

Appendix A

NOTICE OF VIOLATION

Michigan City Radiologists,  
Incorporated

License No. 13-15586-01

Based on the inspection conducted on November 27, 28, 29, 1979, it appears that certain of your activities were in noncompliance with NRC requirements, as noted below. Items 1 through 11 are infractions, and items 12 and 13 are deficiencies.

1. License Condition No. 18 requires that licensed material be possessed and used in accordance with statements, representations and procedures contained in application dated August 16, 1978, and letter dated January 26, 1979. Item 5 of that application names D. A. Zalac, M.D. as the radiation protection officer.

Contrary to the above-referenced application, it was learned through statements of licensee representatives that the individual designated as your radiation safety officer was changed and you failed to amend your license to reflect this change.

2. License Condition No. 18 requires that licensed material be possessed and used in accordance with statements, representations and procedures contained in application dated August 16, 1978, and letter dated January 26, 1979.

Contrary to Addendum Item No. 10 of the above referenced application, which requires survey instruments be calibrated at least annually, it was determined by review of records that the instrument calibration schedule is not being met. Specifically, your records indicated a calibration was performed on March 1, 1979 and July 18, 1977, a frequency of 20 months.

3. License Condition No. 18 requires that licensed material be possessed and used in accordance with statements, representations and procedures contained in application dated August 16, 1978, and letter dated January 26, 1979.

The above referenced application states in part, that Appendix D, Section 2 of the NRC Medical Licensing Guide will be followed. Appendix D of the above referenced Licensing Guide requires specific tests and calibrations of the dose calibrators. During the inspection of Walters Hospital and Memorial Hospital it was learned through statements of licensee representatives and review of records that quarterly linearity checks and annual accuracy checks of the dose calibrators were not made.

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4. License Condition No. 18 requires that licensed material be possessed and used in accordance with statements, representations and procedures contained in application dated August 16, 1978, and letter dated January 26, 1979.

Contrary to Addendum Item No. 10 of the above referenced application, you failed to perform and record the daily constancy check of your dose calibrator. Specifically, on the day of inspection, November 27, 1979 at Walters Hospital a daily constancy check of the dose calibrator was not made.

5. License Condition No. 18 requires that licensed material be possessed and used in accordance with statements, representations and procedures contained in application dated August 16, 1978, and letter dated January 26, 1979.

Contrary to Addendum No. 15 of the above referenced application, it was learned through statements of licensee representatives and the absence of records, that the requirement for weekly and monthly area surveys to measure contamination levels has not been met at Walters Hospital. Specifically, weekly or monthly surveys were not performed from July 31, 1979 to the day of inspection, November 27, 1979.

6. License Condition No. 18 requires that licensed material be possessed and used in accordance with statements, representations and procedures contained in application dated August 16, 1978, and letter dated January 26, 1979.

Contrary to the requirements of Items No. 10 and No. 15 of the above referenced application, it was learned through statements of licensee representatives and review of records, that you failed to assign finger ring badges to individuals preparing and administering radiopharmaceuticals at Memorial Hospital.

7. License Condition No. 18 requires that licensed material be possessed and used in accordance with statements, representations, and procedures contained in application dated August 16, 1978, and letter dated January 26, 1979.

Contrary to the requirements of Attachment 4-1 of the above referenced application and 10 CFR 19.12 it was learned through statements of licensee representatives that you failed to instruct individuals who transport radioactive materials, in the safe handling of radioactive materials, the hazards associated with the work, the conditions of your license and the appropriate regulations.

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8. License Condition No. 18 requires that licensed material be possessed and used in accordance with statements, representations and procedures contained in application dated August 16, 1978, and letter dated January 26, 1979.

Contrary to the requirements of Item No. 16 of the above referenced application, it was learned through statements of licensee representatives that you permitted smoking in areas where unsealed radioactive materials are handled.

9. License Condition No. 18 requires licensed material to be possessed and used in accordance with statements, representations, and procedures contained in application dated August 16, 1978, and letter dated January 26, 1979.

Contrary to the above referenced application, it was learned through statements of licensee representatives and the absence of records, that the requirement for checking all incoming packages at surface and at three feet with a GM survey meter has not been met from the date of license issuance, February 14, 1979. Specifically, the Technetium generator delivered to Memorial Hospital every Monday, is not checked or monitored on the external surfaces according to procedures submitted with application dated August 16, 1978.

10. 10 CFR 35.12(b) states in part, the Commission will not approve an application by an individual physician or group of physicians for a specific license to receive, possess or use byproduct material on the premises of a medical institution unless the physician brings the byproduct material with him and removes the byproduct material when he departs. The institution cannot receive, possess or store byproduct material other than the amount of material remaining in the patient.

Letter dated January 26, 1979 signed by Windham Bremer, M.D. states in part that criteria set forth in 10 CFR 35.12 will be met at all authorized locations.

Contrary to the above requirement, it was learned through statements of licensee representatives and observations by the NRC inspectors that the criteria set forth in 10 CFR 35.12(b) is not being met. Specifically, a Molybdenum-Technetium generator was used and stored at Memorial Hospital and multiple vials, syringes and capsules containing byproduct material were being stored at both authorized locations of use.

11. 10 CFR 20.201(b) requires that such surveys be conducted as may be necessary for you to comply with all sections of Part 20.

Contrary to this requirement, as of the date of license issuance, you failed to make such surveys as were necessary to assure compliance with 10 CFR 20.101 and 20.105(b), "Permissible levels of radiation in unrestricted areas." Specifically, you failed to make adequate surveys of the radiation levels of the vehicle used to transport used Molybdenum-Techneium generators from Saint Anthony Hospital to Memorial Hospital.

12. 10 CFR Section 20.401(a) requires in part, each licensee to maintain film badge records on Form NRC-5 or a record containing all information required in Form NRC-5.

Contrary to this requirement, film badge records did not show social security numbers and birthdates of individuals for which film badge monitoring is required at Walters Hospital.

13. 10 CFR 20.401(b) requires that you maintain records showing the results of surveys that you made to assure compliance with 10 CFR 20.201(b) "Surveys."

Contrary to the above, you failed to maintain records of results of such surveys as were necessary to assure compliance with 10 CFR 20.301, a regulation that describes authorized means of disposing of licensed material contained in waste. Specifically, no records were maintained by Memorial Hospital of results for surveys of waste material disposed of as normal ("cold") trash.