NOTICE OF VIOLATION

Emma L. Bixby Medical Center
Adrian, MI 49221

03002027
03011570

License No. 21-03194-01
License No. 21-03194-04

As a result of the inspection conducted on September 26, 1989, and in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C, (1989) (Enforcement Policy) the following violations were identified:

License No. 21-03194-01

1. 10 CFR 35.22(a)(1) (superseding 10 CFR 35.11(b) on April 1, 1987) requires that the Radiation Safety Committee consist of at least three individuals and must include an authorized user of each type of use permitted by the license, the Radiation Safety Officer, a representative of the nursing service, and representative of management who is neither an authorized user nor the Radiation Safety Officer.

   Contrary to the above, from approximately 1984 to August 9, 1989, the Radiation Safety Committee did not include a representative of the nursing service.

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

2. License Condition 14 states that this license is based on the licensee's statements and representations contained in certain referenced applications and letters.

   a. Item No. 7 of the referenced letter dated January 30, 1984, states that the Medical Isotopes Committee will meet quarterly.

      Contrary to the above, the Radiation Safety Committee failed to meet during the third quarters of 1985 and 1987.

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

      This is a repeat violation.

   b. The referenced application dated October 18, 1978, requires in Item 15.6 that each patient dose be assayed in the dose calibrator prior to administration.

      Contrary to the above, on one occasion in 1989, and on 5 occasions in 1988, dosages containing millicurie quantities of iodine-131 were administered to patients and the amount of activity was not assayed in the dose calibrator prior to administration.

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

c. The referenced application dated October 18, 1978, requires in Item 10 that survey meters be calibrated at least annually.

Contrary to the above, the Victoreen-492 survey instrument currently being used to show compliance with regulatory requirements has not been calibrated since May 21, 1984.

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

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10 CFR 35.615(d)(4) (superseding 10 CFR 35.27 on April 1, 1987), requires that a licensee shall maintain a record of the check required by Paragraph (d)(3) of this section for three years. Paragraph (d)(3) requires a radiation monitor in the entrance of the teletherapy room be checked with a dedicated check source for proper operation each day before the teletherapy unit is used.

Contrary to the above, since the inception of the requirement, records were not maintained of radiation monitor checks performed each day before the teletherapy unit was used.

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

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 violation: (1) the corrective steps that have been taken and the results achieved; (2) the corrective steps that will be taken to avoid further violations; and (3) the date when full compliance will be achieved. Consideration may be given to extending your response time for good cause shown.

November 2, 1989
Dated

Bruce S. Mallett
Bruce S. Mallet, Ph.D., Chief
Nuclear Materials Safety Branch