UNITED STATES
NUCLEAR REGULATORY COMMISSION

In the Matter of	)	Docket No. 30-01244
Yale New Haven Hospital	)	License No. 06-00819-03
New Haven, Connecticut	)	EA 89-119

ORDER IMPOSING A CIVIL MONETARY PENALTY

I

Yale New Haven Hospital (licensee) is the holder of Byproduct Material License No. 06-00819-03 issued by the Nuclear Regulatory Commission (Commission or NRC) which authorizes the licensee to use various licensed radioactive materials for diagnostic and therapeutic medical purposes as well as research. The license was issued on June 27, 1960, was most recently renewed on August 13, 1985, and is due to expire on August 31, 1990.

II

An NRC safety inspection of the licensee's activities under the license was conducted at the licensee's facility on March 21, 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 Penalty (Notice) was served upon the licensee by letter dated August 3, 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 civil penalty proposed for the violations. The licensee responded to the Notice by two letters dated September 7, 1989. In its response, the licensee denies the violations, and, in the alternative, requests mitigation of the proposed civil penalty.

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. However, the proposed penalty of $2,500 should be mitigated to $1,250 based on the licensee's past performance. Accordingly, a civil penalty in the amount of $1,250 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 $1,250 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, DC 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, DC 20555, with a copy to the Regional Administrator, Region 1, 475 Allendale Road, King of Prussia, PA 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 issues to be considered at such hearing shall be:

(a) whether the licensee was in violation of the Commission's requirements as set forth in the Notice of Violation and Proposed Imposition of Civil Penalty referenced in Section II above and

(b) whether, on the basis of such violations, this Order should be sustained.

FOR THE NUCLEAR REGULATORY COMMISSION

James Lieberman, Director
Office of Enforcement

Dated at Rockville, Maryland
this 27th day of December 1989

APPENDIX

EVALUATION AND CONCLUSION

On August 3, 1989, a Notice of Violation and Proposed Imposition of Civil Penalty (Notice) was issued to Yale New Haven Hospital for violations identified during an NRC inspection. The licensee responded to the Notice by two letters, both dated September 7, 1989. In its responses, the licensee denies the violations assessed a civil penalty, and in the alternative, requests mitigation of the civil penalty. The NRC's evaluation and conclusion regarding the licensee's arguments are as follows:

Restatement of the Violations

A. Condition 27 of License No. 06-00819-03 requires that licensed radioactive material be possessed and used in accordance with the procedures, representations, and statements contained in the application dated December 13, 1984 and in the letters submitted in support of that application.

Item 20(e) of the license application requires, in part, that for cesium-137 sealed sources, the dosimetrist account for each of the sources, the next working day after the sources are removed from the patient and returned to the radium room, and then put the sources back in storage.

Contrary to the above, on March 6, 1989, the dosimetrist did not adequately account for each of the cesium-137 sources before returning the sealed source assemblies to storage. Specifically, the inventory of the sources was conducted by counting the distal portion of each source assembly (which did not contain the actual source), rather than to check the source tip on each assembly (which did contain the actual source).

B 10 CFR 20.201(b) requires that each licensee make such surveys as (1) may be necessary to comply with the regulations of 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 production, use, release, disposal, or presence of radioactive materials or other sources of radiation under a specific set of conditions.

Contrary to the above, on March 6, 1989, necessary and reasonable surveys were not made to assure compliance with 10 CFR 20.301, which describes authorized means of disposing of licensed material contained in waste. Specifically, surveys were not conducted of the trash receptacles in the cesium-137 source storage room prior to removal of the trash from the source room for disposal as non-radioactive waste. Such surveys were necessary and reasonable under the circumstances to evaluate the extent of the radiation hazards that may have been present, and in this case, would have identified the presence of a Heyman brachytherapy applicator containing a 27.53 millicurie cesium-137 source in the trash receptacle, thereby preventing the source from being disposed of in the normal trash.

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

Contrary to the above, on March 6, 1989, a 27.53 mCi Cs-137 brachytherapy source contained in a disposable Heyman applicator was placed into the normal trash and sent to a trash-to-energy plant for incineration, a method not authorized by 10 CFR 20.301.

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

Cumulative Civil Penalty - $2,500 (assessed equally among the violations)

Summary Of Licensee's Response Denying Violations A, B, and C

Summary of Licensee's Response

In its answer to the Notice of Violation and Proposed Imposition of Civil Penalty dated September 7, 1989, the licensee admits that it lost control of a licensed source. However, the licensee objects to what it claims is the NRC's inaccurate assessment of this incident and the NRC's implication that the licensee is solely responsible for this event. The licensee maintains that the root cause of the incident was a manufacturing defect in the source assembly itself that was not foreseeable or reasonably preventable by the licensee utilizing normally accepted practices. The licensee asserts that to be held solely accountable for an event, which was not foreseen either by the manufacturer or the NRC during its source review process, is to hold the licensee to an unreasonable standard of compliance. In addition, the licensee feels that it has been wrongly accused by the NRC of inadequate management oversight, including inventory and survey techniques, and objects to the suggestion that the licensee intended to dispose of the source in the normal trash. Further, the licensee states that the proposed enforcement action will in no way enhance its performance with respect to preventing other incidents of a similar nature. Instead, the licensee claims that an Information Notice should be issued to the industry describing this occurrence and the need to improve inventory techniques to prevent further incidents of this nature.

With respect to Violation A, the licensee maintains that its methodology for performing the source inventory after use was adequate and consistent with industry practice and ALARA considerations. The licensee asserts that it had received no indication of a potential problem with such sources and, without prior knowledge that the braze connection on the source assembly could be defective, it is improbable that it would have independently developed a method of inventory specifically requiring the tips of the assemblies to be checked. The licensee states it has conducted over 3800 brachytherapy treatments since 1966 and this was the first incident of this type to occur in the program, and that its inventory methods had always been adequate to control these sources so that it had no reason to believe that its practices prior to this incident were inadequate.

With respect to Violation B, the licensee asserts that a requirement to perform routine surveys of the normal waste containers in sealed source storage areas, when the sources are physically large and usually easily accounted for by inventory methods, is unreasonable. The licensee maintains that, in such applications, routine surveys are unnecessarily redundant and prone to be neglected because of the extremely low probability of a positive result.

Finally, with respect to Violation C, the licensee admits that the licensed material was inadvertently discarded, but denies that it had any intention to dispose of the source by this method. The licensee asserts that the NRC should not construe this incident as a purposeful willingness to dispose of licensed material in an unauthorized manner.

NRC Evaluation of License Response

Section V.A of the NRC Enforcement Policy provides that licensees are not ordinarily cited for violations resulting from matters not within their control, such as equipment failures that were not avoidable by reasonable quality assurance controls. However, the issue is not whether it was reasonable for the licensee to foresee that the Heyman source assembly brazing might break, but whether the type of inventory performed to account for the source after each use was adequate and reasonable when considering the type of source involved, the nature and mechanics of its use, and the difficulties to be encountered in performing such an inventory. Although the malfunction of the source assembly was not foreseeable from the licensee's perspective, the citation is not premised on the fact that the malfunction of the assembly occurred, but on the licensee's failure to adequately inventory the sources.

With regard to the licensee's assertion that it has been wrongly accused of inadequate management oversight, the NRC notes that a number of related violations occurred which contributed to the improper disposal of radioactive material. In the NRC's view, this indicates that there was a breakdown in the licensee's radiation safety program which could have been prevented by improved control and oversight of licensed material and aggressive management oversight of the radiation safety program to ensure that all aspects of the program were carried out in conformance with regulatory requirements.

With regard to the licensee's argument that the proposed enforcement action will not enhance its performance with respect to preventing such unforeseen incidents, as stated above, this enforcement action is not being taken because the licensee did not foresee that the source assembly brazing might break, but because of the licensee's failures to adequately inventory sources, make surveys which were necessary and reasonable, and properly dispose of licensed material, which could have been prevented had management exercised more aggressive oversight of the radiation safety program. The NRC is imposing this civil penalty to emphasize the need for lasting remedial action and to deter future violations in these areas.

With regard to the licensee's argument that an Information Notice should be issued, 3M, the manufacturer, issued in October 1989 a notice of "Important Safety Information About 3M Heyman Applicators" addressing possible source separations. In addition, 3M has initiated a recall of these sources. However, as indicated below, such actions do not relieve the licensee from doing appropriate surveys.

With respect to Violation A (failure to perform an adequate inventory of the source after each use), the inventory methodology was inadequate because the licensee only inventoried the distal portion of the assembly, rather than actually accounting for the source. The fundamental basis of the regulatory

requirements for the conduct of an adequate source inventory, radiological surveys and other related criteria is that, regardless of the design, quality or engineering review applied to any system or device, such systems or devices may be subject to human or mechanical failures over time. These aforementioned regulatory requirements serve to ensure that additional levels of protection are available to protect the public from the adverse effects of radiation should such a mechanical or human failure occur. The fact that this was the first incident of this type is irrelevant. Therefore, the NRC does not accept the licensee's assertion that, because neither the manufacturer of the assembly nor the NRC warned the licensee of the probability of this specific failure, the licensee is being held to an unreasonable standard of compliance.

The NRC also disagrees with the licensee's assertion that its method of performing the source inventory was consistent with industry practice and ALARA considerations. At the enforcement conference, the licensee clearly stated that the direct (visual) inventory of the source itself would not result in any measurable increase in radiation exposure.

With regard to Violation B (failure to perform adequate surveys), the NRC also disagrees with the licensee's assertion that it is unreasonable to require, nor should the NRC expect, routine surveys of the normal waste containers in sealed source areas where the sources are physically large and usually easily accounted for by inventory methods. Surveys of any waste (intended for disposal in ordinary trash) generated in an area where radioactive materials are handled are not only reasonable, but necessary to assure compliance with 10 CFR 20.301. Furthermore, potentially significant health and safety consequences could result from the loss of a 27.53 millicurie cesium-137 brachytherapy source, including (1) high dose rates (well above 2 mR/hr) in unrestricted areas, and (2) the potential radiological consequences of source incineration. Therefore, it is not unreasonable to require that such a survey be performed at any of the several procedural steps or locations (namely, the source handling, the trash receptacles in the cesium room, or the facility trash dumpster). In this case performing such a survey would have been necessary and reasonable to assure compliance with 10 CFR 20.301, and could have prevented the disposal of the material to the regional incineration facility in violation of that regulation.

With respect to Violation C (unauthorized disposal of licensed material), the NRC disagrees with the licensee's assertion that the NRC has characterized the disposal of the source as an intentional act. To the contrary, the NRC agrees that the disposal of the source was inadvertent. If the NRC believed that the disposal was intentional, a more significant civil enforcement action would have been considered, as well as referral of the matter to the U.S. Department of Justice for consideration of criminal prosecution. Although the violation was not willful, that fact does not provide the basis for retraction of the violation or mitigation of a civil penalty.

Summary of Licensee Response Requesting Further Mitigation of the Civil Penalty

Summary of Licensee Response

The licensee states that, in the event that its above-summarized arguments "are not successful in closing this issue," it requests mitigation of the

proposed civil penalty in accordance with the factors set forth in Section V of the Enforcement Policy. Specifically, the licensee raises the following arguments:

1. With regard to prompt identification and reporting, the licensee states that the Enforcement Policy provides that in weighing this factor, consideration will be given to, among other things, the length of time the violation existed prior to discovery, the opportunity available to discover the violation, the ease of discovery and completeness of any required report.

   In this regard, the licensee argues that it did not have a reasonable opportunity to discover the violation, as it had no prior knowledge that an event like this could occur because of a defective source assembly. The licensee asserts that the source storage room is not an area where radioactive wastes are normally produced, and routine surveys of the normal waste container in this room were not performed because the likelihood of a lost source was believed to be remote. The licensee claims that, once it became aware of the incident, it acted immediately and effectively to control the situation and that its report to the NRC of the incident was complete and comprehensive.

2. The licensee claims that its corrective actions were complete and comprehensive.

3. The licensee takes issue with the NRC's assertion that its past performance has not been good.

   The licensee asserts in the cover letter forwarding the Notice that: (a) the NRC has neither provided any basis for distinguishing good performance from poor performance nor offered a comparison of its performance with that of similar licensees to prove that its performance has been deficient; (b) most of the violations cited in previous inspections were due to infractions in Nuclear Medicine procedures, not in the use and handling of sealed sources; and (c) its performance in the general area of concern regarding control and inventory of sealed sources has been good.

NRC Evaluation of the Licensee's Response

As previously stated in the NRC letter to the licensee transmitting the Notice of Violation and Proposed Imposition of Civil Penalty (Notice), the NRC agrees that the licensee promptly reported the improper disposal to the NRC once it was identified. However, the NRC does not agree that the licensee did not have a reasonable opportunity to discover that the source had been lost prior to the source being found by non-licensee personnel at the incineration plant. As set forth in Violations A and B of the NOV, and further explained above, if the licensee had performed a proper inventory of the source assembly after each use, and/or performed a survey of the normal trash prior to its removal from the radioactive material handling area, the source would have been located by the licensee prior to it ever being transported away from the licensee's facility to the incinerator. Balancing these considerations, the NRC concludes that the decision not to adjust the base civil penalty on this factor is appropriate.

With respect to the licensee's corrective actions, Section V.B of 10 CFR Part 2, Appendix C, provides for a maximum of either 50% mitigation or escalation of the base civil penalty based on the promptness and comprehensiveness of the licensee's corrective actions. As explained in the cover letter transmitting the Notice, the NRC found that the licensee's corrective actions were prompt and comprehensive and provided a basis for mitigating the base civil penalty by 50 percent.

With respect to the licensee's arguments regarding the past performance factor that resulted in a 50 percent increase in the proposed civil penalty, the NRC has,reconsidered this factor and concluded that the 50 percent escalation originally applied for this factor should be withdrawn. We based this on reconsideration of the size of the licensee's program, the number and severity of the previous violations and the lack of previous violations in the brachytherapy program, the area of concern. Therefore, on balance of the area of concern with the licensee's overall past performance, neither escalation nor mitigation is appropriate for this factor. Based on the NRC's reevaluation as to the application of this factor, reduction of the $2,500 proposed civil penalty to $1,250 is appropriate.

NRC CONCLUSION

The licensee has not provided a sufficient basis for retraction of any violations; however, the licensee's argument for reconsideration of its past performance provided a sufficient basis for a 50 percent reduction of the amount of the proposed civil penalty. Therefore, the NRC concludes that a civil penalty in the amount of $1,250 should be imposed.