



UNITED STATES  
NUCLEAR REGULATORY COMMISSION  
WASHINGTON, D. C. 20555

DCS

SEP 26 1989

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

EA 89-131

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

Gentlemen:

Subject: A) NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTIES -  
\$12,000 (NRC Inspection No. 89-001)  
B) ORDER TO SHOW CAUSE WHY LICENSES SHOULD NOT BE MODIFIED

This letter refers to the NRC inspection conducted between May 30 and June 2, 1989 at your facility in New Haven, Connecticut of activities authorized by NRC License Nos. 06-00183-03, 06-00183-06 and SNM-52. The inspection report was sent to you on July 5, 1989. The inspection was conducted to review the circumstances associated with a reported 178 rem radiation exposure to the tip of one finger on the left hand of a researcher at your facility. This exposure was in excess of the regulatory limit of 18.75 rem. During the inspection, which included a review of the entire radiation safety program, numerous other violations of NRC requirements were identified, including violations associated with this exposure, as well as other violations of NRC program requirements. On July 13, 1989, an enforcement conference was conducted with E. Adelberg, Ph.D., Deputy Provost, and Mr. G. Holeman, Radiation Safety Officer, of your staff to discuss the violations, their causes, and your corrective actions. The violations are described in the enclosed Notice of Violation and Proposed Imposition of Civil Penalties (Notice).

The violations involving the exposure are set forth in Section I of the enclosed Notice. The exposure occurred because the individual did not adequately account for all of the radioactive material during the performance of an experiment and did not conduct a physical survey of a protein separation column to detect radioactive material. The individual observed that there was no more radioactive material being detected in eluate from the column; however, rather than surveying the column with an appropriate radiation detection instrument, or performing a material balance to assure that there was no radioactive material on the column, he assumed that the column was free of radioactive material. As a result, the individual did not wear gloves while performing further elutions of the column.

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during preparations of proteins, and this failure led to contamination of his hand with radioactive material and the resultant exposure. Furthermore, since the individual assumed that the column was free of radioactive material, he discarded the material left in the column in the normal trash upon completion of the experiment.

The other violations of NRC requirements are set forth in Sections II and III of the enclosed Notice and include: (1) approval of incomplete applications to use radioactive materials; (2) failure to perform audits/surveys of the various laboratories at the required frequency; (3) inadequate training of certain individuals performing licensed activities; and (4) personal eating and drinking in laboratories where radioactive material was used.

The NRC is concerned that adequate and sufficient management attention has not been provided to the Radiation Safety Program at Yale University to ensure that the program is properly implemented, as evidenced by the consistently poor regulatory performance at your facility since 1984. Since that time, twenty violations were identified during four previous NRC inspections. Furthermore, since that time, two enforcement conferences were held with Yale University and two civil penalties were issued for the specific violations identified by the NRC during the inspections conducted in 1984 and 1988.

In a letter dated October 31, 1984, transmitting one of the Notices of Violation, the NRC expressed concern that "the Radiation Safety Committee (RSC) has not provided sufficient oversight of the Radiation Safety Program, that the substance and frequency of audits of the program by the RSC and the Radiation Safety Office (RSO) have been insufficient, and that the authorizations for use of licensed materials issued to individual principal investigators have lacked specificity regarding the frequency of radiation surveys and other requirements to be met." Notwithstanding these prior concerns and this prior history, effective actions have not been taken to improve the performance at your facility, as evidenced by the recent violations identified in May and June 1989. This raises serious questions concerning the adequacy of the management attention provided to this program.

Accordingly, a need exists for increased and improved management attention to, and oversight and control of, the radiation safety program to ensure that licensed activities are conducted safely and in accordance with the terms of the license. 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 Penalties in the amount of Twelve Thousand Dollars (\$12,000) for the violations described in the enclosed Notice.

The violations in Section I related to the radiation exposure in excess of regulatory limits 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," 10 CFR Part 2, Appendix C (1989) (Enforcement Policy). These violations could have been classified at Severity Level II in accordance with the Enforcement Policy because this extremity exposure was in excess of 75 rem. However, since this 178 rem exposure was only to a small portion of the tip of one finger, and the exposure to the rest of the hand was within the regulatory limit of 18.75 rem, the violation is more appropriately classified

at Severity Level III. The violations in Section II of the enclosed Notice have been classified in the aggregate as a Severity Level III problem in accordance with the Enforcement Policy to focus on the lack of adequate oversight of licensed activities which resulted in a number of violations representing a breakdown in control of licensed activities. The base civil penalty amount for a Severity Level III violation or problem is \$2,500.

The escalation and mitigation factors in the Enforcement Policy were considered. Both of these civil penalties have been increased by 100% because your prior compliance history has been poor. The civil penalty assessed for the Violations in Section II has been increased by an additional 50% because these problems were identified by NRC and the University should have identified and corrected them sooner as a result of its own efforts to ensure compliance with NRC requirements. The remaining escalation and mitigation factors were considered and no further adjustment is deemed appropriate. Although the exposure in excess of regulatory limits was identified and reported by your staff, it may have occurred about six weeks prior to discovery and you should have discovered the problem sooner if thyroid counts (bioassays) had been performed within one or two days following iodinations as required by your license.

The violation in Section III of the enclosed Notice involves eating and drinking in areas where radioactive materials are present. This violation is being considered separately to emphasize the significance of repetitive violations and the failure to take corrective action. This violation is categorized at Severity Level IV. The Enforcement Policy states that NRC considers civil penalties for Severity Level IV violations that recur after the date of the last inspection or within two years, whichever period is greater. This violation was identified during previous inspections in July 1987 and March 1986. Furthermore, the University failed to implement the corrective action specified in response to the July 1987 violation, and no alternative corrective action was implemented nor was NRC contacted to discuss alternative corrective action. We wish to emphasize that this violation, as identified during this inspection, was not caused by a simple lapse on the part of certain individuals in following a well known University prohibition. Rather, some laboratory personnel indicated that they were not familiar with the University's policy. For example, one individual who routinely used hydrogen-3 and who was observed to be drinking from a paper cup stated that she often drank in the laboratory, had not attended the Radiation Safety Seminar, and was not aware of the University's prohibition against eating and drinking in laboratories where radioactive materials are present.

The base civil penalty for a Severity Level IV violation is \$750. The escalation and mitigation factors in the Enforcement Policy were considered. Although NRC identified this violation, your past compliance history has been poor, and you failed to take corrective action, these facts were taken into account in deciding to propose a separate civil penalty for this Severity Level IV violation. On the facts of this case, further escalation or mitigation is not considered appropriate.

In addition to the civil penalties, the NRC has determined that the consistently poor performance by Yale University in the administration and implementation of the radiation safety program and the violations in the attached Notice associated with a management breakdown in the control of


licensed activities warrants issuance of the enclosed Order to show cause why the licenses should not be modified to require development and implementation of a comprehensive plan to improve performance.

You are required to respond to this letter and the enclosed Notice and Order, and should follow the instructions specified in the enclosed Notice and Order when preparing your responses. In your responses, you should document the specific actions taken and any additional actions you plan to prevent recurrence. After reviewing your responses to the Notice and Order, including your proposed corrective actions and the results of future inspections, the NRC will determine whether further action is needed to ensure compliance with regulatory requirements. Furthermore, we emphasize that a license to use byproduct material is a privilege granted by the NRC, and any recurrent violation of the terms of that license may result in more significant enforcement action, such as higher civil penalties, or modification, suspension or revocation of your licenses.

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,

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

Enclosures:

- (1) Notice of Violation and Proposed Imposition  
of Civil Penalties
- (2) Order Modifying Licenses

cc w/encls:

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