

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTIES

Yale University
New Haven, Connecticut 06520

Docket Nos. 030-00582
030-06886
070-00053
License Nos. 06-00183-03
06-00183-06
SNM-52
EA 89-131

During an NRC inspection conducted between May 30 and June 2, 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, 1989, the Nuclear Regulatory Commission proposes to impose civil penalties pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (Act), 42 U.S.C. 2282, and 10 CFR 2.205. The particular violations and associated civil penalties are set forth below:

- I. A. 10 CFR 20.101(a) limits the radiation dose to the extremities of an individual in a restricted area to 18.75 rems per calendar quarter.

Contrary to the above, during the first calendar quarter of 1989, an individual working in Room 302 of Farral Memorial Building, a restricted area, received an extremity radiation dose of 178 rem to the tip of the middle finger of the left hand while handling microcurie quantities of iodine-125.

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

Contrary to the above, between February 23 and April 19, 1989, a research investigator disposed of approximately 0.1 microcuries of iodine-125 in the normal trash, a method not authorized by 10 CFR 20.301. Specifically, the investigator disposed of materials which he eluted from a protein separation column that contained residual iodine-125.

- C. 10 CFR 20.201(b) requires the licensee to make such surveys as (1) may be necessary to comply with all sections of 10 CFR 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

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incident to the use or presence of radioactive materials under a specific set of conditions.

Contrary to the above, between February 23 and April 3, 1989, a researcher failed on at least six occasions to perform a survey or evaluation to determine whether residual iodine-125 remained in a protein separation column before discontinuing radiation safety precautions for the use and handling of that column, and this failure was a principal factor contributing to violations of 10 CFR 20.101 and 20.301.

- D. Until the license was renewed on May 23, 1989, Condition 21 of License No. 06-00183-03 required, in part, that licensed material be possessed and used in accordance with the statements, representations, and procedures contained in an application dated May 15, 1979, including a manual of Radiation Safety Procedures dated July 1977.

Item 4.a. on page 5 of the manual of Radiation Safety Procedures included with the May 15, 1979 application requires that each individual who has contact with radioactive materials utilize all appropriate protective measures, such as wearing gloves when necessary. Item 5 of an application approved by the Radiation Safety Sub-Committee for a specific Principal Investigator in January 1989 requires that gloves be worn for handling iodine-125.

Contrary to the above, between March 6 and April 19, 1989, an individual using radioactive material under the application approved in January 1989 by the Radiation Safety Sub-Committee for that specific Principal Investigator did not wear gloves when he used microcurie amounts of iodine-125, which contributed to the exposure identified above.

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

Cumulative Civil Penalty - \$5,000 (assessed equally among the 4 violations).

- II. A. Condition 21 of License No. 06-00183-03 requires that licensed material be possessed and used in accordance with the statements, representations and procedures contained in various applications and letters. Until the license was renewed on May 23, 1989, this condition included an application dated May 15, 1979, including a manual of Radiation Safety Procedures dated July 1977, and a letter dated May 20, 1982. Following renewal, this condition includes an application dated August 10, 1987, and a letter dated December 21, 1987.
1. Item 9 of the letter dated May 20, 1982, requires that applications for authorization to use radioactive material include an outline of the experimental procedure.

Contrary to the above, as of May 23, 1989, approximately 60 authorizations (approved by the Radiation Safety Sub-Committee) did not include an outline of the experimental procedure. Specifically, most applications used only one or two lines to describe the program, and did not include details of techniques which would be used in the experiments. For example, an application was approved in January 1989, which allowed the use of iodine-125 to perform iodinations, and that application did not include an outline of the experimental procedure.

2. Item 14 of the licensee's application dated May 15, 1979, provides that the Radiation Safety Committee has authority to grant permission for the use of isotopes, and that procedures for the use of radioactive materials are outlined in committee recommendations issued to approved investigators.

Item 3 in the recommendations issued to an approved investigator on January 26, 1989, provided that persons performing iodinations must have their thyroids monitored within one or two days following iodination.

Contrary to the above, on March 7, March 14, and March 31, 1989, an individual performed iodinations using one millicurie of iodine-125 under the Authorization issued in January 1989 to that specific Principal Investigator, and the individual did not have his thyroid monitored until April 19, 1989.

3. Item 9 of the May 20, 1982 letter requires that radiation technicians perform surveys in all laboratories using radioisotopes on a quarterly basis.

Contrary to the above, during the last three quarters of 1988, laboratories where radioactive materials were used were not surveyed by the radiation technicians on a quarterly basis. Specifically:

- a. between April 1 and June 30, 1988 (the second quarter), only 484 of the approximately 530 laboratories were surveyed;
 - b. between July 1 and September 30, 1988 (the third quarter), only 311 of the approximately 530 laboratories were surveyed; and
 - c. between October 1 and December 30, 1988 (the fourth quarter), only 452 of the approximately 530 laboratories were surveyed.
4. The item entitled, "Radioactive Waste Disposal," on page 9 of the manual of Radiation Safety Procedures included with the May 15, 1979, application requires that records be maintained of all disposals of radioactive material. Item 11, "Radioactive Waste Management and Procedures" of the

application dated August 10, 1987, requires that appropriate records be maintained for all waste streams. 10 CFR 30.51 requires the licensee to keep records showing the disposal of byproduct material.

Contrary to the above, as of May 30, 1989, records were not maintained of monthly disposals of animal carcasses, which had been administered millicurie quantities of phosphorus-32, and which were held for decay and then disposed of as non-radioactive waste by laboratory personnel.

5. Item 2 under "Authorized Principal Investigator Responsibility" on page 3 of the manual of Radiation Safety Procedures included with the May 15, 1979 application and Item 8 of the application dated August 10, 1987, require that the Principal Investigator train individuals in specific laboratory safety procedures prior to these individuals beginning their work with radioactive materials.

Contrary to the above, from March 23 to June 2, 1989, an individual used 200 microcuries of hydrogen-3 per week, and the Principal Investigator had not instructed the individual in certain laboratory safety procedures prior to the individual beginning work with radioactive materials. Specifically, the individual was not instructed on the appropriate techniques for performing radioactive contamination surveys or in the University's prohibition of consuming beverages in areas where radioactive materials are used.

- B. Condition 19 of License No. 06-00183-06 requires that radioactive material with a physical half-life of less than 65 days be held for a minimum of 10 half-lives prior to disposal as non-radioactive waste.

Contrary to the above, as of May 30, 1989, animal carcasses, which had been administered millicurie amounts of phosphorus-32 (which has a physical half-life of 14 days), were not held for the minimum 10 half-lives prior to disposal as non-radioactive waste; rather, they were routinely disposed after being stored for only seven half-lives.

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

Cumulative Civil Penalty - \$6,250 (assessed equally among the 6 violations.)

- III. Condition 21 of License No. 06-00183-03 requires, in part, that licensed material be possessed and used in accordance with the statements, representations and procedures contained in a letter dated December 21, 1987. Item 4.c. of the letter dated December 21, 1987 prohibits eating and drinking in areas where radioactive materials are present.

Contrary to the above, on June 1 and 2, 1989, personnel consumed beverages and food in two different laboratories (specifically, Room 409 of Lauder Hall and Room 515 of the J. W. Gibbs building) where millicurie quantities of iodine-125, phosphorus-32 and hydrogen-3 were present. This is a repeat violation.

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

Civil Penalty - \$750.

Pursuant to the provisions of 10 CFR 2.201, Yale University 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, U.S.C. 2232, this response shall be submitted under oath or affirmation.


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

In requesting mitigation of the proposed penalties, the factors addressed in Section V.B of 10 CFR Part 2, Appendix C (1989), should be addressed. Any written answer in accordance with 10 CFR 2.205 should be set forth separately from the statement or explanation in reply pursuant to 10 CFR 2.201, but may incorporate parts of the 10 CFR 2.201 reply by specific reference (e.g., citing page and paragraph numbers) to avoid repetition. The attention of the Licensee is directed to the other provisions of 10 CFR 2.205, regarding the procedure for imposing a civil penalty.

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

The responses 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, U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 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


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

Dated at Rockville, Maryland
this 26th day of September 1989