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Docket Nos. 030-00582
030-06886
070-00053
License Nos. 06-00183-03 ✓
06-00183-06
SNN-52

EA 89-131

Yale University
ATTN: Benro C. Schmidt, Jr.
President
43 Hillhouse Avenue
New Haven, Connecticut 06520

Gentlemen:

This will acknowledge receipt of your letter dated May 11, 1990 and your check for \$12,000 in payment for the civil penalties imposed by NRC in its Order dated April 13, 1990. The amendment request that you submitted with your letter will be reviewed by the NRC Region 1 licensing staff. Following the completion of that review, further action will be taken on your request that NRC rescind the Order to Show Cause dated September 26, 1989. Your corrective actions will be examined during future inspections.

Sincerely,

Original Signed By
James Lieberman

James Lieberman, Director
Office of Enforcement

cc: T. Martin, RI

Distribution
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UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
476 ALLENDALE ROAD
KING OF PRUSSIA, PENNSYLVANIA 19406

August 3, 1989

Docket No. 030-01244
License No. 06-00819-03
EA 89-119

Yale-New Haven Hospital
ATTN: Norman G. Roth
Assistant Vice President,
Administration
22 York Street
New Haven, Connecticut 06504

Gentlemen:

Subject: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY - \$2500
(Inspection Report No. 030-01244/89-002)

This letter refers to the NRC inspection conducted on March 21, 1989 at Yale-New Haven Hospital, New Haven, Connecticut, to review the circumstances associated with a violation involving the improper disposal of radioactive material in the normal trash. The trash was subsequently sent to a trash-to-steam plant for incineration. The improper disposal was reported to the NRC by your Radiation Safety Officer on March 10, 1989 after personnel at the trash-to-steam plant performed a radiation survey, identified radioactive material in the trash prior to incineration, returned the trash to you, and you subsequently recovered the material.

During the NRC inspection, additional violations, some of which contributed to the improper disposal of the radioactive material, were identified. The inspection report was sent to you on June 8, 1989. On June 21, 1989, an enforcement conference was conducted with you and a member of your staff to discuss the violations, their causes and your corrective actions.

Three violations described in Section I of the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice) involve: (1) failure to perform an adequate inventory of radioactive sources; (2) failure to survey brachytherapy waste prior to disposal; and (3) the improper disposal of a 27.53 millicurie cesium-137 source. A fourth violation, which is set forth in Section II of the enclosed Notice, involves the failure to limit radiation levels in an unrestricted area. This violation was previously identified during a 1988 inspection.

With respect to the violations set forth in Section I of the Notice, the disposal occurred when the radioactive source, which was brazed to the end

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RETURN RECEIPT REQUESTED

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of a therapeutic treatment device, detached while the device was inside of the nylon sheath used during application of the treatment. Although the treatment device was being returned to storage after the treatment, the sheath was discarded in the normal trash as is normally the case, without any awareness that the source had detached and was being discarded. Further, although the device was inventoried after each use, the performance of the inventory did not include a specific check of the end of the device to verify the source was still attached.

The NRC is very concerned that this source would have been incinerated at a public waste facility had a radiation survey not been performed by personnel at the trash-to-steam plant. Although you maintained at the enforcement conference that there are no known occurrences of this type of source failure, had you performed an adequate inventory of the sources after use and a survey of the source room prior to the disposal of waste from the source room, as required, you would have detected the presence of the material prior to its disposal. These violations demonstrate the need for: (1) improved control and oversight of licensed material to prevent the improper disposal of radioactive material in the future; and (2) aggressive management oversight of the radiation safety program to ensure that all aspects of the program are carried out in conformance with regulatory requirements and license conditions. To emphasize this need, I have been authorized, after consultation with the Director, Office of Enforcement, and the Deputy Executive Director for Nuclear Materials Safety, Safeguards and Operations Support, to issue the enclosed Notice of Violation and Proposed Imposition of Civil Penalty in the amount of Two Thousand Five Hundred Dollars (\$2,500) for the violations set forth in Section I of the Notice.

Since the amount of material disposed of was significant and could have been a potential threat to public health and safety, the violation involving the improper disposal would normally be classified individually as a Severity Level III violation. However, the other violations set forth in Section I of the Notice were causal factors leading to the improper disposal and represent a significant lack of attention to the oversight and control of your radiation safety and material control program. Therefore, in accordance with Supplement IV of the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C, 53 Fed. Reg. 40019 (October 13, 1988), the violations set forth in Section I of the Notice have been classified in the aggregate as a Severity Level III problem.

The base civil penalty for a Severity Level III violation or problem is \$2,500. The escalation and mitigation factors set forth in the policy were considered and the base civil penalty amount has not been changed because: (1) on balance, although you promptly reported the improper disposal, this disposal was identified by personnel not associated with your licensed activities and therefore, no adjustment based on this factor is appropriate; (2) your corrective actions, as documented in the inspection report, were considered prompt and comprehensive and therefore, provide a basis for 50% mitigation of the penalty amount; and (3) your past performance has not been good, as evidenced by the occurrence of 14 violations since 1984, and therefore, a basis exists for 50% escalation of the penalty amount. Full

100% escalation based on your past performance was not applied in this case because a total of six violations were identified during the two most recent inspections (as opposed to eight violations in 1984), thereby indicating improved performance. The other escalation and mitigation factors in the Enforcement Policy were considered and no further adjustment was deemed appropriate.

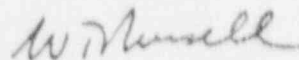
The violation set forth in Section II of the Notice is classified at Severity Level IV. Although classified as a Severity Level IV violation, the NRC is concerned that this violation is a repetitive violation from a previous inspection and your corrective actions taken at that time were inadequate to correct the problem. We note that part of your current corrective action included obtaining authorization on May 4, 1989 to exceed the 2 mRem per hour limits provided no member of the general public receives in excess of 500 mRem in one year in the unrestricted areas adjacent to rooms containing brachytherapy patients. Although this exception specifically resolves the problem of radiation levels in unrestricted areas adjacent to brachytherapy patients, future violations involving exceeding the radiation limits for unrestricted areas in other areas of your facilities may be considered a repetitive violation and result in escalated enforcement action.

You are required to respond to this letter and the enclosed Notice, and should follow the instructions specified in the enclosed Notice when preparing your response. In your response, you should document the specific actions taken and any additional actions you plan to take to prevent recurrence. Furthermore, you should describe the actions taken or planned to improve the oversight of the program by the Radiation Safety Officer. After reviewing your response to this Notice, including your proposed corrective actions and the results of future inspection, the NRC will determine whether further enforcement action is needed to ensure compliance with regulatory requirements.

In accordance with Section 2.790 of the NRC's "Rules of Practice," Part 2, Title 10, Code of Federal Regulations, a copy of this letter and its enclosure will be placed in the NRC Public Document Room.

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, PL No. 96-511.

Sincerely,



William T. Russell
Regional Administrator

Enclosure: Notice of Violation and Proposed
Imposition of Civil Penalty

cc w/encl:
Public Document Room
Nuclear Safety Information Center (NSIC)
State of Connecticut

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

Yale-New Haven Hospital
New Haven, Connecticut

License No. 06-00819-03
Docket No. 030-01244
EA 89-119

During an NRC inspection conducted on March 21, 1989, violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C, 53 Fed. Reg. 40019 (October 13, 1988), the Nuclear Regulatory Commission proposes to impose a civil penalty pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (Act), 42 U.S.C. 2282, and 10 CFR 2.205. The particular violations and associated civil penalty are set forth below:

I. VIOLATIONS ASSESSED A CIVIL PENALTY

- A. Condition 27 of License No. 06-00819-03 requires that licensed radioactive material be possessed and used in accordance with the procedures, representations, and statements contained in the application dated December 13, 1984 and in the letters submitted in support of that application.

Item 20(e) of the license application requires, in part, that for cesium-137 sealed sources, the dosimetrist account for each of the sources, the next working day after the sources are removed from the patient and returned to the radium room, and then put the sources back in storage.

Contrary to the above, on March 6, 1989, the dosimetrist did not adequately account for each of the cesium-137 sources before returning the sealed source assemblies to storage. Specifically, the inventory of the sources was conducted by counting the distal portion of each source assembly (which did not contain the actual source), rather than to check the source tip on each assembly (which did contain the actual source).

- B. 10 CFR 20.201(b) requires that each licensee make such surveys as (1) may be necessary to comply with the regulations of Part 20 and (2) are reasonable under the circumstances to evaluate the extent of radiation hazards that may be present. As defined in 10 CFR 20.201(a), "survey" means an evaluation of the radiation hazards incident to the production, use, release, disposal, or presence of radioactive materials or other sources of radiation under a specific set of conditions.

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Contrary to the above, on March 6, 1989, necessary and reasonable surveys were not made to assure compliance with 10 CFR 20.301, which describes authorized means of disposing of licensed material contained in waste. Specifically, surveys were not conducted of the trash receptacles in the cesium-137 source storage room prior to removal of the trash from the source room for disposal as non-radioactive waste. Such surveys were necessary and reasonable under the circumstances to evaluate the extent of the radiation hazards that may have been present, and in this case, would have identified the presence of a Heyman brachytherapy applicator containing a 27.53 millicuries cesium-137 source in the trash receptacle, thereby preventing the source from being disposed of in the normal trash.

- C. 10 CFR 20.301 requires that no licensee dispose of licensed material except by certain specified procedures.

Contrary to the above, on March 6, 1989, a 27.53 mCi Cs-137 brachytherapy source contained in a disposable Heyman applicator was placed into the normal trash and sent to a trash-to-energy plant for incineration, a method not authorized by 10 CFR 20.301.

These violations have been categorized in the aggregate as a Severity Level III problem. (Supplement IV)

Cumulative Civil Penalty - \$2,500 (assessed equally among the violations).

II. VIOLATION NOT ASSESSED A CIVIL PENALTY

10 CFR 20.105(b) requires that, except as authorized by the Commission, a licensee limit radiation levels in unrestricted areas so that an individual who was continuously present in the area could not receive a dose in excess of 2 mRem in any one hour or 100 mRem in any seven consecutive days.

Contrary to the above, on March 21, 1989, radiation levels in an unoccupied room (unrestricted area) next to the brachytherapy patient treatment room was not limited to 2 mRem in any one hour and the licensee was not authorized by the Commission to exceed this limit. Specifically, the exposure rate in a visitor's chair located in the room was in excess of 2 mRem per hour.

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

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

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

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

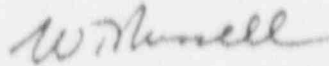
The response to the Director, Office of Enforcement, noted above (Reply to a Notice of Violation, letter with payment of civil penalty, and Answer to a Notice of Violation) should be addressed to: Director, Office of Enforcement,

Notice of Violation

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U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington,
D.C. 20555 with a copy to the Regional Administrator, U.S. Nuclear Regulatory
Commission, Region I, 475 Allendale Road, King of Prussia, Pennsylvania 19406.

FOR THE NUCLEAR REGULATORY COMMISSION



William T. Russell
Regional Administrator

Dated at King of Prussia, Pennsylvania
this 3rd day of August 1989