UNITED STATES
NUCLEAR REGULATORY COMMISSION

In the Matter of

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

ORDER IMPOSING CIVIL MONETARY PENALTIES

I

Yale University (the licensee), New Haven, Connecticut 06520 is the holder of NRC Materials License Nos. 06-00183-03, 06-00183-06, and SNM-52 issued pursuant to 10 CFR Parts 30 and 70 on December 6, 1956, March 12, 1958, and May 25, 1965, respectively. The licenses authorize the licensee to use licensed material for research and development, teaching and training of students, calibration of instruments, and performing irradiations in accordance with the conditions specified in the licenses. he licenses were most recently renewed on May 23, 1989; February 4, 1987; and May 23, 1989 respectively, and are due to expire on May 31, 1994; February 29, 1992; and May 31, 1994, respectively.

II

An NRC safety inspection of the licensee's activities under these licenses was conducted at the licensee's facility from May 30 to June 2, 1989. The results of this inspection indicated that the licensee had not conducted its activities

in full compliance with NRC requirements. A written Notice of Violation and Proposed Imposition of Civil Penalties (Notice) and Order to Show Cause Why the Licenses Should Not Be Modified was served upon the licensee by letter dated September 29, 1989. The Notice stated the nature of the violations, the provisions of the Nuclear Regulatory Commission's requirements that the licensee had violated, and the amount of the civil penalty proposed for the violations. The licensee responded to the Notice by letter dated December 20, 1989, and to the Order by letter dated January 16, 1990. In its response to the Notice, the licensee admitted the violations, but requested mitigation of the proposed civil penalties for the violations in Section I and Section II of the Notice.

III

Upon consideration of the licensee's response and the statement of facts, explanation, and argument for mitigation contained therein, the NRC Staff has determined, as set forth in the Appendix to this Order, that the violations occurred as stated and that the penalties proposed for the violations designated in the Notice of Violation and Proposed Imposition of Civil Penalties should be imposed.

IV

In view of the foregoing and pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (act) 42 U.S.C. 2282, and 10 CFR 2.205, IT IS HEREBY ORDERED THAT:

The licensee pay a civil penalty in the amount of $12,000 within 30 days of the date of this Order, by check, draft, or money order, payable to the Treasurer of the United States and mailed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555.

V

The licensee may request a hearing within 30 days of the date of this Order. A request for a hearing shall be clearly marked as a "Request for an Enforcement Hearing" and shall be addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555. A copy of the hearing request shall also be sent to the Assistant General Counsel for Hearings and Enforcement, Office of the General Counsel, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, with a copy to the Regional Administrator, 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 the hearing. If the licensee fails to request a hearing within 30 days of the date of this Order, the provisions of this Order shall be effective without further proceedings. If payment has not been made by that time, the matter may be referred to the Attorney General for collection.

In the event the licensee requests a hearing as provided above, the issue to be considered at such hearing shall be whether, on the basis of the violations set forth in the Notice and admitted by the licensee, this Order should be sustained.

FOR THE NUCLEAR REGULATORY COMMISSION

James Lieberman, Director
Office of Enforcement

Dated at Rockville, Maryland
this 5th day of April 1990

APPENDIX

EVALUATIONS AND CONCLUSIONS

On September 26, 1989, a Notice of Violation and Proposed Imposition of Civil Penalties (Notice) was issued to Yale University for violations identified during an NRC inspection completed in June 1989. The licensee responded to the Notice by letter dated December 20, 1989. In its response to the Notice, the licensee admits that the violations occurred, but requests mitigation of the respective $5,000 and $6,250 civil penalties for the violations set forth in Section I and II of the Notice. The NRC's evaluation and conclusion regarding the licensee's arguments are as follows:

Restatement of the Violations in Sections I and II of the Notice

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 Farnam 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 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 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 Wast 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).

Summary of Licensee Response Requesting Mitigation of the $5,000 Civil Penalty Proposed for the Violations in Section I of the Notice

Summary of Licensee Response

With respect to the violations in Section I of the Notice, the licensee asserts that Violation I.A (involving the overexposure to a research investigator) was an isolated incident that was identified and promptly reported to the NRC. The licensee further states that the exposed individual

suffered no adverse effects from the overexposure and also states that its corrective actions (which included an investigation by the Radiation Safety Committee, removal of the individual from radiation work, requiring the individual to appear before the RSC to explain the incident, and instructions to the other Principal Investigators) were promptly taken. Furthermore, the licensee asserts that it has no record of past reportable radiation overexposure, and maintains that its prior performance in this area has been good. On this premise, the licensee believes that the NRC's characterization of its prior compliance history as "poor" is neither accurate nor fair.

The licensee also maintains that the remaining violations in Section I of the Notice (Violations I.B, I.C and I.D) were precipitated by Violation I.A and should be similarly mitigated. The licensee asserts that prompt actions were adopted to correct the violations and prevent recurrence, and that Violations I.B and I.C did not result in additional exposures. For these reasons, the licensee contends that the base civil penalty for these violations should be mitigated rather than escalated by 100% as proposed.

NRC Evaluation of Licensee Response

The NRC acknowledges that the licensee reported the overexposure to the NRC once it was identified. However, in determining whether escalation or mitigation of a civil penalty is warranted under Section V.B.1 of the Enforcement Policy, the NRC also considers the opportunities available for the licensee to discover the violation, as well as the relative ease of discovery. In this case, an opportunity existed to identify this violation sooner. Specifically, if, as required by License Condition 21, a routine thyroid burden measurement (bioassay) had been taken within two days of the research investigator's iodination (during which the overexposure is believed to have occurred), the overexposure would have been identified approximately 6 weeks sooner. Therefore, although the overexposure, once identified, was promptly reported to the NRC, the NRC has concluded that the failure to identify the violation sooner indicates that no basis for mitigating the penalty has been provided based on this factor.

The licensee states that the exposed individual suffered no adverse effects from the overexposure. Normally, violations involving an extremity exposure of 178 rem would be classified at Severity Level II. In deciding to downgrade the classification of the violations in Section I from a Severity Level II to a Severity Level III problem, NRC has already taken into account the fact that the individual likely suffered no adverse effects from the overexposure. Further mitigation on this basis is not appropriate.

The NRC has considered the licensee's assertion that the civil penalty should be mitigated because its corrective actions in response to the overexposure (as well as the other violations in Section I of the Notice) were prompt. However, since corrective actions are always required whenever a regulatory violation occurs, mitigation of a civil penalty based on this factor must include consideration of both the promptness and comprehensiveness of those corrective actions.

In this case, while the licensee's corrective actions for the violations set forth in Section I of the Notice were adequate, these actions focused narrowly on the particular deficiencies that led to the overexposure and did not address the broader programmatic issues associated with these violations. For example, although the other Principal Investigators were informed of the overexposure incident, and were "reminded" of the necessity of monitoring research apparatus, no additional formal training was provided to the staff to emphasize the importance of performing research activities in conformance with the procedures established in the authorization for use of radioactive material. In addition, although measures were instituted to detect deficiencies in procedures contained in the renewal of authorization for use, no measures were implemented to ensure that investigators were complying with these procedures during the actual performance of their research. Therefore, given the size of the licensee's program and the number of authorized users, the licensee's actions to correct the violations in Section I of the Notice were not considered sufficiently comprehensive to warrant mitigation of the civil penalty.

With respect to the licensee's argument that the civil penalty for the violations in Section I should not be escalated based on its past performance, the NRC acknowledges the licensee's statement that no other overexposures have occurred within the licensee's research program, notwithstanding the large size of the program. However, in our view, many of the same problems associated with the licensee's poor past performance contributed in substantial part to the overexposure and associated violations. These problems persisted even though NRC previously identified them as matters requiring the licensee's attention. Among them, the Radiation Safety Committee (RSC) was not providing sufficient oversight of the Radiation Safety Program, the substance and frequency of audits of the program by the RSC and the Radiation Safety Office were insufficient, and authorizations for use of licensed materials issued to individual principal investigators lacked specificity regarding the requirements to be met.

Therefore, after considering the licensee's request for mitigation of the civil penalty for the violations in Section I of the Notice, the NRC has determined that such mitigation is not appropriate.

Summary of Licensee Response Requesting Mitigation of the $6,250 Civil Penalty Proposed for the Violations in Section II of the Notice

Summary of Licensee Response

The licensee generally asserts that the violations set forth in Section I of the Notice should have no bearing in determining the penalty for the violations in Section II of the Notice, since these violations (in Section II) did not result in the reported exposure of anyone to radioactive material. Further, the licensee states that escalation of the base civil penalty by 100% is not warranted because none of the violations in Section II were repeat violations. Additionally, the licensee asserts that 50% escalation of the base civil penalty because the NRC had identified the violations is

inappropriate since the licensee had already identified and initiated actions to improve performance in this area.

Specifically, with respect to Violation II A.1, the licensee asserts that 50% mitigation rather than 100% escalation of the civil penalty is warranted in light of its "self-corrective" action in advance of the NRC inspection, and prompt augmented action to devote additional personnel to compliance. The licensee maintains that it had recognized the desirability of requiring an outline with greater information requirements for renewal authorizations, and had taken steps, commencing on December 15, 1988, to develop a new renewal form. The licensee states that this form was revised by the Radiation Safety Committee (RSC) on March 29, 1989 and had been in use for some months.

With respect to Violation II.A.2, the licensee states that a thyroid count is not always required within 1 to 2 days following an iodination. The licensee argues that the January 26, 1989 cover letter from the RSC to the investigator erroneously characterized a recommendation (which called for a thyroid count within two days of iodination) as a requirement. The licensee states the RSC's intent of the statement was that discretion (to perform the count) was left to the investigator. Therefore, the licensee contends that the investigator actually followed the policy intended by the RSC when he did not obtain the thyroid count after the iodination procedure.

With respect to Violation II.A.3, the licensee asserts that its inability to complete all of the quarterly surveys of each of its laboratories in 1988 is not a situation that it had "failed to identify and correct." The licensee states that it had established an ambitious monitoring program because of its concern for proper safety and management, and it had failed to meet the program requirements due to resource problems, and not because of program management. The licensee also states that prior to the NRC inspection, a radiation safety reorganization was being put into place to address this deficiency, and that corrective steps initiated by the licensee were addressing this issue when the violations were identified.

With respect to violations II.A.4 and II.B, the licensee argues that these violations involved discrete and isolated incidents. The licensee asserts that these violations did not result in personnel radiation exposures, were not condoned by or known to the Radiation Safety Committee or Yale, and were promptly dealt with upon discovery. Further, the licensee states that steps designed to prevent these types of incidents from occurring generally were already being developed by the licensee when the violations occurred. With regard to Violation II.A.5, the licensee argues that this incident was an isolated lapse and that Yale took prompt and effective corrective action.

For the reasons set forth above, the licensee contends that mitigation (rather than escalation) of the penalty is warranted.

NRC Evaluation of Licensee Response

The NRC agrees with the licensee's assertion that the violations in Section I should have no direct bearing on the assessment of a civil penalty for the

violations in Section II of the Notice. The violations in Section I were classified in the aggregate at Severity Level III based on the severity of the specific overexposure incident, whereas the violations in Section II reflect weaknesses in the overall Radiation Safety Program. For this reason, the violations and associated civil penalties were categorized into separate areas of concern and were each independently assessed a civil penalty in accordance with the guidance set forth in the Enforcement Policy. The violations in Section I were not considered in determining whether a basis existed for escalation of the civil penalty in Section II.

The NRC did conclude, however, that the licensee's past performance prior to the inspection did provide a basis for 100% escalation of the civil penalty for the violations in Section II of the Notice. This NRC decision was premised on the fact that the NRC identified twenty violations during the previous four NRC inspections, and also assessed two civil penalties to the licensee as a result of specific violations identified during NRC inspections in 1984 and 1988. While the NRC recognizes that none of the violations in Section II of the Notice were repetitive, the licensee's past performance was nevertheless poor. Furthermore, if any of the violations had been repetitive, then separate civil penalties could have been assessed for each repetitive violation, similar to the civil penalty issued for the violation in Section III of the Notice which involved repeat examples of eating or drinking in areas where radioactive materials are used.

With respect to Violations II.A.1 (involving a failure to include an outline of experimental procedures in Authorization Renewals) and II.A.3 (involving a failure to perform quarterly surveys of laboratory areas), the NRC acknowledges that the licensee decided to revise the Renewal Authorization forms in December 1988 to require a procedure outline with more detailed information, and also reorganized the Radiation Safety Department to address inadequate laboratory surveys. Nonetheless, during the May-June 1989 inspection (which was five months after the decision to revise the Renewal Authorization forms, and after completion of the radiation safety reorganization), the NRC identified approximately 60 Authorizations in which the outlines were inadequate, as well as numerous examples of the failure to survey laboratory areas. Therefore, consistent with Section V.B.1 of the enforcement policy, no consideration was given to a reduction in a civil penalty on this factor since the licensee did not take immediate action to effectively correct the problem upon discovery. Furthermore, the licensee did not advise the NRC of these violations either prior to or during the inspection. Therefore, the NRC concludes that mitigation of the civil penalty based upon this factor is not warranted.

With respect to Violation II.A.2 (failure to perform thyroid monitoring within two days of performing an iodination), the NRC disagrees that mitigation of the civil penalty is warranted. The cover letter to the Investigator authorizing his use of radioactive material clearly established that thyroid monitoring was to be performed within two days of an iodination. Therefore, the NRC concludes that the violation occurred as stated and mitigation of the civil penalty is not warranted.

With respect to the licensee's explanation concerning Violation II.A.3, NRC views the assurance of adequate resources as a necessary and integral aspect of the proper management of any radiation safety program. NRC does not condone the lack of sufficient resources to carry out radiation safety commitments, nor do the licensee's resource problems excuse the violation.

With respect to violations II.A.4, II.A.5, and II.B, the NRC acknowledges the licensee's statement that these violations were not condoned by or known to the Radiation Safety Committee. If they had been, NRC would have increased the Severity Level and further escalated the enforcement action. However, the fact that a violation was not willful does not form a basis for mitigation of a civil penalty. NRC also agrees that these violations, if considered as isolated or discrete incidents, would be of minor safety significance. However, when considered collectively with the other violations set forth in Section II, these violations demonstrate a lack of management oversight of licensed activities and, as such, were appropriately classified in the aggregate as a Severity Level III problem.

Furthermore, the corrective actions for these violations were not considered extensive because they focused on the individual aspects of each violation and did not address the broader areas of concern, specifically, the lack of adequate management and supervisory oversight of daily activities in the various laboratories. In addition, although the licensee asserts that steps had already been taken in December 1988 to revise the Renewal Authorization forms to require additional requirements for waste disposal, these violations demonstrate that the licensee's actions have not been sufficiently comprehensive to correct the deficiencies. Therefore, the NRC concludes that no adjustment to the proposed civil penalties on this factor is warranted.

NRC Conclusion

The licensee did not provide a sufficient basis for mitigation of the amounts of the civil penalties for the violations in Sections I and II of the Notice. Therefore, the NRC concludes that civil penalties in the amounts of $5,000 and $6,250 should be imposed for the violations in Sections I and II, respectively. In addition, the licensee did not request mitigation of the $750 civil penalty for the violation in Section III of the Notice. Therefore, the NRC concludes that a civil penalty of $750 should be imposed for the violations in Section III.

Therefore, the NRC concludes that a cumulative civil penalty in the amount of $12,000 should be imposed.

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