Appendix

NOTICE OF VIOLATION

St. Michael's Hospital

License No. 48-12272-01
License No. 48-12272-02

As a result of the inspection conducted on May 14, 1985, and in accordance with the General Policy and Procedures for NRC Enforcement Actions, (10 CFR Part 2, Appendix C), the following violations were identified:

License No. 48-12272-02

1. 10 CFR 35.22 requires monthly spot checks of teletherapy units to include a determination of the accuracy of the distance measuring device and an evaluation of the difference between the measured and expected output.

   Contrary to the above, this requirement is not being met. Specifically, your monthly spot checks do not include a determination of the accuracy of the distance measuring device nor do they include an evaluation of the difference between the measured and expected output.

   This is a repeat violation.

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

2. 10 CFR 35.23(a) states that full calibration measurements required by 10 CFR 35.21 shall be performed using a dosimetry system that has been calibrated by the National Bureau of Standards or by a Regional Calibration Laboratory accredited by the American Association of Physicists in Medicine.

   Contrary to the above, the dosimetry system used to perform the full calibration measurements on your teletherapy unit was not calibrated as required. Specifically, the dosimetry system was calibrated at Argonne National Laboratory and not by the National Bureau of Standards or an accredited laboratory, as required.

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

3. 10 CFR 35.23(b) states that spot-check measurements required by 10 CFR 35.22 shall be performed using a dosimetry system that has been calibrated in accordance with paragraph (a) of this section. Alternatively, a dosimetry system used solely for spot-check measurements may be calibrated by direct intercomparison with a system that has been calibrated in accordance with paragraph (a) of this section.

Contrary to the above, the dosimetry system used for spot-check measurements of your teletherapy unit was not calibrated as required. Specifically, the dosimetry system used to perform the monthly spot check measurement of your teletherapy unit was intercompared with a dosimetry system which was not calibrated according to the requirements of 10 CFR 35.23(a).

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

4. 10 CFR 35.21(b) requires full calibration measurements on each teletherapy unit to include a determination of the exposure rate or dose rate to an accuracy within ± 3 percent for the range of field sizes and for the range of distances used in radiation therapy.

Contrary to the above, this requirement is not being met. Specifically, the full calibration measurements on your teletherapy unit did not include a determination of the exposure rate to an accuracy of ± 3 percent.

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

5. License Condition No. 24 requires that licensed material be possessed and used in accordance with the statements, representations, and procedures contained in certain referenced applications and letters.

Contrary to the above, on the date of the inspection, this requirement was not being met. Specifically, the Victoreen 740D survey meter was not operational and no other instrument with comparable capabilities was available for use.

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

License No. 48-12272-01

6. License Condition No. 18 requires that licensed material be possessed and used in accordance with the statements, representations, and procedures contained in certain referenced applications and letters.

The referenced application dated May 20, 1982 states in Item No. 15 that syringe shields shall be used at all times for the preparation and administration of patient doses except when the patients well being would be compromised.

Contrary to the above, on the day of the inspection the licensee did not have a syringe shield available for 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 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.

JUN 10 1985

Dated

D. G. Wiedeman, Chief
Nuclear Materials Safety
Section 1