UNITED STATES
NUCLEAR REGULATORY COMMISSION

In The Matter of	)	
	)	License Nos. 52-16033-01
HOSPITAL METROPOLITANO	)	52-16033-02
Box E.H., Caparra Heights Station	)	EA 83-14
San Juan, Puerto Rico 00922	)	

ORDER IMPOSING CIVIL MONETARY PENALTIES

I

Hospital Metropolitano, San Juan, Puerto Rico 00922, (the "licensee") is the holder of License Nos. 52-16033-01 and 02 (the "licenses") issued by the Nuclear Regulatory Commission (the "Commission") which authorizes the licensee to operate nuclear medicine and teletherapy activities in accordance with the conditions specified therein. The licenses were issued on February 9, 1981, and September 14, 1982, respectively.

II

As a result of a routine safety inspection conducted on February 2 and 3, 1983 by the Nuclear Regulatory Commission Region II inspection staff, the NRC staff determined that the licensee had conducted activities in its Nuclear Medicine and Teletherapy departments in violation of NRC's regulations and the conditions of its licenses. The NRC served the licensee with a written Notice of Violation and Proposed Imposition of Civil Penalties by letter dated March 23, 1983. The Notice identified the NRC regulations and license conditions that had been violated, disclosed the inspection findings substantiating the violations, and stated the amount of civil penalty proposed for each violation. The licensee responded to the Notice of Violation and Proposed Imposition of Civil Penalties with letters dated April 18, 1983, May 25, 1983, and August 10, 1983.

III

Upon consideration of the responses received and the statements of fact, explanation and argument for remission of the proposed civil penalties contained therein as set forth in the Appendix to this Order, the Director of the Office of Inspection and Enforcement determined that the violations, except example B.2 in the Notice, did occur as set forth in the Notice of Violation. The Director concluded that the proposed penalties should be mitigated in recognition of the licensee's limited ability to pay and the NRC's withdrawal of example B.2.

IV

In view of the foregoing and pursuant to Section 234 of the Atomic Energy Act of 1954, as amended, 42 U.S.C. 2282, PL 96-295, and 10 CFR 2.205, IT IS HEREBY ORDERED THAT:

The licensee pay a civil penalty in the amount of Two Thousand Five Hundred Dollars ($2,500) 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 of the Office of Inspection and Enforcement, USNRC, Washington, D.C. 20555.

V

The licensee may within thirty days of the date of this Order request a hearing. A request for a hearing shall be addressed to the Director, Office of Inspection

and Enforcement. A copy of the hearing request shall also be sent to the Executive Legal Director, USNRC, Washington, D.C. 20555. If a hearing is requested, the Commission will issue an Order designating the time and place of hearing. Should the licensee fail to request a hearing within thirty days of the date of this Order, the provisions of this Order shall be effective without further proceedings and, 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 Penalties as modified in Section III above, and

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

FOR THE NUCLEAR REGULATORY COMMISSION

R C DeYoung

Richard C. DeYoung, Director
Office of Inspection and Enforcement

Dated at Bethesda, Maryland
this 29 day September 1983

APPENDIX

EVALUATIONS AND CONCLUSIONS

For each violation and associated civil penalty identified in the Notice of Violation and Proposed Imposition of Civil Penalties (dated March 23, 1983) the original violation is restated and the Office of Inspection and Enforcement's evaluation and conclusion regarding the licensee's reponses (dated April 18, May 25, and August 10, 1983) to each item is presented.

Item A

Statement of Violation (Part 1)

Collectively, 10 CFR 30.3, 10 CFR 30.34(a), and 10 CFR 35.2 require that the licensee shall receive, use, possess, and transfer byproduct material intended for human use in accordance with all valid NRC rules and regulations and specific licenses issued by the NRC.

Contrary to the above:

A. The licensee did not use and possess byproduct material for human use at its Nuclear Medicine facility in accordance with NRC regulations and the conditions of its specific license, No. 52-16033-02, including the statements contained in its application dated June 27, 1980, which are incorporated into the license by Condition 18, as indicated by the following examples, each of which constitutes a violation:

   1. Item 15 G.1 of the application states that therapeutic radioiodine solutions will be opened and handled within a fume hood. However, since June 1980, the licensee opened and handled doses of 100 to 200 millicuries of radioiodine solutions, approximately five times each year, without using a fume hood. The Nuclear Medicine Department was not equipped with a fume hood.

Licensee Response - The licensee admitted the violation.

Statement of Violation (Part 2)

2. Item 15 G.5 of the application states that all persons handling more than 1 millicurie of radioiodine will have a measurement of thyroid uptake on the following day. However, since June 1980, the licensee has not measured the thyroid uptake of the persons who opened and administered the therapeutic doses identified above. Accordingly, the licensee made no evaluation of the internal radiation exposure incurred by the personnel who handled radioiodine solutions under conditions presenting a substantial potential for exposure.

Licensee Response - The licensee admitted the violation.

Statement of Violation (Part 3)

3. Item 15 F.30 of the application states that syringe shields will be used for preparation and administration of patients' doses. However, since June 1980, syringe shields have not been used for preparation and administration of patients' doses.

Licensee Response - The licensee denied the violation stating that they had a broken shield on hand.

NRC Evaluation and Conclusion - Since the licensee did not have available for use at the time of the inspection an operable syringe shield for preparation and administration of patients' doses as required, and had not been using the shields, the violation stands as proposed in the Notice of Violation.

Statement of Violation (Part 4)

4. Item 10 of the application states that the procedures specified in Appendix D of Regulatory Guide 10.8 will be followed for the dose calibrator. Appendix D specifies a procedure for testing the linearity of a dose calibrator that requires the use of a Tc-99m source, the activity of which is equivalent to the maximum activity to be assayed (typically, 700 to 1000 mCi), over a period of 48 hours. However, since June 1980, the licensee has tested the linearity of its dose calibrator over a period of 12 hours using a 100 mCi source of Tc-99m.

Licensee Response - The licensee admitted the violation.

Statement of Violation (Part 5)

5. Item 9 of the application states that the licensee possesses an Exposure Ratemeter Nuclear Chicago Model 2592 having a sensitivity range of 0-1000 mR/hr. However, on February 3, 1983 (the day of the inspection) the only survey meter in the Nuclear Medicine Department had a range from 0-200 mR/hr.

Licensee Response - The licensee denied the violation on the basis that the instrument was being calibrated on the day of the inspection.

NRC Evaluation and Conclusion - The NRC requires a licensee to have survey instrumentation, having a range commensurate with the magnitude of exposure rates encountered in its licensed activities, available for use when required. On the day of the inspection, the licensee was performing licensed activities but did not have available for use the required survey meter (i.e., a survey meter with a range of 0-1000 mR/hr) because that meter was out for calibration. The violation stands as proposed in the Notice of Violation.

Statement of Violation (Part 6)

6. Item 15 F.28 of the application states that areas used for elution of Mo-99/Tc-99m generators, for preparation of radiopharmaceuticals from reagent kits, and for preparation of individual patient doses will be surveyed for contamination after each procedure and/or at the end of each working day. However, since June 1980, the licensee did not follow this regime; the Nuclear Medicine Department was surveyed at weekly intervals.

Licensee Response - The licensee admitted the violation.

Statement of Violation (Part 7)

7. 10 CFR 35.11(b) requires an institution having a specific license for human use of byproduct material to appoint a radiation safety committee to oversee the use of licensed material throughout the institution and to review the institution's radiation safety program. It specifies that the membership of the committe must include a representative of the nursing staff. However, the membership of the licensee's radiation safety committee did not include a representative of the nursing staff.

Licensee Response - The licensee admitted the violation.

Item B

Statement of Violation (Part 1)

Collectively, 10 CFR 30.3, 10 CFR 30.34(a), and 10 CFR 35.2 require that the licensee shall receive, use, possess, and transfer byproduct material intended for human use in accordance with all valid NRC rules and regulations and specific licenses issued by the NRC.

Contrary to the above:

B. The licensee did not use and possess byproduct material for human use at its teletherapy facility in accordance with NRC regulations and the conditions of its specific license, No. 52-16033-02, as indicated by the following examples:

1. 10 CFR 35.22(a) and (c) require the licensee to cause spot-check measurements to be performed on each teletherapy unit at intervals not exceeding one month. It requires that these measurements be conducted by a qualified expert or, if not conducted by such an expert, reviewed by a qualified expert within 15 days.

   10 CFR 35.24 requires the licensee to determine that the person who reviews the results of spot-check measurements of its teletherapy units is an expert qualified by training and experience to perform this service. Footnote 2 to 10 CFR 35.24 allows a licensee, who has its teletherapy unit calibrated by persons who do not meet the criteria for minimum training and experience, to request a license amendment excepting them from the provisions of 10 CFR 35.24.

However, since April 1982, the licensee did not determine if the person who either conducted or reviewed spot-check measurements of its teletherapy unit had the qualifications specified in 10 CFR 35.24 to perform this service. Spot-check measurements were not performed or reviewed by a qualified expert. The licensee did not request a license amendment in accordance with the provisions of Footnote 2.

Licensee Response - The licensee denied the violation stating that the monthly spot-check measurements had been accomplished by a medical physicist from the School of Medicine from April 11, 1982 until June 1, 1982 and by a dosimetrist - physicist from June 1982 until March 1983.

NRC Evaluation and Conclusion - In the licensee's response, no information was provided to show that the individuals who conducted the spot-check measurements were appropriately certified or had the minimum training and experience specified in 10 CFR 35.24. Accordingly, the violation stands as proposed in the Notice of Violation.

Statement of Violation (Part 2)

2. 10 CFR 35.21(b)(3) requires a licensee who is authorized to use teletherapy units for treating humans to cause full calibration measurements to be performed on each teletherapy unit at intervals not exceeding one year. It requires that these measurements include a determination of the uniformity of the radiation field.

   However, the full calibration measurements performed in March 1982 did not include a determination of the uniformity of the radiation field.

Licensee Response - The licensee denied the violation. He stated that the measurements had included a determination of the uniformity of the radiation field but records of these determinations had not been made.

NRC Evaluation and Conclusion - The denial is accepted by the NRC and part 2 of Violation B is withdrawn. The licensee's failure to record the determinations was a violation of the requirements of 10 CFR 35.25.

Statement of Violation (Part 3)

3. 10 CFR 35.21(c) requires a licensee, who is authorized to use teletherapy units for treating humans, to cause full calibration measurements to be performed on each teletherapy unit following the procedures recommended by the Scientific Committee on Radiation Dosimetry of the American Association of Physicists in Medicine (Physics in Medicine and Biology, Vol. 16, November 3, 1971, pp. 379-396). However, on the last full calibration of the teletherapy unit (March 1982), the licensee did not follow the procedures cited above. The referenced protocol recommends, when determining the absorbed dose from in-air measurements of exposure, the use of an "F" factor for water or muscle (exposure-to-dose conversion for cobalt-60), and an "Aeq" factor (attenuation correction factor) for cobalt-60 in

the final absorbed dose equation. However, the licensee, in determining the absorbed dose from in-air measurements did not use these factors in the final absorbed dose equation.

Licensee Response - The licensee admitted the violation.

Statement of Violation (Part 4)

4. Condition 16 of License No. 52-16033-02 requires the licensee to post written emergency instructions at the teletherapy machine control.

   However, on February 3, 1983 the licensee had the emergency instruction posted on the teletherapy room door versus the teletherapy machine control.

Licensee Response - The licensee admitted the violation.

Licensee Request for Remission of Proposed Civil Penalties

The licensee requested remission of the $2,000 penalty assigned to Item A asserting that the Nuclear Medicine Laboratory has not shown a profit of more than approximately $3,000 per year since 1972. The licensee stated that the penalty would have a substantial and adverse affect on its attempt to improve patient care in the Nuclear Medicine Department. Its request for remission of the $2,000 penalty assigned to Item B was nonspecific.

NRC Evaluation and Conclusion

In consideration of the hardship plea, the penalty for Item A is reduced to $1,000. The penalty for Item B is reduced to $1,500 to reflect the withdrawal of Item B.2 as a violation.