

May 5, 1997

Memo To: Jim Kaiser Jody Dean David Pearse
John Schweers Mark Thomas Ruth Garcia
Mark Sharp Victor Kach Jerry Kriebel
Ken Christiansen Mark Legarda Ken Kohler
Ed Lahey Tom Dempsey Chris Roberts
Frank Yacino Scott Comstock

cc: Chuck Truby J. Dzwierzynski A. Rosado

From: Jon Young

Subject: Operating the Irradiator with Inadequately Trained Personnel

USNRC Regulations (as well as all Agreement States) mandate that both an irradiator operator and at least one other individual trained the respond to emergency alarm conditions be present while the irradiator is in operation. This requirement and its regulatory interpretation have been in place since 1992.

Attached is a copy of the Notice of Violation and Proposed Imposition of Civil Penalty recently issued by NRC Region III to the 3M facility in Brookings, South Dakota. The document clearly states 3M's apparent disregard for compliance and the seriousness which NRC views this issue.

To audit your current position and ensure compliance at your facility, it is requested that the following be completed prior to the end of May.

1. Review the 3M incident with all Irradiator Operators, Supervisors and Managerial personnel. Stress the following:
 - a. the requirements as stated in 10 CFR 36.65,
 - b. the steps to be taken by supervisors should absenteeism create a non compliant situation,
 - 1) Call for a qualified off shift individual,
 - 2) Call the site RSO,
 - 3) Cease irradiator operations by placing the source in the storage pool.
2. Generate and post a name and phone number listing of all qualified irradiator operators and individuals trained in the appropriate emergency response to radiation alarms.
3. Review your training records to determine the qualification adequacy of your operating personnel. Initiate the appropriate training sessions to increase the pool of qualified individuals.
4. Provide to Corporate a copy of your qualified operator list and documentation of your training session associated with item 1.

Call if you have any questions.

ISOMEDIX INC.

A/13

January 7, 1997

EA 96-403

Dr. F. J. Palensky
 Division Vice President
 Medical Products Technology Division
 3M Center
 Post Office Box 33283
 St. Paul, Minnesota 55133-3283

OPTIONAL FORM 99 (7-90)		# of pages = 10
FAX TRANSMITTAL		
To John Young / George Deitz	From Bruce Mallett	
Dept./Agency	Phone # 404-562-4702	
Fax #	Fax # 404-562-4899	
NSM 7540-01-317-7368		5000-101 GENERAL SERVICES ADMINISTRATION

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY -
 \$8,000 (NRC Inspection Report No. 030-14999/96001 (DNMS))

Dear Dr. Palensky:

This refers to the inspection conducted on October 7 through 31, 1996, at the 3M facility in Brookings, South Dakota. The purpose of the inspection was to determine whether activities authorized by the license were conducted safely and in accordance with NRC requirements. The inspection report was sent to you by letter dated November 4, 1996. On November 15, 1996, a transcribed predecisional enforcement conference was held in the NRC Region III office with you and other members of the 3M staff to discuss the violations, their causes, and proposed corrective actions.

Based on the information developed during the inspection and the information that you provided during the conference, the NRC has determined that violations of NRC requirements occurred. 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.

The violation described in Section I of the Notice is very significant. On four occasions, the mega-curie irradiator located at your Brookings, South Dakota, facility was left in the operating mode without an operator in attendance. During two of the four known occasions of operator absences, tote jams occurred which caused the conveyor to stop and resulted in the source rack withdrawing into the storage pool, as designed. On these occasions a security guard, having only minimum training, was required to respond to the annunciator because a qualified operator was unavailable. 10 CFR Part 36 clearly requires an operator to be in attendance when the irradiator is in use. The NRC is particularly concerned that your staff either did not know or did not understand the operator attendance requirement, and your audit program failed to identify the problem. Considering the possible hazardous consequences which could occur, this inattention to irradiator operation had the potential for significant (radiological) exposure to 3M personnel.

3M Center

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3M, as an entity licensed to possess and use radioactive material, is responsible for ensuring that its irradiation facility is operated in a safe manner. It is essential that the NRC be able to maintain the highest confidence that licensees entrusted with the operation of irradiator sources will comply fully with applicable regulatory requirements. The potential hazard to public health and safety of this type of operation, as well as 3M's failure to identify the attendance issue through its audit program, heightens the safety and regulatory significance of this violation. Failure to assure operator attendance during irradiator use rendered inoperable the managerial control system designed to ensure safe irradiator operation. Therefore, this violation has been categorized at Severity Level II in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions" (Enforcement Policy), NUREG-1600.

In accordance with the Enforcement Policy, a base civil penalty in the amount of \$8,000 is considered for a Severity Level II violation. Due to the severity level 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. The NRC determined that credit was warranted for identification in that a 3M employee recognized that an operator must be in attendance at all times that the irradiator is in operation. The issue was identified on a "Fix-It" ticket and a shift supervisor then issued a memorandum to the operators to clarify the attendance requirement; however, the facility Radiation Safety Officer, the Corporate Health Physics Service, and senior 3M management were not notified of the incident. The NRC determined that credit was not warranted for corrective action. A Confirmatory Action Letter (CAL) was sent to the licensee on October 30, 1996, confirming that certain actions would be taken to: (1) formalize the control room key turnover between operator shifts; (2) conduct an internal audit of the training program; (3) conduct weekly reviews to confirm that operators have been onsite at all times the irradiator had been in operation; (4) review staffing levels based on 100 percent availability of the irradiator, and (5) add two trained and certified authorized users (operators) by December 1, 1996. During the November 15, 1996 predecisional enforcement conference conducted in the Region III office, the licensee reviewed the methods employed to address each of the five actions discussed in the CAL. The licensee has developed procedures for key control, updated the training manual, will add two additional operators, and has instituted a weekly audit of certain key transfer logs which is performed by the facility Radiation Safety Officer (RSO). However, as of the enforcement conference, the licensee failed to address one of the root causes of the problem of operator attendance, *i.e.*, the inadequate auditing program, in sufficient detail to assure management oversight of operator coverage. Specifically, the licensee discussed auditing by the corporate and facility RSO during normal working hours but had made no provision for auditing during non-regular duty hours (nights and weekends). The NRC views this as a significant omission in the licensee's corrective action program because the four known occasions of operator absences all occurred on non-regular duty hours. Additionally, at the time of the enforcement conference, the RSO had not taken positive steps to ensure that he received and reviewed every "Fix-It" ticket that identified a safety issue.

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Therefore, to emphasize the importance of procedures and compliance of regulatory requirements, I have been authorized to issue the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice) in the base amount of \$8,000 for the Severity Level II violation. In addition, issuance of this Notice constitutes escalated enforcement action that may subject you to increased inspection effort.

The violation in Section II of the Notice involving the failure to calibrate an in-line pool water radiation monitor at least annually has been categorized as a Severity Level IV violation in accordance with the Enforcement Policy and was not assessed 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(s), and your response will be placed in the NRC Public Document Room (PDR).

Sincerely,

Original signed by A. Bill Beach

A. Bill Beach
Regional Administrator

Docket No. 030-14999
License No. 22-00057-61

Enclosure: Notice of Violation and Proposed
Imposition of Civil Penalty

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OFFICIAL RECORD COPY

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

3M Center
St. Paul, MN

Docket No. 030-14999
License No. 22-00057-61
EA 96-403

During an NRC inspection conducted on October 7-31, 1996, violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," NUREG-1600, the NRC proposes to impose a civil penalty pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (Act), 42 U.S.C. 2282, and 10 CFR 2.205. The particular violations and associated civil penalty are set forth below:

I. Violation Assessed a Civil Penalty

10 CFR 36.65(a)(1) requires that both an irradiator operator and at least one other individual, who is trained on how to respond and prepared to promptly render or summon assistance if the access control alarm sounds, shall be present onsite whenever the irradiator is operated using an automatic product conveyor system.

Contrary to the above, on December 23, 1995, July 27, 1996 and August 17 and 18, 1996, an irradiator operator was not onsite for a approximately 3 hours, 4.25 hours, 4 hours, and 2.5 hours, respectively, while the irradiator was operated using an automatic product conveyor system. (01012)

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

II. Violation Not Assessed a Civil Penalty

Condition 20 of License No. 22-00057-61 requires, in part, that the licensee conduct its program in accordance with the statements, representations and procedures contained in certain referenced letters and applications, including any enclosures.

Item D of a referenced letter dated April 8, 1992, requires the on-line cobalt-60 radiation monitoring system, located on the treatment plant prior to the carbon filter bed, to be calibrated on an annual basis.

Contrary to the above, as of October 31, 1996, the on-line cobalt-60 radiation monitoring system had not been calibrated since February 1994. (02014)

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

Pursuant to the provisions of 10 CFR 2.201, 3M 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

Notice of Violation and Proposed
Imposition of Civil Penalty

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"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 the cumulative amount of the civil penalties if more than one civil penalty is proposed, or may protest imposition of the civil penalty in whole or in part, by a written answer addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission. Should the Licensee fail to answer within the time specified, an order imposing the civil penalty will be issued. Should the Licensee elect to file an answer in accordance with 10 CFR 2.205 protesting the civil penalty, in whole or in part, such answer should be clearly marked as an "Answer to a Notice of Violation" and may: (1) deny the violation(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.

Notice of Violation and Proposed
Imposition of Civil Penalty

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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.

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

Dated at Lisle, Illinois
this 7th day of January 1997