

Yale University *New Haven, Connecticut 06520*

OFFICE OF THE PROVOST

January 16, 1990

Docket Nos. 030-00582  
030-06886  
070-00053  
License Nos. 06-00183-03'  
06-00183-06 ✓  
SNM-52  
EA 89-131  
Re: 10 C.F.R. 2.202

Director, Office of Enforcement  
United States Nuclear Regulatory Commission  
Washington, D.C. 20555

Attention: Document Control Desk

Re: Yale University Answer to Order To Show Cause Why  
Licenses Should Not be Modified: EA 89-131

Gentlemen:

On September 26, 1989, the Nuclear Regulatory Commission ("NRC") transmitted to Yale University a Notice of Violation ("NOV") and an Order to Show Cause Why Licenses Should Not Be Modified ("Order") relating to NRC Inspection Report No. 89-001. The inspection occurred, and these documents arrived, during a comprehensive review of the radiation safety program at Yale that began in 1988 and has led to a number of significant organizational and operational changes designed to enhance all of Yale's health and safety programs through improved management oversight, dedication of additional human and financial resources and improved communication between management and users of radioactive materials.

As a result of Yale's radiation safety program review, the University now provides for a direct reporting relationship between a new Office of University Safety, of which the Radiation Safety Department is a part, and the Provost, the University's chief academic and budget officer. The Radiation Safety Committee, a 12-member committee of faculty and administrators, continues to report directly to me as well. In addition, Yale has authorized the hiring of additional radiation safety personnel to provide more frequent laboratory surveys and more thorough review of research protocols using radioactive materials. I personally addressed

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Management Information Services Department, the Radiation Safety Department is implementing a local computer network for the Radiation Safety Department to include a health physics database to facilitate follow-up and routine record-keeping concerning authorized users. The University will also continue to conduct routine surveys and hazard evaluations, as needed, as part of the follow-up effort.

## 2. Communications to Users of Licensed Material.

The Radiation Safety Committee and Radiation Safety Department both communicate directly with Principal Investigators, and recognize the need for those communications to be clear and effective. Each new individual user attends a training seminar which, for clarity and completeness, is conducted in accordance with the informational outline provided by the Commission (10 C.F.R. Part 19). Principal Investigators are being reminded of their obligation to ensure that all new employees receive training before they begin work with radioactive materials. In addition, the Yale University Radiation Safety Procedures Manual is distributed to every laboratory that uses radioactive materials and to individual users. These procedures follow the Commission's guidelines set forth in 10 C.F.R. Part 20 and various NRC Regulatory Guides.

When applications to use radioactive materials are approved, the approval letters clearly specify the requirements that must be followed as a condition of the authorization. Moreover, all conditions in the approval letters are now clearly identified as requirements by words such as "shall" and "must".

The routine surveys and hazard evaluations discussed below will help assure that these requirements, as well as other communications, have been understood and complied with.

## 3. Radiation Safety Department Staff.

No violation cited by the Commission in the NOV or Order directly implicated the substance of Yale's overall training or performance criteria for its radiation safety staff members who conduct surveys of laboratories. Rather, the violation relating specifically to surveys arose from Yale's inability to adhere to a rigorous schedule of surveys that it had established. This inability resulted solely from an insufficient number of technical staff. To prevent further recurrence of deficiencies in surveys, an additional technician was added on November 6, 1989 to the Radiation Safety Department. This technician augments the existing staff and will allow for meeting the required frequency of laboratory surveys.

The University's radiation safety technicians conduct radiation surveys which assess the radiation levels within laboratories. They undergo extensive, supervised on-the-job training and receive a minimum of 40 hours of specific radiation safety training. They review the results of their surveys weekly with their supervisor and the Radiation Safety Officer. The Radiation Safety Committee reviews all significant survey results on a quarterly basis.

The health physicists in the Radiation Safety Department, in addition to their other duties, conduct hazard evaluations as needed. These evaluations typically include review of the experiments, facilities and equipment to ensure observance of ALARA principles. The health physicists have either a relevant academic degree or comparable experience that allows them to function to the required standards. They meet individually with the Radiation Safety Officer to discuss significant results of their hazard evaluations.

#### 4. Oversight of Individual Users of Licensed Material.

The Radiation Safety Committee, the Radiation Safety Officer and his professional staff and the radiation safety technicians all review individual users of licensed material in different ways. The Radiation Safety Committee does so in the course of its regular meetings. The Committee reviews authorization applications as a formal agenda item at virtually every meeting. As part of this process, a subcommittee evaluates the training of the investigators, the appropriateness of their radiation safety instrumentation and facilities and the adequacy of the proposed research procedures for purposes of radiation safety. The authorization applications require detailed information about available portable radiation monitors and fixed radiation detection instrumentation. Health physicists from the Radiation Safety Department, who participate in the review of authorization applications, also review the training of investigators as part of that process, and may also observe dry runs during visits to laboratories of applicants. The Radiation Safety Committee authorization review subcommittee is very active in the review process, and frequently a faculty member of the subcommittee visits the laboratory of a new investigator before approval of his application.

The health physicists conduct hazard evaluations of laboratories as needed, and in the course of those evaluations may observe the performance of certain protocols. Hazard evaluations typically include an in-depth review of instrumentation and its

proper use and the need for any additional training of laboratory personnel in radiation safety. The technicians and health physics staff also provide oversight of each experiment conducted in the University's central radioisotope facilities. In the course of reviewing requests to use those facilities, training of investigators is evaluated.

In addition to authorization application reviews and hazard evaluations, the Radiation Safety Department must approve all purchases of radioactive material, and the Radiation Safety Officer reviews each investigator's quarterly inventory of radioactive materials with the assistance of a health physicist. The Radiation Safety Officer also oversees the pickup and removal of all radioactive waste from laboratories and the personnel monitoring program. These programs provide indirect oversight over the users. The Radiation Safety Committee reviews the quarterly radiation exposure summaries provided by the film badge vendor and all reported incidents involving radioactive materials.

Radiation safety technicians provide oversight of individual users in the form of unannounced routine radiation surveys. In addition, they may also conduct decommission and repair or alteration surveys. If an experiment is in progress during a survey advice may be provided. During routine surveys technicians may also check that individual users have been trained and, if necessary, may recommend additional training which is provided by the Radiation Safety Department. The radiation safety technicians also note if appropriate instrumentation for surveying and monitoring radioactivity is available and functioning. Any observed violation of regulations or University procedures is noted and, if possible, corrected on the spot. A written report of the results of the survey is submitted to the principal investigator. The Radiation Safety Officer meets weekly with the radiation safety technicians to review their surveys and provide additional oversight to each individual technician. The Radiation Safety Committee also conducts quarterly reviews of the routine radiation surveys for both the frequency being achieved and laboratory conditions.

##### 5. Human and Financial Resources.

The University, through the organizational and operational changes described above and in the Reply to the NOV, has significantly expanded its already substantial human and financial commitment to Yale's health and safety programs. At present, Yale budgets approximately \$1.5 million for radiation safety, which is implemented by the Radiation Safety Committee, the Director of the

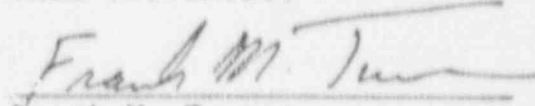
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Office of University Safety, the Radiation Safety Officer, five Health Physicists, seven technicians, and five supporting personnel.

The extensive measures taken by Yale to review and reorganize its radiation safety program demonstrate its strong commitment to high standards of safety and full compliance with applicable NRC requirements. Yale's Reply to the NOV makes it clear that where isolated instances of improper action have occurred the University has taken prompt and effective corrective action. That commitment makes the Order to Show Cause unnecessary, and it should therefore be rescinded. Thank you for your consideration.

Very truly yours,

YALE UNIVERSITY




Frank M. Turner  
Provost

cc: Assistant General Counsel for Hearings and Enforcement, NRC  
Regional Administrator, NRC Region I

I, Frank M. Turner, being duly sworn, subscribe to and say that I am Provost of Yale University; that I have full authority to sign and file with the Nuclear Regulatory Commission the attached Answer to Order to Show Cause Why Licenses Should Not Be Modified -- EA89-131 and am familiar with the contents thereof; and that the matters set forth therein are true and correct to the best of my knowledge and belief.

  
Frank M. Turner

Subscribed and sworn to before me, a Notary Public/Commissioner of the Superior Court in and for the State of Connecticut this 16th day of January, 1990.

  
Notary Public/Commissioner  
of the Superior Court