NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

University of Cincinnati
Cincinnati, Ohio

Docket No. 030-02764
License No. 34-06903-05
EA 94-039

During an NRC inspection conducted from February 7 to February 11, 1994, violations of NRC requirements were identified. In accordance with the "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:

I. Violation Assessed a Civil Penalty

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

Contrary to the above, between June 22, 1993, and October 5, 1993 licensed material consisting of approximately 20 millicuries of strontium-90 stored in Room No. 4 of the Old Operating Pavilion, an unrestricted area, was not secured against unauthorized removal, and was not under constant surveillance and immediate control of the licensee (01013).

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

II. Violations Not Assessed A Civil Penalty

License No. 34-06903-05

A. 10 CFR 71.5(a) requires, in part, that a licensee 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 - 189.

49 CFR 173.475(i) requires, in part, that before each shipment of any radioactive materials package, the shipper ensure by examination or appropriate test that the external radiation and contamination levels are within the allowable limits specified in 49 CFR Parts 171 - 177.

Contrary to the above, as of February 11, 1994, the licensee did not ensure by examination or appropriate test that the external radiation and contamination levels of each package delivered to a carrier for

transport were within the allowable limits specified in 49 CFR Parts 171 - 177. Specifically, the licensee did not determine the external radiation and contamination levels of packages containing residual and unused radiopharmaceutical dosages prior to return shipment to the supplier. (02014)

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

B. Condition 27 of License No. 34-06903-05, effective with the issuance of Amendment No. 70 on June 29, 1992, requires that the licensee conduct its program in accordance with statements, representations and procedures contained in an application received September 20, 1990, a letter dated February 26, 1992, and other referenced documents.

Condition 20 of License No. 34-06903-05, effective at the time of issuance of Amendment No. 59 on March 16, 1989, required that the licensee conduct its program in accordance with statements, representations and procedures contained in an application dated August 13, 1984 including attachments dated August 9, 1984, and other referenced documents.

1. Item 11, "Administrative Procedures," of the referenced February 26, 1992 letter, requires, in part, that personnel wash and monitor their hands when a procedure is completed, and prior to leaving the laboratory.

   Contrary to the above, as of February 11, 1994, licensee personnel in the Children's Hospital and Medical Center nuclear medicine department routinely did not monitor their hands upon completion of a procedure and prior to leaving the hot laboratory. (02024)

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

2. 10 CFR 35.50(b)(4) requires, in part, that a licensee test each dose calibrator for geometry dependence upon installation over the range of volumes and volume configurations for which it will be used.

   Appendix 13.C., "Dose Calibrators," of the referenced application received September 20, 1990, requires, as of June 29, 1992 with the issuance of Amendment No. 70 to License No. 34-06903-05, that the licensee perform dose calibrator geometry dependence testing in accordance with the model procedure for calibrating dose calibrators published in Appendix C to Regulatory Guide 10.8, Revision 2, August 1987. Items 6.b. through 6.f. of the model procedure require that geometry dependence testing be performed for the type of syringe that is normally used for injections.

   Pages 24 and 25 of the referenced August 9, 1984 attachments to the August 13, 1984 referenced application required that the licensee conduct geometrical dependence testing on its dose calibrators in accordance with the procedure specified in

Regulatory Guide 10.8, Revision 1, October 1980. Section 2, Item F, of Appendix D to Regulatory Guide 10.8, Revision 1, October 1980, requires that geometry dependence testing be determined for a syringe.

Contrary to the above, as of February 11, 1994, the licensee did not conduct dose calibrator geometrical dependence testing on any of its dose calibrators for the type of syringe that is normally used for injections. Specifically, the licensee did not perform syringe geometrical dependence testing on the dose calibrator installed on March 5, 1992 at the Radioisotope Laboratory, on the dose calibrator installed in July 1992 at the Children's Hospital and Medical Center, and on the dose calibrator installed on April 3, 1989 at the Medical Arts Building. (02034)

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

License No. 34-06903-13

A. 10 CFR 36.23(b) requires, in part, that each entrance to a radiation room at a panoramic irradiator have an independent backup access control to detect personnel entry while the source is exposed. Detection of entry while the source is exposed must cause the source to return to its fully shielded position and must also activate a visible and audible alarm to make the individual entering the room aware of the hazard.

Contrary to the above, as of February 11, 1994, the entrance to the radiation room at the licensee's panoramic irradiator located in Room E357 of the Medical Science Building did not have an independent backup access control to detect personnel entry while the source was exposed. (02044)

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

B. 10 CFR 36.23(d) requires, in part, that before the source moves from its shielded position, the source control must automatically activate conspicuous visible and audible alarms to alert people in the radiation room that the source will be moved from its shielded position.

Contrary to the above, as of February 11, 1994, the source control of the licensee's panoramic irradiator located in Room E357 of the Medical Science Building did not automatically activate conspicuous visible and audible alarms to alert people in the radiation room prior to source movement from its shielded position that the source will be moved from its shielded position. (02054)

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

C. 10 CFR 36.23(f) requires, in part, that each radiation room of a panoramic irradiator contain a control that prevents the source from moving from the shielded position unless the control has been activated and the door or barrier to the radiation room has been closed within a

Opreset time after activation of the control.

Contrary to the above, as of February 11, 1994, the radiation room of the licensee's panoramic irradiator located in Room E357 of the Medical Science Building did not contain a control that prevents the source from moving from the shielded position unless the control has been activated and the door or barrier to the radiation room has been closed within a preset time after activation of the control. (02064)

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

D. 10 CFR 36.25(c) requires, in part, that the radiation dose at 5 centimeters from the shield of a dry-source-storage panoramic irradiator when the source is shielded not exceed 20 millirems per hour (0.2 millisievert per hour).

Contrary to the above, on February 9, 1994, the radiation dose at 5 centimeters from the shield of the licensee's dry-source-storage panoramic irradiator located in Room E357 of the Medical Science Building was approximately 40 millirems per hour (0.4 millisievert per hour) when the source was shielded. (02074)

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

E. 10 CFR 36.27(a) requires, in part, that the radiation room at a panoramic irradiator have heat and smoke detectors.

Contrary to the above, as of February 11, 1994, the radiation room at the licensee's panoramic irradiator located in Room E357 of the Medical Science Building did not have heat and smoke detectors. (02084)

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

F. 10 CFR 36.31(a) requires, in part, that the key which actuates the source movement mechanism of a panoramic irradiator be attached to a portable radiation survey meter by a chain or cable.

Contrary to the above, as of February 11, 1994, the key which actuates the source movement mechanism of the licensee's panoramic irradiator located in Room E357 of the Medical Science Building was not attached to a portable radiation survey meter. (02094)

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

G. 10 CFR 36.31(b) requires, in part, that the console of a panoramic irradiator have a source position indicator that indicates when the source is in transit.

Contrary to the above, as of February 11, 1994, the console of the licensee's panoramic irradiator located in Room E357 of the Medical Science Building did not have a source position indicator that indicated when the source was in transit. (02104)

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

Pursuant to the provisions of 10 CFR 2.201, the University of Cincinnati (Licensee) is hereby required to submit a written statement or explanation to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, within 30 days of the date of this Notice of Violation and Proposed Imposition of Civil Penalty (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each alleged violation: (1) admission or denial of the alleged violation, (2) the reasons for the violation if admitted, and if denied, the reasons why, (3) the corrective steps that have been taken and the results achieved, (4) the corrective steps that will be taken to avoid further violations, and (5) the date when full compliance 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 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 VII.B of 10 CFR Part 2, Appendix C, should be addressed. Any written answer in accordance with 10 CFR 2.205 should be set forth separately from the statement or explanation in reply pursuant to 10 CFR 2.201, but may incorporate parts of the 10 CFR 2.201 reply by specific reference (e.g., citing page and paragraph numbers) to avoid repetition. The attention of the Licensee is directed to the other provisions of 10 CFR 2.205, regarding the procedure for imposing a civil penalty.

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

The responses noted above (Reply to Notice of Violation, letter with payment of civil penalty, and Answer to a Notice of Violation) should be addressed to: Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555 with a copy to the Regional Administrator, U.S. Nuclear Regulatory Commission, Region III, 801 Warrenville Road, Lisle, Illinois 60532-4351.

Dated at Lisle, Illinois
this 25 day of March 1994

UNITED STATES
NUCLEAR REGULATORY COMMISSION
OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS
WASHINGTON, D.C. 20555

August 18, 1989

NRC INFORMATION NOTICE NO. 89-60: MAINTENANCE OF TELETHERAPY UNITS

Addressees:

All U.S. Nuclear Regulatory Commission (NRC) Medical Teletherapy Licensees.

Purpose:

An information notice provides information to licensees to consider for application to their activities. While an Information Notice provides information to improve safety, to improve compliance, or to notify licensees of problems or violations of other licensees, it does not establish a new requirement or require a written response to the NRC.

This notice is intended to alert recipients to NRC concerns about proper maintenance of teletherapy units. It emphasizes the importance of five-year inspections and services as required by 10 CFR Section 35.647. It is expected that licensees will review this information for applicability to their programs, distribute this Notice to those responsible for radiation safety, and consider actions, if appropriate, to preclude safety problems from occurring at their facilities.

Description of Circumstances:

During a routine inspection, NRC inspectors found that the licensee's teletherapy unit was in poor condition and significantly overdue for service and preventive maintenance, thus raising the question of whether the unit was safe to operate. A service company had performed a five-year inspection in August 1988, and found that many parts that the manufacturer considered critical components had not been replaced according to the recommended frequency. In fact, many of the critical components were original parts, dating from when the unit was first placed into service in 1974.

Examples of critical components needing periodic replacement are: the field light cord reel, source drawer solenoids, air pressure switch, air hoses and fittings, and treatment timer. If any of these components failed, it could significantly increase the potential of the source failing to return to the shielded position. This could lead to unnecessary radiation exposures to both employees and patients, or an overexposure or medical misadministration. In fact, the field light cord reel on this unit had failed in 1983, and the source could not be fully retracted.

Although the service company informed the licensee of the critical need for service, the licensee had not taken any action to service the unit. Apparently, the licensee planned to eventually replace the entire unit.

As a result of the safety concerns raised by NRC, the licensee was required to complete the needed service on an emergency basis. A heavy patient load was disrupted temporarily, but the disruption could have been worse if the service had taken a long time.

Discussion:

Title 10 CFR Section 35.647 requires licensees to have their teletherapy units fully inspected and serviced during teletherapy source replacements, or at intervals not to exceed five years, whichever comes first. The purpose of the inspection is to assure safe operation of the units, specifically proper functioning of the source exposure mechanism.

Licensees should pay close attention to the results of their five-year inspections, and assure that recommended service is performed promptly. Failure to maintain teletherapy units in safe operating condition could result in radiation incidents and/or enforcement action by NRC.

This information notice does not require any written response. If you have any questions about this matter, please contact the appropriate NRC Regional Office or this office.

Richard E. Cunningham

Richard E. Cunningham, Director
Division of Industrial and
Medical Nuclear Safety, NMSS

Technical Contacts: Jack R. Metzger, NMSS
(301) 492-3424

R. J. Caniano, Region III
(312) 790-5721

Attachments:
1. List of Recently Issued NMSS Information Notices
2. List of Recently Issued NRC Information Notices

U.S. NUCLEAR REGULATORY COMMISSION

REGION III

Enforcement Conference Report No. 030-02764/94002(DRSS)

Docket No. 030-02764

License No. 34-06903-05

Licensee: University of Cincinnati
Cincinnati, Ohio

Enforcement Conference At: NRC Region III Office (via Telephone)
Lisle, Illinois

Enforcement Conference Conducted: March 16, 1994

Inspection Conducted: January 16-17 and February 7-11, 1994

Project Manager: _____ 3/23/94
James L. Cameron Date
Radiation Specialist

Reviewed By: _____ 3/23/94
B. J. Holt, Chief Date
Nuclear Materials Inspection
Section 1

Approved By: _____ 3/23/94
Roy J. Caniano, Chief Date
Nuclear Materials Safety Branch

Meeting Summary

Enforcement Conference on March 16, 1994 (via Telephone) (Report No. 030-02764/94002(DRSS))
Areas Discussed: A review of the findings from the January 16-17 and February 7-11, 1994 inspections, including a discussion of the apparent violations, the accuracy of the facts, causal factors, the corrective actions taken or planned by the licensee, and the NRC Enforcement Policy.

DETAILS

1. Conference Attendees

University of Cincinnati

C. W. Kupferberg, Radiation Safety Committee and Associate Senior Vice President, Medical Center
Ronald Millard, Ph.D., Chair, Radiation Safety Committee
Victoria Morris, M.S., Radiation Safety Officer
Mike Burba, Assistant Radiation Safety Officer
Howard Elson, Ph.D., Radiation Safety Committee and Associate Professor
C. Castillo, Director, Environmental Services, University Hospitals
M. Grodi, Radiation Safety Committee and Associate Administrator, Facilities Management, University Hospitals
Rick Smith, Public Relations
Michael Finucane, University Counsel

Nuclear Regulatory Commission

Roy J. Caniano, Chief, Nuclear Materials Safety Branch, Region III
B. J. Holt, Chief, Nuclear Materials Inspection Section 1, Region III
Bruce Berson, Regional Counsel, Region III
Jamnes L. Cameron, Radiation Specialist, Region III
Robert Gattone, Radiation Specialist, Region III
Robert DeFayette, Director, Enforcement and Investigation Coordination Staff, Region III
Patricia Pelke, Health Physicist, Region III

2. Enforcement Conference Summary

An Enforcement Conference was held in the NRC Region III office via telephone on March 16, 1994, between members of the NRC and University of Cincinnati staffs. The conference was held to discuss the findings of the NRC inspections conducted on January 16-17 and February 7-11, 1994, which identified several apparent violations. One apparent violation, which is being considered for escalated enforcement, involved the licensee's failure to secure licensed material stored in an unrestricted area from unauthorized removal from the place of storage.

The purpose of the conference was to: (1) review the apparent violations, including root and contributing causes; (2) discuss the accuracy of the inspection findings; (3) discuss the licensee's corrective actions; (4) determine whether there were any aggravating or mitigating circumstances; and (5) obtain other information that would help determine the appropriate enforcement action. NRC inspection findings are documented in Inspection Reports No. 030-02764/94001(DRSS), et. al., transmitted to the licensee by letter dated March 10, 1994.

The licensee did not contest the apparent violations and agreed with the accuracy of the information presented with the exception of the following:

a. The licensee disagreed with the NRC's characterization of the inadvertent opening of a sealed source containing iodine-125 as an apparent violation. The licensee contends that the License Condition referenced in the apparent violation should be applied to the intentional opening of a sealed source containing licensed material and not inadvertent mishaps on the licensee's part.

b. The licensee disagreed with the NRC's characterization of the University's failure to conduct dose calibrator geometry dependence testing for the syringes normally used for injection as an apparent violation. The licensee contends that each of the dose calibrators had been installed prior to the last routine inspection conducted in September-October 1992, and that dose calibrator geometry dependence was reviewed by the NRC inspectors at that time and no problems were brought to the licensee's attention at that time. The licensee believes that it would be unfair for NRC inspectors to review licensed activities that occurred prior to the inspection interval.

c. The licensee disagreed with the NRC's characterization of the University's failure to secure licensed material in storage in an unrestricted area from unauthorized removal as an apparent violation. The licensee contends that since Old Op 4 was posted with radiation warning signs, the room was restricted.

d. The licensee noted an error in the section of the report entitled "Misadministration Review." The licensee indicated that following the explant of the iodine-125 seeds, the seeds were placed into a pan of water to remove blood and other excess material, and not for the purpose of determining whether a seed was leaking, as specified in the report.

The licensee described its corrective actions for the apparent violations that were discussed during the conference. With regard to the apparent violation being considered for escalated enforcement action, the licensee's corrective actions include: (1) changing the lock on the door to the storage area; (2) providing reinstruction to housekeeping personnel regarding radiation safety practices; and (3) conducting meetings with housekeeping supervisors to stress the importance of adhering to radiation warning signs.

The NRC staff acknowledged the licensee's statements and indicated that they would be considered in the NRC's decision for enforcement action.

3. Concluding Statement

NRC representatives summarized the NRC Enforcement Policy and process and indicated that the licensee will be notified in writing of NRC's proposed enforcement actions.