NOTICE OF VIOLATION

Borgess Medical Center
Kalamazoo, Michigan

License No. 21-12275-02
License No. 21-12275-01
Docket No. 030-02115
Docket No. 030-00280

As a result of the inspection conducted on January 15, 1991, and in accordance with the "General Statements of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C, (1991) (Enforcement Policy) the following violations were identified:

License No. 21-12275-02

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

   Contrary to the above, as of January 15, 1991, the membership of the licensee's Radiation Safety Committee did not include a representative of the nursing service.

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

2. 10 CFR 35.310(b) requires that a licensee keep for three years a list of individuals receiving safety instruction required by 10 CFR 35.310(a) concerning patients receiving radiopharmaceutical therapy.

   Contrary to the above, as of January 15, 1991, the licensee did not make a list of individuals receiving safety instruction for a patient who received 150 millicuries of iodine-131 on December 26, 1990.

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

3. 10 CFR 35.315(a)(8) requires that a licensee measure the thyroid burden of each individual who helped prepare or administer a dosage of iodine-131 for each patient receiving radiopharmaceutical therapy and hospitalized for compliance with 10 CFR 35.75, within three days after administering the dosage.

   Contrary to the above, as of January 15, 1991, the licensee did not measure the thyroid burden of James R. Dolan, M.D., who helped administer a dosage of iodine-131 for a patient receiving radiopharmaceutical therapy on December 26, 1990, and hospitalized for compliance with 10 CFR 35.75, within three days after administering the dosage.

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

4. 10 CFR 35.92(b) requires that a licensee retain records of disposal of byproduct material held for decay-in-storage for three years, and that the records include the date of the disposal, the date on which the byproduct material was placed in storage, the radionuclides disposed, the survey instrument used, the background dose rate, the dose rate measured at the surface of each waste container, and the name of the individual who performed the disposal.

   Contrary to the above, as of January 15, 1991, the licensee's retained records of disposal of byproduct material held for decay in storage did not include the date on which the byproduct material was placed in storage, the survey instrument used, the background dose rate and the dose rate measured at the surface of each waste container.

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

5. 10 CFR 35.21(a) requires, in part, that the licensee, through the Radiation Safety Officer (RSO), ensure that radiation safety activities are being performed in accordance with approved procedures. The licensee's procedures for training personnel who work with or in the vicinity of radioactive materials are described in the application for license renewal dated March 20, 1990 and were approved by License Condition 16 of License No. 21-12275-02.

   Item 8.1 of the March 20, 1990, application "Personnel Training Program" requires, in part, that all radiation workers and ancillary personnel whose duties require them to work in the vicinity of radioactive material receive instruction in certain specified topics and at specified intervals including (a) before assuming duties with, or in the vicinity of radioactive materials, (b) during annual refresher training, and (c) whenever there is a significant change in duties, regulations, or terms of the license.

   Contrary to the above, as of January 15, 1991, the licensee failed to train at least two radiation workers in the applicable regulations and license conditions, topics specified in the application.

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

6. 10 CFR 35.21(a) requires, in part, that the licensee, through the Radiation Safety Officer (RSO), ensure that radiation safety activities are being performed in accordance with approved procedures. The licensee's procedures for air concentration control of Xenon-133 are described in the application for license renewal dated March 20, 1990, and were approved by License Condition 16 of License No. 21-12275-02.

   Item 10.13 of the March 20, 1990 application "Air Concentration Control of Xenon-133" requires the trap effluent from one patient study to be collected in a plastic bag from the exhaust of the trapping system upon initial use of each trap and once each month in which the trap is used. Further, 10.13 requires that an action level be established based on the

background cpm or a multiple of background and that significant increases in the bag cpm above normal indicate that the trap is breaking down and will be replaced.

Contrary to the above, as of January 15, 1991, the licensee did not collect trap effluent from one patient study for evaluation since inception of the requirement on November 15, 1990. The licensee's established action level, 100 microcuries, was not based on background cpm or a multiple of background and a significant increase above the licensee's action level, 102.3 microcuries on November 23, 1990, did not result in replacement of the trap.

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

License No. 21-12275-01

7. 10 CFR 35.632(a)(3) and (f) require that full calibration measurements on each teletherapy unit be conducted at intervals not to exceed one year and that these measurements must be performed by the licensee's teletherapy physicist.

Contrary to the above, the licensee did not perform a full calibration of its teletherapy unit during the calendar year 1990.

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

8. 10 CFR 35.634(a)(1) requires that monthly output spot checks include determination of timer constancy and timer linearity over the range of use.

Contrary to the above, monthly output spot checks conducted during the period December 4, 1989 through January 15, 1991, did not include determination of timer linearity over the range of use.

This is a Severity Level IV 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.

FEB 14 1991
Dated

Roy Zimmerman for
John A. Grobe, Chief
Nuclear Materials Safety
Branch