

Appendix A

NOTICE OF VIOLATION

Max Starkloff Memorial Hospital

License No. 24-00061-04

As a result of the inspection conducted on July 28, 1982, and in accordance with the NRC Enforcement Policy, 47 FR 9987 (March 9, 1982), the following violations were identified:

1. License Condition No. 17 requires that licensed material be possessed and used in accordance with the statements, representations, and procedures contained in application dated April 25, 1978; letters dated January 15, 1979, February 7, 1980, June 23, 1980, December 19, 1980, December 2, 1981, and April 27, 1982; and ALARA Program dated December 1, 1981.

The license application dated April 25, 1978, states that the procedures described in Appendix D, Section 2 of the draft medical licensing guide shall be followed for calibration of the dose calibrator. Appendix D, Section 2 states that a geometrical variation check of the dose calibrator shall be performed at installation.

Contrary to this requirement, a geometrical variation check of the Picker Micro-Cal dose calibrator has not been performed since the date of license issuance.

This is a Severity Level IV violation (Supplement VI).

2. License Condition No. 17 requires that licensed material be possessed and used in accordance with the statements, representations, and procedures contained in application dated April 25, 1978; letters dated January 15, 1979, February 7, 1980, June 23, 1980, December 19, 1980, December 2, 1981, and April 27, 1982; and ALARA Program dated December 1, 1981.

The license application dated April 25, 1978, states that the procedures described in Appendix F, of the draft medical licensing guide shall be followed for opening packages containing radioactive materials. Appendix F, states that wipe tests of the external surface of the final source container shall be performed.

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Contrary to this requirement, wipe tests of the external surface of the final source container were not performed.

This is a Severity Level IV violation (Supplement VI).

3. License Condition No. 17 requires that licensed material be possessed and used in accordance with the statements, representations, and procedures contained in application dated April 25, 1978; letters dated January 15, 1979, February 7, 1980, June 23, 1980, December 19, 1980, December 2, 1981, and April 27, 1982; and ALARA Program dated December 1, 1981.

The license application dated April 25, 1978, states that the procedures described in Appendix I, of the draft medical licensing guide shall be followed for performing area surveys. Appendix I, states that injection areas shall be surveyed daily.

Contrary to this requirement, injection areas were not surveyed daily.

This is a Severity Level IV violation (Supplement VI).

4. 10 CFR 71.5(a) requires that no licensee shall transport any licensed material outside of the confines of his plant or other place of use unless the licensee complies with the applicable regulations of the Department of Transportation in 49 CFR Parts 170-189.

49 CFR 173.393(h) states that no significant removable radioactive contamination shall be on the external surface of packages.

Contrary to this requirement, it was learned through statements of licensee representatives that wipe tests were not performed to ensure that no removable radioactive contamination was present on the barrels of waste shipped on August 12, 1980, and December 16, 1981.

This is a Severity Level IV violation (Supplement V).

5. 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, the Nuclear Medicine Department failed to maintain records of surveys of radioactive waste to assure that no measurable radiation above background was present before disposal as normal trash.

This is a Severity Level V violation (Supplement IV).

Pursuant to the provisions of 10 CFR 2.201, you are required to submit to this office within thirty days of the date of this Notice a written statement or explanation in reply, including for each item of noncompliance: (1) corrective action taken and the results achieved; (2) corrective action to be taken to avoid further noncompliance; and (3) the date when full compliance will be achieved. Consideration may be given to extending your response time for good cause shown.

8/18/82

Dated \_\_\_\_\_

Original Signed by J. R. Miller

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J. R. Miller, Chief  
Technical Inspection Branch

## Appendix B

### MANAGEMENT CONTROL

In order to provide you with some guidance in assessing the adequacy of your management control program, the NRC Region III office provides the following as the acceptance criteria for adequate management control for materials licensees. "Management Control" is a system instituted by management to assure that licensed activities are performed safely and in accordance with regulatory requirements (license conditions and applicable regulations).

This will include:

- a. Delineation of duties and responsibilities of all persons involved in licensed activities.
- b. Providing for indoctrination and training of all personnel performing licensed activities, specifically in those areas directly affecting compliance with NRC regulations and license conditions.
- c. Verification, as by checking, auditing and inspecting, that activities affecting safety related functions have been correctly performed. The verifying process should be performed by individuals or groups other than those performing the safety related procedures.
- d. Insuring continued compliance of licensed activities throughout periods during which routine activities may be interrupted, such as changes in equipment, personnel or facilities.

Because of the many variables involved, such as the number of personnel, type of activity being performed and the location or locations where activities are performed, the organizational structure for executing the management control program may take various forms; however, irrespective of the organizational structure, the individual or group responsible for this control should have the flexibility and authority to institute changes or corrections as required to maintain compliance with NRC regulations and license conditions.