

UNITED STATES  
NUCLEAR REGULATORY COMMISSION

In the Matter of

Yale University  
New Haven, Connecticut 06520

Docket Nos. 030-00582  
                  0-06886  
                  070-00053  
License Nos. 06-00183-03  
                  06-00183-06  
                  SNM-52

EA 89-131

ORDER TO SHOW CAUSE WHY LICENSES  
SHOULD NOT BE MODIFIED

I

Yale University (the licensee), New Haven, Connecticut 06520 is the holder of NRC License Nos. 06-00183-03, 06-00183-06, and SNM-52 issued pursuant to 10 CFR Parts 30 and 70. The licenses authorize the licensee to use licensed material for research and development, teaching and training of students, calibration of instruments, and performing irradiations. The licenses were most recently renewed on May 23, 1989, February 4, 1987, and May 23, 1989 and are due to expire on May 31, 1994, February 29, 1992 and May 31, 1994, respectively.

II

From May 30 to June 2, 1989, an NRC inspection was conducted at the licensee's facility to review the circumstances associated with an exposure in excess of regulatory limits which occurred at the facility and which was initially identified by the licensee on April 19, 1989 and reported to the NRC on May 1, 1989, after the magnitude of the dose became apparent to the licensee. The event involved a radiation exposure of 178 rem to the tip of the finger of

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one hand of an individual who was eluting iodine-125 from a protein separation column. The circumstances associated with this exposure are described in the Notice of Violation and Proposed Imposition of Civil Penalties (Notice) issued on this date.

In addition to this exposure, other violations of NRC requirements were identified at the facility. These violations, more fully described in the Notice, include: (1) failure to wear gloves when handling radioactive material, (2) failure to perform bioassays at required intervals, (3) failure to perform required surveys, (4) failure to keep records of disposal of radioactive material, (5) failure to train laboratory personnel in radiation safety procedures, (6) disposal of radioactive material by unauthorized means, and (7) repeat occurrences of a previous violation involving eating and drinking in areas where radioactive materials are present.

III

The enforcement history at Yale University has been poor, as evidenced by the fact that twenty violations were identified during four NRC inspections of the radiation safety program conducted since 1984. Furthermore, enforcement conferences were conducted with licensee management at the NRC Region I offices and civil penalties were assessed for the violations identified during the NRC inspections in 1984 and 1988 (EA 84-99 and EA 88-157). Notwithstanding prior enforcement actions, the current violations, which are indicative of a breakdown in management control over licensed activities, demonstrate that the licensee has not effected adequate improvements in the administration and implementation of the radiation safety program.

The continued failure to effectively prevent violations demonstrates that the previous corrective actions taken by the licensee do not sufficiently address the underlying causes of the violations and that additional requirements are necessary to ensure that the licensee's activities are conducted safely and in accordance with the terms of the licenses. Accordingly, I have determined that this Order should be issued to require the preparation of a comprehensive analysis of the deficiencies and requirements of the licensee's Radiation Safety Program, and a detailed plan for correction of the deficiencies, including an analysis of the human and financial resources required, and a timetable for implementation of the plan.

IV

Accordingly, pursuant to Sections 81, 161b, 161c, 161i, 161o, 182 and 186 of the Atomic Energy Act of 1954, as amended, and the Commission regulations in 10 CFR 2.202 and 10 CFR Part 31, IT IS HEREBY ORDERED THAT THE LICENSEE SHALL:

1. Within the time specified in IV.B. below, perform a comprehensive assessment of activities conducted under the licenses issued by the NRC and, based on the assessment findings, develop a detailed improvement plan for correcting identified deficiencies and ensuring effective implementation of the radiation safety program. The plan shall include a description of all changes to be implemented, the specific improvements in management oversight to be instituted, and additional resources to be dedicated, to upgrade the radiation safety program.

As a minimum, the assessment shall address the current status of, and the plan shall address improvements in, the following areas:

1. Procedures for reviewing and approving both new and renewal applications submitted to the Radiation Safety Committee for use of licensed material, including the procedures specifying:
  - a. the degree of detail contained in the application,
  - b. criteria on the need for pre-approval visit or contact with the applicant,
  - c. clarity of the requirements imposed as a condition of authorizing the application, and
  - d. follow-up to assure that those requirements are met.
  
2. Communications directed to individuals who use licensed material under the approval of the Radiation Safety Committee, including the clarity of the language used to indicate requirements that must be followed, and the methods used to assure that these requirements, as well as other communications, have been understood and are complied with.
  
3. Training, responsibilities, and performance criteria for members of the Radiation Safety Staff who perform audits and surveys of laboratories.
  
4. Oversight of individual users of licensed material by the surveyors, Radiation Safety Officer (RSO), and Radiation Safety Committee (RSC), including: observation of performance, review of procedures,

evaluation of training, and determination that the necessary instrumentation is available, and is used, to perform radiation safety tasks.

5. the human and financial resources that are provided to maintain the radiation safety program.
  
- B. Within sixty days of the effective date of this Order, submit to the Regional Administrator, NRC Region I, for approval: 1) a summary of the assessment findings, 2) the improvement plan developed as a result of the assessment findings, and 3) a specific timetable for implementing the various aspects of the improvement plan.
  
- C. Within seven days of the Regional Administrator's approval of the plan, begin implementation of the plan.
  
- D. Three months after the Regional Administrator's approval of the plan, and at intervals of three months thereafter until the plan is fully implemented, submit a written report to the Regional Administrator, NRC Region I, reporting on the progress in implementing the plan. Each report shall explain the reasons why any milestones in the timetable have been missed and provide, for review and approval of the Regional Administrator, a new date for completion of any milestone that has been missed.

The Regional Administrator, NRC Region I, may, in writing, relax or rescind any of these provisions for good cause shown.

Pursuant to 10 CFR 2.202(b), the licensee may show cause why this Order, in whole or in part, should not have been issued by filing a written answer under oath or affirmation within 30 days of the date of issuance of this Order, setting forth the matters of fact and law on which the licensee relies. The licensee may answer, as provided in 10 CFR 2.202(d), by consenting to the entry of this Order. If the licensee fails to file an answer within the specified time, or consents to this Order, this Order shall be final without further proceedings.

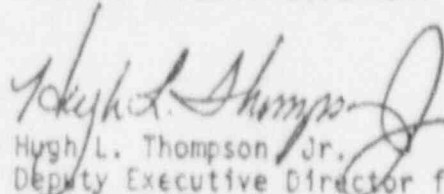
VI

The licensee or any other person whose interest is adversely affected by this Order may request a hearing within 30 days of its issuance. Any answer to this Order or request for a hearing shall be addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington D.C. 20555, with a copy to the Assistant General Counsel for Hearings and Enforcement, Office of the General Counsel, at the same address, and to the Regional Administrator, NRC Region I, 475 Allendale Road, King of Prussia, Pennsylvania, 19406. If a hearing is requested, the Commission will issue an Order designating the time and place of hearing. If a hearing is held, the issue to be considered at the hearing shall be whether this Order should be sustained. If a person other than the licensee requests a hearing, that person shall set forth with particularity the manner in which the petitioner's interest is adversely affected by this Order and should address the criteria



set forth in 10 CFR 2.714(d). Upon failure of the licensee or any person adversely affected by this Order to answer or request a hearing within the specified time, this Order shall become final without further proceedings.

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 26<sup>th</sup> day of September 1989