

VA Medical Center, New Orleans, Louisiana
Escalated Enforcement Background Information

1. On October 27, 2004, the medical center discovered and reported the inadvertent disposal of 10 mCi ($>1000 \times 10$ CFR 20, Appendix C) ^{125}I in a local landfill.
2. Per 10 CFR 20 reporting requirements, the National Health Physics Program (NHPP) notified the Nuclear Regulatory Commission (NRC) Operations Center by telephone and subsequently submitted a written report to NRC, Region III.
3. The NHPP completed a reactive inspection to evaluate the circumstances of the unauthorized disposal.
 - a. The NHPP cited the medical center for a Severity Level III problem with two underlying violations. The first violation was under 10 CFR 20.2201 for disposal of radioactive materials. The second violation was under 10 CFR 20.1906 for receiving and opening radioactive packages.
 - b. The primary basis for escalated enforcement at Severity Level III was the quantity of the radioactive material involved in the disposal.
 - c. The NHPP reviewed the NRC enforcement policy, enforcement manual, and similar NRC inspection cases to determine a regulatory basis for the citation and severity level. In particular, the NHPP determined that the precedence established by NRC, Region III, for a similar disposal by VA Medical Center, St. Louis, Missouri, in 2002 (EA-02-105) was applicable.
 - d. Attachment 1 has additional information and evaluation of the available NRC precedence cases.
4. The NHPP general strategy for follow-up to escalated enforcement action is outlined below.
 - a. Complete a basic causes or root cause analysis to help identify underlying casual factors and the appropriate corrective actions for a comprehensive response.
 - b. Require permittee to complete separately a comprehensive evaluation and specifically address NHPP-identified corrective actions using NRC guidelines for NOV response as outlined in NRC Information Notice 96-28.
 - c. Contact the permittee, as needed, during completion of the comprehensive evaluation.
 - d. Evaluate permittee response to the comprehensive evaluation task.
 - e. Modify the permit with the permittee response as a new tie down condition or, if needed, require the permittee to renew the permit to commit to additional programmatic requirements identified as corrective actions. See Attachment 2 as an example modified permit.

FEB 10 2005

f. Inform the National Radiation Safety Committee about the escalated enforcement as a significant core performance indicator.

g. Inform other permittees about the circumstances for escalated enforcement actions using the NHPP intranet Web site and periodic newsletters.

h. Schedule and complete a six-month follow-up inspection

5. The medical center responded to the loss of radioactive material and the NHPP inspection task to complete comprehensive evaluation with the following specific corrective actions.

a. Conducted an immediate and thorough search of the medical center, including surveys of laboratories and garbage receptacles. VA Police assisted with the initial investigation and search. See attached police report, Att.3.

b. Completed comprehensive training for incident review and changes to radiation safety manual chapter 10 procedures for receiving and securing radioactive packages for warehouse, mailroom, housekeeping, law enforcement, and research staffs. See Att.4 for summary of training provided and dates.

c. Evaluated all other work centers using radioactive materials for the possibility of a loss of radioactive materials occurring.

d. Changed radiation safety procedures to include proposal of a chain-of-custody form for tracking each radioactive package from ordering to disposal, to be instituted by March 1, 2005. Review of procedure effectiveness is reviewed by the medical center Radiation Safety Committee.

e. Radioactive package receipt procedures include securing all radioactive packages upon arrival at the medical center.

f. Completed radiation surveys at the landfill in an attempt to locate the radioactive materials.

g. Performed a root cause analysis using VHA procedures. Investigation phase completed with report pending. Affected work centers will be advised of the investigation results by March 1, 2005. The report may cause further changes to procedures for ordering and receipt of radioactive materials.

h. Completed a dose assessment with the conclusion that the circumstances of the loss of radioactive materials did not result in a dose above a regulatory limit. Conclusions were similar to those reached by NRC in its inspection report for EA-02-105 (~.16 mrem public dose). A more extensive pathway analysis, such as it could be done using NUREG-1717, was not deemed necessary.

6. Security

a. NHPP, in its NOV, Att. B, **Required action**, c.(3)(e) and (f), required the permittee to address security. The permittee response was provided in section V and VI of their 1/13/04 (sic) response.

b. Also note that the entire research area is secured by card key access. See last section of VA Police Service report.

c. The permittee provided other information pertaining to security – see attachments

(1) Research training slides – see esp. # 17

(2) Excerpt from Chapter 10 – see highlighted sections

(3) Training outline, Att.4, second page

7. The NHPP reached the following conclusions related to the reactive inspection results and the medical center response.

a. The corrective actions were adequate and sufficient to address the primary underlying issue of loss of control of radioactive materials.

b. The requirements for security for the locations of use and the possible access to these areas and radioactive materials was not compromised and did not specifically impact the circumstances, which resulted in a Severity Level III problem being cited. The radioactive materials that were disposed incorrectly remained in a controlled area and were handled or processed by staff with appropriate radiation safety training.

c. The unauthorized disposal did not result in a health and safety hazard or circumstances that exceeded a regulatory limit.

d. The medical center has not been subject to previous escalated enforcement and has adequate professional and other staff to ensure regulatory compliance.

| Attachment 1 | | | | |
|--|-------------|--|-------------------------------|-------------------------|
| violations resulting from lost sources | | | | |
| Case | Date | Description | NRC Citation | SL |
| VA St Louis EA-02-105 | 2002 | Inadvertent disposal 2 mCi I-131 in normal trash. RAM detected at landfill, buried. | 20.2001(a) | III |
| VA Fresno Docket 030-1221 | 2002 | 980 uCi 153Gd disposed in the normal trash | NRC: 35.92(a) NHPP:20.2001 | NRC: NCV NHPP:III |
| VA St Louis EA-01-312 | 2001 | 2 incidents: (1) 7 mCi I-131 not secured (2) 200uCi S-35 in marked radwaste can in lab disposed in normal trash. | (1) 20.1801 (2) 20.2001(a) | (1)III(2) IV |
| VA San Fran EA-97-529 | 1997 | Inadvertent disposal 305 uCi P-32 in normal trash. | 20.2001(a) | III |
| VA Long Beach EA-95-149 | 1995 | Inadvertent disposal 5 mCi I-125 in normal trash (pkg placed in hall). RAM believed disposed in landfill. | 20.2001(a) | III |
| TJUH. IR 03002941/2003001 | 2004 | Inadvertent disposal 1.3 mCi S-35 and 250 uCi H-3 (1/23/04) and 1.07 mCi S-35 (11/11/04) in normal trash. | 20.2001(a) | NCV |
| ABB, Inc EA-03-196 | 2003 | Loss of gauge, 78 mCi Sr-90. Left unattended, disposed in normal trash | 20.1801 | III |
| Howard University, EA-02-102 | 2002 | Loss of 2.6 mCi Ir-192 ribbon. Ribbon lost into toilet from patient room. | 20.1801 | III |
| Univ Med & Dentist NJ EA-01-186 | 2001 | Loss of 7.7 mCi Ir-192 ribbon. Ribbon lost into toilet from patient room. | 20.1801 | III |
| Lower Bucks Hosp EA-97-005 | 1997 | Explanted pacemaker lost. 4.8 Ci Pu-238. | 20.2001(a) & 20.1801 | III |
| Merck EA-97-241 | 1997 | Inadvertent disposal 880 uCi I-125 in normal trash. RAM disposed in municipal incinerator. | 20.2001(a) | III |
| Harvard EA-96-068 | 1996 | 2 incidents: (1) 50 mCi p-32 not secured (2) 1.0 mCi S-35 disposed in normal trash. | (1) 20.1801 (2) 20.2001(a) | (1)III(2) IV |
| NHPP Observations: | | | | |
| 1. 20.1801 violations resulting from lost sources appear to be usually from sources not controlled, ie in uc area. | | | | |
| Other cases for lost sources/ inadvertent disposal were cited under 20.2001. | | | | |
| 2. 20.1801 violations most commonly used for access control violations, not involving loss. | | | | |


[Index](#) | [Site Map](#) | [FAQ](#) | [Help](#) | [Glossary](#) | [Contact Us](#)
 Search
[Advanced Search](#)

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[Home](#)
[Who We Are](#)
[What We Do](#)
[Nuclear
Reactors](#)
[Nuclear
Materials](#)
[Radioactive
Waste](#)
[Facility Info
Finder](#)
[Public
Involvement](#)
[Electronic
Reading Room](#)

[Home](#) > [Electronic Reading Room](#) > [Document Collections](#) > [Enforcement Documents](#) > [Significant Enforcement Actions](#) > [Materials Licensees](#) > EA-02-105

EA-02-105 - Veterans Health Administration

July 30, 2002

EA-02-105

Lynn McGuire, Director
National Health Physics Program (115HP/NLR)
Department of Veterans Affairs
Veterans Health Administration
2200 Fort Roots Drive
North Little Rock, AR 72114

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY -\$6,000 (NRC SPECIAL INSPECTION REPORT NO. 03002267/2002-001(DNMS)) (V.A. MEDICAL CENTER, ST. LOUIS, MISSOURI)

Dear Mr. McGuire:

This refers to the inspection conducted on May 2, 2002, at the V.A. Medical Center in St. Louis, Missouri. The purpose of the inspection was to review the circumstances surrounding two events involving disposal of licensed radioactive material to a non-radioactive trash landfill. The results of the inspection identified two apparent violations involving the failure to dispose of radioactive material properly and to provide immediate notification to the NRC, once the inappropriate disposal was identified. The apparent violations were described in our inspection report transmitted to you in a May 24, 2002, letter. On June 18, 2002, a predecisional enforcement conference was conducted in the Region III office with you, Mr. Peter McBrady, Associate Director, V.A. Medical Center in St. Louis, and members of your respective staffs to discuss the apparent violations, their significance, their root causes, and your 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 the circumstances surrounding them are described in detail in the subject inspection report. On two occasions in March 2002, V.A. Medical Center staff placed radioactive waste in a normal trash receptacle rather than a specially designated container, resulting in unauthorized disposal of licensed material to non-radioactive trash. On March 18 and 29, 2002, the Illinois Department of Nuclear Safety informed the NRC of the events and the NRC notified your staff. On April 11, 2002, the V.A. Medical Center staff determined that one of these disposals contained approximately 2 millicuries of iodine-131, 2000 times the quantity specified in Appendix C to 10 CFR Part 20. However, after determining the quantity of iodine-131 disposed, the V.A. Medical Center staff failed to notify the NRC Operations Center as required by 10 CFR 20.2201 until requested to do so by NRC staff on April 30, 2002.

While the amount of radioactive material was small, and calculations indicate that significant exposure to the public from the improper disposal was unlikely, this violation, nonetheless, represents a regulatory concern because it involved the improper disposal of radioactive material. The improper disposal of radioactive material is a significant safety concern because of the potential for inadvertent and unnecessary exposures to employees and members of the public. Additionally, the V.A. Medical Center was cited in December 2001, for unauthorized disposal of a small quantity of sulfur-35. Although the circumstances were different and corrective actions implemented for that violation would not have prevented the March disposals, the NRC is concerned that there have been three unauthorized disposals in the past year. Finally, the NRC depends on timely reporting of events in order to respond effectively when required. Therefore, these violations are categorized collectively in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions" (Enforcement Policy), NUREG-1600, as a Severity Level III problem.

<http://www.nrc.gov/reading-rm/doc-collections/enforcement/actions/materials/ea02105.html>

2/2/2005

In accordance with the Enforcement Policy, a base civil penalty in the amount of \$3,000 is considered for a Severity Level III problem. Because your facility has been the subject of escalated enforcement actions within the last two years,⁽¹⁾ the NRC considered whether credit was warranted for *Identification* and *Corrective Action* in accordance with the civil penalty assessment process in Section VI.C.2 of the Enforcement Policy. Credit for identification is not warranted, since the improper disposal resulted in the landfill facility contacting the Illinois Department of Nuclear Safety who in turn informed the NRC of the event. Credit for corrective actions is not warranted because your actions were not comprehensive in that they were narrowly focused on the lab where the waste was generated and did not include other locations of use listed on your license. In addition, your corrective actions excluded users of pure beta- emitting radionuclides.

Therefore, to emphasize the importance of timely and proper notification, and of prompt identification and comprehensive correction of violations, and in recognition of your previous escalated enforcement action, 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 \$6,000, twice the base amount of \$3,000, for the Severity Level III problem. In addition, issuance of this Notice constitutes escalated enforcement action, that may subject you to increased inspection effort.

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

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter, its enclosures, and your response will be made available electronically for public inspection in the NRC Public Document Room or from the Publicly Available Records (PARS) component of NRC's document system (ADAMS). ADAMS is accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html> (the Public Electronic Reading Room).

Sincerely,

/RA/

J. E. Dyer
Regional Administrator

Docket No. 030-02267
License No. 24-00144-05

Enclosures:

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

cc w/encl 1:
Linda Kurz, Director
V.A. Medical Center - St. Louis

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

V.A. Medical Center
St. Louis, Missouri

Docket No. 030-02267
License No. 24-00144-05
EA-02-105

During an NRC inspection conducted on May 2, 2002, 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:

- A. 10 CFR 20.2001(a) requires that the licensee dispose of licensed material only by transfer to an authorized recipient; by decay in storage; by release in effluents within the limits in 10 CFR 20.1301; or as authorized by the NRC.

Condition 26 of License No. 24-00144-05 requires, in part, that the licensee conduct its program in accordance with the statements, representations, and procedures contained in the letter dated July 22, 1997 (excluding the licensee's Quality Management Program).

Item 11.2.G of the letter dated July 22, 1997, requires that radioactive waste be disposed only in specially designated containers.

Contrary to the above, on or about March 14 and 28, 2002, the licensee disposed of licensed material by a method not authorized by 10 CFR 20.2001 or License Condition 26. Specifically, the licensee used a regular waste container to dispose of approximately 150 microcuries of technetium-99m and 2 millicuries of iodine-131, resulting in release to the non-radioactive trash.

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

Contrary to the above, the licensee did not immediately report to the NRC the loss of licensed material in an aggregate quantity greater than 1,000 times the quantity specified in Appendix C to 10 CFR Part 20 that could result in an exposure to persons in unrestricted areas. Specifically, on April 11, 2002, the licensee discovered that approximately 2 millicuries of iodine-131 was lost by disposal to non-radioactive trash with resulting exposures to persons in unrestricted areas, and did not report the loss to the NRC until April 30, 2002.

This is a Severity Level III problem (Supplement IV).
Civil Penalty - \$6,000.

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

Within the same time as provided for the response required above under 10 CFR 2.201, the Licensee may pay the civil penalty proposed above or the cumulative amount of the civil penalties if more than one civil penalty is proposed, in accordance with NUREG/BR-0254 and by submitting to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, a statement indicating when and by what method payment was made, or may protest imposition of the civil penalty in whole or in part, by a written answer addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission. Should the Licensee fail to answer within 30 days of the date of this Notice of Violation and Proposed Imposition of Civil Penalty, 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.C.2 of the Enforcement Policy should be addressed. Any written answer in accordance with 10 CFR 2.205 should be set forth separately from the statement or explanation in reply pursuant to 10 CFR 2.201, but may incorporate parts of the 10 CFR 2.201 reply by specific reference (e.g., citing page and paragraph numbers) to avoid repetition. The attention of the Licensee is directed to the other provisions of 10 CFR 2.205, regarding the procedure for imposing a civil penalty.

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

The response noted above (Reply to Notice of Violation, statement as to payment of civil penalty, and Answer to a Notice of Violation) should be addressed to: Frank J. Congel, 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, Suite 255, Lisle, IL 60532-4351.

Because your response will be made available electronically for public inspection in the NRC Public Document Room or from the Publicly Available Records (PARS) component of NRC's document system (ADAMS), to the extent possible, it should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the public without redaction. ADAMS is accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html> (the Public Electronic Reading Room). If personal privacy or proprietary information is necessary to provide an acceptable response, then please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request withholding of such material, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim of withholding (e.g., explain why the disclosure of information will create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.790(b) to support a request for withholding confidential commercial or financial information). If safeguards information is necessary to provide an acceptable response, please provide the level of protection described in 10 CFR 73.21.

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

Dated this 30th day of July 2002.

-
1. A Severity Level III violation was issued on December 28, 2001 (EA-01-312).

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Last revised Tuesday, September 09, 2003

**DEPARTMENT OF
VETERANS AFFAIRS**

Memorandum

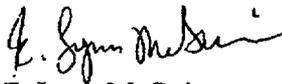
Date: **MAY 30 2002**

From: Director, VHA National Health Physics Program (115HP/NLR)

Subj: Nuclear Regulatory Commission (NRC) Response to Report of Improper Disposal of Gadolinium-153 Sealed Source

To: Director (570/00), VA Central California Health Care System, Fresno, California

1. Attached is a letter from the Nuclear Regulatory Commission (NRC) regarding the improper disposal of a radioactive sealed source by the VA Central California Health Care System. The VA Central California Health Care System submitted a report, dated March 12, 2002, to the National Health Physics Program regarding the disposal. We sent your report and our hazard analysis to the NRC attached to a letter dated March 25, 2002.
2. The NRC letter states a violation of NRC requirements occurred. However, the NRC has decided to treat the violation as a Non-Cited Violation (NCV).
3. Because the violation was not cited, no response is required. If you wish to contest the NCV, you should submit your response to the National Health Physics Program within 20 days of the date of the NRC letter. We will forward the response to the NRC.
4. Your corrective actions regarding the improper disposal may be reviewed during future inspections.
5. If you have any questions, please contact Edwin M. Leidholdt, Jr., Ph.D., VHA National Health Physics Program, at (707) 562-8374.



E. Lynn McGuire

Attachment

cc: Chair, National Radiation Safety Committee
Network Director, VISN 21 (10N21)



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

May 24, 2002

Lynn McGuire, Director
National Health Physics Program (115HP/NLR)
Department of Veterans Affairs
Veterans Health Administration
2200 Fort Roots Drive
North Little Rock, AR 72114

SUBJECT: REPORT OF IMPROPER DISPOSAL OF GADOLINIUM-153 SEALED SOURCE

Dear Mr. McGuire:

This letter is to acknowledge receipt of your letter dated March 25, 2002, whereby the Department of Veterans Affairs National Health Physics Program reported the improper disposal of a sealed source containing approximately 35.8 megabecquerels (968 microcuries) of gadolinium-153. The sealed source was possessed under NRC License 04-01935-03 held by the Department of Veterans Affairs Central California Health Care System (CCHCS) located in Fresno, California. Your March 25 letter also forwarded a letter dated March 12, 2002, from the CCHCS which provides detailed information regarding the disposal.

Your report states that on February 20, 2002, during a Veterans Health Administration National Health Physics Program (VHA NHPP) inspection of the CCHCS's Nuclear Medicine Section, the improper disposal of a sealed source was discovered. Specifically, the VHA NHPP inspector determined that on May 11, 2001, the CCHCS radiation safety officer (RSO) removed the source from the licensee's radioactive waste storage room and disposed of it in regular hospital waste. Prior to being placed in storage, the sealed source had been used in a Norland Corporation Model 2600 Dichromatic Bone Densitometer device for the measurement of bone mineral content.

Your report also indicates that the RSO apparently did not fully understand NRC's regulations regarding the disposal of radioactive material with a physical half-life greater than 65 days. Consequently, the RSO considered decay-in-storage an appropriate method of disposal for gadolinium-153 even though the source has a physical half-life of 242 days. Therefore, the RSO removed the sealed source from a radioactive waste storage room where it had been stored since July 1996, performed a radiation survey of the source and found it to be indistinguishable from background, then proceeded to dispose of it in the facility's normal waste receptacle. The source, along with other hospital waste, was then compacted and transported to a local landfill where it was deposited in the landfill's medical waste section. Further, your report indicates that on February 28, 2002, the RSO and other members of the CCHCS staff conducted a radiation survey at the landfill but were unable to locate the source as the dose rates measured were essentially indistinguishable from background.

NMED No. 020268

Based on the licensee's evaluation of the incident, CCHCS concluded that recovery of the sealed source was not feasible; however, it is unlikely that an exposure to individual members of the public would exceed regulatory limits due to the disposal of the sealed source in the landfill. Finally, as corrective actions to prevent similar disposals, your report indicates that in the future the CCHCS radioactive waste handling policy will be revised and posted; biannual refresher training will be provided to the RSO; and a third party, annual assessment of the CCHCS radiation safety program will be established.

10 CFR 35.92(a) permits a licensee to dispose of byproduct material with a physical half-life of less than 65 days in ordinary trash provided, in part, that the licensee first monitors such byproduct material at the container surface and determines that its radioactivity cannot be distinguished from the background radiation level with a radiation detection survey meter set on its most sensitive scale and with no interposed shielding. However, as described above, on May 11, 2001, the licensee disposed of a sealed source containing approximately 968 microcuries of gadolinium-153, byproduct material with a physical half life greater than 65 days.

Based on our review of this incident, the NRC has determined that a violation of NRC requirements occurred. However, this non-repetitive, licensee-identified and corrected violation is being treated as a Non-Cited Violation (NCV), consistent with Section VI.A.8 of the "General Statement of Policy and Procedure for NRC Enforcement Actions" (Enforcement Policy), NUREG 1600. Therefore, no response to this letter is required. If you contest the NCV, you should provide a response within 30 days of the date of this letter, with the basis for your denial, to the Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington DC 20555-0001, with a copies to the Regional Administrator, Region IV, and the Director, Office of Enforcement, United States Nuclear Regulatory Commission, Washington, DC 20555-0001

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter, and your response (if any) will be made available electronically for public inspection in the NRC Public Document Room or from the Publicly Available Records (PARS) component of NRC's document system (ADAMS). ADAMS is accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html> (the Public Electronic Reading Room).

If you have any questions regarding this letter, please contact the undersigned at 817-860-8287 or Ms. Christi Maier at 817-860-8217.

Sincerely,



Mark R. Shaffer, Chief
Nuclear Materials Inspection Branch

Docket No.: 030-01221
License No.: 04-09135-03

Department of Veterans Affairs
Veterans Health Administration

-3-

cc:
Allan S. Perry, Medical Center Director
Department of Veterans Affairs
Central California Health Care System
2615 East Clinton Avenue
Fresno, CA 93703-2286



UNITED STATES
NUCLEAR REGULATORY COMMISSION

REGION III
801 WARRENVILLE ROAD
LISLE, ILLINOIS 60532-4351

December 28, 2001

EA-01-312

Lynn McGuire, Director
National Health Physics Program (115HP/NLR)
Department of Veterans Affairs
Veterans Health Administration
2200 Fort Roots Drive
North Little Rock, AR 72114

SUBJECT: NOTICE OF VIOLATION
NRC INSPECTION REPORT 03002267/2001-003(DNMS) -
V. A. MEDICAL CENTER, ST LOUIS, MISSOURI

Dear Mr. McGuire:

This refers to the inspection conducted on November 27, 2001, at the V. A. Medical Center in St. Louis, Missouri. The purpose of the inspection was to determine whether activities authorized by the license were conducted safely and in accordance with NRC requirements. As a result of the inspection, two apparent violations of NRC requirements were identified. The violations involve the failures to secure licensed material from unauthorized access and to dispose of licensed material in an authorized manner. At the conclusion of the inspection, the findings were discussed with Linda Kurz, the Medical Center Director, and Larry Chandler, the Facility Radiation Safety Officer.

In a telephone conversation on December 14, 2001, Marc Dapas of my staff informed Ms. Kurz that the NRC was considering escalated enforcement for the apparent violation involving the failure to secure from unauthorized access or maintain constant surveillance over licensed material in an unrestricted area. Mr. Dapas also informed Ms. Kurz that we had sufficient information regarding the apparent violations and V. A. Medical Center's corrective actions to make an enforcement decision without the need for a predecisional enforcement conference or a written response. Ms. Kurz indicated that V. A. Medical Center did not believe that a predecisional enforcement conference was needed; however, a written response would be provided.

Based on the information developed during the inspection and the information provided in the V. A. Medical Center's December 18, 2001 response, 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.

Violation A of the Notice involves the failure to secure from unauthorized access or maintain constant surveillance over licensed material in an unrestricted area. Specifically, on

November 27, 2001, a radioactive material package was left unattended at the nuclear medicine reception desk, when the receptionist became involved with scheduling tasks.

The failure to adequately secure and limit access to licensed material in an unrestricted area is a significant safety concern. Implementing adequate security requirements for licensed material is intended to prevent members of the public from being unknowingly and unnecessarily exposed to radiation, and prevent the loss or theft of licensed material. 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 \$3000 is considered for a Severity Level III violation. Because your facility has not been the subject of escalated enforcement actions within the last two inspections, the NRC considered whether credit was warranted for *Corrective Action* in accordance with the civil penalty assessment process in Section VI.C.2 of the Enforcement Policy. Credit was warranted for corrective actions that included: (1) securing the package immediately after the violation was identified; (2) revising the package receipt procedure to include specific requirements to maintain constant surveillance of packages and lock them within a secured room as soon as possible after receipt; (3) training applicable staff regarding the revised package receipt procedure; and (4) planning to revise the refresher training to include discussion of the revised package receipt procedure.

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

Violation B of the Notice involves the failure to properly dispose of radioactive material in accordance with the requirements of 10 CFR 20.2001. This violation is categorized in accordance with the Enforcement Policy at Severity Level IV.

The NRC has concluded that information regarding the reason for the violations, the corrective actions taken and planned to correct the violations and prevent recurrence, and the date when full compliance was achieved is already adequately addressed on the docket in Inspection Report No. 03002267/2001-003(DNMS), and the V. A. Medical Center's letter, dated December 18, 2001. 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 enclosures, and your response, if any, will be made available electronically for public inspection in the NRC Public Document Room or from the Publicly Available Records (PARS) component

L. McGuire

-3-

of NRC's document system (ADAMS). ADAMS is accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html> (the Public Electronic Reading Room).

Sincerely,



J. E. Dyer
Regional Administrator

Docket No. 030-02267
License No. 24-00144-05

Enclosures: 1. Notice of Violation
2. Inspection Report 03002267/2001-003(DNMS)

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B. Smith, NMSS

S. Gagner, OPA

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D. Dandois, OCFO/DAF/LFARB

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State of Missouri

NOTICE OF VIOLATION

V. A. Medical Center
St. Louis, Missouri

Docket No. 030-02267
License No. 24-00144-05
EA-01-312

During an NRC inspection conducted on November 27, 2001, violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," NUREG-1600, the violations are listed below:

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

Contrary to the above, on November 27, 2001, the licensee did not secure from unauthorized removal or limit access to a package containing 7,052 microcuries of iodine-131, located on the Nuclear Medicine Department reception desk, which is an unrestricted area, nor did the licensee control and maintain constant surveillance of this licensed material.

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

- B. 10 CFR 20.2001(a) requires, in part, that the licensee dispose of licensed material only by transfer to an authorized recipient, or by decay in storage, or by release in effluents within the limits in Part 20, or by an approved method not otherwise authorized in the regulations in this chapter.

Contrary to the above, on May 4, 2001, the licensee disposed of 200 microcuries of sulfur-35, a licensed material, by release to the non-radioactive trash, a method not authorized by 10 CFR 20.2001.

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

The NRC has concluded that information regarding the reason for the violations, the corrective actions taken and planned to correct the violations and prevent recurrence and the dates when full compliance was achieved is already adequately addressed on the docket in Inspection Report No. 03002267/2001-003(DNMS), and the V. A. Medical Center's letter, dated December 18, 2001. 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. 20555-0001 with a copy to the Regional Administrator, Region III, 801 Warrenville Road, Lisle, IL 60532-4351 within 30 days of the date of the letter transmitting this Notice of Violation (Notice).

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

If you choose to respond, your response will be made available electronically for public inspection in the NRC Public Document Room or from the *Publicly Available Records (PARS)* component of NRC's document system (ADAMS). ADAMS is accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html> (the Public Electronic Reading Room). Therefore, to the extent possible, it should not include any personal, privacy, proprietary, or safeguards information so that it can be placed in the PARS without redaction.

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

Dated this 28th day of December 2001.

U.S. NUCLEAR REGULATORY COMMISSION

REGION III

Docket No: 030-02267
License No: 24-00144-05

Report No: 03002267/2001-003(DNMS)

Licensee: V. A. Medical Center
915 North Grand Boulevard
St. Louis, MO 63125

Location: 915 North Grand Boulevard
St. Louis, MO 63125

Date: November 27, 2001

Inspectors: Robert G. Gattone, Jr., Health Physicist (Lead Inspector)
Cassandra F. Frazier, Senior Health Physicist

Approved By: Gary L. Shear, Chief
Materials Inspection Branch
Division of Nuclear Materials Safety

EXECUTIVE SUMMARY

V. A. Medical Center NRC Inspection Report 03002267/2001-003(DNMS)

This was a routine, unannounced inspection to determine whether activities authorized by the license were conducted safely and in accordance with NRC requirements. The licensee's conduct of licensed activities during the inspection period was generally characterized by safety-conscious medical and research and development operations. However, two violations of NRC regulatory requirements were identified involving failure to: (1) secure from unauthorized removal or limit access to licensed material in an unrestricted area; and (2) dispose of licensed material by authorized means.

The security violation occurred when licensee staff failed to maintain constant surveillance of a package containing 7,052 microcuries of iodine-131 on the Nuclear Medicine reception desk resulting in unauthorized persons having unchallenged access to it for about five minutes. The staff's distraction during performance of scheduling tasks was the root cause of the violation. The licensee's corrective actions included: (1) securing the package immediately after the violation was identified; (2) revising the package receipt procedure to include specific requirements to maintain constant surveillance of packages and lock them within a secured room immediately after receipt; (3) completing training of applicable staff regarding the revised package receipt procedure by November 30, 2001; and (4) planning to revise the refresher training to include discussion of the revised package receipt procedure. The licensee's corrective actions were prompt and adequate.

The disposal violation occurred when Environmental Management staff disposed of 200 microcuries of sulfur-35 within a properly marked radioactive waste receptacle by release to the normal trash. Licensee staff identified the violation, and determined that the root cause was failure to include recognition of and response to radiation warning markings as a topic in new employee orientation training. The licensee's corrective actions included: (1) enlarging the radiation warning markings to make them easier to recognize; (2) revising the new employee orientation training to include recognition of and response to radiation warning markings as a topic; and (3) retraining all applicable staff who had already received deficient new employee orientation training to ensure that they understood recognition of and response to radiation warning markings. Although licensee staff self-identified the violation, the licensee's corrective action was not prompt. Several months elapsed from the time the licensee planned to revise the new employee orientation training (to include recognition of and response to radiation warning markings as a topic) and the time when it was revised.

Report Details

1.0 Program Scope and Inspection History

The V. A. Medical Center (licensee) operated a medical broad scope program under the authority of NRC Byproduct Material License No. 24-00144-05. The medical broad scope license authorized, in part, the possession of: (1) radiopharmaceuticals and sealed sources for medical diagnosis and therapy; (2) ten curies of iridium-192 in a high dose rate (HDR) remote after-loading brachytherapy device for therapeutic treatments; (3) curie quantities of any byproduct material with atomic numbers 1 to 83, in any form, for research and development (R&D) pursuant to 10 CFR 30.4; (4) 4,200 curies of cesium-137 in an irradiator for irradiation of small animals and in-vitro samples; and (5) millicurie to curie quantities of specifically listed sealed byproduct materials for instrument calibration, student instruction and R&D. Licensed activities were conducted at several authorized locations.

In the last two years, the NRC inspected the licensee's main facilities in St. Louis, Missouri and satellite facilities in Poplar Bluff, Missouri, and Marion, Illinois. The inspections did not result in the issuance of any significant violations or regulatory concerns.

2.0 Security of Licensed Material

a. Inspection Scope

The inspectors toured selected facilities and interviewed the Radiation Safety Officer (RSO) and other selected staff to evaluate how the licensee secured licensed material from unauthorized access. Additionally, the inspectors performed ambient exposure rate surveys of a package containing iodine-131.

b. Observations and Findings

Licensee staff secured licensed material by locking the room or building with access limited to authorized staff, or by having authorized staff maintain constant surveillance of licensed material. Licensed material contained in R&D labs, the nuclear medicine hot lab, and the HDR facility were secured from unauthorized access.

On November 27, 2001, a licensee receptionist personally accepted delivery of a properly marked and labeled package containing 7,052 microcuries of iodine-131 at the Nuclear Medicine Department reception desk. The receptionist contacted a radiopharmacy technician to request pickup. The receptionist left the package on the reception desk to go across the hall to perform scheduling tasks. Although the receptionist knew about the need to maintain constant surveillance of the package and prevent unauthorized access to it, she became distracted for about five minutes. While

she was distracted, she did not maintain constant surveillance of the package, and unauthorized persons had unchallenged access to the package for about five minutes.

Title 10 CFR 20.1801 requires that the licensee secure from unauthorized removal or access licensed materials that are stored in controlled or unrestricted areas. Title 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. The unattended package on the nuclear medicine reception desk (an unrestricted area) was accessible to unauthorized persons. The failure to secure and maintain constant surveillance of the package containing licensed material in an unrestricted area is a violation of 10 CFR 20.1801 and 20.1802.

Using a Ludlum Model 2403 (Serial 038727) that was last calibrated on April 26, 2001, and interfaced with a side-window Geiger-Mueller probe, the inspectors measured maximum radiation levels of 11 milliroentgens per hour and 0.8 milliroentgen per hour at the surface and at one meter from the package, respectively. The measured exposure rates were within the expected range for the labeled package.

The licensee implemented corrective action in response to the violation. Licensee staff immediately secured the package. By November 30, 2001, the licensee revised its package receipt procedure to include specific requirements to maintain constant surveillance of packages and lock them within a secured room as soon as possible after receipt, and completed training of applicable staff regarding the revised package receipt procedure. Additionally, the licensee planned to revise its refresher training to include discussion of its revised package receipt procedure.

c. Conclusions

The licensee secured licensed material by locking the room or building with access limited to authorized staff, or by having authorized staff maintain constant surveillance of licensed material. However, an isolated violation of 10 CFR 20.1801 was identified. The violation was caused by staff becoming distracted with other tasks. The violation resulted in unauthorized persons having access to iodine-131 for approximately five minutes. The licensee's corrective actions were prompt, and they were adequate to achieve compliance and prevent recurrence of a similar violation.

3.0 Disposal of Licensed Material

a. Inspection Scope

The inspectors interviewed the RSO and other selected staff and reviewed selected Radiation Safety Committee (RSC) minutes to evaluate the licensee's radioactive waste disposal activities. The inspectors independently reviewed the licensee's evaluation of

the maximum dose to an individual as a result of disposal of radioactive waste by release to the normal trash.

b. Observations and Findings

The licensee disposed of licensed material by authorized means, with one exception. On May 4, 2001, Environmental Management staff inadvertently disposed of 200 microcuries of sulfur-35 that was in a properly marked radioactive waste receptacle inside of an R&D lab by release to the normal trash. Licensee staff identified the violation on May 23, 2001, and subsequently determined that the sulfur-35 waste was sent to a landfill. The disposal did not likely result in any radiation exposure to a member of the public.

Title 10 CFR 20.2001 requires, in part, that the licensee dispose of licensed material only by certain specified methods. Disposal of 200 microcuries of sulfur-35 radioactive waste by release to the non-radioactive trash, an unauthorized method, is a violation of 10 CFR 20.2001.

After identifying the violation, licensee staff performed an investigation to identify the cause and develop corrective actions. Licensee staff determined that the cause of the violation was not including recognition of and response to radiation warning markings as a topic in new employee orientation training. As a result, Environmental Management staff did not recognize the radiation warning markings on the radioactive waste receptacle. The licensee's corrective actions included: (1) enlarging the radiation warning markings to make them easier to identify; (2) revising the new employee orientation training to include recognition of and response to radiation warning markings as a topic; and (3) retraining all applicable staff who had received deficient new employee orientation by December 20, 2001 to ensure that they could recognize and adequately respond to radiation warning markings.

Although the licensee self-identified the violation, the licensee's corrective action was not prompt. Several months elapsed from the time licensee staff planned to revise the new employee orientation training (to include recognition of and response to radiation warning markings as a topic) and when they completed the revision in November 2001. Additionally, as of November 27, 2001, licensee staff had not retrained all applicable staff who had already received deficient new employee orientation training to ensure that they could recognize and adequately respond to radiation warning markings.

c. Conclusions

The licensee disposed of licensed material by authorized means, with one exception. An isolated violation of 10 CFR 20.2001 occurred when Environmental Management staff inadvertently disposed of 200 microcuries of sulfur-35 by release to the normal trash. Licensee staff identified the violation and determined that the root cause was not including recognition of and response to radiation warning markings as a topic in new employee orientation training. The violation did not likely result in any radiation

exposure to a member of the public. The licensee planned adequate corrective actions after identifying the violation in May 2001; however, all of the corrective actions were not completed as of November 27, 2001.

4.0 Other Areas Inspected

a. Inspection Scope

The inspectors reviewed other areas of the licensee's radiation protection program by interviewing selected staff, observing licensed activities in progress, observing demonstrations of how staff had performed certain activities, and reviewing selected records. Areas reviewed included management oversight, radiation safety committee meetings, equipment and instrumentation, daily operational checks, leak tests, personnel dosimetry, emergency procedures, area surveys, diagnostic imaging, radiopharmaceutical therapy, and high dose rate remote after-loader brachytherapy (HDR).

b. Observations and Findings

Management oversight of the radiation protection program included quarterly audits of licensed activities at all locations of use on the license to verify compliance with NRC regulatory requirements. The RSO, Health Science Officer, or Lead Nuclear Medicine Technologist performed the audits. Quarterly RSC meetings included discussion of audit findings, and the required quorum was present. Licensee staff typically developed and implemented short and long term corrective actions to address identified problems.

Licensee staff used proper, calibrated instrumentation to perform required radiation surveys. The staff knew the survey trigger levels and what to do when trigger levels are exceeded.

The staff performed daily operational checks on radiation survey instruments and HDR equipment. The staff knew how to recognize abnormal operational check results, and what to do in response to them.

The licensee ensured that sealed sources were leak tested at the required frequency. Leak test results were less than 0.005 microcuries.

Licensee staff wore personnel dosimetry badges as required. The staff exchanged dosimetry badges at the required frequency. The maximum whole body and extremity doses received by monitored staff from 1999 through October 2001 were 519 millirems and 3790 millirems, respectively. Licensee staff promptly reviewed dosimetry results to identify trends.

The staff were knowledgeable regarding proper response to emergencies. Proper emergency response equipment was available, and the staff understood how to use it.

Nuclear medicine diagnostic imaging and radiopharmaceutical staff used time, distance, and shielding to reduce radiation exposure. Physician authorized users prescribed dosages on written directives. The staff implemented the Quality Management Program (QMP) to provide high confidence that administered dosages were in accordance with written directives.

Licensee staff used authorized, functional equipment during HDR treatments. Physician authorized users prescribed HDR treatments on written directives. Licensee staff implemented the QMP to provide high confidence that administered doses were in accordance with written directives. The staff implemented the licensee's QMP to provide high confidence that administered dosages were as prescribed.

c. Conclusions

The licensee effectively implemented other areas of its radiation safety program. Licensee staff conducted licensed activities safely and in accordance with NRC regulatory requirements.

5.0 Exit Meeting Summary

The inspectors discussed the preliminary conclusions described in this report with the RSO and the Medical Center Director during an exit meeting conducted at the site on November 27, 2001. The licensee did not identify any information reviewed during this inspection and selected for inclusion in this inspection report as proprietary in nature.

LIST OF PERSONS CONTACTED

Bob Adams, Nuclear Medicine Technologist
Doug Beauchamp, Radiopharmacy Technician
Julie Dawson, Ph.D., Physicist
Sally Feldmeier, Nuclear Medicine Receptionist
Walter Hall, Administrative Officer
Bob McDonald, Physicist
Chuck Nelson, Physicist
Stacy Parker, Nuclear Medicine Technologist
Shiela, Rosenfeld, Health Science Officer
Barbara Sterkel, M.D., Program Manager for Diagnostic Imaging
Dennis Umfleet, Radiation Therapy Supervisor



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Involvement](#)
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EA-97-529 - V.A., Department of, CA

January 15, 1998

EA 97-529

Sheila Cullen
Acting Medical Center Director
Department of Veterans Affairs
Medical Center
4150 Clement Street
San Francisco, California 94121

SUBJECT: NOTICE OF VIOLATION
(NRC Inspection Report No. 030-01214/97-01)

Dear Ms. Cullen:

This refers to your letter dated December 23, 1997, in response to apparent violations described in an NRC inspection report issued on November 26, 1997. The NRC's inspection was completed November 14, 1997, and was in response to an event involving the loss of a phosphorus-32 (P-32) source on August 18, 1997. The Department of Veterans Affairs reported this incident to the NRC on September 2, 1997. Prior to making an enforcement decision, we provided you with an opportunity to respond in writing to the apparent violations or to request a predecisional enforcement conference. You chose to provide a written response and did so on December 23, 1997. You did not dispute the apparent violations.

Based on the information developed during the inspection and the information that you provided in your December 23, 1997, response to the inspection report, the NRC has determined that violations of NRC requirements occurred. These violations are cited in the enclosed Notice of Violation (Notice). The circumstances surrounding them were described in more detail in the subject inspection report. The first violation involved a failure to verify that the contents of a package containing three P-32 vials agreed with the packing list for the shipment received and to survey the package for contamination before it was disposed to normal trash. The second violation involved the unauthorized disposal of a single P-32 vial to normal, non-radioactive trash.

Approximately 305 microcuries of P-32 was estimated to have been inadvertently disposed of in normal trash, and is not believed to have resulted in any actual safety consequences to your staff or members of the public. As you indicated in your response, this event appears to have been isolated and was caused by the lack of attention to detail by a single researcher. Nonetheless, the NRC considers the lack of control of radioactive material to be a serious matter, especially in cases of inadvertent disposal because of the potential for inadvertent exposures to employees and members of the public. Therefore, the violations that caused this incident 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-1600.

In accordance with the Enforcement Policy, a civil penalty with a base value of \$2,750 is considered for a Severity Level III problem. Because your facility has not been the subject of escalated enforcement actions within the last two inspections, the NRC considered only whether credit was warranted for Corrective Action in accordance with the civil penalty assessment process in Section VI.B.2 of the Enforcement Policy. The corrective actions described in your December 23 letter included: 1) a prompt and thorough search for the missing material; 2) the issuance of a violation to the responsible laboratory; 3) surveys of laboratories and garbage receptacles; 4) bioassays of laboratory personnel; 5) a thorough investigation to determine root and contributing causes; 6) promptly informing all researchers of the events leading to the loss of the material and the need to survey packages prior to disposal; 7) retraining of all radiation safety personnel and annual

the violations are listed below:

A. 10 CFR 20.2001(a) requires that the licensee dispose of licensed material only by certain specified procedures.

Contrary to the above, on August 18, 1997, the licensee disposed of approximately 305 microcuries of phosphorus-32 by release to non-radioactive trash, a method not authorized by §20.2001. (01013)

B. License Condition 24.A requires the licensee to conduct its program in accordance with the statements, representations, and procedures, including any enclosures contained in the application dated October 11, 1990. The application October 11, 1990, states in Item No. 10.7 that, except for radiopharmaceuticals and kits procured and administered to patients directly by the Nuclear Medicine Service, the licensee will establish and implement the model procedure for opening packages containing radioactive material as described in Appendix L to Regulatory Guide 10.8, Revision 2. Model procedure 2.d.(3), Appendix L in the above regulatory guide, requires the licensee to open a shipment's inner package and verify that the contents agree with the packing slip. Appendix L model procedure 2.g. requires the licensee to monitor the packing material and the empty packages for contamination with a low-range GM survey meter before discarding.

Contrary to the above, on August 18, 1997, a licensee researcher who opened an inner package of a shipment enclosing three vials, each containing 305 microcuries of phosphorus-32, did not verify that the radioactive contents agreed with the packing slip accompanying the shipment. Also, on August 18, 1997, the researcher did not monitor the packing material and package with a low-range GM survey meter to ensure that it was empty and free of contamination before it was discarded as normal, non-radioactive waste. The discarded package, containing a single vial of approximately 305 microcuries of phosphorus-32, was later disposed as normal trash in a general waste landfill. (01023)

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

The NRC has concluded that information regarding the reason for the violations, the corrective actions taken and planned to correct the violations and prevent recurrence, and the date when full compliance will be achieved is already adequately addressed on the docket in Inspection Report No. 030-01214/97-01 and the letter from the Licensee dated December 23, 1997. 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 IV.

If you contest this enforcement action, you should also provide a copy of your response to the Director, Office of Enforcement, United States Nuclear Regulatory Commission, Washington, DC 20555-0001, and a copy to the Enforcement Officer, NRC Region IV.

Because any response you choose to submit 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).

Dated at Arlington, Texas
this 15th day of January 1998

refresher training of all radioactive material users; 8) performance based audits of package receipt; and 9) procedural revisions to assure that users are aware of the number of vials of materials in each package. As such, we have determined that you are deserving of credit for your prompt and comprehensive corrective actions.

Therefore, to recognize and encourage 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, you are on notice that significant violations in the future, particularly any involving the loss of radioactive material, could result in a civil penalty. In addition, issuance of this Severity Level III problem constitutes escalated enforcement action that may subject you to increased inspection effort.

The NRC has concluded that information regarding the reason for the violations, 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 in your December 23 letter. Therefore, you are not required to respond to this letter unless the description therein does not accurately reflect your corrective actions or your position. In that case, or if you choose to provide additional information, you should follow the instructions specified in the enclosed Notice.

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

Sincerely,

Ellis W. Merschoff
Regional Administrator

Docket No. 030-01214
License No. 04-00421-05

Enclosure: Notice of Violation

cc w/Enclosure:
California Radiation Control Program Director
Dr. Milton Gross
Department of Veterans Affairs
Nuclear Medicine Program
24 Frank Lloyd Wright Drive
Lobby M
P.O. Box 505
Ann Arbor, Michigan 48106

Edwin M. Leidholdt, Jr., Ph.D
Radiation Safety Program Manager (134RAD)
Department of Veterans Affairs
Western Region
301 Howard Street, Suite 700
San Francisco, CA 94105-2241

NOTICE OF VIOLATION

Department of Veterans Affairs
San Francisco, California

Docket No. 030-01214
License No. 04-00421-05
EA 97-529

During an NRC inspection conducted October 16 through November 14, 1997, violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," NUREG-1600,



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION IV

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

August 21, 1995

EA 95-149

Department of Veterans Affairs
Medical Center
ATTN: Mr. Jerry Boyd
Medical Center Director
5901 East Seventh Street
Long Beach, California 90822

SUBJECT: NOTICE OF VIOLATION
(NRC INSPECTION REPORT 030-01215/95-01)

This refers to the routine, unannounced inspection conducted by Mr. David D. Skov of this office on April 17 through July 10, 1995. The inspector was accompanied by Mr. Eugene J. Power, Investigator, Region IV Office of Investigations (Field Office). The inspection included a review of activities authorized by Byproduct Material License 04-00689-07. At the conclusion of the inspection, the findings were discussed with members of your staff. The enclosed NRC Inspection Report 030-01215/95-01 documents this inspection.

The inspection was an examination of activities conducted under the license as they relate to radiation safety and to compliance with the Commission's rules and regulations and the conditions of the license. The inspection consisted of selective examinations of procedures and representative records, interviews of personnel, independent measurements, and observation of activities in progress. The purpose of the inspection was to determine whether activities authorized by the license were conducted safely and in accordance with NRC requirements.

Based on the results of this inspection, the NRC has determined that violations of NRC requirements occurred. These violations are cited in the enclosed Notice of Violation (Notice) and the circumstances surrounding them are described in detail in the subject inspection report. The violations are of concern because they represent implementation weaknesses in several areas of the radiation safety program.

In addition, one apparent violation of NRC requirements was identified for escalated enforcement action in accordance with the General Statement of Policy and Procedure for NRC Enforcement Actions (Enforcement Policy) (NUREG 1600, 60 FR 34381, June 30, 1995). The apparent violation involved the

ENCLOSURE 1
NOTICE OF VIOLATION

Department of Veterans Affairs
Medical Center
Long Beach, California 90822

Docket: 030-01215
License: 04-00689-07

During an NRC inspection conducted at the Department of Veterans Affairs Medical Center, Long Beach, California on April 17 through July 10, 1995, seven violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedures for NRC Enforcement Actions," 60 FR 34381, June 30, 1995, the violations are listed below:

- A. 10 CFR 20.2001(a) requires that the licensee dispose of licensed material only by certain specified procedures.

Contrary to the above, on approximately February 24, 1994, the licensee disposed of 5 millicuries of iodine-125 in liquid form by release to the non-radioactive trash, a method not authorized by 10 CFR 20.2001. (01013)

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

- B. 10 CFR 35.406(b) requires that a licensee make a record of brachytherapy source use, including: (1) the names of the individuals permitted to handle the sources; (2) the number and activity of sources removed from storage, the patient's name and room number, the time and date they were removed from storage, the number and activity of the sources in storage after the removal, and the initials of the individual who removed the sources from storage; and (3) the number and activity of sources returned to storage, the patient's name and room number, the time and date they were returned to storage, the number and activity of sources in storage after the return, and the initials of the individual who returned the sources to storage.

Contrary to the above, the licensee did not make a record of brachytherapy source usage for a 30-seed patient implant containing 95 millicuries of iridium-192 used between September 14 and 16, 1994.

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

- C. 10 CFR 35.51(a) requires, in part, that a licensee calibrate the survey instruments used to show compliance with 10 CFR Part 35.

10 CFR 35.51(b) states, in part, that when calibrating a survey instrument, a licensee shall consider a point as calibrated if the indicated exposure rate differs from the calculated exposure rate by not more than 20 percent.

Contrary to the above, as of April 28, 1995, the licensee was using a Technical Associates Model TBM-3 survey instrument to show compliance

Department of Veterans Affairs
Medical Center

-4-

Should you have any questions concerning this letter, please contact
Mr. Frank A. Wenslawski at (510)975-0219.

Sincerely,



L. J. Callan
Regional Administrator

Docket: 030-01215
License: 04-00689-07

Enclosures:

1. Notice of Violation
2. NRC Inspection Report
030-01215/95-01
3. Copy of General Statement of Policy and Procedure for NRC Enforcement
Actions (60 FR 34381, June 30, 1995)

cc w/enclosures:
California Radiation Control Program Director

Department of Veterans Affairs
National Health Physics Program (115HP)
ATTN: Dr. F. Herbig
915 North Grand Boulevard
St. Louis, MO 63106

Edwin M. Leidholdt, Jr., Ph.D.
Radiation Safety Program Manager (134RAD)
Department of Veterans Affairs
Western Region
301 Howard Street, Suite 700
San Francisco, CA 94105-2241

unauthorized disposal of licensed material by release to the normal trash in violation of 10 CFR 20.2001(a).

The NRC learned of the improper disposal through a telephone call to the NRC operations center from your radiation safety officer on March 4, 1994. This was followed by a written report (dated March 30, 1994) of the incident and the corrective actions taken. It was determined that a research laboratory principal investigator had ordered 5 millicuries of iodine-125 (I-125) as sodium iodide in liquid form on February 23, 1994. The carrier's delivery report (signed by a Department of Veterans Affairs Medical Center representative) provided positive evidence that the I-125 package was received at the Medical Center the following day. However, the investigator did not receive the shipping package and after an extensive search, it was concluded that the package had been accidentally disposed to normal trash and was probably buried at a landfill disposal site.

The NRC staff considered both the safety and regulatory significance of having disposed of the I-125 in the normal trash. The NRC recognizes the relative low safety significance of the I-125 disposal provided the material remains intact within its shielded container. However, considering the relatively long half life of I-125 (approximately 60 days) and the quantity involved, a potential hazard to the general public would have existed for an extended period of time if the container had been breached, releasing its radioactive contents. Secondly, the NRC considers the regulatory significance of this event to be very high. The NRC, in licensing the use of byproduct material, requires that the licensee maintain positive control over the storage, use and disposal of the material to ensure the health and safety of the user, patients and the public.

On July 17, 1995, a telephone conversation was held between you and Mr. Skov of my staff regarding a predecisional enforcement conference. Based on this conversation it was determined that an enforcement conference was not necessary and that the apparent violation including the description of the event and associated corrective action were appropriately understood for the NRC staff to come to an enforcement decision. Therefore, in accordance with the Enforcement Policy this apparent violation has been classified at Severity Level III because of the overall significance the NRC places on the proper disposal of radioactive materials.

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 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. Based on the extensive efforts to recover the source which included interviewing personnel about the missing package and a wide-spread search with a survey meter of nuclear medicine, research, and waste storage areas, and based on the additional controls that were put in place for receipt of radioactive materials, the NRC staff

determined that credit for corrective actions taken was appropriate. Therefore, to encourage prompt and comprehensive correction of violations, and in recognition of the absence of previous escalated enforcement action, I have been authorized, after consultation with the Director, Office of Enforcement, not to propose a civil penalty in this case. However, any significant violations in the future could result in a civil penalty.

The NRC has concluded that information regarding the reason for Violation A, the corrective actions taken and planned to correct the violation and prevent recurrence is already adequately addressed in the enclosed inspection report and on the docket in the licensee's letter dated March 30, 1994. Therefore, you are not required to respond to Violation A 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. You are however required to respond to Violations B-G and should follow the instructions specified in the enclosed Notice when preparing your response.

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.

In addition to the concerns discussed above regarding violations identified during this inspection, we are concerned about the implementation of your program in the area of management control. Although management oversight and overall radiation safety program performance in preventing, identifying, and correcting violations and deficiencies has markedly improved since the last two NRC inspections, the violations identified during the current inspection indicate the need for additional management attention to this program area. For example, three of the violations involved failures to calibrate or adequately calibrate various counting instruments used for conducting area radiation surveys and bioassays of personnel. Therefore, in your reply to this letter, we request that you also describe those actions planned or taken to improve the effectiveness of the management control of your licensed operations, with particular emphasis on measures currently being taken to prevent further violations.

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.

with a copy to the Regional Administrator, Region IV, 611 Ryan Plaza Drive, Suite 400, Arlington, Texas 76011, and Walnut Creek Field Office, 1450 Maria Lane, Walnut Creek, California 94596, 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. Where good cause is shown, consideration will be given to extending the response time.

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, or safeguards information so that it can be placed in the PDR without redaction. However, if it necessary to include such information, it should clearly indicate the specific information that should 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 21st day of August 1995



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

February 18, 2004

Docket Nos. 03002941
03030007
03035567

License Nos. 37-00148-06
37-00148-07
37-00148-08

Bart Murtaugh
Vice President Support Services
TJUH, Inc.
111 South 11th Street
Philadelphia, PA 19107

- 2001
- NCV

SUBJECT: INSPECTIONS 03002941/2003001, 03030007/2003001, AND
03035567/2003001, TJUH, INC., PHILADELPHIA, PENNSYLVANIA SITE AND
THE DELAWARE VALLEY COLLEGE OF AGRICULTURE AND SCIENCE,
DOYLESTOWN, PENNSYLVANIA

Dear Mr. Murtaugh:

On December 16-19, 2003, James P. Dwyer of this office conducted a safety inspection at the above address and the Delaware Valley College of Agriculture and Science, Doylestown, Pennsylvania, of activities authorized by the above listed NRC licenses. The inspection was an examination of your licensed activities as they relate to radiation safety and to compliance with the Commission's regulations and the license conditions. The inspection consisted of observations by the inspector, interviews with personnel, and a selected examination of representative records. The findings of the inspection were discussed with you and members of your staff at the conclusion of the inspection on December 19, 2003. Your report dated January 8, 2004, submitted in accordance with 10 CFR 20.2201(b), was reviewed following the onsite inspection.

Within the scope of this inspection, 2 Non-Cited Violations (NCV) of 10 CFR 20.2001(a) were identified. You failed to dispose of licensed material only by certain specified procedures. On January 23 or 24, 2003, you disposed of source vials containing 1.3 millicuries of sulfur-35 and 250 microcuries of hydrogen-3, and on November 11, 2003, you disposed of a source vial containing 1.07 millicuries of sulfur-35 by release to the non-radioactive trash, a method not authorized by 10 CFR 20.2001. These were non-repetitive, licensee-identified and corrected violations and are being treated as NCVs in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy), NUREG 1600. The NRC has concluded that information regarding the reason for the violations, the corrective actions taken and planned to correct the violations and prevent recurrence is already adequately addressed on the docket in the report dated March 20, 2003, and the report dated January 8, 2004. If you contest the violations or significance of these NCVs, you should provide a response within 30 days of the date of this letter with the basis for your denial, to the United States Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001, with copies to the Regional Administrator, Region I, and the Director, Office of Enforcement, United State Nuclear Regulatory Commission, Washington, DC, 20555-0001.

B. Murtaugh
TJUH, Inc.

2

In accordance with 10 CFR 2.790, a copy of this letter will be placed in the NRC Public Document Room and will be accessible from the NRC Web site at <http://www.nrc.gov/reading-rm.html>.

Your cooperation with us is appreciated.

Sincerely,

Original signed by:

Pamela J. Henderson, Chief
Nuclear Materials Safety Branch 1
Division of Nuclear Materials Safety

cc:
John Keklak, Radiation Safety Officer
Commonwealth of Pennsylvania

B. Murtaugh
TJUH, Inc.

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|--------|-----------------|---|----------------|---|--|--|--|--|
| OFFICE | DNMS/RI | N | DNMS/RI | N | | | | |
| NAME | Jdwyer/pjh for: | | PHenderson/pjh | | | | | |
| DATE | 2/13/04 | | 2/13/04 | | | | | |

OFFICIAL RECORD COPY

INSPECTION RECORD

Region I Inspection Report No. 2003-001 License(s) No. 37-00148-06
37-00148-08
37-00148-07
Docket(s) No. 030-02941
030-35567
030-30007

Licensee (Name and Address): TJUH, Inc. (Thomas Jefferson University Hospital)
Location (Authorized Site) Being Inspected: Philadelphia and Doylestown, PA
Licensee Contact: John Keklak, RSO Telephone No. (215)955-7813

Priority: 2/2/5 Program Code: 2110/2310/3510
Date of Last Inspection: Jun 21-26, 2001 (2110)
Jun 25-26, 2001 (2310)
Feb 2-5, 1998 (3510) Date of This Inspection: Dec 16-19, 2003

Type of Inspection: () Initial (X) Announced () Unannounced
(X) Routine (X) Special
Next Inspection Date: Dec 2005 (2110/2310) (X) Normal () Reduced
Dec 2008 (3510)

Justification for reducing the routine inspection interval: not applicable

Summary of Findings and Actions:

- () No Violations cited, clear U.S. Nuclear Regulatory Commission (NRC) Form 591 or regional letter issued
- (X) Non-cited violations (NCVs)
- () Violation(s), Form 591 issued
- () Violation(s), regional letter issued
- () Followup on previous violations

Inspector(s): for James P. Dwyer Date: 2/12/04
Name(s)
Signature(s)

Approved: Pamela J. Henderson Date: 2/12/04
Name
Signature

PART I-LICENSE, INSPECTION, INCIDENT/EVENT, AND ENFORCEMENT HISTORY

1. AMENDMENTS AND PROGRAM CHANGES:

(License amendments issued since last inspection, or program changes noted in the license)

| <u>AMENDMENT No.</u> | <u>DATE</u> | <u>SUBJECT</u> |
|----------------------|-------------|----------------|
|----------------------|-------------|----------------|

Since the last inspection, the broad scope license (37-00148-06) was amended on May 23, 2002 (#29) to increase the possession limit of Sr-90 for use in the Novoste Beta Cath intravascular brachytherapy device. The license file also includes documentation of the licensee's request to obtain a Nucletron Seed-Selectron device for performing permanent implants. NRC determined that no amendment was required. The license was also amended during the inspection to allow the use of a new supplier of the Nucletron HDR source (#30).

Since the last inspection, the gammaknife license (37-00148-08) was amended on 4 occasions. In all cases the amendment was limited to adding or removing authorized users and authorized medical physicists to/from the license.

Since the last inspection, the self-shielded irradiator license (37-00148-07) was amended on August 12, 2003 (#7) to renew the license.

2. INSPECTION AND ENFORCEMENT HISTORY:

(Unresolved issues; previous and repeat violations; Confirmatory Action Letters; and orders)

There were no unresolved issues or violations identified during the previous inspections of the three licenses.

3. INCIDENT/EVENT HISTORY:

(List any incidents, or events reported to NRC since the last inspection. Citing "None" indicates that regional event logs, event files, and the licensing file have no evidence of any incidents or events since the last inspection.)

On Feb 28 (Event No. 39628) and Dec 11, 2003 (Event No. 40386), in accordance with 10 CFR 20.2201(a)(1)(ii), the licensee contacted the NRC Ops Center to report the loss of packages containing radioactive material in quantities greater than 10 times Appendix C of Part 20. See Part II, Item 4, of this report for additional information.

PART II - INSPECTION DOCUMENTATION

1. ORGANIZATION AND SCOPE OF PROGRAM:

(Management organizational structure; authorized locations of use, including field offices and temporary job sites; type, quantity, and frequency of material use; staff size; delegation of authority)

Under the broad license, 8-10 technologists perform ~50 diagnostic nuclear medicine (including cardiology) studies/day and 100 radiopharmaceutical therapy procedures/ year. More than 98% of therapies involve I-131. ~40% of therapies involve inpatients. On an annual basis in radiation oncology, 7-10 manual brachytherapy procedures (none since 2002), 50-60 HDR fractions and 50 permanent implants using I-125 Rapidstrand (not the Seed-Selectron) are performed. Intravascular brachytherapy is performed regularly using a Novoste 3.5F system. The licensee possesses a Sr-90 eye applicator which has not been used in several years. All clinical use at one site - the hospital. There are 150 authorized users supervising research (small CHIPS) in ~350 laboratories. Local RSOs assist with oversight for each Department. Research is performed at the Philadelphia campus and also at the Doylestown facility. No licensed activities are conducted at the former Ford Road Hospital location.

The licensee possesses a "U-Model" gammaknife. The sources were installed in June 1996 and output is less than 40% of the original output determined at commissioning. The licensee has had to move the room area radiation monitor closer to the gammaknife to assure it will activate with the gammaknife shield door open. The licensee is upgrading other areas of the Department and hopes to find the funds to replace the sources. The licensee currently treats patients on 8-10 days each month. The back up medical physicist is onsite once each week to assist with treatment. Elekta is onsite to perform preventative maintenance every six months. No problems have been identified. The 5-year maintenance was performed by Elekta on schedule. The last annual calibration was performed in November 2003. Output at that time was measured at 131.2 centigray/minute.

The irradiator license authorizes possession of three self-shielded units. Two of the units are used in research, the third unit is used in the hospital's blood bank. The irradiators are secured in rooms equipped with smoke detectors and containing minimal amounts of combustible material. Two of the rooms are equipped with sprinklers. The third room contains a fire extinguisher. RSO staff provide training and perform routine surveys and leak tests. Individuals are required to utilize a dedicated survey meter during irradiator use. A licensee engineer performs maintenance on the units that does not involve shielding and safety systems. While no problems have been identified, the licensee indicated the manufacturer would be contacted for repair of safety related problems.

John Keklak is the RSO on these three licenses plus a fourth license issued to Jefferson University Radiology Associates (JURA). JURA is run by a physician's group and is not under TJUH management. The RSO is assisted by a senior health physicist and four health physics technicians. The RSO staff performs audits of research, nuclear medicine, radiation oncology and gammaknife at least quarterly. The inspector noted that the scope of audits performed in radiation oncology is limited in comparison to the other areas and recommended that consideration be given to expanding this audit. The RSC meets regularly and when needed. The inspector noted that representatives from the licensee's three most significant areas (nuclear medicine, radiation oncology and gammaknife) were only able to attend approximately 50% of the regularly scheduled meetings. The inspector recommended that the scheduling of RSC meetings be examined to see if there was a way to improve participation from these areas.

2. **SCOPE OF INSPECTION:**

(Identify the inspection procedure(s) used and focus areas evaluated. If records were reviewed, indicate the type of record and time periods reviewed)

Inspection Procedure(s) Used: 87134, 87133, 87122, TI2800-032

Focus Areas Evaluated: 87134 (03.01 through 03.08)
87133 (03.01 through 03.07)
87122 (03.01 through 03.07)

Reviewed minutes of RSC meetings held since the June 2001 inspection; a March 2003 report of radioactive materials disposed of to the normal trash; a draft December 2003 report of additional materials disposed of to the normal trash; a synopsis of personnel exposure records for 2003 year to date and for calendar year 2002; a sample of RSO audits performed of Nuclear Medicine and research; records of HDR source exchanges/maintenance and patient treatments performed in the last 12 months; a sample of records of patient room surveys and room release surveys for I-131 and manual brachytherapy patient treatments performed in 2002-2003; a sample of written directives for I-131 and manual brachytherapy patient treatments in 2002-2003; records of gammaknife preventative maintenance performed in 2002 and 2003; records of annual calibration and a sample of monthly and daily QA checks for the gammaknife performed in 2002-2003; and a sample of package receipt survey records, radioactive material utilization records, survey records and waste disposal disposal records from various research laboratories.

3. **INDEPENDENT AND CONFIRMATORY MEASUREMENTS:**

(Areas surveyed, both restricted and unrestricted, and measurements made; comparison of data with licensee's results and regulations; and instrument type and calibration date)

Surveys were performed using a Bicron MicroRem meter (NRC #033432, calibrated 6/5/2003).

Maximum on contact measurement of the gammaknife was 5 millirem/hour. With the shield door open, a measurement of 50 microrem/hour was made at the control console and treatment room door. The inspector also checked monthly output measurements for the last 18 months against the decayed output values determined at annual calibrations.

Measured ambient radiation levels in the sealed source storage room of up to 0.5 millirem/hour. Levels outside of the room were at background. A maximum radiation level of 1 millirem/hour was measured on contact with the HDR unit. With the source exposed, a radiation level of 100 microrem/hour was measured at the control console. The inspector also checked monthly output measurements for the last 12 months against decayed output values determined by source manufacturer at source calibration and by the licensee at source exchange.

In Nuclear Medicine, 0.25 millirem/hour was measured in most areas of the hot lab with a maximum of 2.5 millirem/hour measured in front of the I-131 hood. In a hallway unrestricted area located between the hot lab and the rad waste storage room, an ambient radiation level of 75 microrem/hour was measured.

Only background radiation was measured in research areas.

4. VIOLATIONS, NCVs, AND OTHER SAFETY ISSUES:

(State the requirement, how and when the licensee violated the requirement, and the licensee's proposed corrective action plan. For NCVs, indicate why the violation was not cited. Attach copies of all licensee documents needed to support violations.)

10 CFR 20.2001(a) requires that a licensee dispose of licensed material only by certain specified procedures. Contrary to the above, on January 23 or 24, 2003, the licensee disposed of source vials containing 1.3 mCi of S-35 and 250 uCi of H-3 and on November 11, 2003, the licensee disposed of source vials containing 1.07 mCi of S-35 by release to the non-radioactive trash, a method not authorized by 10 CFR 20.2001. These non-repetitive, licensee-identified and corrected violations are being treated as Non-Cited Violations (NCV) in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy), NUREG 1600.

Following identification of the first event, the licensee performed an investigation and concluded the researcher threw out the opened package containing the source vials without first looking to see if the package contained radioactive material. The licensee's procedures required that packaging be surveyed prior to disposal to make certain the packaging was not contaminated. The licensee concluded that the source vials would have been identified had the package been surveyed as required but added a requirement that packaging not be disposed of until it is confirmed that all stock vials were removed. The licensee reviewed procedures for receipt of radioactive material packages with those individuals directly involved with the loss and circulated a written notice to all researchers describing the essential facts and lessons-learned from the event. The licensee also required each authorized user to review the notice with all personnel under their supervision and review the lab's procedures for receiving, opening and securing radioactive shipments. Radiation Safety Office staff evaluated each authorized user's response to the notice and personnel knowledge of requirements. In addition, the RSC concluded that a major contributing factor to the loss was the fact that the quantity of radioactive material in the package did not require labeling (White-I, Yellow-II or Yellow-III). The RSC required that the Radiation Safety Office staff, after performing the initial receipt of the package, affix a yellow and black sheet of paper containing a radiation warning to packages otherwise exempt from DOT labeling. The licensee's response is described in their report dated March 20, 2003 (ADAMS Accession No. ML031140281).

Following identification of the second event, the licensee performed an investigation and concluded the loss occurred because the individual in the lab who received the package placed the S-35 back into the dry ice within the packaging to prevent its thawing after she had already searched the packaging, defaced the radioactive material labels, removed the warnings and surveyed the packaging. The individual believed the material would be taken immediately to the low temperature freezer by another researcher however this was not done. A third individual noticed the unlabeled and defaced package in the lab and placed it in the normal trash container, unaware that the source vial had been placed back into the package. In response, the licensee cited the authorized user for failing to confirm that all stock vials were removed and suspended the authorized user's ordering privileges pending completion of corrective actions which included completion of a formal review, by the RSO staff, of the duties and responsibilities of the authorized user and complete refresher training for all personnel with access to the lab. The refresher training would specifically include discussion of the incident and lessons-learned and a review of the package opening procedures and package survey requirements. The licensee also modified the package opening instructions to emphasize the need for visual inspection of the package interior prior to disposal. The licensee's response is described in their report dated January 8, 2004.

Note: The corrective action for the first event would not have prevented the second event from occurring. The licensee receives 1200-2000 radioactive material packages each year and, prior to 2003, had not lost a package in more than 11 years.

5. **PERSONNEL CONTACTED:**

(Identify licensee personnel contacted during the inspection, including those individuals contacted by telephone.)

Use the following identification symbols:

- # Individual(s) present at entrance meeting
- * Individual(s) present at exit meeting

#* John Keklak, Radiation Safety Officer
Larry Martino, Senior Health Physicist
*** Bart Murtaugh, Vice President, Support Services**
*** Charles Intenzo, MD, Director of Nuclear Medicine**
*** Jim Galvin, Chief, Medical Physics**
Beverly Downes-Phillips, Medical Physicist
Hyun Kim, Medical Physicist
Ami Patel, Health Physicist
Jay Patel, Chief Nuclear Medicine Technologist
Jamil Zawadul, Nuclear Medicine Technologist
Sheldon Miller, Ph.D., Researcher
Tom Biel, Researcher
Sue Gotta, Researcher

Numerous other clinical and research workers

-END-


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U.S. Nuclear Regulatory Commission
[Home](#)
[Who We Are](#)
[What We Do](#)
[Nuclear Reactors](#)
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[Radioactive Waste](#)
[Facility Info Finder](#)
[Public Involvement](#)
[Electronic Reading Room](#)

Home > [Electronic Reading Room](#) > [Document Collections](#) > [Enforcement Documents](#) > [Significant Enforcement Actions](#) > [Materials Licensees](#) > EA-03-196

EA-03-196 - ABB, Inc.

November 26, 2003

EA 03-196

Mr. Steven Sturm
 Director of Measurement Technology
 ABB Inc.
 650 Ackerman Road
 Columbus, OH 43202-1577

- 1801
 - Lost source 78 mCi
 (gauge) 90Sr
 Left unattended

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY - \$3,000
 (NRC Inspection Report No. 999-90002/2003-004)

Dear Mr. Sturm:

This refers to the NRC inspection conducted on September 16, 2003, at a temporary job site located at Lees Carpets in Glasgow, Virginia, to review the circumstances associated with your loss of a sealed source capsule containing 78 millicuries of strontium-90. You reported this loss to the NRC via telephone on September 11, 2003, after you had discovered the source was missing. You provided additional information to the NRC regarding this event by telephone on September 17 and 25, 2003, as well as in a written report dated October 7, 2003.

At the time the source was lost, your employees were working in the Commonwealth of Virginia (an NRC Non-Agreement State) under a general license per 10 CFR Part 31.6, and therefore, were working under NRC jurisdiction. As described in the NRC inspection report sent to you on October 15, 2003, one apparent violation of NRC requirements was identified during the inspection involving your failure to control radioactive material that resulted in the loss of the source. In a written report sent to the NRC on October 7, 2003, you stated that the ABB staff believes that the lost source was inadvertently placed in a dumpster and sent to a sanitary landfill. You also stated that you have implemented corrective actions to prevent recurrence.

In a telephone conversation on October 29, 2003, Mr. Wade Loo, of my staff, provided Dr. Jonathan Fortkamp, of your staff, the opportunity to address the apparent violation identified in the NRC inspection report by either attending a predecisional enforcement conference or by providing a written response before the NRC made a final enforcement decision. During that conversation, Dr. Fortkamp informed Mr. Loo that you declined to have a conference but that you elected to provide a written response to the NRC. You provided the written response to the NRC on October 29, 2003.

Based on the information developed during the inspection, and the additional

information provided in your letter dated October 29, 2003, the NRC has determined that one violation of NRC requirements occurred. The violation is cited in the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice) and the circumstances surrounding it are described in detail in the subject inspection report. The violation involved the failure to control radioactive material that resulted in the loss of the source. The violation occurred in August 2003, during dismantlement of three gauges and packaging of three sources for shipment to your facility in Columbus, Ohio. Although you were unable to specifically determine exactly how the one source was lost, you have concluded based on an investigation conducted by your staff, that the source inadvertently fell out of its holder during the preparation for shipment and was later swept up with other debris. You also concluded that the source was placed in a dumpster and sent to the sanitary landfill in Rockbridge County, Virginia, since a physical search and radiation surveys conducted at the temporary job site did not identify any radioactive material.

The safety consequence of this violation was minimized by the fact that the source, if sent to the sanitary landfill, is unlikely to come in close contact with any individual. Nonetheless, this violation is of concern to the NRC because: (1) the failure to control radioactive material resulted in the subsequent loss of the source; and (2) such sources can result in substantial unintended radiation dose to an individual if placed in close contact with the individual's skin. Therefore, this violation is categorized at a 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 current version of the Enforcement Policy, a base civil penalty is considered for a Severity Level III violation or problem involving the loss or improper disposal of this type of radioactive material. Since 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.C.2 of the Enforcement Policy. Credit for corrective actions is warranted because your corrective actions were considered prompt and comprehensive. These corrective actions included, but were not limited to: (1) obtaining detailed source drawings from the manufacturers; (2) revising instructions and procedures for future service involving this type of device to include specific information obtained from the manufacturer; and (3) reviewing all policies and procedures to assure timely identification of discrepancies or problems with source receipt.

Application of the civil penalty assessment process would not normally result in a civil penalty when there are no escalated enforcement actions issued to the facility within the past two years or two inspections, and appropriate corrective actions were taken to prevent the violation from recurring. However, the revised Enforcement Policy published December 18, 2000 (effective February 16, 2001), provides that, notwithstanding the normal civil penalty assessment process, a civil penalty of at least the base amount should normally be proposed for cases involving lost material to reflect the significance of the violation and to emphasize the importance of maintaining control of licensed material (see section VII.A.1.(g) of the Enforcement Policy). In this case, the base civil penalty amounts in the application of the civil penalty assessment process, as reflected in Tables 1A.f2 and 1B of the Enforcement Policy, would result in a civil penalty of \$7500, which has been determined to be approximately three times the average cost for authorized disposal. The revised Enforcement Policy also provides that civil penalties may be adjusted to better correspond to three times the actual cost

for authorized disposal. You stated in your October 29 letter that your vendor's estimated cost of disposal for the device was approximately \$260. However, the Enforcement Policy also states that a civil penalty amount less than lowest civil penalty listed in the Enforcement Policy Tables 1A.f3 and 1B (\$3000) would not be sufficient to adequately emphasize the importance of maintaining control of radioactive material. Therefore, 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 \$3,000 for this Severity Level III violation. In addition, issuance of this Notice constitutes escalated enforcement action that may subject you to increased inspection effort.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. In your response, you may reference any previous correspondence that is applicable to this case to avoid repetitive submissions. The NRC will use your response, in part, to determine whether further enforcement action is necessary to ensure compliance with regulatory requirements.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter, its enclosures, and your response will be made available electronically for public inspection in the NRC Public Document Room or from the Publicly Available Records (PARS) component of NRC's document system (ADAMS). ADAMS is accessible from the NRC Web site at <http://www.nrc.gov/NRC/ADAMS/index.html> (the Public Electronic Reading Room).

Sincerely,

/RA/ original signed by J.T. Wiggins for

Hubert J. Miller
Regional Administrator

Docket No. 999-90002
General License (10 CFR 31.6)

Enclosures:

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

cc w/encl:
Jonathan Fortkamp, Ph. D.
State of Ohio
Commonwealth of Virginia

ENCLOSURE

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

ABB, Inc.
Columbus, OH

General License (10 CFR 31.6)
Docket No. 999-90002
EA 03-196

During an NRC inspection conducted at a temporary jobsite at Lees Carpets in Glasgow, Virginia on September 16, 2003, one violation of NRC requirements was identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy), NUREG-1600, the NRC proposes a civil penalty pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (Act), 42 U.S.C. 2282 and 10 CFR 2.205. The violation and associated civil penalty are set forth 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. As defined in 10 CFR 20.1003, *controlled area* means an area, outside of a restricted area but inside the site boundary, access to which can be limited by the licensee for any reason; and *unrestricted area* means an area, access to which is neither limited nor controlled by the licensee.

Contrary to the above, on July 30, 2003, the licensee failed to secure from unauthorized removal a sealed source capsule containing approximately 78 millicuries of strontium-90 located at a temporary job site at the Lees Carpet facility in Glasgow, Virginia, which is an unrestricted area, nor did the licensee limit access and maintain constant surveillance of this licensed material. Specifically, the licensee failed to secure the source while conducting maintenance on the fixed gauging device, resulting in the loss of the source into the public domain (likely sent to the Rockbridge County landfill).

This is a Severity Level III problem (Supplement IV).
Civil Penalty - \$3,000.

Pursuant to the provisions of 10 CFR 2.201, ABB 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, EA 03-196" and should include for each alleged violation: (1) admission or denial of the alleged violation, (2) the reasons for the violation if admitted, and if denied, the reasons why, (3) the corrective steps that have been taken and the results achieved, (4) the corrective steps that will be taken to avoid further violations, and (5) the date when full compliance will be achieved. Your response may reference or include previous docketed correspondence, if the correspondence adequately addresses the required response. If an adequate reply is not received within the time specified in this Notice, an Order or a Demand for Information may be issued as why the license should not be modified, suspended, or revoked or why such other action as may be proper should not be taken. Consideration may be given to extending the response time for good cause shown.

Within the same time as provided for the response required above under 10 CFR 2.201, the Licensee may pay the civil penalty proposed above, or the cumulative amount of the civil penalties if more than one civil penalty is proposed, in

accordance with NUREG/BR-0254 and by submitting to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, a statement indicating when and by what method payment was made, or may protest imposition of the civil penalty in whole or in part, by a written answer addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission. Should the Licensee fail to answer within 30 days of the date of this Notice, 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.C.2 of the Enforcement Policy should be addressed. Any written answer in accordance with 10 CFR 2.205 should be set forth separately from the statement or explanation in reply pursuant to 10 CFR 2.201, but may incorporate parts of the 10 CFR 2.201 reply by specific reference (e.g., citing page and paragraph numbers) to avoid repetition. The attention of the Licensee is directed to the other provisions of 10 CFR 2.205, regarding the procedure for imposing a civil penalty.

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

The response noted above (Reply to Notice of Violation, statement as to payment of civil penalty, and Answer to a Notice of Violation) should be addressed to: F. Congel, 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 made available electronically for public inspection in the NRC Public Document Room or from the Publicly Available Records (PARS) component of NRC's document system (ADAMS), to the extent possible, it should not include any personal privacy or proprietary information so that it can be made available to the public without redaction. ADAMS is accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html> (the Public Reading Room). If personal privacy or proprietary information is necessary to provide an acceptable response, then please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request withholding of such material, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim of withholding (e.g., explain why the disclosure of information will create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.790(b) to support a request for withholding confidential commercial or financial information).

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

Dated this 26th day of November 2003

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Last revised Tuesday, December 02, 2003



[Index](#) | [Site Map](#) | [FAQ](#) | [Help](#) | [Glossary](#) | [Contact Us](#)

[Advanced Search](#)

U.S. Nuclear Regulatory Commission



- Home
- Who We Are
- What We Do
- Nuclear Reactors
- Nuclear Materials
- Radioactive Waste
- Facility Info Finder
- Public Involvement
- Electronic Reading Room

[Home](#) > [Electronic Reading Room](#) > [Document Collections](#) > [Enforcement Documents](#) > [Significant Enforcement Actions](#) > [Materials Licensees](#) > EA-02-102

EA-02-102 - Howard University Hospital

June 21, 2002

- 1801
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EA 02-102

Marlene H. McKetty, Ph.D.
Chair, Radiation Safety Committee
Howard University Hospital
2041 Georgia Avenue, N.W.
Washington, DC 20060

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY - \$3,000 (NRC Inspection Report No. 030-01321/2002-001)

Dear Dr. McKetty:

This refers to the NRC inspection conducted on April 17 and 19, 2002, at your facility in Washington, D.C., to review the circumstances associated with the loss of an iridium-192 (Ir-192) ribbon containing four seeds with a total activity of 2.6 millicuries (mCi). You reported this loss to the NRC on April 5, 2002. The results of the inspection were discussed with members of your staff during exit meetings on April 17 and April 22, 2002.

As described in the NRC inspection report sent to you on May 22, 2002, two apparent violations of NRC requirements were identified during the inspection. In your written follow-up report sent to the NRC on April 12, 2002, you stated that Howard University staff believes that the lost source was inadvertently flushed into the sanitary sewer system. You also stated that you have implemented corrective actions to prevent recurrence.

In the May 22, 2002 letter transmitting the inspection report, we provided you the opportunity to address the apparent violations identified in the report by either attending a predecisional enforcement conference or by providing a written response before we made our final enforcement decision. On June 4, 2002, you telephonically notified Mr. Steven Courtemanche, of my staff, that you declined to have a conference and also elected not to provide a written response to the NRC.

Based on the information developed during the inspection, and the information provided in your report, the NRC has determined that two violations of NRC requirements occurred. The 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 more significant violation involved the failure to control radioactive material that resulted in the loss of the ribbon used for patient brachytherapy treatment. The violation occurred when one of the eleven ribbons implanted into the patient's oral cavity was lost during the scheduled brachytherapy treatment. That ribbon was found to be missing during the planned treatment period. Although you were unable to specifically determine exactly how the ribbon was lost, based on an investigation conducted by your staff, you have concluded that the waste was flushed down the toilet because surveys of the hospital, the laundry, and other areas within the hospital did not identify any radioactive material. Alternatively, the ribbon may have been placed in the laundry along with the patient's soiled gown. Because your staff also failed to perform a survey for radioactive material of items removed from the patient's room, this failure constituted the second violation which may have contributed to the failure to control the radioactive material.

The safety significance of these violations was minimized by the fact that the source, whether discarded in the sewer or the laundry, is unlikely to come in close contact with any individual. Nonetheless, these violations are of concern to the NRC

because: (1) the failure to control radioactive material resulted in the subsequent loss of the source; and (2) such sources can result in substantial unintended radiation dose to an individual if placed in close contact with the individual's skin. Therefore, these violations are categorized collectively as a Severity Level III problem in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions" (Enforcement Policy), NUREG-1600.

In accordance with the current version of the Enforcement Policy, a base civil penalty in the amount of \$3,000 is considered for a Severity Level III violation or problem involving the loss or improper disposal of radioactive material. 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.C.2 of the Enforcement Policy. Credit for corrective actions is warranted because your corrective actions were considered prompt and comprehensive. These corrective actions included, but were not limited to: (1) the posting of warning signs at various locations during brachytherapy treatments informing staff not to remove any patient's fluids, trash, or soiled linen from the patient's room without clearance from the radiation safety officer; (2) providing an in-service training session for the nursing staff to emphasize proper disposal of wet and dry waste during brachytherapy treatments; (3) revising the nursing instructions for handling of patients with temporary implant source treatments; and (4) changing patient's charts to include specific physician orders and a radiation precaution label.

Application of the normal civil penalty assessment process would not result in a civil penalty in this case. However, the revised Enforcement Policy published December 18, 2000 (effective February 16, 2001), provides that, notwithstanding the normal civil penalty assessment process, a civil penalty of at least the base amount should normally be proposed in this type of case to reflect the significance of the violation and to emphasize the importance of maintaining control of licensed material (see section VII.A.1.(g) of the Enforcement Policy). Therefore, 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 \$3,000 for the Severity Level III problem. In addition, issuance of this Notice constitutes escalated enforcement action, that may subject you to increased inspection effort.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. In your response, you may reference any previous correspondence that is applicable to this case to avoid repetitive submissions. The NRC will use your response, in part, to determine whether further enforcement action is necessary to ensure compliance with regulatory requirements.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter, its enclosures, and your response will be made available electronically for public inspection in the NRC Public Document Room or from the Publicly Available Records (PARS) component of NRC's document system (ADAMS). ADAMS is accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html> (the Public Electronic Reading Room).

Sincerely,

James T. Wiggins Acting For

Hubert J. Miller
Regional Administrator

Docket No. 030-01321
License No. 08-03075-07

Enclosures:

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

cc w/encl:
District of Columbia

ENCLOSURE

NOTICE OF VIOLATION

AND
PROPOSED IMPOSITION OF CIVIL PENALTYHoward University Hospital
Washington, DCLicense No. 08-03075-07
Docket No. 030-01321
EA 02-102

During an NRC inspection conducted at Howard University Hospital on April 17 and 19, 2002, and continued in the Region I office until April 22, 2002, two violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy), NUREG-1600, the NRC proposes a civil penalty pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (Act), 42 U.S.C. 2282 and 10 CFR 2.205. The violations and associated civil penalty are set forth below:

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

Contrary to the above, on April 4, 2002, the licensee did not secure from unauthorized removal or limit access to licensed material in a controlled or unrestricted area, nor did the licensee control and maintain constant surveillance of this licensed material. Specifically, the licensee used a brachytherapy ribbon containing 2.6 millicuries of iridium-192 during the treatment of a patient in a restricted area. However, the licensee could not account for the material during the treatment period and reported that the material could not be found in the patient's room or in any other area of the hospital. The licensee failed to control and maintain constant surveillance of the material in controlled or unrestricted areas after it left the patient's room.

- B. 10 CFR 20.1501 requires, in part, that the licensee make, or cause to be made, surveys that may be necessary for the licensee to comply with 10 CFR Part 20 and are reasonable under the circumstances to evaluate: the magnitude and extent of radiation levels; concentrations or quantities of radioactive material; and the potential radiological hazard 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, on April 4, 2002, the licensee did not make, or cause to be made, surveys that were necessary for the licensee to comply with 10 CFR 20.1802 and were reasonable under the circumstances to evaluate the magnitude and extent of radiation levels, concentrations or quantities of radioactive material, and the potential radiological hazard that could be present. Specifically, the licensee did not make, or cause to be made, surveys necessary to prevent the loss of control of a brachytherapy ribbon containing 2.6 millicuries of iridium-192 which was removed from a patient's room during treatment. The surveys that were performed did not include the soiled clothing or patient's fluids before they were removed from the patient's room.

This is a Severity Level III problem (Supplement IV).
Civil Penalty - \$3,000.

Pursuant to the provisions of 10 CFR 2.201, Howard University Hospital 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. Your response may reference or include previous docketed correspondence, if the correspondence adequately addresses the required response. If an adequate reply is not received within the time specified in this Notice, an Order or a Demand for Information may be issued as why the license should not be modified, suspended, or revoked or why such other action as may be proper should not be taken. Consideration may be given to extending the response time for good cause shown.

Within the same time as provided for the response required above under 10 CFR 2.201, the Licensee may pay the civil penalty proposed above, or the cumulative amount of the civil penalties if more than one civil penalty is proposed, in accordance with NUREG/BR-0254 and by submitting to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, a statement indicating when and by what method payment was made, or may protest imposition of the civil penalty in whole or in part, by a written answer addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission. Should the Licensee fail to answer within 30 days of the date of this Notice, 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.C.2 of the Enforcement Policy should be addressed. Any written answer in accordance with 10 CFR 2.205 should be set forth separately from the statement or explanation in reply pursuant to 10 CFR 2.201, but may incorporate parts of the 10 CFR 2.201 reply by specific reference (e.g., citing page and paragraph numbers) to avoid repetition. The attention of the Licensee is directed to the other provisions of 10 CFR 2.205, regarding the procedure for imposing a civil penalty.

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

The response noted above (Reply to Notice of Violation, statement as to payment of civil penalty, and Answer to a Notice of Violation) should be addressed to: F. Congel, 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 made available electronically for public inspection in the NRC Public Document Room or from the Publicly Available Records (PARS) component of NRC's document system (ADAMS), to the extent possible, it should not include any personal privacy or proprietary information so that it can be made available to the public without redaction. ADAMS is accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html> (the Public Reading Room). If personal privacy or proprietary information is necessary to provide an acceptable response, then please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request withholding of such material, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim of withholding (e.g., explain why the disclosure of information will create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.790(b) to support a request for withholding confidential commercial or financial information).

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

Dated this 21st day of June 2002

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Last revised Tuesday, September 09, 2003


[Index](#) | [Site Map](#) | [FAQ](#) | [Help](#) | [Glossary](#) | [Contact Us](#)
 Search
[Advanced Search](#)

U.S. Nuclear Regulatory Commission

[Home](#)
[Who We Are](#)
[What We Do](#)
[Nuclear Reactors](#)
[Nuclear Materials](#)
[Radioactive Waste](#)
[Facility Info Finder](#)
[Public Involvement](#)
[Electronic Reading Room](#)

[Home](#) > [Electronic Reading Room](#) > [Document Collections](#) > [Enforcement Documents](#) > [Significant Enforcement Actions](#) > [Materials Licensees](#) > EA-01-282

EA-01-282 - University of Wisconsin-Madison

December 21, 2001

EA-01-282

Mr. John Torphy, Vice Chancellor
University of Wisconsin-Madison
Room 100
Bascom Hall
Madison, WI 53706

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY- \$3000 (NRC Special Inspection Report No. 03003465/2001-003(DNMS))

Dear Mr. Torphy:

This refers to the inspection conducted on October 9, 2001, at the University of Wisconsin in Madison, Wisconsin. The inspection was conducted to review the circumstances surrounding the loss of six plated sources containing americium-241 (Am-241). The results of the inspection identified an apparent violation involving the failure to secure from unauthorized removal or access to licensed material stored in controlled or unrestricted areas. The inspection report was issued November 6, 2001.

In the letter transmitting the inspection report, we provided you the opportunity to address the apparent violations identified in the report by either attending a predecisional enforcement conference or providing a written response before we made our final enforcement decision. In a letter dated November 15, 2001, your radiation safety officer, Mr. Ronald Bresell, provided a response to the apparent violations.

Based on the information developed during the inspection and the information provided in the University's November 15, 2001, letter, 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 University lost six Am-241 plated sources during the renovation of laboratory No. 342 in the Structural Botany Building in or around June 2001. On September 27, 2001, the University reported the loss of three sources, which the NRC subsequently determined to be four lost sources. Prior to the University notifying the NRC, the radiation protection staff recovered two of the six sources on September 13, 2001. The University believes the remaining sources were disposed of in the normal trash when the floor of the laboratory was cleaned. The sources each contained nominally 6.5 microcuries of Am-241.

The failure to secure the Am-241 sources from unauthorized removal or access resulted in the loss of licensed material. The failure to adequately secure and limit access to licensed material is a significant safety issue. Implementation of adequate security measures for licensed materials is intended to prevent members of the public from being unknowingly and unnecessarily exposed to radiation. 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 civil penalty is considered for a Severity Level III violation involving the loss of greater than 1 microcurie of Am-241. Because your facility has not been the subject of escalated enforcement actions within the last two inspections, the NRC considered whether credit was warranted for *Corrective Action* in accordance with the civil penalty assessment process in Section VI.C.2 of the Enforcement Policy. Credit was warranted for corrective actions that included: (1) conducting four separate surveys of the laboratory and surrounding area seeking the sources; (2)

<http://www.nrc.gov/reading-rm/doc-collections/enforcement/actions/materials/ea01282.html>

11/9/2004

storing the remaining sources in the radiation safety department; (3) terminating the user's authorization since these were the only sources possessed; (4) designing a new Caution Radioactive Materials door sign, which includes the instructions to call radiation safety before removing any items from a radioactive material laboratory or storage area; and (5) planning to publish an article in the University's December newsletter describing the event and the corrective actions taken.

Application of the normal civil penalty assessment process would not result in a civil penalty in this case. However, the revised Enforcement Policy published December 18, 2000, (effective February 16, 2001), provides that, notwithstanding normal application of the civil penalty assessment process, a civil penalty of at least the base amount should normally be proposed in this type of case to reflect the significance of the violation and to emphasize the importance of maintaining control of licensed material. See Section VII.A.1(g) of the Enforcement Policy. The base civil penalty values were developed to correspond to approximately three times the average cost of disposal. Normal application of the civil penalty assessment process, as reflected in Tables 1A.f.3 and 1B of the Enforcement Policy, would result in a civil penalty of \$3000 in this case. Therefore, 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 \$3000 for the Severity Level III violation. In addition, issuance of this Notice constitutes escalated enforcement action that may subject you to increased inspection effort.

The NRC has concluded that information regarding the reason for the violation, the corrective actions taken and planned to correct the violation and prevent recurrence is already adequately addressed on the docket in a letter from the University, dated November 15, 2001. Therefore, you are not required to respond to the provisions of 10 CFR 2.201 unless the description therein does not accurately reflect your corrective actions or your position. In that case, or if you choose to provide additional information, you should follow the instructions specified in the enclosed Notice.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter, its enclosure, and your response, if any, will be made available electronically for public inspection in the NRC Public Document Room or from the Publicly Available Records (PARS) component of NRC's document system (ADAMS). ADAMS is accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html> (the Public Electronic Reading Room)

Sincerely,

/RA/

J. E. Dyer
Regional Administrator

Docket No. 030-03465
License No. 48-09843-18

Enclosure: Notice of Violation and Proposed Imposition of Civil Penalty

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

University of Wisconsin-Madison
Madison, Wisconsin

Docket No. 030-03465
License No. 48-09843-18
EA-01-282

During an NRC inspection conducted on October 9, 2001, a violation of NRC requirements was 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 violation and associated civil penalty are set forth below:

<http://www.nrc.gov/reading-rm/doc-collections/enforcement/actions/materials/ea01282.html>

11/9/2004

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 an unrestricted area and that is not in storage. As defined in 10 CFR 20.1003, *controlled area* means an area, 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, in approximately June 2001, the licensee did not secure from unauthorized removal or limit access to 39 microcuries of americium-241 in six sealed sources stored in laboratory No. 342, an unrestricted area, nor did the licensee control and maintain constant surveillance of this licensed material. Specifically, six 6.5 microcurie americium-241 sealed sources were lost during the renovation of laboratory No. 342. Subsequently, two of the six sources were recovered with four sources remaining lost.

This is a Severity Level III violation (Supplement IV).
Civil Penalty - \$3000

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 will be achieved, is already adequately addressed on the docket in a letter from the University, dated November 15, 2001. However, you are required to submit a written statement or explanation pursuant to 10 CFR 2.201 if the description therein does not accurately reflect your corrective actions or your position. In that case, or if you choose to respond, clearly mark your response as a "Reply to a Notice of Violation," and send it to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001 with a copy to the Regional Administrator, Region III, 801 Warrenville Road, Lisle, IL 60532, within 30 days of the date of the letter transmitting this Notice of Violation (Notice).

The Licensee may pay the civil penalty proposed above or the cumulative amount of the civil penalties if more than one civil penalty is proposed, in accordance with NUREG/BR-0254 and by submitting to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, a statement indicating when and by what method payment was made, or may protest imposition of the civil penalty in whole or in part, by a written answer addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission. Should the Licensee fail to answer within 30 days of the date of this Notice of Violation and Proposed Imposition of Civil Penalty, 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.C.2 of the Enforcement Policy should be addressed. Any written answer in accordance with 10 CFR 2.205 should be set forth separately from the statement or explanation in reply pursuant to 10 CFR 2.201, but may incorporate parts of the 10 CFR 2.201 reply by specific reference (e.g., citing page and paragraph numbers) to avoid repetition. The attention of the Licensee is directed to the other provisions of 10 CFR 2.205, regarding the procedure for imposing a civil penalty.

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

The response noted above (Reply to Notice of Violation, statement as to payment of civil penalty, and Answer to a Notice of Violation) should be addressed to: Frank Congel, Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Mail Stop 14E1, Washington, DC 20555-0001, with a copy to the Regional Administrator, U.S. Nuclear Regulatory Commission, Region III.

If you choose to respond, your response will be made available electronically for public inspection in the NRC Public Document Room or from the Publicly Available Records (PARS) component of NRC's document system (ADAMS). ADAMS is accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html> (the Public Electronic Reading Room). Therefore, to the extent possible, the response should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the Public without redaction.

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

Dated this 21st day of December 2001.

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Last revised Tuesday, September 09, 2003


[Index](#) | [Site Map](#) | [FAQ](#) | [Help](#) | [Glossary](#) | [Contact Us](#)
 Search
[Advanced Search](#)

U.S. Nuclear Regulatory Commission

[Home](#)
[Who We Are](#)
[What We Do](#)
[Nuclear
Reactors](#)
[Nuclear
Materials](#)
[Radioactive
Waste](#)
[Public
Involvement](#)
[Electronic
Reading Room](#)

[Home](#) > [Electronic Reading Room](#) > [Document Collections](#) > [Enforcement Documents](#) > [Significant Enforcement Actions](#) > [Materials Licensees](#) > EA-01-186

EA-01-186 - University of Medicine & Dentistry of New Jersey

September 25, 2001

EA 01-186

— 1802

Celia Dorantes Abalos, Esq.
 Vice President for Regulatory Affairs
 University of Medicine & Dentistry of New Jersey
 335 George Street, Room 3100
 P.O. Box 2688
 New Brunswick, NJ 08903-2688

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY - \$3,000 (NRC Inspection Report No. 030-09926/2001-001)

Dear Ms. Abalos:

This refers to the NRC inspection conducted on May 26 and 30, 2001, at your facility in Newark, New Jersey to review the circumstances associated with the loss of an iridium-192 (Ir-192) ribbon containing nine seeds of Ir-192 with a total activity of 7.7 millicuries (mCi). You reported this loss to the NRC on May 25, 2001. The inspection was continued in the Region I office until June 29, 2001, to review additional information (namely, the 30-day event report) provided to the NRC subsequent to the onsite inspection. As described in the NRC inspection report sent to you on August 9, 2001, two apparent violations of NRC requirements were identified during the inspection.

In the letter transmitting the inspection report, we provided you the opportunity to address the apparent violations identified in the report by either attending a predecisional enforcement conference or by providing a written response before we made our final enforcement decision. You declined to have a conference with the NRC and instead you provided a response to the apparent violations in a letter dated September 5, 2001. In your response, you stated that your staff believes that the lost source may have inadvertently fell into a toilet in the patient's room and been flushed into the sewer system. You also stated that you have implemented corrective actions to prevent recurrence.

Based on the information developed during the inspection, and the information provided in your response, the NRC has determined that two violations of NRC requirements occurred. The 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 more significant violation involved the failure to control radioactive material which resulted in the loss of the ribbon which was used for patient brachytherapy treatment. The violation occurred when one of the six ribbons implanted into the patient's neck was lost during the scheduled brachytherapy treatment. That ribbon was found to be missing at the end of the treatment period (approximately 42 hours). Although you were unable to specifically determine exactly how the ribbon was lost, the patient may have dislodged the source from his neck with a towel that he had used to absorb secretions from the treatment site. Afterwards, the source may have been put in the trash (and not surveyed before it left the patient's room), or it may have been inadvertently flushed down the toilet. Based on an investigation conducted by your staff, you have concluded that the waste was flushed down the toilet because surveys of the hospital, the solid waste disposal system, and the landfill did not identify any radioactive material. Although the source may not have been placed in the trash, your staff failed to perform a survey for radioactive material of trash and other items removed from the patient's room. This failure constituted the second violation which may have contributed to the failure to control the radioactive material.

<http://www.nrc.gov/reading-rm/doc-collections/enforcement/actions/materials/ea01186.html>

2/2/2005

The safety significance of these violations was minimized by the fact that the source, whether discarded in the toilet or the trash, is unlikely to come in close contact with any individual. Nonetheless, these violations are of concern to the NRC because (1) the failure to control radioactive material resulted in the subsequent loss of the source; and (2) such sources can result in substantial unintended radiation dose to an individual if placed in close contact with the individual's skin. Therefore, these violations are categorized collectively as a Severity Level III problem in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions" (Enforcement Policy), NUREG-1600.

In accordance with the current version of the Enforcement Policy, a base civil penalty in the amount of \$3,000 is considered for a Severity Level III violation or problem regarding the loss or improper disposal of radioactive material. 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.C.2 of the Enforcement Policy. Credit for corrective actions is warranted because your corrective actions were considered prompt and comprehensive. These corrective actions included, but were not limited to: (1) ensuring that sources have colored ribbon to make them easier to see if they are dropped on the floor; (2) providing refresher training to all personnel involved in brachytherapy procedures; (3) issuance of an internal letter to the authorized user/physician and head of housekeeping because of their staffs' involvement in the incident (both individuals were required to provide a written response regarding what was done wrong, as well as actions taken to prevent recurrence); and (4) regarding surveys, revising your procedure to require survey instruments outside the patients' rooms during all treatments to detect unexpected events.

Therefore, application of the normal civil penalty assessment process would not result in a civil penalty in this case. However, the revised Enforcement Policy published December 18, 2000 (effective February 16, 2001), provides that, notwithstanding the normal civil penalty assessment process, a civil penalty of at least the base amount should normally be proposed in this type of case to reflect the significance of the violation and to emphasize the importance of maintaining control of licensed material (see section VII.A.1(g) of the Enforcement Policy). Therefore, 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 \$3,000 for the Severity Level III problem. In addition, issuance of this Notice constitutes escalated enforcement action, that may subject you to increased inspection effort.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. In your response, you may reference any previous correspondence that is applicable to this case to avoid repetitive submissions. The NRC will use your response, in part, to determine whether further enforcement action is necessary to ensure compliance with regulatory requirements.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter, its enclosures, and your response will be made available electronically for public inspection in the NRC Public Document Room or from the Publicly Available Records (PARS) component of NRC's document system (ADAMS). ADAMS is accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html> (the Public Electronic Reading Room).

Sincerely,

/RA/ James T. Wiggins Acting For

Hubert J. Miller
Regional Administrator

Docket No. 030-09926
License No. 29-02957-13

Enclosure: Notice of Violation and Proposed Imposition of Civil Penalty

ENCLOSURE

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

University of Medicine & Dentistry of New Jersey
Newark, NJ

License No. 29-02957-13
Docket No. 030-09926
EA 01-186

During an NRC inspection conducted on May 26 and 30, 2001 and continued in the Region I office until June 29, 2001, two violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy), NUREG-1600, the NRC proposes a civil penalty pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (Act), 42 U.S.C. 2282 and 10 CFR 2.205. The violations and associated civil penalty are set forth below:

- A. 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 May 23 and May 25, 2001, the licensee used licensed material, namely a ribbon containing 7.7 millicuries of iridium-192 (Ir-192), during the treatment of a patient in a restricted area. However, the licensee could not account for the material at the end of the treatment period and reported that the material could not be found in the patient's room or in any other area of the hospital. Therefore, the licensee failed to control and maintain constant surveillance of the material in controlled or unrestricted areas after it left the patient's room.

- B. 10 CFR 20.1501 requires, in part, that the licensee make, or cause to be made, surveys that may be necessary for the licensee to comply with 10 CFR Part 20 and are reasonable under the circumstances to evaluate: the magnitude and extent of radiation levels; concentrations or quantities of radioactive material; and the potential radiological hazard that could be present.

Pursuant to 10 CFR 10.1003, *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, between May 23 and May 25, 2001, the licensee did not make, or cause to be made, surveys that were necessary for the licensee to comply with 10 CFR 20.1802 and were reasonable under the circumstances to evaluate the magnitude and extent of radiation levels, concentrations or quantities of radioactive material, and the potential radiological hazard that could be present. Specifically, the licensee did not make, or cause to be made, surveys necessary to prevent the loss of control of 7.7 millicuries of iridium-192 which was removed from a patient's room prior to the end of treatment. The surveys performed did not include surveys of the trash removed from the patient's room.

This is a Severity Level III problem (Supplement IV).
Civil Penalty - \$3,000.

Pursuant to the provisions of 10 CFR 2.201, University of Medicine & Dentistry of New Jersey is required to submit a written statement or explanation to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, within 30 days of the date of this Notice of Violation and Proposed Imposition of Civil Penalty (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each alleged violation: (1) admission or denial of the alleged violation, (2) the reasons for the violation if admitted, and if denied, the reasons why, (3) the corrective steps that have been taken and the results achieved, (4) the corrective steps that will be taken to avoid further violations, and (5) the date when full compliance will be achieved. Your response may reference or include previous docketed correspondence, if the correspondence adequately addresses the required response. If an adequate reply is not received within the time specified in this Notice, an Order or a Demand for Information may be issued as why the license should not be modified, suspended, or revoked or why such other action as may be proper should not be taken. Consideration may be given to extending the response time for good cause shown.

Within the same time as provided for the response required above under 10 CFR 2.201, the Licensee may pay the civil penalty proposed above, or the cumulative amount of the civil penalties if more than one civil penalty is proposed, in accordance with NUREG/BR-0254 and by submitting to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, a statement indicating when and by what method payment was made, or may protest imposition of the civil penalty in whole or in part, by a written answer addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory

Commission. Should the Licensee fail to answer within 30 days of the date of this Notice, 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.C.2 of the Enforcement Policy should be addressed. Any written answer in accordance with 10 CFR 2.205 should be set forth separately from the statement or explanation in reply pursuant to 10 CFR 2.201, but may incorporate parts of the 10 CFR 2.201 reply by specific reference (e.g., citing page and paragraph numbers) to avoid repetition. The attention of the Licensee is directed to the other provisions of 10 CFR 2.205, regarding the procedure for imposing a civil penalty.

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

The response noted above (Reply to Notice of Violation, statement as to payment of civil penalty, and Answer to a Notice of Violation) should be addressed to: F. Congel, 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 made available electronically for public inspection in the NRC Public Document Room or from the Publicly Available Records (PARS) component of NRC's document system (ADAMS), to the extent possible, it should not include any personal privacy or proprietary information so that it can be made available to the public without redaction. ADAMS is accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html> (the Public Electronic Reading Room). If personal privacy or proprietary information is necessary to provide an acceptable response, then please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request withholding of such material, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim of withholding (e.g., explain why the disclosure of information will create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.790(b) to support a request for withholding confidential commercial or financial information).

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

Dated this 25th day of September 2001



Search

U.S. Nuclear Regulatory Commission



- Home
- Who We Are
- What We Do
- Nuclear Reactors
- Nuclear Materials
- Radioactive Waste
- Public Involvement
- Electronic Reading Room

[Home](#) > [Electronic Reading Room](#) > [Document Collections](#) > [Enforcement Documents](#) > [Significant Enforcement Actions](#) > [Materials Licensees](#) > EA-97-005

EA-97-005 - Lower Bucks Hospital

May 27, 1997

- 1801
- 2001

EA 97-005

Mr. Nathan Bosk
Chief Executive Officer
Lower Bucks Hospital
Bath Road at Orchard Avenue
Bristol, Pennsylvania 19007

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY - \$2,750 (NRC Inspection Report No. 070-02792/97-001)

Dear Mr. Bosk:

This letter refers to the NRC inspection conducted on December 12, 1996, at Nazareth Hospital in Philadelphia, Pennsylvania; on December 30, 1996, at waste facilities located in Morgantown and Allentown, Pennsylvania; and on January 9, 1997, at Lower Bucks Hospital in Bristol, Pennsylvania. The inspection was conducted to review the circumstances associated with the loss of control of a nuclear pacemaker (containing approximately 4.8 curies of plutonium-238) that had been implanted in a patient at your facility in 1978. The inspection was continued in the NRC Region I office through April 9, 1997, to review the results of analyses performed on samples taken from the Morgantown and Allentown, Pennsylvania waste facilities on December 30, 1996. These analyses were performed to determine whether the pacemaker had been damaged resulting in contamination at these locations. The sample results did not provide any evidence of contamination.

During the inspection, three apparent violations of NRC requirements were identified, as described in the NRC inspection report transmitted with our letter, dated May 2, 1997. On May 13, 1997, a predecisional enforcement conference was conducted with you and 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, as well as information provided during the enforcement conference, the three violations are being cited and are described 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.

In 1978, a patient was implanted with a nuclear pacemaker by staff at Lower Bucks Hospital (LBH) as authorized by LBH's NRC license. The pacemaker was explanted at Nazareth Hospital on October 31, 1996, after the patient had expired. Although you were notified on November 2 or 3, 1996, that the patient had expired and that the pacemaker had been explanted, you did not contact the NRC within 24 hours, which constitutes one of the three violations. Also, on December 10, 1996, you were notified by a representative of Nazareth Hospital that the pacemaker could not be located and was assumed lost. Although you had contacted the supplier of the pacemaker to retrieve the pacemaker and properly dispose of it, you did not communicate effectively with Nazareth Hospital, to ensure appropriate control and disposal of the pacemaker. These failures resulted in two additional violations of NRC requirements.

Furthermore, during the inspection, the NRC learned of two additional instances (January 5, 1981 and September 18, 1983), in which pacemakers were buried with patients, and one additional instance in which the pacemaker

was not returned to the supplier (August 1987). All three of these occurrences are similar to an occurrence at your facility in 1987 in which two pacemakers were buried with patients after the patients had expired. As the hospital that had initially implanted the pacemakers, as authorized by your NRC License No. SNM-1800, you were responsible for taking appropriate and timely action to ensure proper retrieval and disposal of pacemakers. This did not occur. Given the significance of improper disposal of this material, the violations have been 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-1600.

In accordance with the Enforcement Policy, a base civil penalty in the amount of \$2,750 is considered for a Severity Level III violation or problem. Because your facility has not been the subject of an escalated enforcement action within the last two years or two inspections, the NRC considered whether credit was warranted for *Corrective Action* in accordance with the civil penalty assessment process in Section VI.B.2 of the Enforcement Policy. These actions, which were described during the enforcement conference, included: (1) hiring a consultant physicist after the December 1996 notifications in an attempt to locate the pacemaker, although such attempts were unsuccessful; (2) planned revision of procedures to include physical retrieval of sources, including during off hours, for explants performed in locations nearby; (3) plans to have a member of the Radiation Safety Committee provide quarterly training on procedures to all personnel who may be contacted regarding a pacemaker explant; and (4) plans to have the performance of this training reported during the RSC meetings. However, credit for corrective actions is not warranted because your corrective actions, at the time of the enforcement conference, were not considered sufficiently prompt and comprehensive to warrant such credit. For example, although notified on December 10, 1996, that the pacemaker was missing, your contractor's attempts to locate and retrieve the pacemaker were not taken until December 20, 1996. Also, procedure modifications, including a checklist for the person following the progress of the return of explanted pacemakers to the supplier, were still in draft form at the time of the enforcement conference, and did not address your stated intention to physically retrieve pacemakers explanted in the future at locations nearby.

Therefore, to encourage appropriate attention to your licensed program, as well as prompt and comprehensive correction of violations, I have been authorized to propose a civil penalty in the amount of \$2,750 for the violations described in the enclosed Notice.

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

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

Sincerely,

Hubert J. Miller
Regional Administrator

Docket No. 070-02792
License No. SNM-1800

Enclosure: Notice of Violation and Proposed Imposition of Civil Penalty

cc w/encl:
Commonwealth of Pennsylvania

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

Lower Bucks Hospital
Bristol, Pennsylvania

Docket No. 070-02792
License No. SNM-1800
EA 97-005

During an NRC inspection conducted between December 12, 1996 and April 9, 1997, violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy), NUREG 1600, the NRC proposes a civil penalty pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (Act), 42 U.S.C. 2282 and 10 CFR 2.205. The violations and associated civil penalty are set forth below:

A. 10 CFR 20.1801 requires that a licensee secure from unauthorized removal or access licensed materials that are stored in controlled or unrestricted areas. 10 CFR 20.1802 requires that a 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, the licensee neither controlled nor maintained constant surveillance of licensed material which was in an unrestricted area. Specifically, a Coratomic Model C-101 nuclear pacemaker (containing a sealed source of approximately 4.8 Curies of plutonium-238) was explanted on October 31, 1996 at Nazareth Hospital in Philadelphia, Pennsylvania, and the licensee was informed of the explantation on November 2 or 3, 1996. However, the licensee did not control nor maintain constant surveillance of licensed material in that it did not attempt to directly recover the source until it was reported missing to them on December 10, 1996.

B. 10 CFR 20.2001 requires that the licensee dispose of licensed material only by certain specified procedures. License Condition 15 of NRC License No. SNM-1800 requires that the licensee continue patient follow-up and replacement procedures for nuclear pacemakers during the life of a patient, and follow procedures for recovery and authorized disposal of the nuclear pacemaker by return to the manufacturer upon the death of a patient.

Contrary to the above,

1. at some time between November 1, 1996 and November 19, 1996, licensed material, for which the licensee was responsible, was disposed by unauthorized means. Specifically, on October 31, 1996, a nuclear pacemaker (containing approximately 4.8 curies of plutonium-238) which was implanted at the licensee's facilities in 1978, was explanted from a patient at Nazareth Hospital in Philadelphia, Pennsylvania, and although the licensee was notified of the explantation on November 2 or 3, 1996, the pacemaker was not properly disposed of as required by the procedures specified in NRC License No. SNM-1800.

2.*1 a review of the records from the supplier of the pacemakers indicates that two additional deceased patients were buried with their pacemakers and one pacemaker was never returned to the supplier from a funeral home. Specifically,

- a. a Coratomic Model C-101, SN 1055 was buried with a patient on January 5, 1981,
- b. a Coratomic Model C-101, SN 1017 was buried with a patient on September 18, 1983, and
- c. a Coratomic Model C-101, SN 1015 was explanted from a patient on August 24, 1987, and never returned to the supplier.

C. Condition 13 of NRC License No. SNM-1800 requires, in part, that the licensee notify NRC Region I within 24 hours of the occurrence of the death of any nuclear pacemaker patient.

Contrary to the above, the licensee did not notify the NRC Region I within 24 hours of the death of nuclear pacemaker patients. Specifically,

1. a nuclear pacemaker patient died on October 31, 1996 at Nazareth Hospital, Philadelphia, Pennsylvania, and although the licensee was informed of the death of the patient on November 2 or 3, 1996, the licensee did not notify NRC Region I until December 11, 1996.

2.* a review of the records of the supplier of the pacemakers indicated, at least, two additional examples of the failure to notify NRC Region I of the death of pacemaker patients as the patients

were buried with their pacemakers.

These violations have been categorized in the aggregate as a Severity Level III problem. (Supplements VI).
Civil Penalty - \$2,750

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

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

Dated at King of Prussia, Pennsylvania
this 27th day of May 1997

1. These examples (marked with an asterisk) occurred beyond the five year statute of limitations period for assessing penalties (28 USC 2462) and are not considered for purposes of determining the civil penalty.


[Index](#) | [Site Map](#) | [FAQ](#) | [Help](#) | [Glossary](#) | [Contact Us](#)
 Search
[Advanced Search](#)

U.S. Nuclear Regulatory Commission


[Home](#)
[Who We Are](#)
[What We Do](#)
[Nuclear
Reactors](#)
[Nuclear
Materials](#)
[Radioactive
Waste](#)
[Public
Involvement](#)
[Electronic
Reading Room](#)

[Home](#) > [Electronic Reading Room](#) > [Document Collections](#) > [Enforcement Documents](#) > [Significant Enforcement Actions](#) > [Materials Licensees](#) > EA-97-241

EA-97-241 - Merck and Company, Inc.

June 26, 1997

EA 97-241

Michael D. Kastello, D.V.M., PH.D.
Executive Director
Research Resources
Merck and Company, Inc.
Merck, Sharp, and Dohme Research Laboratories
P.O. Box 2000
Rahway, New Jersey 07065

2001(a)

SUBJECT: NOTICE OF VIOLATION
(NRC Inspection Report No. 030-14680/97-001)

Dear Dr. Kastello:

This refers to the NRC inspection conducted on April 8-11 and 24, 1997, at the above address in Rahway, New Jersey. During the inspection, two violations of NRC requirements were identified, as described in the NRC inspection report transmitted with our letter, dated May 23, 1997. In the May 23, 1997 letter, the NRC provided you an opportunity to either respond in writing to the apparent violations addressed in the inspection report or request a predecisional enforcement conference. In a telephone conversation on June 2, 1997, Mr. Glenn Sturchio, of your staff, requested a conference. The predecisional enforcement conference was held on June 23, 1997, to discuss the violations, their causes, and your corrective actions. A copy of the enforcement conference report will be sent to you by separate correspondence.

Based on the information developed during the inspection and the information you provided during the enforcement 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 the violations are described in detail in the subject inspection report. The violations involve: (1) the improper disposal of 880 microcuries of iodine-125 at a municipal waste incinerator; and (2) the failure to perform a radiation survey of the package containing the material prior to releasing it for disposal. The user of the material what he incorrectly thought was an empty package in a corridor outside his laboratory for routine trash pickup. However, he did not perform the required direct reading survey for fixed contamination and radiation prior to placing it in the corridor. Afterwards, the package, which apparently still contained iodine-125, was removed and disposed of in the normal trash, and incinerated in a local community incinerator.

While the amount of radioactive material was small, and calculations indicate that exposure to the public from the improper disposal was unlikely, these violations, nonetheless, represents a regulatory concern because they involved the improper disposal of radioactive material. Therefore, 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 \$2,750 is considered for a Severity Level III violation. Because your facility has not been the subject of an escalated enforcement action within the last two inspections conducted in 1995 and 1992/1993, 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 in your letter to the NRC, included: (1) initial attempts to locate the material including contacts with the incinerator; (2) survey of the incinerator's ash collection system, including surveys and samples, in an attempt to detect

any radioactive material; (3) revision of guidance for receiving and opening packages containing radioactive material, and requiring all users to review and sign the guidance; (4) issuance of a noncompliance letter to the Radioactive Material Holder to reiterate the package opening procedure; and (5) issuance of a radiation safety notice to all radioactive material users, reminding them of the need to do surveys and search packages thoroughly when they are received.

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.

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 and its enclosure, will be placed in the NRC Public Document Room (PDR).

Sincerely,

Hubert J. Miller
Regional Administrator

Docket No. 030-14680
License No. 29-00117-06

Enclosure: Notice of Violation

cc w/encl:
State of New Jersey

NOTICE OF VIOLATION

Merck and Company, Inc.
Rahway, New Jersey

Docket No. 030-14680
License No. 29-00117-06
EA 97-241

During an NRC inspection conducted on April 8-11 and 24, 1997, 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 20.2001(a) requires that the licensee dispose of licensed material only by certain specified procedures.

Contrary to the above, on April 10, 1997, the licensee disposed of 880 microcuries of iodine-125 by release to the non-radioactive trash, a method not authorized by §20.2001.

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, the licensee did not make surveys to assure compliance with 10 CFR 20.2001(a), which describes authorized means of disposing of licensed material. Specifically, on April 10, 1997, the licensee did

not perform a survey before disposing of a package, which contained iodine 125, as normal, non-radioactive waste. (02013)

These violations are classified in the aggregate at Severity Level III (Supplement IV).

Pursuant to the provisions of 10 CFR 2.201, Merck and Company, Inc., is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555, with a copy to the Regional Administrator, Region 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. 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 King of Prussia, Pennsylvania
this 26th day of June 1997



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

April 18, 1996

EA 96-068

Mr. Thomas E. Vautin, E.B.S.
 Associate Vice President for Facilities
 and Environmental Services
 Harvard University
 1350 Massachusetts Avenue, Room 871
 Cambridge, Massachusetts 02138

SUBJECT: NOTICE OF VIOLATION
 (NRC INSPECTION REPORT NO. 030-00753/96-001)

- 1801 50mCi
 32P not secured
 NO LOSS SL-III
 - 2001(a) 1mCi
 35 S list in
 normal trash
 SL-IV

Dear Mr. Vautin:

This letter refers to the NRC inspection conducted on February 12-16, 1996, at your facilities in Cambridge, Boston (Longwood area) and Southborough, Massachusetts, of activities authorized by NRC License No. 20-00297-53. The exit meeting for the inspection was held on February 16, 1996. During the inspection, seven apparent violations of NRC requirements were identified. A copy of the NRC inspection report was sent to you on March 12, 1996. On April 2, 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 was issued on April 10, 1996.

Based on the information developed during the inspection, information provided in your response dated March 1, 1996, to the Confirmatory Action Letter (CAL) issued on February 16, 1996, and information provided during the conference, the NRC has determined that six violations of NRC requirements occurred. The violations are cited in the enclosed Notice of Violation (Notice) and the circumstances surrounding them are described in detail in the subject inspection report. Violation A described in the enclosed Notice is the most significant violation, your staff failed to secure from unauthorized removal, or limit access to, licensed material in several laboratories at your facility, nor did your staff maintain control or surveillance of this licensed material.

The NRC is concerned because the failure to maintain control and surveillance of radioactive materials could result in the material being lost or stolen, or could result in unnecessary radiation exposure to, or contamination of, individuals. The NRC also is concerned because the violation involved several examples of failure to secure, or to maintain under constant surveillance, licensed material that was in unrestricted areas. Of particular concern was a vial containing 50 millicuries of phosphorus-32 which was stored in an unsecured freezer in an unlocked laboratory, and was not under constant surveillance. 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.

ANS MITTAL
 0)

In accordance with the Enforcement Policy, a base civil penalty in the amount of \$2,500 is considered for this Severity Level III violation. Because your facility has not been the subject 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 for your prompt and comprehensive corrective actions taken in response to the inspection findings. Your corrective actions, which were described in the CAL, your letters dated March 1, 1996 and April 5, 1996, included, but were not limited to: (1) immediate institution of appropriate controls to ensure security of licensed material in the facilities of Harvard University, especially in the laboratories where lack of security was identified during the current NRC inspection, including notification of all users of licensed material at Harvard University of the NRC security requirements and to assure that all stock solutions are locked in containers when not in use and to lock all unoccupied laboratories; (2) performance of an assessment of the status of security of licensed material possessed and used under the Harvard University licenses, and development and distribution of specific written minimum security requirements to be implemented at the facilities authorized by the Harvard University licenses; (3) assurance that routine radiation survey procedures of Harvard University laboratories where licensed materials are used or stored include an evaluation of the security of licensed materials, including a review by the Environmental Health and Safety Radiation Protection staff of the revised security requirements and of the radiation survey procedures with those individuals responsible for implementing the radiation survey procedures; and (4) plans to conduct by April 12, 1996, an audit of a representative sample of laboratories where licensed materials are used to determine the status of security of licensed materials.

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, any similar violations in the future could result in more significant escalated enforcement action, including issuance of a civil penalty.

In addition to the violations, nine weaknesses in your program also were identified during the inspection. At the predecisional enforcement conference you specified that procedures were in place at the time of the inspection that would have addressed some of the areas identified; however, these procedures had not been implemented by users and were not surveyed by Radiation Protection Office staff. Corrective actions for some weaknesses have not yet been instituted, but you indicated that you have plans to address them promptly. We are concerned that the violations of NRC requirements along with these weaknesses indicate that there has been a general relaxation in implementation of your radiation safety program. These weaknesses will be examined during future inspections.

The NRC has concluded that information regarding the reasons for the violations, and the corrective actions taken and planned to correct these violations and prevent recurrence and the date when full compliance will be achieved is already addressed on the docket in your March 1, 1996 letter and your letter dated April 5, 1996. Therefore, unless the description therein does not accurately reflect your corrective actions or your position, you are not required to respond to this letter. 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 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.

Sincerely,


Thomas T. Martin
Regional Administrator

Docket No. 030-00753
License No. 20-00297-53

Enclosure: Notice of Violation

cc w/encl:
Jacob Shapiro, Ph.D, Radiation Protection Officer
Bertha Madras, Ph.D., Chairperson, Radiation Safety Committee
Commonwealth of Massachusetts

ENCLOSURE

NOTICE OF VIOLATION

Harvard University
Cambridge, Massachusetts

Docket No. 030-00753
License No. 20-00297-53
EA 96-068

During an NRC inspection conducted on February 12-16, 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 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; unrestricted area means an area, access to which is neither limited nor controlled by the licensee.

Contrary to the above, between February 14-16, 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. For example, one area (located at the Longwood Area Campus) housed an unopened 50 millicurie stock vial of phosphorus-32, and seven other vials containing between 0.25 to 5 millicuries of phosphorus-32 and sulfur-35. A second area (located in Cambridge) housed approximately 20 millicuries of hydrogen-3 and approximately 0.5 millicuries of phosphorus-32. A third area (located in Cambridge) housed approximately 5 microcuries of phosphorus-32 and less than 200 microcuries of sulfur-35. (01013)

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

- B. 10 CFR 20.2001(a) requires that the licensee dispose of licensed material only by certain specified procedures.

Contrary to the above, between June 23-24, 1994, the licensee disposed of 1 millicurie of sulfur-35 by release to the non-radioactive trash, a method not authorized by §20.2001. (02014)

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

- C. 10 CFR 20.1501(a) 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 material, 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 February 16, 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 into the sanitary sewerage, but had not determined whether the material discharged was readily soluble (or readily dispersible biological material) in water. (03014)

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

- D. Condition 23 of License No. 20-00297-53 requires, in part, that the licensee shall conduct its program in accordance with statements, representations, and procedures contained in a letter dated November 30, 1989 with enclosed application.

1. Item 10, subitem 2 of the application states, in part, that the Radiation Safety Committee is responsible for investigating all proposals for radionuclide use and conditions of use. Item 10, subitem 4.5 of the application states, in part, that radioactive materials use applicants will be instructed to complete an application that includes listing training and experience.

Contrary to the above, as of February 16, 1996, the Radiation Safety Committee did not investigate all proposals for radionuclide use and conditions of use in that, the Committee did not review the applicant's training and experience. The Committee relied, instead, on the recommendations of Radiation Protection Office staff rather than a review of the application that included training and experience. (04014)

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

2. Item 10, subitem 3 of the application states, in part, that the Radiation Protection Officer is responsible for investigating all proposals for radionuclide use and conditions of use and giving provisional approval to satisfactory proposals.

Contrary to the above, as of February 16, 1996, the Radiation Protection Officer was not responsible for investigating all proposals for radionuclide use and giving provisional approval to satisfactory proposals. Specifically, new proposal applications were routinely reviewed and provisionally approved by the Radiation Protection Office staff and not the Radiation Protection Officer. (05014)

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

3. Item 10, subitem 3 of the application requires, in part, that the Radiation Protection Officer conduct a semiannual inventory of all radionuclides at the institution.

Contrary to the above, as of February 16, 1996, the Radiation Protection Officer did not conduct a semiannual inventory of all radionuclides at the institution. Specifically, while the Radiation Protection Officer collected data on the quantities of radionuclides from several hundred authorized users and tabulated radionuclides in waste semiannually, the Radiation Protection Officer did not sum the individual quantities. (06014).

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

The NRC has concluded that information regarding the reasons for the violations, and the corrective actions taken and planned to correct the violations and prevent recurrence and the date when full compliance will be achieved is already adequately addressed on the docket in your March 1, 1996 letter and your letter dated April 5, 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, 475 Allendale Road, King of Prussia, Pennsylvania 19406, within 30 days of the date of the letter transmitting this Notice of Violation (Notice).

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

Enclosure

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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 18th day of April 1996

ENCLOSURE

DEPARTMENT OF
VETERANS AFFAIRS

Memorandum

Date: FEB 09 2005
From: Director, VHA National Health Physics Program (115HP/NLR)
Subj: VHA Permit Number 17-01322-07 (for radioactive material use)
To: Director (629/00), VA Medical Center, New Orleans, Louisiana

1. We are forwarding the attached VHA Permit Number 17-01322-07, Amendment No. 42. This amendment is issued based on National Radiation Safety Committee approval to issue a revised standard permit condition for sealed source inventories and security.
2. The amendment also modifies the permit condition for decay-in-storage to remove the 10 half-lives requirement. This change is approved under Nuclear Regulatory Commission Regulatory Issue Summary 2004-17.
3. In addition, we added a tie down for the permit to reflect commitments in your memorandum received January 13, 2005, that responded to our recent inspection.
4. Please review the permit amendment carefully to ensure you understand the permit approvals and conditions. This permit is issued as a program code 2110/3610 permittee for broad-scope medical and research use of radioactive materials.
5. If you have any questions, please contact me at (501) 257-1571. The e-mail address is vhconhpp@med.va.gov.


E. Lynn McGuire

Attachment

AH.2

Department of Veterans Affairs

| | | |
|-------------------|-------------------------|------------------|
| Page 1 of 4 pages | MATERIALS PERMIT | Amendment No. 42 |
|-------------------|-------------------------|------------------|

In accordance with VHA Directive 1105.1 and reliance on statements made by the applicant, permission is hereby granted to receive, possess, transfer, and store radioactive materials listed below, and to use this material for the purpose and at the places listed below.

| | |
|--|--|
| <p style="text-align: center;">Permittee</p> <p>1. VA Medical Center</p> <p>2. 1601 Perdido Street</p> <p style="padding-left: 20px;">New Orleans, Louisiana 70146</p> | <p>3. In accordance with NRSC meeting of January 31, 2005, Permit Number 17-01322-07 is amended to read as follows:</p> <p>4. Expiration date: May 31, 2009</p> <p>5. Docket or Reference Number: 030-15040</p> |
|--|--|

| | | |
|---|--|---|
| <p>6. Byproduct, source, and/or special nuclear material</p> <p>A. Any byproduct material with Atomic Numbers 1-83</p> <p>B. Hydrogen 3</p> <p>C. Technetium 99m</p> <p>D. Molybdenum-99</p> <p>E. Iodine 125</p> <p>F. Iodine 131</p> <p>G. Any byproduct material with Atomic Numbers 3-83</p> <p>H. Depleted uranium</p> | <p>7. Chemical and/or physical form</p> <p>A. Any</p> <p>B. Any</p> <p>C. Any</p> <p>D. Any</p> <p>E. Any</p> <p>F. Any</p> <p>G. Sealed sources</p> <p>H. Solid metal</p> | <p>8. Maximum amount permittee may possess at any one time under this permit</p> <p>A. 200 millicuries per radionuclide and 15 curies total</p> <p>B. 900 millicuries</p> <p>C. 10 curies</p> <p>D. 10 curies</p> <p>E. 750 millicuries</p> <p>F. 1 curie</p> <p>G. 1.5 curies per radionuclide and 15 curies total</p> <p>H. 999 kilograms</p> |
|---|--|---|

9. Authorized Use:
- A. through G. Medical diagnosis, therapy, and research in humans. Research and development as defined in 10 CFR 30.4, including animal studies, instrument calibration, student instruction, and *in vitro* studies.
 - H. For use as radiation shielding.

CONDITIONS

- 10. Permitted material may be used only at the permittee's facilities located at 1601 Perdido Street, New Orleans, Louisiana.
- 11. A The Radiation Safety Officer for this permit is Carl L. Gaspard.
- B. The use of permitted material in or on humans shall be by an authorized user as defined in 10 CFR 35.2.
- C. Individuals designated to work as authorized users, authorized nuclear pharmacists, or authorized medical physicists as defined in 10 CFR 35 shall meet the training, experience, and recentness of training criteria established in 10 CFR 35, and shall be designated, in writing, by the permittee's Radiation Safety Committee.

**MATERIALS PERMIT
SUPPLEMENTARY SHEET**

Page 2 of 4

Permit Number: 17-01322-07

Docket or Reference Number: 030-15040

Amendment No. 42

- D. Permitted material for other than human use shall be used by, or under the supervision of, individuals designated by the Radiation Safety Committee.
12. Permitted material shall not be used in field applications where activity is released except as provided otherwise by specific condition of this permit.
13. Experimental animals, or the products from experimental animals, that have been administered permitted material shall not be used for human consumption.
14. This permit does not authorize commercial distribution of permitted material.
15. For sealed sources not associated with 10 CFR 35 use, the following conditions apply:
- A. Sealed sources shall be tested for leakage and/or contamination at intervals not to exceed the intervals specified by the certificate of registration issued by the Nuclear Regulatory Commission under 10 CFR 32.210 or under equivalent regulations of an Agreement State.
 - B. Notwithstanding Paragraph A of this permit condition, sealed sources designed to primarily emit alpha particles shall be tested for leakage and/or contamination at intervals not to exceed three months.
 - C. Each sealed source fabricated by the permittee shall be inspected and tested for construction defects, leakage, and contamination prior to any use or transfer as a sealed source.
 - D. In the absence of a certificate from a transferor indicating a leak test has been made within the intervals specified in the certificate of registration issued by the Nuclear Regulatory Commission under 10 CFR 32.210 or under equivalent regulations of an Agreement State, prior to the transfer, a sealed source received from another person shall not be put into use until tested and the test results received.
 - E. Sealed sources need not be tested if they contain only hydrogen 3, or they contain only a radioactive gas, or the half-life of the isotope is 30 days or less, or they contain not more than 100 microcuries of beta- and/or gamma-emitting material, or not more than 10 microcuries of alpha-emitting material.
 - F. Sealed sources need not be tested if they are in storage and are not being used; however, when they are removed from storage for use or transfer to another person, and have not been tested within the required leak test interval, they shall be tested before use or transfer. No sealed source shall be stored for a period of more than 10 years without being tested for leakage and/or contamination.
 - G. The leak test shall be capable of detecting the presence of 0.005 microcurie (185 becquerels) of radioactive material on the test sample. If the test reveals the presence of 0.005 microcurie (185 becquerels) or more of removable contamination, a report shall be filed with the National Health Physics Program in accordance with 10 CFR Part 30.50(c)(2), and the source shall be removed immediately from service and decontaminated, repaired, or disposed of in accordance with Nuclear Regulatory Commission regulations.
 - H. Tests for leakage and/or contamination, including leak test sample collection and analysis, shall be performed by the permittee or by other persons specifically licensed by the Nuclear Regulatory Commission or an Agreement State to perform such services.
16. Sealed sources containing permitted material shall not be opened or sources removed from source holders by the permittee.
17. **A. The permittee shall conduct physical inventories to account for all sealed sources and/or devices received and possessed under this permit.**
- (1) **Quarterly, for sealed sources with either current activity greater than one millicurie or current activity greater than 1000 times the quantities in 10 CFR 20, Appendix C.**

**MATERIALS PERMIT
SUPPLEMENTARY SHEET**

Page 3 of 4

Permit Number: 17-01322-07

Docket or Reference Number: 030-15040

Amendment No. 42

- (2) Semiannually, for all other sealed sources, except sources specifically exempted by 10 CFR 30.
- B. The permittee shall maintain records for five years from the date of each inventory and include the radionuclides, quantities, manufacturer's name and model numbers, and the date of the inventory.
- C. The permittee shall classify sealed sources, not in active use for their intended clinical or research purpose for a period of 24 months, as disused sources and evaluate the disused sources for disposal as expeditiously as possible.
- D. The permittee shall provide oversight for security of radioactive materials by:
- (1) Compliance with regulations per 10 CFR 20.1801 and 10 CFR 20.1802.
 - (2) Prevention of adversary or unauthorized removal of, or access to, radioactive materials.
 - (3) Use of two-delay methods for sealed sources not in use.
 - (4) Focus to security commensurate with possible risks of radioactive materials unauthorized use.
18. A. Detector cells containing a titanium tritide foil or a scandium tritide foil shall only be used in conjunction with a properly operating temperature control mechanism which prevents the foil temperature from exceeding that specified by the manufacturer and approved by the Nuclear Regulatory Commission.
- B. When in use, detector cells containing a titanium tritide foil or a scandium tritide foil shall be vented to the outside.
19. Maintenance, repair, cleaning, replacement, and disposal of foils contained in detector cells shall be performed only by the device manufacturer or other persons specifically authorized by the Nuclear Regulatory Commission or an Agreement State to perform such services.
20. For radioactive material held for decay in storage other than that held in accordance with 10 CFR 35.92, the permittee is authorized to hold radioactive material with a physical half-life of less than 120 days for decay in storage before disposal in ordinary trash, provided
- A. Before disposal as ordinary trash, the waste shall be surveyed at the container surface with the appropriate survey instrument set on its most sensitive scale and with no interposed shielding to determine its radioactivity cannot be distinguished from background. All radiation labels shall be removed or obliterated.
 - B. A record of each such disposal permitted under this permit condition shall be retained for three years. The record must include the date of disposal, the date on which the byproduct material was placed in storage, the radionuclides disposed, the survey instrument used, the background dose rate, the dose rate measured at the surface of each waste container, and the name of the individual who performed the disposal.
21. The permittee is authorized to transport permitted material only in accordance with the provisions of 10 CFR 71, "Packaging and Transportation of Radioactive Material."
22. In addition to the possession limits in Item 8, the permittee shall further restrict the possession of unsealed byproduct material to quantities less than 10^5 times the applicable limits in Appendix B of 10 CFR 30, as specified in 10 CFR 30.35(d).
23. Incineration of permitted material for the purpose of disposal may be performed only as authorized by 10 CFR 20.2004(a)(2).

**MATERIALS PERMIT
SUPPLEMENTARY SHEET**

Page 4 of 4

Permit Number: 17-01322-07

Docket or Reference Number: 030-15040

Amendment No. 42

24. Except as specifically provided otherwise in this permit, the permittee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. This permit condition applies only to those procedures required to be submitted in accordance with the regulations. Additionally, this permit condition does not limit the permittee's ability to make changes to the radiation protection program as provided for in 10 CFR 35.26. The Nuclear Regulatory Commission regulations shall govern unless the statements, representations, and procedures in the permittee's application and correspondence are more restrictive than the regulations.

- A. Application dated April 28, 2004
- B. E-mail message dated May 18, 2004
- C. Memorandum received January 13, 2005

[NRC Form 313]
[additional information for renewal]
[response to NHPP inspection]



FOR THE DEPARTMENT OF VETERANS AFFAIRS

Date FEB 09 2005

By *E. Lynn McGuire*
E. Lynn McGuire
Director, National Health Physics Program
North Little Rock, AR

AA.3

DEPARTMENT OF VETERANS AFFAIRS
VA POLICE
UNIFORM OFFENSE REPORT
UOR# 04-10-27-1059

VA Facility
NEW ORLEANS VAMC
Automated VA Form 10-1393

Date/Time Printed
FEB 07, 2005@13:59

DATE/TIME RECEIVED: OCT 27, 2004@10:59
DATE/TIME OF OFFENSE: OCT 26, 2004@13:30
ENDING DATE/TIME OF OFFENSE: OCT 27, 2004@09:00
LOCATION: Room 7F143
WEAPON USED: None
INVESTIGATING OFFICER: WASHINGTON, CONNIE
METHOD OF OPERATION:
Lost/Stolen Government Property (Radioactive Material).

CLASSIFICATION CODE: NON-CRIMINAL/INFORMATION

***** COMPLAINANT DATA *****

COMPLAINANT NAME: GASPARD, CARL L
STATUS: EMPLOYEE
HOME ADDRESS: 2908 TRANSCONTIENTAL
METAIRIE, LOUISIANA 70006
HOME PHONE:
WORK ADDRESS: New Orleans, LOUISIANA
WORK PHONE:

***** LOST/STOLEN PROPERTY *****

ITEM NAME: Radioactive Material
DESCRIPTION: Iodine-125, IN Naoh solution
DOLLAR LOSS: 308
DOLLAR RECOVERED:

WAS CIP WEAPON USED? NO
WAS POLICE BATON USED? NO

OTHER AGENCY NOTIFIED

U.S. ATTORNEY NOTIFIED

***** NARRATIVE *****

ORIGIN:

On Wednesday October 27, 2004, at approximately 10:59am, I was dispatched to Room 7F143 by Leonard DANIEL, (Chief, Police Service) in reference to missing government property (Radioactive Material).

INITIAL OBSERVATION:

DEPARTMENT OF VETERANS AFFAIRS
VA POLICE
UNIFORM OFFENSE REPORT
UOR# 04-10-27-1059

Page 2

VA Facility
NEW ORLEANS VAMC
Automated VA Form 10-1393

Date/Time Printed
FEB 07, 2005@13:59

None

INVESTIGATION:

On today's date Wednesday October 27, 2004, at approximately 10:59am, Mr. Carl GASPARD (Contractor, Chesapeake Nuclear Service, Inc) approached me in room 1B102 (Police Administrations Office) in reference to missing government property (Radioactive Material).

Upon interviewing GASPARD, I was informed of the following:

GASPARD stated on today's date Wednesday October 27, 2004, at approximately 9:00am, Ms. Elena GLOTSER (Research Service) informed him of missing radioactive material. GASPARD stated he along with GLOSTER and Albert LAGROUE (Employee, Safety Management) conducted a search of rooms 7F143 and room 7F139 for the missing radioactive material, but was unsuccessful in locating the package.

I spoke with Ms. GLOTSER, and was informed of the following:

GLOTSER stated on yesterday's date (Tuesday October 26, 2004), at approximately 1:30pm, she arrived at room 5F151 (Research Service) where she met with employee Mr. Larry DILLON of Research Service. GLOTSER stated she received a package from DILLON, which contained radioactive material. Upon receiving the package, she returned to her office 7F143 where she placed the package on the countertop. GLOTSER stated she remember leaving the package on the countertop in room 7F143, but may have relocated to the top of a trashcan located room 7F139. During the day she became busy with experiments and failed to properly process the package (immediately) as required by NHPP/NRC (National Health Physics Program/Nuclear Regulatory Commission). She stated she intended to process the package later, but as she was leaving the lab (7F143) at 4:30pm, she forgot because she probably did not see it.

GLOTSER stated on today's date (Wednesday October 27, 2004), at approximately 9:00am, she remembered that she received the radioactive package on yesterday, but was unable to locate it on today. GLOTSER stated she immediately notified Carl GASPARD and Albert LAGROUE (Safety Management) of the missing package. GLOTSER stated the package was in an open position when she received it from DILLON on yesterday.

Upon interviewing Mr. Quintelle ADAMS (Employee, Facility Management Service), I was informed of the following:

060 F 002/004 F-060

+2373

FEB-07-05 03:25pm From-SAFETY MANAGEMENT

DEPARTMENT OF VETERANS AFFAIRS
VA POLICE
UNIFORM OFFENSE REPORT
UOR# 04-10-27-1059

Page 3

VA Facility
NEW ORLEANS VAMC
Automated VA Form 10-1393

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ADAMS stated on yesterday's date (Tuesday October 26, 2004), he entered the 7F Research area at approximately 2:00pm to gather the trash for take out. I provided ADAMS with a description of the radioactive package as provided to me by GLOTSER and GASPARD twelve by five by six inch cardboard box labeled "Radioactive white 1". ADAMS stated he do not recall taking out or seeing a box label radioactive. ADAMS stated he did remove a box from the area, but the box only contained an icepack. ADAMS stated he did not removed anything from the counter which he is not authorized to do only specific instructed to do so. He stated upon completion of removing the trash from the floor area, he placed the bags inside of his trash cart and reported to the loading dock where he then placed the trash in the compact dumpster.

On this morning between the hours of 6:00am and 7:00am the driver of Waste Management Service arrived on station and removed the dumpster from it's location. The dumpster was transported to River Birch Landfill which is located in Kenner, Louisiana for disposal of it's contents.

GASPARD stated he informed Mr. Walter HESTON (Safety Officer) regarding the incident. Mr. Fernando RIVERA, Associate Director, Medical Center was also informed of the incident. GASPARD stated he was presently waiting on the confirmation from upper management before taking the next step.

DISPOSITION:

Open

CONNIE WASHINGTON # 530
INVESTIGATING OFFICER

DEPARTMENT OF VETERANS AFFAIRS
VA POLICE
UNIFORM OFFENSE REPORT
UOR# 04-10-27-1059

Page 4

VA Facility
NEW ORLEANS VAMC
Automated VA Form 10-1393

Date/Time Printed
FEB 07, 2005@13:59

FOLLOW-UP NOTES:

On today's date, Thursday October 28, 2004, at approximately 2:30pm, I was informed by Mr. Carl GASPARD that he was notified by National Health Physics Program that Nuclear Regulatory Commission will be conducting a following up of the incident next week.

Follow up February February 4, 2005: It has been determined that the radioactive material was accidently thrown away. This conclusion came after Police Service inspected the security of the area. Door lock and card reader identer pass. At this time the Safety Officer has conducted more training so that this type of incident would never occur again.

CONNIE WASHINGTON # 530
FOLLOW-UP INVESTIGATOR

Carl Gaspard Assist Chief

Attachment 4

Training Information

Training Table Summary

| Who | When | Method | Content | Documented |
|-------------------------------------|----------------------|---------------|--|--|
| Materials Mgt (Warehouse) | 11/1/04 | Group Session | Training Outline & Handouts* | 30 day letter, Training post tests |
| Housekeeping | 11/1/04, 11/10/04 | Group Session | Training Outline & Handouts* | 30 day letter Training post tests |
| Mail Room | 11/1/04 | Group Session | Training Outline & Handouts* | Training post tests |
| Research Scientists and staff | 11/23/04 | Group Session | Training Outline, slides, Chapter 10 changes & Handouts* | Training post tests |
| Police | 12/1/04 | Group Session | Training Outline & Handouts* | Training post tests |

*Handouts distributed at the training sessions are RSO email attachments Attachments 4 and 4a, 5 and 5a.

RSO maintains post-test results

Training Outline

For

Radiation Safety

Items Covered – Group Method of Training:

1. Introduction of RSO and facility health physicist; pass out attachments
2. Coverage of the most recent event radiological event.
(Refer to New Orleans Attachment 1)
 - a. Loss of the 10 mCi I-125 package.
 - b. Details include work centers affected, personnel involved, hazards expected, current incoming package policies and the recommendations for policy changes.
(Refer to New Orleans Attachments 2 & 3 – (Revised Chapter 10))
3. Radioactive Material – Definition and physical characteristics
(Refer to N.O. Attachment 4 - File 4 & 4a)
4. Cover/describe typical package labeling
(Refer to N.O. Attachment 5-File 5 & 5a)
 - a. Show examples properly labeled boxes.
 - b. Perform/demonstrate physical radiation survey of package.
5. RSO responsibilities
6. Employee expectations when encountering radioactive material.
 - a. Door signs and postings
 - b. Unexpected opened and unopened RAM packages in the trash
7. Emphasis RAM security; cover RAM package pathways into the facility *(Refer to New Orleans Attachment 3 – Revised Chapter 10)*
8. Questions & Answers
9. Give exam; cover and expound on each question on the exam.
10. Dismiss

Summary of Event

1. The 10-millicurie package of I-125 received by well-trained warehouse personnel on 10/26/04 may not have been labeled. In spite of what the pre-printed invoices state, everyone who came in contact with the package stated that they do not remember handling a package with White I labels. Hence, the package would have been handled according to radioactive material handling procedures.
2. The box consisted of the isotope I-125, which has a half-life of 59.4 days. This means that in approximately 60 days that the activity of the isotope will be 5 millicuries, one half of the initial activity. After 10.5 half-lives, approximately 663 days, the isotope will have decayed to a level considered exempted from regulation.
3. Warehouse personnel did not contact the Radiation Safety Officer because it may not have been labeled properly.
4. The package was delivered to the Research Department and picked up by the laboratory technician who was expecting the package of radioactive material.
5. The trained laboratory technician failed to follow radioactive material receiving protocols and probably placed the package on the top of a trash container. Had the task of performing the test for contamination (wipe test) been performed within the 3-hour time frame, the package may have been placed in storage right away.
6. Housekeeping personnel discarded the trash along with the package and the trash was sent to the landfill.
7. On November 1, 2004, a notification was sent to Mid-America Waste Management (Vendor that has Waste Management as a sub contractor) describing the event.

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N.O. AA 1

Excerpt from Chapter 10

4. Routine for Ordering, Receiving, Opening Packages Containing Radioactive Material; Procedure for Documenting Use of Material:

a. Ordering and Receiving:

1) Ordering:

a) The Radiation Safety Officer (RSO) or a designee must authorize each order for radioactive materials for Research Service. The address line for all incoming radioactive orders from vendors, other than local commercial radiopharmacies delivering to Nuclear Medicine Section of Radiology Service Line, will state: **Attention RSO: Safety Management, Building 2, Room 216, Ext. 5233.** The RSO will ensure that the requested materials and quantities are authorized by the Medical Center's Radioactive Material Permit and that possession limits are not exceeded.

b) Authorized nuclear medicine technologists will place all orders for radioactive material to be used in the Nuclear Medicine Section of Radiology Service.

c) Ordering Diagnostic Quantities of Radionuclides: A written record that identifies the nuclide, chemical form, activity level shall be maintained.

d) Ordering Therapeutic Quantities of Radionuclides:

(1) A written request will be obtained from the physician who will perform the procedure.

(2) Persons ordering the materials will reference the physician's written request when placing the order. The physician's request will indicate nuclide, chemical form, activity level.

2) Receiving:

* a) During normal working hours, carriers delivering radioactive packages from the local radiopharmacy will check in with Hospital Police and will be escorted directly to Nuclear Medicine Section of Radiology Service Line. After access is granted by the Nuclear Medicine Technologist, the carrier will place the package(s)/ammo box(es) in the approved secured area of the Hot Lab of Nuclear Medicine. The door to Hot Lab will be locked after completion.

* b) During off-duty hours, carriers delivering radioactive packages from the local radiopharmacy will check in with Hospital Police and will be escorted directly to Nuclear Medicine Section of Radiology Service Line. The Hospital Police Officer will open the Hot Lab door and the carrier will place the package(s)/ammo box(es) in the approved secured area of the Hot Lab of Nuclear Medicine. The door to the Hot Lab will be locked by the Hospital Police.

N.O. RA 2

c) Radioactive packages with "White I", "Yellow II" or "Yellow III" labels or packages that state radioactive materials that are exempt or limited quantities must be delivered to the Hospital Warehouse and placed in the designated locked filing cabinet. (These packages will usually be delivered by FedEx, Airborne Express or UPS). The RSO or designee must be notified immediately. *

d) For radioactive material package deliveries that may occur directly to a research lab, the recipient will be required to immediately notify the RSO who will take custody of the package for verification of survey, inventory, and proper disposition. The RSO will then investigate why the package was delivered directly to the user, take corrective actions, and report the incident and investigation results to the Radiation Safety Committee.

e) New employee orientation training for Materials Handlers, Materials Management and Housekeeping staff will be made prior to their assuming duties that require their entry into areas or handling of radioactive packages.

3) Monitoring:

Packages as described above must be monitored for external radiation levels and surface contamination within 3 hours after receipt, if received during working hours or within 18 hours, if received after working hours. The NHPP must be notified by the RSO if removable contamination exceeds 0.01 microcuries (22,000 dpm/100 cm²).

Notification Numbers:

Radiation Safety Officer
Carl L. Gaspard, M.A.
Office: 589-5233 or 568-0811, extension 5678
Home : 885-0316
Beeper: 501-0983
Cell : 606-7868

Charles Reindl, M.S.,
Radiological Physicist/Health Physicist
(Acting RSO in the absence of RSO)
Office: 584-2867
Beeper: 544-9109

Safety Bytes

Radiation Safety

WHAT IS RADIATION?

Radiation is the emission of energy from matter. There are two main types of radiation: ionizing and non-ionizing. Non-ionizing radiation includes visible, ultraviolet and infrared light, radio waves and microwaves; it may or may not deposit thermal energy in matter.

Ionizing radiation includes alpha, beta, gamma and neutrons, and has sufficient energy to cause chemical changes to biological matter. A large exposure to ionizing radiation may damage cells and tissues. Radionuclides and x-ray machines are sources of ionizing radiation at the VA Medical Center.

Radiation has always been present on Earth and is part of our natural environment. *Background radiation* is the term used for the natural radiation that surrounds us. Sources of natural radiation include cosmic rays, terrestrial radiation from the ground (including radon), and the human body itself.

Besides being a valuable research tool, radiation is also used in the medical field to diagnose and treat many illnesses. Radioactive material is also found in consumer products such as smoke detectors, tobacco, cosmetics and self-illuminating devices, including some exit signs, gun sights, and watches.

RADIOACTIVE MATERIAL USE AREAS

There are many laboratories at VAMC that use radiation for research. Having the radiation symbol on the entryway, or on the radiation-producing machine, identifies them. Before performing any tasks in these areas, ancillary personnel should contact the laboratory personnel or the RSO.



RULES TO FOLLOW

There are minimal risks associated with using ionizing radiation. These risks are no greater than other common activities such as using power tools, climbing a ladder, using electricity, or getting sunburn. By following these basic rules, you can ensure your safety while working in areas posted with the radiation symbol.

N.D.
AH.4

1. Check with the Radiation Safety Officer if there are any questions about the proper procedures or any potential radiation hazard.
2. Eating and/or storage of food or beverages is not permitted in radionuclides laboratories: personnel may not bring food into these areas.
3. Do not handle any items labeled as radioactive or attempt to move containers labeled as containing radioactive material.
4. Do not remove "radioactive" labels from boxes or other items.
5. Do not empty radioactive waste containers.
6. All equipment and furniture from radionuclide laboratories must be checked for contamination by the Radiation Safety Officer or designee before being discarded, moved to another lab or transferred to Salvage.
7. Ask laboratory personnel to identify areas that should be avoided.
- * 8. Federal regulations require that radioactive material be secured when unattended. If any door is locked when you enter a room to perform your duties, lock the door behind you while you are in the room, and lock it when you leave. Do not prop doors open.
9. In addition to radioactive materials, radionuclide laboratories may contain other hazardous material or equipment. All the normal safety precautions used in other areas also apply to radionuclide laboratories.
10. Call the Radiation Safety Officer at 5233 at any time if you have questions or concerns.

WHAT SHOULD I DO IF...

There is an emergency?

If there is a personal injury, fire or other major emergency follow the normal emergency procedures and disregard any concern about radiation exposure. The potential of receiving any measurable radiation dose is minimal. After the emergency is over, evacuate the area and contact the Radiation Safety Officer for assistance.

There is a spill?

If the spill is in a radioactive material use laboratory or involves radioactive material, do not attempt to clean up the spill yourself. Secure the area, notify the laboratory supervisor and any personnel in adjacent labs, and contact the Radiation Safety Officer for assistance.

I have to repair equipment?

You should never attempt to repair equipment with a radiation symbol unless it has been surveyed by the Radiation Safety Officer and declared free of radioactive contamination. Equipment should be green-tagged by the Radiation Safety Officer before any repairs are to be made.

I have to repair facilities?

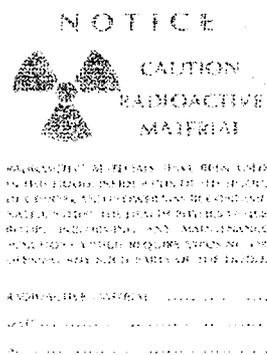
If the work involves being inside the ductwork of a hood used for radionuclides, the work area must be surveyed by the RSO before work begins. If the work only involves the outside of the ductwork, a survey is not required. Hoods may be labeled at the hood face in the laboratory, at the exhaust duct on the roof, or both.

The traps of sinks used with radioactive materials are tagged by the Radiation Safety Officer or designee and should not be opened until checked for contamination by the Radiation Safety Officer.

If you are unsure whether a facility is potentially contaminated with radioactive materials, contact the RSO at extension 5233 before performing any work in that area.

AG 4.a

These labels can be used for radioactive materials or waste containers containing radioactive materials. Do not empty or remove any waste container bearing this label.



**FOR
RADIOACTIVE WASTE
ONLY
DO NOT EMPTY**

Signs Found on Radiation Producing Equipment



"Caution High Intensity X-Ray Beam" Radiation-producing machine label. This label is attached to any machine that produces high intensity x-radiation. Do not service any machine with this label without prior approval from the Radiation Protection Office.

"Caution Radiation This Equipment Produces Radiation When Energized" Radiation-producing machine label. This label is attached to any machine that produces radiation. Do not service any machine with this label without prior approval from the Radiation Protection Office.

Department of Transportation (DOT) Shipping Labels Found on Boxes Containing Radioactive Material



White I

Yellow II

Yellow III

N.O.
AH 5

OUTER PACKAGE INFORMATION

| LABEL CATEGORIES |  |  |  | | | | | | | | | |
|--|--|---|---|--|-----------|-----|-------------------------|-----------|----|--------------------|--|--|
| | Radioactive White-I | Radioactive Yellow-II | Radioactive Yellow-III | | | | | | | | | |
| Radiation Limits for Label Categories | Surface: ≤ 0.5 mrem/hr 1 meter: N/A | Surface: > 0.5 to ≤ 50 mrem/hr 1 meter: > 0 to ≤ 1.0 mrem/hr | Surface: > 50 to ≤ 200 mrem/hr 1 meter: > 1.0 to ≤ 10 mrem/hr | | | | | | | | | |
| <p>*T.I. = Dose rate at 1 meter</p> <p>NOTE: There are labeling exceptions for certain "limited quantities" of radioactive material (See 49 CFR 173.421 for further details).</p> <p>NOTE: If a motor vehicle contains one or more packages bearing Radioactive Yellow-III labels, placards (signs) showing a trefoil and the word "RADIOACTIVE" must be posted on all four sides of the vehicle.</p> | | | | | | | | | | | | |
| <p>CONTAMINATION LEVEL LIMITS</p> <p>The exterior of the package must not have significant removable contamination. The maximum permissible limits averaged over a maximum 300 cm² area are as follows:</p> <table style="width: 100%; border: none;"> <thead> <tr> <th style="text-align: left;"><u>$\mu\text{Ci}/\text{cm}^2$</u></th> <th style="text-align: left;"><u>dpm/cm^2</u></th> <th></th> </tr> </thead> <tbody> <tr> <td>10^{-4}</td> <td>220</td> <td>for Beta-Gamma emitters</td> </tr> <tr> <td>10^{-5}</td> <td>22</td> <td>for Alpha emitters</td> </tr> </tbody> </table> | | <u>$\mu\text{Ci}/\text{cm}^2$</u> | <u>dpm/cm^2</u> | | 10^{-4} | 220 | for Beta-Gamma emitters | 10^{-5} | 22 | for Alpha emitters | <p>PASSENGER FLIGHT RESTRICTIONS</p> <p>Only limited quantity material may normally go on a passenger flight. Medical or research products may go on a passenger flight if the T.I. does not exceed 3.0. All packages with a T.I. of greater than 3.0 must go on a cargo aircraft or truck.</p> | |
| <u>$\mu\text{Ci}/\text{cm}^2$</u> | <u>dpm/cm^2</u> | | | | | | | | | | | |
| 10^{-4} | 220 | for Beta-Gamma emitters | | | | | | | | | | |
| 10^{-5} | 22 | for Alpha emitters | | | | | | | | | | |
| | | <p>Medi-Physics, Inc., Amersham Healthcare 2636 South Clearbrook Drive Arlington Heights, IL 60005</p> | | | | | | | | | | |

AH 5a