maple Street, Bristol, Indiana.

Contrary to the above, as of January 1995, Troxler moisture/density gauges containing NRC licensed material (nominally 8 millicuries (0.30 GBq) of cesium-137 and 40 millicuries (1.5 GBq) of americium-241) have been used at the licensee's facilities located at 906 Maple Street, Bristol, Indiana. (01013)

B. Condition 11. A. of License No. 13-26181-01 requires that licensed material shall be used by, or under the supervision and in the physical presence of, individuals who have successfully completed the device manufacturer's training program for gauge users and have been designated by the licensee's Radiation Protection Officer. The licensee shall maintain records of the individuals who have been designated as authorized users.

Contrary to the above, between December 1995 and June 19, 1996, a Troxler moisture/density gauge containing NRC licensed material (nominally 8 millicuries (0.30 GBq) of cesium-137 and 40 millicuries (1.5 GBq) of americium-241) was used by individuals not designated by the licensee's Radiation Protection Officer. Specifically, licensed materials were used by employees of the City of Goshen who were not designated by the licensee's RPO. (01023)

C. Condition 12 of License No. 13-26181-01 requires, in part, that sources specified in Items 7.A., 7.B., and 7.C. shall be tested for leakage and/or contamination at intervals not to exceed 6 months. Any source in storage and not being used need not be tested. When the source is removed from storage for use or transfer to another person, it shall be tested before use or transfer.

Contrary to the above, on two occasions in December 1995 and June 1996, a moisture/density gauge containing nominally 8 millicuries (0.30 GBq) of cesium-137 and 40 millicuries (1.5 GBq) of americium-241 was removed from storage and used or transferred to another person without being tested for leakage and/or contamination. (01033)

D. Condition 15 of License No. 13-26181-01 requires that the licensee shall conduct a physical inventory every six months to account for all sealed sources received and possessed under the license. 2

Contrary to the above, since January 1995, physical inventories were not conducted every six months to account for all sealed sources received and possessed under the license. (01043)

E. 10 CFR 71.5(a) requires a licensee who transports licensed material outside of the confines of its plant or other place of use, or who delivers licensed material to a carrier for transport, comply with the applicable requirements of the regulations appropriate to the mode of transport of the Department of Transportation (DOT) in 49 CFR Parts 170 through 189.

49 CFR 177.817(a) requires that a carrier not transport a hazardous material unless it is accompanied by a shipping paper prepared in accordance with 49 CFR 172.200-203. Pursuant to 49 CFR 172.101, radioactive material is classified as hazardous material.

Contrary to the above, on June 6, 1996, the licensee transported a gauge containing nominally 8 millicuries (0.30 GBq) of cesium-137 and 40 millicuries (1.5 GBq) of americium-241 outside the confines of its plant without a shipping paper. (01053)

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

Pursuant to the provisions of 10 CFR 2.201, Niblock Excavating, Inc. is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555 with a copy to the Regional Administrator, Region III, 801 Warrenville Road, Lisle, Illinois 60532-4351 within 30 days of the date of the letter transmitting this Notice of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each violation: (1) the reason for the violation, or, if contested, the basis for disputing the violation, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken to avoid further violations, and (4) the date when full compliance will be achieved. 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.

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

# Notice of Violation

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 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.

3

Dated at Lisle, Illinois, this 25th day of September 1996



UNITED STATES NUCLEAR REGULATORY COMMISSION REGION 3 101 MARIETTA STREET, N.W., SUITE 2900 ATLANTA, GEORGIA 30323-0199

October 23, 1996

EA 96-315

Pensacola Testing Laboratories. Inc. ATTN: Mr. Patrick A. Wheeler President/Radiation Safety Officer 217 East Brent Lane Pensacola, Florida 32503

SUBJECT: NOTICE OF VIOLATION (NRC Special Inspection Report No. 150-00009/96-05)

Dear Mr. Wheeler:

This refers to the inspection conducted on August 5. 1996. at your Pensacola. Florida facility. The inspection included a review of the facts and circumstances surrounding your use of moisture density gauges containing byproduct material at Eglin Air Force Base. Whiting Field. Hurlburt Field. and Pensacola Naval Air Station. Florida. The results of the inspection were formally transmitted to you by letter dated September 4. 1996. That letter also provided you the opportunity to respond to the apparent violation or request a predecisional enforcement conference. On September 12. 1996. you declined the opportunity for a predecisional enforcement conference, and on October 3. 1996. you provided a written response which admitted the apparent violation. and included an explanation of the root cause of the apparent violation and your corrective actions to preclude recurrence. as requested in our letter dated September 4. 1996. 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 written 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 involved Pensacola Testing Laboratories. Inc.'s use of moisture density gauges at locations within NRC's jurisdiction without first obtaining a specific NRC license or filing NRC Form-241. "Report of Proposed Activities in Non-Agreement States." Please note that the violation described in the enclosed Notice does not address work performed at Hurlburt Field. Inclusion of this worksite as part of the apparent violation described in our September 4, 1996. letter to you was in error in that Hurlburt Field does not include areas of exclusive Federal jurisdiction.

This violation is of significant regulatory concern because it denied the NRC an opportunity to inspect Pensacola Testing Laboratories. Inc.'s use of byproduct material in areas of exclusive Federal jurisdiction, thereby impeding the NRC's ability to perform its statutory responsibility of verifying that by-product material is used in accordance with NRC requirements. You Pensacola Testing Laboratories. Inc. 2

attributed the failure to an honest oversight. in that although you were aware of the NRC reciprocity requirements and had filed appropriately for work involving your radiographic source. you inadvertently failed to file for reciprocity for your moisture density gauge work. The NRC accepts this explanation: however. the NRC relies on licensees and their employees to fully understand and comply with NRC requirements prior to performing licensed activities. Therefore, this violation is classified in accordance with the "General Statement of Policy and Procedures 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 \$2,500 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. In your October 3. 1996. response, your corrective actions included promptly filing for reciprocity with NRC Region II to cover moisture density gauge use. payment of the associated fees, and periodic notification of work to be performed in areas of NRC jurisdiction. Based on the above, the NRC determined that your corrective actions were prompt and comprehensive, and credit was warranted for this factor.

Therefore, to encourage prompt and comprehensive correction of violations. I have been authorized, after consultation with the Office of Enforcement, not to propose a civil penalty in this case. Notwithstanding this decision, we would expect that, in the future, Pensacola Testing Laboratories, Inc. would obtain written assessments from, or document assessments by, Federal authorities as to whether a proposed work site is in an area of exclusive Federal jurisdiction. Absent such documentation showing that Federal authorities assessed the work site as not being in an area of exclusive Federal jurisdiction, additional enforcement action including assessment of a civil penalty may be taken for failure to seek the required authorization to perform licensed activities in areas of exclusive Federal jurisdiction.

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 your letter dated October 3, 1996. 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.

Pensacola Testing Laboratories. Inc.

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

3

Sincerely. leves For Stewart D. Ebreter Regional Administrator

Docket No. 150-00009

Enclosure: Notice of Violation

cc w/encl: State of Florida

Pensacola Testing Laboratories. Inc. Pensacola. Florida

Docket No. 150-00009 EA 96-315

During an NRC inspection conducted on August 5. 1996. 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 30.3 requires, in relevant part, that no person shall possess or use by-product material except as authorized by a specific or general license issued by the NRC.

10 CFR 150.20(a) provides. in part, that any person who holds a specific license from an Agreement State is granted an NRC general license to conduct the same activity in non-Agreement States subject to the provisions of 10 CFR 150.20(b)

10 CFR 150.20(b)(1) requires. in part. that any person engaging in activities in non-Agreement States shall. at least three days before engaging in each such activity. file four copies of NRC Form-241. "Report of Proposed Activities in non-Agreement States." with the Regional Administrator of the appropriate NRC Regional Office.

Contrary to the above. on numerous occasions between 1990 and August 5. 1996. Pensacola Testing Laboratories. Inc. used millicurie quantities of Cesium-137 and Americium-241 to perform moisture density activities at Eglin Air Force Base. Whiting Field. and Pensacola Naval Air Station. Florida in areas of exclusive Federal jurisdiction. without either a specific or general license issued by the NRC and without filing Form-241 with the NRC, as required. (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 Pensacola Testing Laboratories. Inc.'s letter to the NRC dated October 3. 1996. However, Pensacola Testing Laboratories, Inc. is required to submit a written statement or explanation pursuant to 10 CFR 2.201 if the description therein does not accurately reflect the corrective actions or the licensee's position. In that case, or if Pensacola Testing Laboratories. Inc. chooses to respond, the response should be marked clearly as a "Reply to a Notice of Violation," and sent 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.

Dated at Atlanta. Georgia this 23rd day of October 1996



# UNITED STATES

REGION IV

611 RYAN PLAZA DRIVE, SUITE 400 ARLINGTON, TEXAS 76011-8064

September 20, 1996

EA 96-205

Mr. Samuel J. Kasley, Program Director Raytheon Engineers & Constructors, Inc. 2850 Pa'a Street Honolulu, Hawaii 96819

SUBJECT: NOTICE OF VIOLATION (NRC Inspection Report No. 030-20425/96-01)

Dear Mr. Kasley:

This refers to the inspection conducted on May 14-15. 1996, of the activities performed by Raytheon Engineers & Constructors. Inc. (RE&C) at Johnston Atoll. The special inspection included a review of the controls implemented by RE&C for byproduct material used in chemical agent detectors, with particular emphasis on the loss of an americium-241 full source reported by RE&C to the NRC Region IV office on May 10. 1996. The findings were discussed with you and members of your staff during a telephonic exit briefing on June 11. 1996. By letter dated July 9. 1996, we sent you the subject inspection report which documented our findings, and provided you with the opportunity to respond to the identified apparent violation or to request a predecisional enforcement conference and instead provided a written response dated September 3. 1996.

Based on the information developed during the inspection and the information that you provided in your September 3. response to the inspection report. 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 americium-241 foil source is contained in an Army M8A1 chemical nerve agent detector, which RE&C uses at Johnston Atoll to detect any potential chemical nerve agent releases in conjunction with the storage and demilitarization operations at Johnston Atoll. The source was last inventoried on August 31. 1991, and was identified as missing during the subsequent inventory performed on January 28. 1992. (At the time, NRC's regulations did not require notification of the lost source.) In its September 3 response. RE&C stated that the company presently believes the unaccounted for source has either been removed from the atoll by a visiting army company that uses identical equipment or is currently in an inaccessible location on Johnston Atoll. As such, RE&C believes there is little opportunity for the equipment to come in contact with the public or pose a safety hazard.

We noted that RE&C's September 3 response states that RE&C does not believe that there has been a violation of NRC regulations or, if there has been a violation, it was due to "extenuating circumstances." However, the fact that the source was lost is a violation of 10 CFR 20.207 (the regulation in effect RAYTHEON ENGINEERS & CONSTRUCTORS. INC.

at the time). With regard to the "extenuating circumstances." RE&C implied that these were related to "much Army transient activity on the Atoll." We would point out that it is incumbent upon RE&C to develop procedures or practices to ensure compliance with applicable regulations including the requirements that deal with the control of radioactive material.

Although the circumstances described by RE&C indicate that the safety significance of the violation is minimal, the violation is of regulatory significance. 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 \$2.500 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, or 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 is warranted for the Corrective Action factor. RE&C's corrective actions included a review of inventory and security procedures, a review of compliance with those procedures by Army personnel, seeking an amendment to allow the Radiation Safety Officer to be located on Johnston Atoll, the formation of a Radioactive Materials User Committee to address common accountability issues and to formulate and approve procedures, weekly inventories of licensed mater al. an improved sign-out and tracking system. and training all users with perticular emphasis on in entory and control.

Therefore, to encourage prompt identification 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 more significant enforcement action, including 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 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 the subject NRC Inspection Report and RE&C's September 3 response to the report. 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 dispute the violation, you should follow the instructions specified in the enclosed Notice.

RAYTHEON ENGINEERS & CONSTRUCTORS, INC.

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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).

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Sincerely.

L.J. Callan Regional Administrator

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Docket No. 030-20425 License No. 53-23258-01

Enclosure: Notice of Violation

cc (w/enclosure): Mr. John P. Hageman Southwest Research Institute 6220 Culebra Road San Antonio, Taxas 78228

State of Hawa: :

## NOTICE OF VIOLATION

Raytheon Engineers & Constructors. Inc. Honolulu. Hawaii Docket: 030-20425 License: 53-23258-01 EA: 96-205

During an NRC inspection conducted on May 14 through June 11. 1996, 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 CFP 20.207, the regulation in effect in 1991 and 19', required that licensed material stored in an unrestricted area be secured from unauthorized removal from the place of storage and that licensed material in an unrestricted area and not in storage be tended under the constant surveillance and immediate control of the licensee. 10 CFR 20.3 defined an unrestricted area as any area to which access is not controlled by the licensee for the purpose of protecting individuals from exposure to radiation and radioactive materials, and any area used for residential guarters.

Contrary to the above, after August 31, 1991, a 250 microcurie americium-241 foil source was stored and used in an unrestricted area and the source was not secured from unauthorized removal nor tended under constant surveillance and immediate control of the licensee. The source was identified as missing during a physical inventory performed in January 1992 and as of June 11, 1996, the source had not been located.

This is a Severity Level III violation Supplement IV).

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 correspondence dated September 3, 1996. 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 response as a "Reply to a Notice of iolation," and send it to the Nuclear Regulatory Commission, ATTN:

ment Control Desk, Washington, D.C. 20555 with a copy to the Regional Aca. Thator Region IV, 611 Ryan Plaza Drive, Suite 400, Arlington, Texas 76011. The Wainut Creek Field Office, 1450 Maria Lane, Walnut Creek, Californi, 94596, within 30 days of the date of the letter transmitting this Notice of Violation.

Because the response will be placed in the NRC Public Document Room (PDR). should ye choose to respond, to the extent possible, it should not include any personal provacy, proprietary, or safeguards information so that it can be placed in the PDR without redaction. However, if it is necessary to include such information it should clearly indicate the specific information that should not be placed in the PDR and provide the legal basis to support the request for withholding the information from the public.

Dated at Arlington. Texas. this 20th day of September. 1996



## UNITED STATES NUCLEAR REGULATORY COMMISSION

REGION III 801 WARRENVILLE ROAD LISLE, ILLINOIS 60532-4351

July 17, 1996

EA 96-099

Mr. Craig J. Marks, President South Haven Community Hospital 955 South Bailey Avenue South Haven, MI 49090-0489

SUBJECT: NOTICE OF VIOLATION (NRC Investigation Report No. 3-95-025)

Dear Mr. Marks:

This refers to the investigation conducted by the NRC Office of Investigations (OI) to review possible willful violations of NRC requirements involving South Haven Community Hospital (SHCH), South Haven, Michigan. The investigation concerned the improper receipt of NRC licensed material by a nuclear medicine technologist (NMT). The investigation concluded that deliberate violations of NRC requirements occurred. The investigation report synopsis was sent to you on April 16, 1996. Additionally, a transcribed predecisional enforcement conference was held with the NMT on May 6, 1996, at which time the NMT admitted to causing each of the deliberate violations.

Based on the information developed during the investigation, the information in a May 13, 1996, SHCH letter in response to NRC's April 16, 1996, letter, and the information provided by the NMT at the May 6, 1996, conference, the NRC has determined that significant violations of NRC requirements occurred. The violations are cited in the enclosed Notice of Violation (Notice). In summary: NRC-licensed material (technetium-99m) was received at locations other than SHCH; dosages of technetium-99m were not measured prior to being administered to patients; records were inaccurate in that calculated dosage activity was recorded in place of measured activity; and a dosage measurement record for February 14, 1995, was annotated to indicate that a measurement had been made at SHCH is in fact, the measurement had not been made. NRC acknowledges that is dosage was measured at the nuclear pharmacy prior to dispensing the radio, marmaceutical to SHCH; however, it was SHCH's responsibility to verify that the proper material and dosage were being administered.

As the holder of an NRC license, SHCH is responsible for radiation safety at the hospital and is expected to provide effective management and oversight of its licensed programs. Incumbent upon each NRC license is the responsibility to protect the public health and safety by assuring that all requirements of the NRC license are met and any potential violations of NRC requirements are identified and expeditiously corrected. To the credit of SHCH, a "Self Identified Regulatory Violation" was issued by SHCH to the NMT on April 7. 1994, documenting the receipt of licensed materials at an unauthorized location. However, this action did not prevent the NMT from again receiving licensed materials at an unauthorized location on February 7, 9, and 14, 1995. The NRC recognizes that SHCH took immediate corrective actions once it became aware of the February 1995 violations. Nevertheless, the recurrence of deliberate violations of NRC requirements indicates that SHCH did not maintain sufficient oversight of licensed activities performed by the NMT which is of significant regulatory concern. The willful violations are categorized in the aggregate in accordance with the "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 \$2,500 is normally considered for a Severity Level III 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 was warranted for the identification factor because SHCH identified the violations. Credit was also warranted for the prompt corrective actions taken following the February 1995 incidents, which included: removing the NMT from NRC-licensed activities at SHCH; ceasing to transport radioactive materials to remote sites; and instructing the remaining NMT about adherence to NRC license conditions.

Therefore, to encourage the prompt identification and 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.

In addition to this enforcement action, a Notice of Violation is being issued to the NMT involved in the deliberate violations. You will receive a copy of this communication under separate cover.

The NRC has concluded that information regarding the reasons for the violations, the corrective actions taken and planned to correct the violations and prevent recurrence and the date when full compliance was achieved is already adequately addressed on the docket in the letter from SHCH dated May 13, 1996. 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 respond, you should follow the directions specified in the enclosed Notice.

- 3 -

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter, its enclosure, and your response (should SHCH choose to respond) 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.

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Sincerely,

Hubert J. Miller Regional Administrator

Enclosure: Notice of Violation

cc: Chairman, Board of Trustees South Haven Community Hospital

#### NOTICE OF VIOLATION

South Haven Community Hospital South Haven, Michigan

Docket No. 030-32015 License No. 21-26266-01 EA 96-039

During an NRC investigation concluded on February 12, 1996, violations of NRC requirements were identified. In accordance with the "Statement of Policy and Procedure for NRC Enforcement Actions" (Enforcement Policy), NUREG-1600, the violations are listed below:

A. Condition 10.A of NRC License No. 21-26266-01 requires that licensed material be received, stored and used at 955 South Bailey Avenue, South Haven, Michigan.

Contrary to the above, licensed material was received at locations other than 955 South Bailey Avenue, South Haven, Michigan. Specifically, on April 7, 1994, licensed material, technetium-99m, was received at the Syncor pharmacy, Grand Rapids, Michigan, and on February 7, 9, and 14, 1995, licensed materials, technetium-99m, were received in a parking lot at Bronson Methodist Hospital, Kalamazoo, Michigan. (01013)

B. 10 CFR 35.53(a) requires, in part, that a licensee measure the activity of each radiopharmaceutical dosage that contains more than 10 microcuries of a photon-emitting radionuclide before medical use.

Contrary to the above, on April 7, 1994, and February 7, 9, and 14, 1995, the licensee did not measure radiopharmaceutical dosages containing technetium-99m, a photon-emitting radionuclide, before they were administered to patients for medical use at Three Rivers Area Hospital, Three Rivers, Michigan. Specifically, dosages of 9.27, 4.7, 5.49, and 6.68 millicuries of technetium-99m were not measured prior to administering the dosages to patients on April 7, 1994, February 7, 9, and 14, 1995, respectively. (02013)

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

10 CFR 35.53(a) requires, in part, that a licensee measure the activity of each radiopharmaciutical dosage that contains more than 10 microcuries of a photon-emitting radionuclide before medical use. 10 CFR 35.53(c) requires that a licensee retain a record of measurements required by Section 35.53 for three years.

Contrary to the above, on April 7, 1994, and February 7, 9, and 14, 1995, information required by the Commission's regulations to be maintained by the licensee was not complete and accurate in all material respects. Specifically, the licensee's radiopharmaceutical dosage measurement records recorded calculated rather than measured values for millicurie dosages of technetium-99m, a photon-emitting radionuclide.

NUREG-0940, PART III

In addition, the record of the February 14, 1995 dosage measurement of technetium-99m was inaccurate in that the record stated that the dosage was specifically measured at South Haven Hospital, South Haven, Michigan, when, in fact, no measurement was made. This information was material because NRC relies on records required by 10 CFR 35.53(c) to determine the licensee's compliance with Section 35.53(a). (03013)

This is a Severity Level III problem. (Supplements VI and VII).

The NRC has concluded that information regarding the reasons for the violations, the corrective actions taken and planned to correct the violations and prevent recurrence and the date when full compliance was achieved is already adequately addressed on the docket in the SHCH letter dated May 13, 1996. 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 chocse 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, NRC Region III, 801 Warrenville Road, Lisle, Illinois 60532-4351, within 30 days of the date of the letter transmitting this Notice of Violation.

Dated at Lisle, Illinois the 17th day of July 1996



UNITED STATES NUCLEAR REGULATORY COMMISSION REGION I

475 ALLENDALE ROAD KING OF PRUSSIA, PENNSYLVANIA 19406-1415

December 30, 1996

EA 96-499

William D. Taylor, Ph.D. Director, Intercollege Programs The Pennsylvania State University 202 Kern Building University Park, Pennsylvania 16802

# SUBJECT: NOTICE OF VIOLATION (NRC Inspection Report Nc. 030-00952/96-001)

Dear Dr. Taylor:

This refers to the inspection conducted on November 18-20, 1996, at your University Park, Pennsylvania facility. The purpose of the inspection was to determine whether activities authorized by the license were conducted safely and in accordance with NRC requirements. At the conclusion of the inspection, the findings were discussed with you and the members of your staff identified in the Inspection Report. The inspector identified apparent violations of NRC requirements, which were described in the NRC inspection report transmitted with our letter, dated December 6, 1996. On December 20, 1996, a predecisional enforcement conference was conducted with you, and other members of your staff to discuss the violations, their causes, and your corrective actions. A copy of the enforcement conference report is enclosed.

Based on the information developed during the inspection, information provided in a letter dated November 29, 1996, in response to a Confirmatory Action Letter issued by the NRC on November 22, 1996, as well as information 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 are described in detail in the subject inspection report. The first violation involves several examples of failure to secure licensed radioactive material or limit access to material at the facility. The unsecured material included: (1) an unopened package containing a 5.656 millicurie stock vial of phosphorus-32, a 1 millicurie stock vial of phosphorus-32, and a 1 millicurie stock vial of hydrogen-3, located in the Agricultural Science and Industry building, an unrestricted area; (2) liquid waste containing 6 millicuries of chromium-51, and a 1 millicurie stock vial of chromium-51 located in the Henning building, an unrestricted area; and (3) two 1 millicurie stock vials, and six stock vials containing at least 250 microcuries of phosphorus-32 located in the Althouse building, an unrestricted area. At the time each example was identified, the areas were not controlled, and constant surveillance was not maintained of the licensed material. This violation represents a significant safety and regulatory concern because it had the potential to cause exposures to members of your staff as well as members of the public. Therefore, the violation is classified in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions" (Enforcement Policy), NUREG-1600, at Severity Level III.

# The Pennsylvania State University

In accordance with the inforcement Policy, a base civil penalty in the amount of \$2,500 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, 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 were both prompt and comprehensive. These actions, which were described either during the enforcement conference and/or in your November 29, 1996 response to an NRC Confirmatory Action Letter, included, but were not limited to the following: (1) sending a written notice, on November 29, 1996, to all supervisors of radioisotope laboratories informing them that the security rule in section 12.10 of the Rules and Procedures for the Use of Radioactive Material at your facility is no longer valid and that 10 CFR 20.1801 and 1802 will be used to ensure security of radioactive material; (2) including evaluating compliance with 10 CFR 20.1801 and 1802 as part of the routine laboratory inspections; (3) training to the health physics staff on the requirements of 10 CFR 20.1801 and 1802 on November 26, 1996: (4) completion of audits of about 60% of the laboratories by the Health Physics Office with plans to also audit the other laboratories by January 21, 1997; (5) plans to include the security requirements of 10 CFR 20.1801 and 1802 in the radiation safety training required for all persons using radioactive material beginning November 26, 1996; and (6) plans to notify the University Isotope Committee of laboratories which do not meet the requirements of 10 CFR 20.1801 and 1802 and determining the corrective action that will be required.

Therefore, to encourage prompt and comprehensive correction of violations, I have been authorized not to propose a civil penalty in this case. However, similar violations in the future could result in further escalated enforcement action.

Three additional violations identified during the inspection also are described in the enclosed Notice and are classified at Severity Level IV. Two other apparent violations set forth in the inspection report, which you identified and corrected prior to the inspection, are being treated as Non-Cited violations consistent with Section VII.B.1 of the NRC Enforcement Policy for the reasons provided in the enforcement conference report. One other apparent violation identified in the Inspection Report has been determined not to constitute a violatio<sup>--</sup>, as also described in the enforcement conference report.

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).

Sincerely,

Mhu /th Villian

Hubert J. Miller Regional Administrator

# The Pennsylvania State University

Docket No. 030-00952 License No. 37-00185-04

#### Enclosures:

1. Notice of Violation

2. Predecisional Enforcement Conference Report

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cc w/encls: Roger W. Granlund, Radiation Safety Officer The Pennsylvania State University 228 Academic Projects Building University Park, PA 16802

Commonwealth of Pennsylvania

## ENCLOSURE 1

#### NOTICE OF VIOLATION

The Pennsylvania State University University Park, Pennsylvania

Docket No. 030-00952 License No. 37-00185-04 EA 96-499

During an NRC inspection conducted on November 18-20, 1996, 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 November 18-20, 1996, the licensee did not secure from unauthorized removal or limit access to licensed material stored in several laboratory areas which were unrestricted areas nor did the licensee control and maintain constant surveillance of this licensed material. The following unsecured materials were observed during the inspection: in the Agricultural Science and Industry building, an unopened package containing a 5.656 millicurie stock vial of phosphorus-32, a 1 millicurie stock vial of phosphorus-32, and a 1 millicurie stock vial of hydrogen-3; in the Henning building, liquid waste containing 6 millicuries of chromium-51 and a 1 millicurie stock vial of chromium-51; in the Althouse building, two - 1 millicurie stock vials containing at least 250 microcuries of phosphorus-32. (01013)

This is a Severity Level III violation (Supplements IV and VI).

B. 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, as of November 20, 1996, the licensee did not make surveys to assure compliance with 10 CFR 20.2003(a)(1), which limits the disposal of licensed material into the sanitary sewerage to material that is readily soluble (or readily dispersible biological material) in water. Specifically, the licensee routinely disposed of licensed material to the sanitary sewerage, but had not determined whether the material discharged was readily soluble (or readily dispersible biological material) in water. (02014)

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

C.

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 who delivers licensed material to a carrier for transport, comply with the applicable requirements of the regulations appropriate to the mode of transport of the Department of Transportation (DOT) in 49 CFR Parts 170 through 189.

49 CFR 172.704(c)(1) requires, in part, that each hazmat employer shall train each hazmat employee within 90 days after employment or the hazmat employee may perform new hazardous material job functions prior to the completion of training provided the employee performs those functions under the supervision of a properly trained and knowledgeable hazmat employee.

Contrary to the above, as of November 18, 1996, the licensee did not train a hazmat employee within 90 days after employment or ensure that the hazmat employee performed new hazardous material job functions prior to the completion of training under the supervision of a properly trained and knowledgeable hazmat employee. Specifically, on five occasions in the two years prior to November 18, 1996, employees who transported moisture density gauges containing licensed materials, a hazardous material, had not received hazmat training within 90 days after employment nor were they performing hazmat functions under the supervision of a properly trained and knowledgeable hazmat employee. (02024)

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

D. 10 CFR 20.1101(c) requires that the licensee shall periodically (at least annually) review the radiation protection program content and implementation.

Contrary to the above, as of November 18, 1996, the licensee did not review the radiation protection program content and implementation at least annually. Specifically, a review of the radiation protection program content and implementation for 1995 had not been completed at the time of the inspection. (02034)

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

#### Enclosure 1

Pursuant to the provisions of 10 CFR 2.201. The Pennsylvania State University (Licensee) is here by required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555 with a copy to the Regional Administrator, Region I, within 30 days of the date of the letter transmitting this Notice of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each violation; (1) the reason for the violation, or if contested, the basis for disputing the violation, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken to avoid further violations, and (4) the date when full compliance will be achieved. 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 the Notice, an order or Demand for Information may be issued as to why the license should not be modified, suspended, or revoked, or why such other action as may be proper should not be taken. Where good cause is shown, consideration will be given to extending the response time.

Under the authority of Section 182 of the 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, or proprietary, 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 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).

Dated at King of Prussia, Pennsylvania this 30% day of December 1996



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

August 2, 1996

EA 96-157

Mr. Phil Young Chief Executive Officer Universal Imaging, Inc. 12450 Universal Drive Taylor, MI 48180

SUBJECT: NOTICE OF VIOLATION (NRC Inspection Report No. 030-33326/96001(DNMS))

Dear Mr. Young:

This refers to the inspection conducted from April 29 to June 10, 1996, to review a misadministration of NRC-licensed material (iodine-131) that occurred on March 18, 1996, at Northwest X-Ray Services, Southfield, Michigan. Northwest X-Ray Services is one of three locations authorized by the NRC Materials License issued to Universal Imaging, Inc., for the use of licensed materials. On April 26, 1995, the NRC was notified of the misadministration. The inspection report was mailed to Universal Imaging, Inc., on June 18, 1996. and a predecisional enforcement conference was held on July 3, 1996.

Based on the information developed during the inspection and the information provided during the conference, the NRC has determined that significant 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 misadministration occurred when the wrong radiopharmaceutical, iodine-131, was administered to a patient, instead of iodine-123. The inspection identified several violations of NRC requirements including the failures to: (1) establish and implement a system for ordering and receiving radioactive material; (2) verify that the material received was the material ordered; (3) provide required training; and (4) provide a timely and complete report of the event.

The NRC entrusts responsibility for radiation safety to the management of Universal Imaging, Inc. Therefore, the NRC expects effective management and oversight of its licensed program. Incumbent upon each NRC licensee is the responsibility to protect the public health and safety by assuring that all requirements of the NRC license are met and any potential violation of NRC requirements is identified and expeditiously corrected. In this case, a nuclear medicine technologist recognized on March 18, 1996, that iodine-131 had been received for the patient; however, iodine-123 was routinely used for the procedure. Notwithstanding the difference noted between the material received and the material normally used, the technologist administered the wrong radiopharmaceutical. Furthermore, on March 25, 1996, an authorized user identified that a misadministration occurred, but did not inform the Radiation Safety Officer (RSO). The misadministration was rediscovered on April 26, 1996, by a consultant during review of radiopharmaceutical use logs.

Universal Imaging, Inc.

The various errors causing and following the event demonstrate that ineffective and insufficient management oversight of the implementation of the radiation safety program exists at Universal Imaging, Inc. The violations represent a breakdown in the control of licensed activities involving a number of violations that are related that collectively represent a potentially significant lack of attention toward licensed responsibilities. Therefore, these violations 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 III problem.

In accordance with the Enforcement Policy, a base civil penalty in the amount of \$2,500 is considered for a Severity Level III problem. Because your facility has not been the subject of escalated enforcement actions 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 the *Corrective Action* factor was warranted because of the timely and thorough actions taken, including, but not limited to: notified the nuclear pharmacy that iodine-125 and iodine-131 should not be delivered; implemented a procedure that future orders of radiopharmaceuticals will be made by facsimile rather than by telephone; instructed technologists not to start a procedure if the technologist had questions; and appointed a new RSO who will provide job specific training to the authorized users and the technologist. In addition during a conversation on July 31, 1996, you agreed to amend the license to remove the authorization to use iodine-125 and iodine-131.

Therefore, to encourage prompt comprehensive correction of violations and in recognition of the absence of previous escalated enforcement action, I have decided not to propose a civil penalty in this case. However, significant violations in the future could result in a civil penalty.

One other potential violation of NRC requirements was identified during the inspection. This issue concerned the failure to notify the patient, or the patient's representative, of the misadministration in accordance with 10 CFR 35.33(a)(2). The intent of the notification requirement was discussed during the predecisional enforcement conference and the patient was subsequently notified. Therefore, the NRC is not citing a violation of 10 CFR 33(a)(2).

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

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.

- 3 -

Sincerely, fr Hubert J. Miller Regional Administrator

Docket No. 030-33326 License No. 21-26532-01

Enclosure: Notice of Violation

Universal Imaging, Inc. Taylor, Michigan Docket No. 030-33326 License No. 21-26532-01 EA 96-157

During an NRC inspection conducted from April 29 to June 10, 1996, 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. License Condition 16.A to NRC License No. 21-26532-01, Amendment No. 2, requires that the licensee conduct its program in accordance with the statements, representations, and procedures contained in the application dated September 15, 1993.
  - Item No. 10.6.2.a. of the application dated September 15, 1993, requires the Radiation Safety Officer establish and maintain a system for ordering and receiving radicactive material that includes: (1) written records that identify the authorized user or department, isotope, chemical form, activity, and supplier; and (2) the records will be checked to confirm that the material received was ordered through proper channels.

Cor the above, the licensee failed to maintain a system for ang and receiving radioactive material that includes: (1) written records that identify the authorized user or department, isotope, chemical form, activity, and supplier; and (2) the records will be checked to confirm that the material received was ordered through proper channels. Specifically, 300 microcuries of sodium iodide-131 was received by the licensee on March 18, 1996 at the Northwest X-Ray facilities and written records did not identify: the authorized user, department or chemical form and the records were not checked to confirm that material received was ordered through proper channels. (01013)

 Item 10.7.6 of the application dated September 15, 1993, requires, in part, that the licensee will verify that the material received is the material ordered.

Contrary to the above, the licensee received licensed material on March 18, 1996 and did not verify that the material received was the material ordered. (01023)

3. Item 8.1 of the application dated September 15, 1993, requires, in part, that before assuming duties, all radiation workers and ancillary personnel whose duties will require them to work in the vicinity of radioactive materials will receive instruction in the following instruction topics: (1) applicable regulations and license conditions, (2) areas where radioactive material is used or stored, (3) potential hazards associated with radioactive material in eaci area where the employees will work, (4) appropriate radiation safety procedures, and (5) the licensee's in-house work rules.

- 2 -

Contrary to the above, prior to April 26, 1996, the licensee failed to provide the above required training to a radiation worker, a nuclear medicine technologist, before allowing the individual to assume duties in December 1995. (01033)

- B. License Condition 16.B to NRC License No. 21-26532-01, Amendment No. 2, requires that the licensee conduct its program in accordance with the statements, representations, and procedures contained in letters dated January 11, 1994 and February 16, 1995.
  - The letter dated January 11, 1994, requires, in part, that the licensee will not administer quantities greater than 30 microcuries of sodium iodide-131 or iodide-125.

Contrary to the above, on March 18. 1996, the licensee administered 200 microcuries of sodium iodide-131 for a diagnostic test. (02013)

 Item 3. of the letter dated February 16, 1995, requires, in part, that Lawrence G. Wayburn, M.D., will spend at least four hours per week at the Northwest X-Ray Clinic location to fulfil his responsibility as Radiation Safety Officer.

Contrary to the above, prior to March 18, 1996, Lawrence G. Wayburn, M.D., was not present at the Northwest X-Ray Clinic location at least four hours per week to fulfil his responsibility as the Radiation Safety Officer. (02023)

C. 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 the misadministration. 10 CFR 35.2 defines, in part, "misadministration," to mean a radiopharmaceutical dosage greater than 30 microcuries of either sodium iodide I-125 or I-131 involving the wrong radiopharmaceutical.

Contrary to the above, on March 25, 1996, the licensee became aware that a misadministration occurred and the licensee did not notify the NRC Operations Center until April 26, 1996, which was later than the next calendar day. Specifically, on March 18, 1996, 200 microcuries of iodine-131 were administered to a patient instead of iodine-123. (03013)

D. 10 CFR 35.33(a)(2) requires, in part, that for a misadministration the licensee must submit a written report to the appropriate NRC Region Office (NRC Region III) within 15 days of discovery of the misadministration.

NUREG-0940, PART III

- 3 -

Contrary to the above, the licensee failed to provide to the NRC Region III Office a written report concerning a misadministration of iodine-131 within 15 days of the discovery of the incident. Specifically, on March 25, 1996, the licensee discovered that a misadministration of iodine-131 had occurred on March 18, 1996, and the licensee did not file the written report of the event until May 16, 1996, which is a period in excess of 15 days. (04013)

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

Pursuant to the provisions of 10 CFR 2.201, Universal Imaging, Inc. is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555, with a copy to the Regional Administrator, Region III, 801 Warrenville Road, Lisle, Illinois 60532-4351 within 30 days of the date of the letter transmitting this Notice of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each violation: (1) the reason for the violation, or, if contested, the basis for disputing the violation, (2) the correct ve 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.

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. 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.

Dated at Lisle, Illinois this <u>2</u> day of August 1996

NUREG-0940, PART III



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

November 29, 1996

Mr. Paul F. Davern Associate Vice President University of Connecticut Health Center Route 4 Farmington, Connecticut 06030

SUBJECT: NOTICE OF VIOLATION (NRC Inspection Report No. 030-01295/96-001)

Dear Mr. Davern:

This refers to the inspection conducted on October 21-25, 1996, at your Farmington and Norwich, Connecticut facilities. The purpose of the inspection was to determine whether activities authorized by the license were conducted safely and in accordance with NRC requirements. At the conclusion of the inspection, the findings were discussed with you and several members of your staff as identified in the subject Inspection Report. The inspector identified apparent violations of NRC requirements, which were described in the NRC inspection report transmitted with our letter, dated November 15, 1996. On November 25, 1996, a Predecisional Enforcement Conference was conducted with you, Mr. Leonard Paplauskas, Vice President for Research, and other members of your staff to discuss the violations, their causes, and your corrective actions. A copy of the enforcement conference report will be forwarded to you by separate correspondence.

Based on the information developed during the inspection 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 (Notice) and the circumstances surrounding them are described in detail in the subject inspection report. The violation involves two examples of failure to secure licensed radioactive material at the facility. The first example occurred on October 21, 1996, and involves the failure to secure from unauthorized removal or limit access to two 2.5 curie molybdenum-technotium generators located in the Nuclear Medicine Department Hot Lab, an unrestricted area. At the time the area was not controlled, and constant surveillance was not maintained of this licensed material. The second example occurred between February 10 and February 16, 1996. It involves the failure to secure from unauthorized removal or limiting access to greater than 100 microcuries of phosphorus-32 (P-32) in the form of alpha adenosine triphosphate (ATP) which was stored in an unlocked freezer in microbiology laboratory (L-2012). The material was removed by an unknown person, from the stock material vial located in an unlocked freezer. The amount withdrawn from the vial could not be determined since the individual did not record the amount withdrawn on the material utilization log. As a result of this, when a researcher attempted to withdraw some of this reagent on February 26, 1996, she found the vial empty.

## University of Connecticut Health Center

2

On February 29, 1996, during a routine monthly laboratory survey, a researcher found significant contamination in the hood located in laboratory L-2012. The Radiation Safety Officer (RSO) was notified and found the contamination to be caused by P-32. The Licensee believes that the contamination was caused by the unknown person using the missing P-32 alpha ATP in the hood within the laboratory. This violation represents a significant safety and regulatory concern because it had the potential to cause exposures to members of your staff as well as members of the public. In addition, a potential existed for the spread of contamination since the P-32 spill was not reported in a timely manner to the RSO or the principal investigator. Therefore, the violation is classified in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions" (Enforcement Policy), NUREG-1600; at a Severity Level III.

In accordance with the Enforcement Policy, a base civil penalty in the amount of \$2,500 is considered for a Severity Level III violation. Because your facility has not been the subject of escalated enforcement actions within the last two 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 were both prompt and comprehensive. These actions, which were noted in the inspection report included, but were not limited to the following: (1) instituting a policy requiring that the Nuclear Medicine Department Hot Lab door remain locked and closed at all times; (2) installing an automatic door closure device on the Hot Lab door; (3) posting a sign on the Hot Lab door indicating that it is to remain locked and closed; (4) conducting several meeting with staff members discussing the requirement to lock the Hot Lab door; (5) including a check of the Hot Lab door during weekly surveys and documenting those checks; (6) requiring that all laboratories be locked when unattended; (7) conducting training sessions with laboratory staff concerning the requirement to lock laboratory doors; and (8) distributing a notice to all principal investigators concerning the security of laboratories.

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, similar violations in the future could result in further escalated enforcement action.

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

The NRC remains concerned with respect to your investigation into the missing P-32. In particular, the unknown person believed to have used the missing P-32 did not come forward with information concerning their use of the P-32. Therefore, when responding to this Notice please describe in detail what additional actions you will take to oversee the accountability of all licensed radioactive material, improve control of radioactive material by authorized users, and minimize the potential for lost or misplaced licensed radioactive material in your laboratories.

## University of Connecticut Health Center

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).

3

Sincerely,

lup Hubert J. Miller

Regional Administrator

Docket No. 030-01295 License No. 06-03022-01

Enclosure: Notice of Violation

cc w/encl: State of Connecticut ENCLOSURE

## NOTICE OF VIOLATION

University of Connecticut Health Center Farmington, Connecticut Docket No. 030-01295 License No. 20-01537-02 EA 96-454

During an NRC inspection conducted on October 21-25, 1996, 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:

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.

Contrary to the above the licensee failed to secure from unauthorized removal or limit access to licensed material stored in controlled or unrestricted areas as evidenced by the following two examples.

- 1. on October 21, 1996, the licensee did not secure from unauthorized removal or limit access to two 2.5 curie molybdenum-technetium generators located in the Nuclear Medicine Department Hot Lab nor did the licensee control and maintain constant surveillance of this licensed material. This was evidenced by the fact that an NRC inspector gained access to the Hot Lab where the radioactive materials were stored and used which ware not under surveillance.
- between February 10, and February 16, 1996, the licensee did not secure from unauthorized removal, or limit access to, greater than 100 microcuries of phosphorus-32 located in laboratory (L-2012), nor did the licensee control and maintain constant surveillance of this licensed material. (01013)

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

Pursuant to the provisions of 10 CFR 2.201, the University of Connecticut Health Center is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555 with a copy to the Regional Administrator, Region I, within 30 days of the date of the letter transmitting this Notice of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each violation; (1) the reason for the violation, or if contested, the basis for disputing the violation, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken to avoid further violations, and (4) the date when tull compliance will be achieved. Your response may reference or include previous docketed correspondence, if the correspondence adequately address the required response. If an adequate reply is not received within the time specified in the Notice,

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#### Enclosure

an order or Demand for Information may be issued as to why the license should not be modified, suspended, or revoked, or why such other action as may be proper should not be taken. Where good cause is shown, consideration will be given to extending the response time.

order 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, or proprietary, 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 3 request for withholding confidential commercial or financial information).

Dated at King of Prussia, Pennsylvania this 29th day of November 1996

NUREG-0940, PART III



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

August 5, 1996

EA 96-245

Mr. Martin B. Lowenthal, Foundent U.S. Engineering Labs, Incorporated 903 East Hazelwood Avenue Rahway, New Jersev 07065

Dear Mr. Lowenthal:

## SUBJECT: NOTICE OF VIOLATION (NRC INSPECTION REPORT NO. 030-33387/96-001)

This letter refers to the NRC inspection conducted on June 28, 1996, at your facility in Rahway, New Jersey. The purpose of this inspection was to determine whether activities authorized by the license were conducted safely and in accordance with NRC requirements, and to review the circumstances surrounding damage to a soil moisture/density gauge containing licensed radioactive material. At the conclusion of the inspection, the findings were discussed with you and Mr. C. O'Malley, your Radiation Safety Officer. During the inspection three apparent violations of NRC requirements were identified, as described in the NRC inspection report, a copy of which was sent to you on July 10, 1996. On July 24, 1996, a predecisional enforcement conference was conducted with you and Mr. O'Malley to discuss the apparent violations, their causes, and your corrective actions. A copy of the Enforcement Conference Report is enclosed.

Based on the information developed during the inspection, and information provided during the conference, two violations of NRC requirements are being cited in the enclosed Notice of Violation (Notice), and the circumstances surrounding them are described in detail in the subject inspection report. The violations described in the enclosed Notice include the following: (1) failure to maintain control of licensed material not in storage; and (2) the use of licensed material by unauthorized users. A third apparent violation described in the inspection report, involving the failure to maintain training records, constitutes a violation of minor safety significance and is being treated as a Non-Cited Violation, consistent with Section IV, of the NRC Enforcement Policy and is not being cited in the enclosed Notice.

On June 27, 1996, you informed the NRC Region I staff that a portable soil moisture/density gauge containing licensed materials (sealed sources of 8 millicuries of cesium-137 and 40 millicuries of americium-241) had been damaged when a truck ran over it at a temporary job site in Jersey City, New Jersey. During the NRC inspection, we determined that the technician had left the gauge unattended in order to inform the foreman, who was approximately 100 feet away, that two compaction tests had failed. After speaking with the foreman, the technician left the general area to speak with the superintendent of the site, who was located in a trailer on site, apparently believing that the foreman was providing security of the area where the gauge was located. When the technician returned, approximately 3 minutes later, to the area where the gauge was located, he found that it had been damaged.

#### U.S. Engineering Labs, Inc.

The NRC recognizes that the technician subsequently took appropriate action in cordoning off the area, and notifying the RSO, who took appropriate action to package and transport the damaged gauge back to your Rahway facility. Nonetheless, the failure to maintain security or constant surveillance of licensed material, particularly at temporary jobsites, represents a significant failure to meet those responsibilities, and constitutes a significant regulatory concern. This failure takes on even greater significance because it resulted in damage to the gauge. Therefore, the violation is categorized at Severity Level III 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 \$2,500 is considered for a Severity Level III violation. Because your facility has not been the subject of escalated enforcement in the past 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 was warranted because your corrective actions were considered both prompt and comprehensive in response to the discovery of the damaged gauge. Your corrective actions, which were described in your presentation during the conference, included: (1) meeting with the responsible individual in order to review what had occurred, and cover the required procedures which should have been followed; (2) immediately contacting all of your gauge users by telephone to inform them of the event; (3) issuing a memorandum, within four days of the event, to all users describing required procedures to be followed; and (4) providing training in one-on-one meetings with all users concerning the procedures for security and control of the gauges, as well as the procedure to follow if a gauge is damaged.

Therefore, to encourage prompt and comprehensive correction of violations, and in recognition of the absence of previous escalated enforcement action at your facility, I have been authorized not to propose a civil penalty in this case. However, any similar violations in the future could result in more significant escalated enforcement action, including issuance of a civil penalty.

The other violation being cited is described in the enclosed Notice and is classified at Severity Level IV. This violation has been classified at Severity Level IV because you were not in compliance with your license but you demonstrated during the conference that the individuals were qualified to use the gauges based on their educational background, and that they also had received training from your radiation safety officer prior to using the gauges.

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

#### U.S. Engineering Labs, Inc.

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 or proprietary information so that it can be placed in the PDR without redaction.

3

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

Sincerely,

The How Hubert J. Miller

Regional Administrator

Docket No. 030-33397 License No. 29-30107-01

Enclosures: 1. Notice of Violation

2. Enforcement Conference Report

cc w/encls: State of New Jersey

NUREG-0940, PART III

#### ENCLOSURE 1

#### NOTICE OF VIOLATION

U.S. Engineering Labs, Inc. Rahway, New Jersey Docket No. 030-33387 License No. 29-30107-01 EA 96-245

During an NRC inspection conducted on June 28, 1996, 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, in part, that the licensee secure from unauthorized removal or access licensed materials that are stored in an unrestricted area. 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, an unrestricted area means an area access to which is neither limited nor controlled by the licensee.

Contrary to the above, on June 27, 1996, the licensee did not secure from unauthorized removal or limit access to a Troxler moisture/density gauge containing an 8 millicurie cesium-137 sealed source and a 40 millicurie americium-241 sealed source located at a temporary jobsite in Jersey City, New Jersey, an unrestricted area. The licensee did not control and maintain constant surveillance of this licensed material in that the gauge was left unattended at the jobsite for approximately three minutes.

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

B. Condition 11.A. of License No. 29-30107-01, requires that licensed material be used by, or under the supervision and in the physical presence of, Christopher O'Malley or individuals who have received the training described in an application dated November 19, 1993, and have been designated in writing by the Radiation Safety Officer. The application, in the attachment under "Training", requires that operators (individuals who use or supervise the use of gauges) must complete the manufacturer's operator's training course.

Contrary to the above, as of June 28, 1996, licensed material was used by individuals who had not completed the manufacturer's operator's training course nor were the operators supervised by individuals who had completed the manufacturer's operator's training course. Specifically, one adividual, who had not completed the manufacturer's training course and was not supervised, used gauges between May 14 and June 28, 1996, and a second individual, who had not completed the manufacturer's training course and was not supervised, used the gauges between May 20 and June 25, 1996.

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

### Enclosure 1

Pursuant to the provisions of 10 CFR 2.201, U.S. Engineering Labs, Inc., is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555, with a copy to the Regional Administrator, Region I, within 30 days of the date of the letter transmitting this Notice of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each violation: (1) the reason for the violation, or, if contested, the basis for disputing the violation, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken to avoid further violations, and (4) the date when full compliance will be achieved. 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 Demand for Information may be issued as to why the license should not be modified, suspended, or revoked, or why such other action as may be proper should not be taken. Where good cause is shown consideration will be given to extending the response time.

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

Because your response will be placed in the NRC Public Document Room (PDR), to the extent possible it should not include any personal privacy or proprietary 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.

Dated at King of Prussia, Pennsylvania this 5thday of August 1996 EA 96-257

Richard D. Wilcox President Wilcox Associates 7711 South U.S. 131 Cadillac, MI 49601

SUBJECT: NOTICE OF VIOLATION (NRC INSPECTION REPORT NO. 030-20901/96001(DNMS))

Dear Mr. Wilcox:

This letter refers to the routine safety inspection conducted from June 25 to July 12, 1996, to review NRC-licensed activities at Wilcox Associates, Cadillac, Michigan. Also reviewed during the inspection were the circumstances surrounding damage to a Troxler moisture/density gauge' that occurred on August 19, 1995, located at a highway construction site in Kent County, Michigan. The inspection report was mailed to Wilcox Associates on August 2, 1996, and in a letter dated August 13, 1996, Wilcox Associates responded to the apparent violations discussed in the inspection report.

Dased on the information developed during the inspection and the information provided in the letter from Wilcox Associates, the NRC has determined that a significant violation of NRC requirements occurred. This violation is cited in the enclosed Notice of Violation (Notice) and the circumstances surrounding it are described in detail in the inspection report.

While the NRC recognizes that the sealed sources were not damaged during the event, the violation is of significant regulatory concern because each NRC licensee is responsible for the protection of the public health and safety, and the health and safety of its employees, by ensuring that all NRC requirements are met. Each licensee must ensure that NRC-licensed material is controlled so that it does not become a hazard to the public. The incident on August 19, 1995, is considered to be a violation representing a significant failure to control licensed material and 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 \$2,500 is considered for a Severity Level III violation. Your facility has not been the subject of a previous NRC escalated enforcement action; therefore, the NRC considered whether credit was warranted for *Corrective Action* in accordance with the civil penalty assessment process in

The gauge contained NRC-licensed material consisting of 10 millicuries (370 MBq) of cesium-137 and 40 millicuries (1.48 GBq) of americium-241, both in sealed sources.

Wilcox Associates

Section VI.B.2 of the Enforcement Policy. Credit was warranted because Wilcox Associates: disciplined the gauge technician; trained four assistant radiation safety officers in the use of Troxler gauges; and implemented a training program for gauge users to prevent similar situations. Other corrective actions included: forming an emergency response team, obtaining beepers so that supervisors can be immediately contacted during an emergency; and contracting with an environmental firm to conduct emergency radiation surveys during an event involving NRC-licensed material.

Therefore, to encourage prompt and comprehensive corrective actions and in recognition of the absence of previous escalated enforcement actions, I have decided not to propose a civil penalty in this case. However, significant violations in the future could result in a civil penalty.

Three other violations were identified during the inspection. These violations concerned the failures to: (1) detain and survey for contamination the vehicle involved in the August 19, 1995 event; (2) test sealed sources for leakage and contamination at prescribed intervals; and (3) review the content and implementation of the radiation program annually.

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 on the docket in Inspection Report No. 030-20901/96001(DNMS) and the letter from Wilcox Associates dated August 13, 1996. 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,

/s/ W. L. Axelson (for)

A. Bill Beach Regional Administrator

Docket No. 030-20901 License No. 21-23314-01

Enclosure: Notice of Violation

Wilcox Associates Cadillac, Michigan

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Docket No. 030-20901 License No. 21-23314-01 EA 96-257

During an NRC inspection conducted from June 25 to July 12, 1996, 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 licensed materials that are stored in an unrestricted area. 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, an unrestricted area means an area, access to which is neither limited nor controlled by the licensee.

Contrary to the above, on August 19, 1995, the licensee did not secure from unauthorized removal or limit access to a Troxler moisture/density gauge containing NRC-licensed material (nominally 10 millicuries (370 MBq) of cesium-137 and 40 millicuries (1.48 GBq) of americium-241 in sealed sources) located at a highway construction site in Kent County, Michigan, an unrestricted area, nor did the licensee control and maintain constant surveillance of this licensed material. Specifically, the gauge technician placed the device in front of his vehicle and walked away. He later returned to his truck and started to drive away at which time the gauge was struck. (01013)

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

License Condition No. 12.A, Amendment No. 2, to NRC Materials License No. 21-23314-01, which was in effect from January 30, 1989, until it was superseded by License Amendment No. 4 on June 16, 1995, required, in part, that sources be tested for leakage and/or contamination at intervals not to exceed 6 months.

License Condition No. 13.A, Amendment No. 4, to NRC Materials License No. 21-23314-01, which became effective or June 16, 1995, requires the licensee test sealed sources and detector cells for leakage and/or contamination at intervals not to exceed 6 months or at such other intervals that are specified by the certificate of registration referred to in 10 CFR 32.210. The certificate of registration of the Troxler Model No. 3411 moisture/density gauge specifies that leak tests shall be made at a frequency of 6 months.

Contrary to the above, the licensee did not test sealed sources for leakage and/or contamination at intervals not to exceed 6 months. Specifically, sealed sources of nominally 10 millicuries (370 //Bq) of cesium-137 and 40 millicuries (1.48 GBq) of americium-241, contained in a Troxler Model No. 3411 (Serial No. 10377) moisture/density gauge, were not tested from January 1995 to February 1, 1996, an interval that exceeded 6 months. (02014)

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

## Notice of Violation

C. License Condition 20.8 of NRC Materials License No. 21-23314-01, requires, in part, that the licensee conduct its program in accordance with the statements, representations and procedures contained in a letter dated May 18, 1995 and the attachments thereto.

The Licensee's "Standard Operating and Emergency Procedures" were attached to the May 18, 1995 letter. Paragraph 3 of the "Emergency Procedure" required the licensee detain any heavy equipment that may be involved in an emergency or unusual situation until it is determined that no contamination is present.

Contrary to the above, on August 19, 1995, a Troxler Model No. 3411 moisture/density gauge containing NRC licensed materials (nominally 10 millicuries (370 MBq) of cesium-137 and 40 millicuries (1.48 GBq) of americium-241 in sealed sources) was struck by a pick-up truck and the licensee did not detain the truck or otherwise determine that there was no contamination present. (03014)

D. 10 CFR 20.1101(c), which became effective on January 1, 1993, requires that the licensee periodically (at least annually) review the radiation protection program content and implementation.

Contrary to the above, from January 1, 1993, to June 25, 1996, the license did not conduct any reviews of the radiation program content or implementation. (04014)

This is a Severity Level IV violation (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 on the docket in Inspection Report No. 030-20901/96001(DNMS) and a letter from Wilcox Associates dated August 13, 1996. 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.

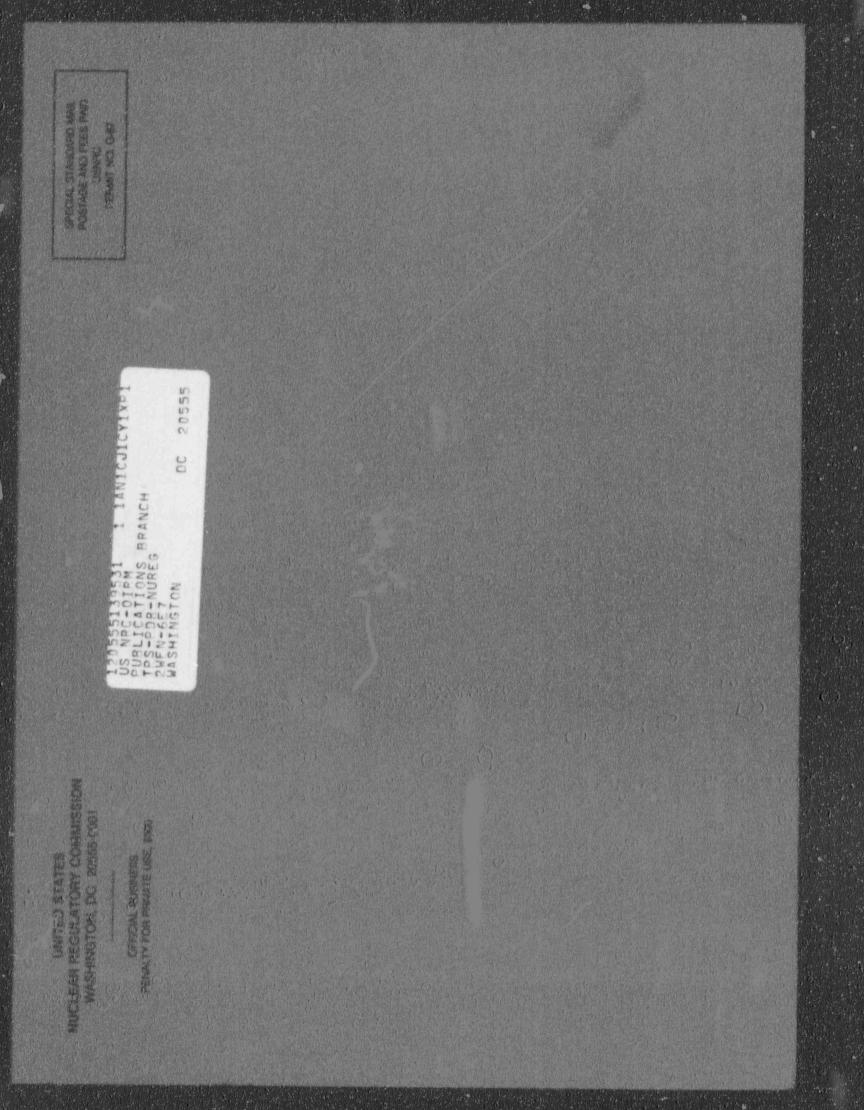
Dated at Lisle, Illinois this 3rd day of September 1996

NUREG-0940, PART III

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during the perio and Orders sent respect to these this publication activities licen	summarizes significant enforcement d (July - December 1996) and includ by the Nuclear Regulatory Commission enforcement actions. It is antici- will be widely disseminated to man sed by the NRC, so that actions can violations similar to those describ	des copies of letters, Notices, on to material licensees with lpated that the information in magers and employees engaged in h be taken to improve safety by
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