NOTICE OF VIOLATION

St. Mary Medical Center
Hobart, IN

License No. 13-03459-03
Docket No. 030-31379

As a result of the inspection conducted on August 29, 1990, 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:

1. 10 CFR 35.50(b)(3) requires that the dose calibrator linearity test be performed over the range of its use between the highest dosage that will be administered to a patient and 10 microcuries.

   Contrary to the above, dose calibrator linearity tests were not performed over the range of its use between the highest dosage that will be administered to a patient, approximately 40 millicuries, and 10 microcuries. Specifically, the linearity test which began on July 18, 1990 was performed only over the range of 40 millicuries and 165 microcuries.

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

2. 10 CFR 35.50(e) requires that records be maintained of each required dose calibrator check and test. Specifically, quarterly dose calibrator linearity tests shall be maintained for three years unless directed otherwise and the records shall include the model and serial number of the dose calibrator, the calculated activities, the measured activities, the date of the test, and the signature of the Radiation Safety Officer. Also, records of daily constancy checks of dose calibrators shall include the model and serial number of the dose calibrator, the identity of the radionuclide contained in the check source, the date of the check, the activity measured, and the initials of the individual who performed the check.

   Contrary to the above, records of the linearity tests which began on October 23, 1989 and July 18, 1990 did not contain the signature of the Radiation Safety Officer. In addition, results of daily constancy checks were not recorded and maintained for 10 occasions between March and August 1990, when radiopharmaceuticals were administered.

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

3. 10 CFR 35.70(h) requires that records be maintained of daily radiation surveys of radiopharmaceutical use and administration areas for three years unless directed otherwise and that the records include the date of the survey, a plan of each area surveyed, the trigger level established for each area, the detected dose rate in each area expressed in millirem per hour, the instrument used to make the survey, and the initials of the individual who performed the survey.

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Contrary to the above, results of daily surveys were not recorded and maintained on 7 occasions between March and August 1990, when radiopharmaceuticals were administered.

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.

September 13, 1990 George M. McCann
Dated