UNITED STATES
NUCLEAR REGULATORY COMMISSION

In the Matter of	)	
	)	Docket No. 030-01204
DEPARTMENT OF VETERANS AFFAIRS	)	License No. 01-00643-02
MEDICAL CENTER	)	EA 92-204
Birmingham, Alabama	)	

ORDER IMPOSING CIVIL MONETARY PENALTY

I

The Department of Veterans Affairs Medical Center, Birmingham, Alabama (Licensee) is the holder of Byproduct Material License No. 01-00643-02 (License), issued by the U. S. Nuclear Regulatory Commission (NRC or Commission) pursuant to 10 CFR Parts 30 and 35. The Licensee is authorized to possess and use byproduct material for diagnostic and therapeutic nuclear medicine procedures, and for research and development purposes. This is a broad scope license and use of licensed material on humans is permitted by or under the supervision of a physician authorized by the Licensee's Radiation Safety Committee, subject to the training and experience requirements in 10 CFR Part 35, Subpart J. The License was most recently amended on April 10, 1992, and was due to expire on July 31, 1992. The License is currently under timely renewal.

II

On September 13, 1991, an allegation was received by the NRC relating to possible administrations of radiopharmaceuticals in excess of prescribed dosages and possible falsification of

records to conceal the misadministrations. As a result, an investigation was conducted by the NRC Office of Investigations from October 9, 1991, through September 14, 1992.

The results of the investigation 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 September 13, 1993. The Notice addressed the nature of the violations, the provisions of the NRC's requirements that had been violated, and the amount of the civil penalty proposed for the violations.

The Licensee responded to the Notice by two letters dated November 9, 1993. In its response, the Licensee admitted Violations A and C.1, denied Violations B and C.2, and requested partial mitigation of the civil penalty based on its prior performance.

III

After consideration of the Licensee's response and the statements of fact, explanation, and argument for partial 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 penalty proposed for the violations designated in the Notice 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 $10,000 within 30 days of the date of this Order, by check, draft, money order, or electronic transfer, 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 hearing should 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, Washington, D.C. 20555, with a copy to the Commission's Document Control Desk, Washington, D.C., 20555. Copies also shall be sent to the Assistant General Counsel for Hearings and Enforcement at the same address and to the Regional

Administrator, NRC Region II, 101 Marietta Street, N.W., Suite 2900, Atlanta, Georgia 30323.

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 a hearing shall be:

(a) whether the Licensee was in violation of the Commission's requirements as set forth in Violation B and Violation C.2 of the Notice referenced in Section II above, and

(b) whether, on the basis of such violations and the additional violations set forth in the Notice of Violation that the Licensee admitted, this Order should be sustained.

FOR THE NUCLEAR REGULATORY COMMISSION

James Lieberman, Director
Office of Enforcement

Dated at Rockville, Maryland
this 9th day of April 1994

APPENDIX

EVALUATIONS AND CONCLUSION

On September 13, 1993, a Notice of Violation and Proposed Imposition of Civil Penalty (Notice) was issued for three violations identified during an investigation conducted by the NRC Office of Investigations (OI) from October 9, 1991 through September 14, 1992. Department of Veterans Affairs (Licensee) responded to the Notice in two letters dated November 9, 1993. In its responses, the Licensee admitted Violations A and C.1, denied Violations B and C.2, and requested partial mitigation of the civil penalty based on its prior performance and lack of evidence of actual harm to any patient or member of the public. The NRC's evaluations and conclusion regarding the Licensee's requests are as follows:

Restatement of Violation B

10 CFR 35.53 requires, in part, that a licensee measure the activity of each radiopharmaceutical dose that contains more than 10 microcuries of a photon-emitting radionuclide before medical use.

Contrary to the above, the technologist failed to measure three radiopharmaceutical doses that contained more than 10 microcuries of a photon-emitting radionuclide administered to patients on July 22, 1991.

Summary of Licensee Response to Violation B

The Licensee denied this violation and indicated that the evidence does not support the technologist's alleged failure to measure the radiopharmaceutical doses on July 22, 1991. In support of its denial, the Licensee stated that the count rates of these doses when compared with the count rates of seven doses administered within sixty days of July 22, 1991, reflect doses within acceptable limits. Therefore, argues the Licensee, it is not credible that this could be a chance result in the absence of measuring by the technologist.

NRC Evaluation of Licensee's Response to Violation B

The Licensee presented data to indicate that the doses administered on July 22, 1991, had count rates similar to those previously administered. This data, however, provides no information which would indicate that the doses administered to patients on July 22, 1991, were measured in a dose calibrator at the appropriate setting for Technetium-99m. The information is not material to Violation B in that your analyses provides information relating to the activity of material as measured during the scans themselves, but not whether activity was measured in the dose calibrator prior to administration.

As stated in the NRC letter transmitting the Notice, the NRC's conclusion that the technologist failed to measure the dosages was based on: (1) the setting of a different isotope channel on both dose calibrators during the time the technologist stated he measured three patient doses, (2) the missing radioactive material, (3) the high volume of radioactive material recorded by the technologist on the patient dose log, and (4) the technologist's past history of committing errors and omissions in patient dose records.

If proper measurements had occurred, the technologist would have noticed the improper radionuclide channel (i.e., Thallium) and reset it when measuring the doses. The technologist would not have recorded the high volumes on the patient dose log. The technologist admitted that the volumes in the records were fabricated, indicating that he had no knowledge of the amount of doses administered providing further evidence that he had not measured the doses. The Licensee's response did not address any of the evidence which indicated that the dosages had not been measured prior to administration.

Moreover, the staff disagrees with the Licensee's argument that it is not credible to have the count rate of the seven doses favorably compare with the doses administered on July 22, 1991, in the absence of measuring the dose in the dose calibrator. An experienced technologist, knowing a prescribed radiopharmaceutical dose, may approximate with some success the radiopharmaceutical dose by approximating the volume of the material. However, this method is not reliable to assess the radiopharmaceutical dose and does not meet the requirement in 10 CFR 35.53(a) to measure each radiopharmaceutical dosage in a dose calibrator.

The preponderance of the evidence in this case indicates that the technologist failed to measure the doses. The NRC concludes that the violation did occur as stated in the Notice.

Restatement of Violation C.2

10 CFR 35.21 requires, in part, that the licensee, through the Radiation Safety Officer (RSO): 1) ensure that radiation safety activities are being performed in accordance with approved procedures and regulatory requirements in the daily operation of the licensee's byproduct material program; and 2) that the RSO investigate misadministrations and other deviations from approved radiation safety practice and implement corrective actions as necessary.

Contrary to the above, the licensee failed to conduct a prompt and adequate investigation of possible misadministrations of radiopharmaceuticals to patients during the week of July 22 through 26, 1991. Specifically, once notified of the allegation,

the RSO failed to obtain a copy and review a letter from the acting supervisor describing the possible misadministrations or to interview individuals who had first-hand knowledge that was material to the investigation.

Summary of Licensee's Response to Violation C.2

The Licensee denied that Violation C.2 constituted a breach of regulations. While it admitted that the regulations require the RSO to investigate misadministrations, the Licensee stated that the regulations provide no standard for the performance of the investigation and do not require that the investigation be performed in a "prompt or adequate" manner or to the satisfaction of the NRC. The Licensee stated that it conducted an investigation concerning this matter.

The Licensee also stated that during the enforcement conference held on February 16, 1993, Mr. Ebneter, Region Administrator, Region II, pointed out that there was no regulation that tells the Licensee what has to be included in an investigation. The Licensee also stated that Dr. Mallett, Deputy Director, Division of Radiation Safety and Safeguards, Region II, indicated that he was comfortable with the Licensee's statement that it had looked at the rates (as part of the investigation) and expressed satisfaction with the results of the Licensee's investigation.

The Licensee denied that the investigation was not prompt or thorough, since the RSO was summoned back to duty from vacation to look into the matter, the technologist at fault was counseled, and the NRC notified. The Licensee's investigation concluded from statistical studies that there was no misadministration and that the errors were ones of record-keeping. In addition, the Licensee stated that the NRC has not suggested what additional information or result could have been obtained had the investigation been performed differently.

NRC Evaluation of Licensee's Response to Violation C.2

The need for the Licensee to perform investigations that are prompt and adequate is implicit in 10 CFR 35.21 . One purpose of the requirement for an investigation of a possible misadministration is to determine whether there has, in fact, been any misadministration. Further, the Commission's regulations require the licensee to implement as necessary and, ensure corrective actions are taken. This protects individual patients and prevents future or potential misadministrations. An investigation that is not prompt and not adequate cannot achieve these goals nor preclude potential or recurring violation. Accordingly, the NRC rejects the Licensee's argument. In view of the above, the issue is whether the Licensee's investigation was in fact prompt and adequate.

The NRC recognizes that the RSO was summoned back from vacation and initiated an investigation within a few days of the request for his return, that the technologist at fault was counseled, and that the NRC was notified.

However, the NRC maintains that the Licensee's investigation was not adequate as defined in the NRC regulations. Section 35.21 of 10 CFR Part 35, requires, in part, that a Licensee investigate misadministrations and other deviations from approved radiation safety practices and "... **implement corrective actions as necessary**" (emphasis added). The NRC does expect, and the regulations do require, that such investigations be adequate to meet the purpose of the investigations - the implementation of effective corrective actions.

The investigation conducted by the Licensee was not adequate to determine the root cause of the problems and thus, the Licensee's corrective actions were ineffective, as evidenced by the technologist's continual failures to record the administered radiopharmaceutical activity and volume and the lack of supervisory oversight (see pages 75 and 76 of the transcribed enforcement conference). During the enforcement conference referenced in the Licensee's response, the NRC pointed out that the Licensee did not perform an adequate investigation (P 75 and 76). The two specific issues contained in the Notice, failure to review the letter that described the possible misadministration and failure to interview individuals who had first-hand knowledge of this matter, are examples of inadequacies in the investigation that led to the Licensee's inability to determine the root cause and take effective corrective actions.

With regard to Mr. Ebneter's statement that there was no regulation that tells the Licensee what has to be included in investigations, it is true that the NRC regulations do not prescribe the exact methodology for conducting investigations. As discussed above in this section and by Mr. Ebneter during the enforcement conference, however, the investigation results are important and the regulations do prescribe that the investigation must be adequate to implement effective corrective actions.

Concerning Dr. Mallett's statement that he was comfortable with the Licensee's review of the count rates, the NRC notes that Dr. Mallett's statement was not intended to suggest that the NRC considered the investigation adequate; the statement was limited to what it said - that Dr. Mallett was comfortable with that one aspect of the investigation (i.e., the Licensee's review of the count rates). The Licensee's assertion that this meant Dr. Mallett was satisfied with the investigation as a whole appears to have been taken out of context. Within the context of the full meeting, it is clear the NRC did not conclude that the investigation had been adequate.

The NRC concludes that the violation did occur as stated in the Notice.

Summary of Licensee's Request for Mitigation

The Licensee stated that Violations B and Violation C.2 did not occur. The Licensee stated that there is no evidence of harm to any patient or member of the public, even of a minor nature. The Licensee further stated that the evidence does not demonstrate a misadministration of dosages on July 22, 1991 and that the technologist who administered the doses denied administering excessive doses to patients on July 22, 1991.

The Licensee further contended that the errors were essentially record-keeping errors of the Severity Level IV or V type that might be aggregated to Severity Level III or IV but are not Severity Level II violations. In addition, the Licensee stated that its performance has improved over the past year as demonstrated by the last two NRC inspections. Thus, the Licensee argues, in accordance with the Enforcement Policy, the NRC should not have escalated the penalty 50 percent for poor past performance because its performance is improving.

NRC Evaluation of Licensee's Request Mitigation

The arguments made by the Licensee concerning the acceptability of the doses and the lack of evidence of harm to patients or members of the general public do not relate to the requirement to measure dosages prior to administration or to the requirements to perform adequate investigation of possible misadministrations. Further, the Licensee's contention that the evidence does not demonstrate misadministration of doses, or excessive or inadequate doses, is not pertinent to the violation cited. The Licensee was not cited for administering excessive or inadequate doses, or misadministrations. These arguments only provide information that the Licensee believes that excessive dosages were not administered.

With regard to the Licensee's request to reduce the severity level from a Severity Level II to a Severity Level III or Severity Level IV, the NRC notes that Section IV of the Enforcement Policy (i,e., 10 CFR Part 2, Appendix C) states, in part, that "Supplements I through VIII provide examples and serve as guidance in determining the severity level for violations in each of the eight activity areas. However, the examples are neither exhaustive nor controlling ... The NRC reviews each case being considered for enforcement action on its own merits to ensure that the severity of the violation is characterized at the level best suited to the significance of the particular violation. In some cases special circumstances may warrant an adjustment to the severity level characterization."

In this case, the NRC had a very significant regulatory concern as noted in the cover letter to the Notice. There were numerous instances where patient dosages were not measured, numerous instances where patient dosages were not accurately recorded prior to administration, and for an extended period of time, effective corrective actions were not taken. The severity of the violations was exacerbated by the technologist's continual failures to accurately record patient dosages despite repeated counseling, and by the failure on the part of the Chairman of the Radiation Safety Committee to take strong and effective corrective actions in the face of the known repeated violations on the part of the technologist. Given these circumstances and the very significant regulatory concern surrounding this case, a Severity Level II Problem categorization was warranted, in accordance with Section IV of the Enforcement Policy,.

With reference to the Licensee's performance, the NRC recognizes that inspections of the Licensee during the period of late 1992 and 1993 have not shown the same level of poor performance as identified in 1991 and early 1992. The Enforcement Policy statement regarding improved performance relates to performance during the period of either the last two years prior to the inspection at issue or the period of the last two inspections prior to the inspection at issue, whichever is longer. Thus, any improvement in performance subsequent to the inspection at issue may not be considered as part of any mitigation for the licensee performance factor.

NRC Conclusion

Based on its evaluation of the Licensee's responses, the NRC concludes that Violations B and C.2 did occur as stated, that all violations delineated in the Notice were properly categorized in aggregate as a Severity Level II problem, and that an adequate basis for mitigation of the proposed civil penalty has not been provided by the Licensee. Accordingly, a civil monetary penalty in the amount of $10,000 should be imposed by order.

Department of Veterans Affairs
Medical Center

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