Appendix

NOTICE OF VIOLATION

St. Mary's Hospital

License No. 12-03391-01
License No. 12-03391-03

As a result of the inspection conducted on October 13 and 14, 1982, and in accordance with the NRC Enforcement Policy, 47 FR 9987 (March 9, 1982), the following violations were identified:

License No. 12-03391-01

1. 10 CFR 20.201(b), requires you to make such surveys as may be necessary for you to comply with all sections of Part 20.

   Contrary to this requirement, you failed to make such surveys as were necessary to determine that individuals who handled significant quantities of iodine-131 were not exposed to airborne concentrations exceeding the limits specified in 10 CFR 20.103, "Exposure of individuals to concentrations of radioactive materials in restricted areas." Specifically, no surveys of airborne radioactivity were conducted during liquid iodine-131 thyroid therapy treatments. In addition routine thyroid monitoring of the individuals involved was not conducted.

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

2. 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, you failed to make such surveys as were necessary to assure compliance with 10 CFR 20.105(b), "Permissible levels of radiation in unrestricted areas." Specifically, on June 26, 1982, you failed to make adequate surveys of the unrestricted areas surrounding room 428, which was occupied by a patient who received a 206 millicurie therapy dose of iodine-131.

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

3. License Condition No. 19 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 January 19, 1979, states in Item No. 14 that the procedures described in Appendix F of the NRC medical licensing guide shall be followed for safely opening packages containing radioactive materials.

   Appendix F states that a survey must be taken at a distance of 3 feet from the package, at the surface of the package, a wipe test of the final source container must be taken and a survey of the empty shipping container before discarding must be performed.

   Contrary to this requirement, it was found through the NRC inspectors' review of records that wipe tests of the final source containers of packages received, had not been performed since January 1980.

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

License No. 12-03391-03

4. 10 CFR 35.21(b)(1) and (3) require that full calibration measurements shall include 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 (or for the axis distance) used in radiation therapy and the uniformity of the radiation field and the field indicated by the light beam localizing device.

   Contrary to this requirement, it was found through the NRC inspectors' review of records and statements of the licensee's representative that the full calibration procedure did not include a determination of accuracy of ±3 percent or a determination of uniformity of the radiation field.

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

5. 10 CFR 35.22(b)(1)(4) and (5) require that spot check measurements shall include determination of timer accuracy; the exposure rate, or dose rate, or a quantity related in a known manner to these rates for one typical set of operating conditions; and the difference between the measurement made and anticipated output, expressed as a percentage of the anticipated output.

Contrary to this requirement, it was found through the NRC inspectors' review of records and licensee statements that timer accuracy checks, the output and the difference between the measurement made and the anticipated output were not performed.

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.

10-29-82
Dated

D. G. Wiedeman, Chief
Materials Radiation Protection
Section 1