NOTICE OF VIOLATION

St. Luke's Hospital
Chesterfield, MO

License No. 24-01570-03
Docket No. 030-02305

As a result of the inspection conducted on April 25 and 26, 1991, and in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C (1990) (Enforcement Policy), the following violations were identified:

1. 10 CFR 20.207(a) requires that licensed materials stored in an unrestricted area be secured against unauthorized removal from the place of storage. 10 CFR 20.207(b) requires that materials not in storage be under the constant surveillance and immediate control of the licensee. As defined in 10 CFR 20.3(a)(17), an unrestricted area is any area access to which is not controlled by the licensee for purposes of protection of individuals from exposure to radiation and radioactive materials.

   Contrary to the above, on April 25, 1991, licensed material consisting of sealed dose calibrator reference sources and radiopharmaceutical doses located in the nuclear medicine hot laboratory, and a sealed brachytherapy source located in Accelerator Room No. 1, both unrestricted areas, were not secured against unauthorized removal and were not under the constant surveillance and immediate control of the licensee.

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

2. 10 CFR 35.53(c) requires, in part, that a licensee retain records of the measurement of radiopharmaceutical dosages for three years, and that the record contain the date and time of the measurement.

   Contrary to the above, as of April 25, 1991, the licensee's retained records of the measurement of radiopharmaceutical dosage did not contain the time of the measurement, since at least April 25, 1988.

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

   This is a repeat violation as it was identified during our January 29, 1988 inspection.

3. 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 the safe uses of radiopharmaceuticals are described in a letter dated August 22, 1990, and were approved by License Condition No. 20.

   Item 10.4 of the August 22, 1990 letter, "Rules for the Safe Use of Radiopharmaceuticals," Subitem 2, requires that disposable gloves be worn at all times while handling radioactive materials.

Contrary to the above, as of April 25, 1991, nuclear medicine technologists failed to wear disposable gloves approximately 40% of the time while handling radioactive materials.

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

4. 10 CFR 35.50(e)(2) requires, in part, that a licensee retain records of annual accuracy tests of dose calibrators for three years, which include the signature of the Radiation Safety Officer (RSO). 10 CFR 35.50(e)(3) requires, in part, that a licensee retain records of quarterly linearity tests of dose calibrators for three years, which include the signature of the RSO. 10 CFR 35.50(e)(4) requires, in part, that a licensee retain records of tests for dose calibrator geometrical dependence for three years, which include the signature of the RSO. 10 CFR 35.59(g) requires, in part, that a licensee in possession of a sealed source retain records of quarterly physical inventories of sealed sources for five years, which contain the signature of the RSO. 10 CFR 35.59(i) requires, in part, that a licensee retain records for three years of quarterly ambient dose rate surveys of sealed sources conducted, which contain the signature of the RSO. 10 CFR 35.59(d) requires, in part, that a licensee retain records of sealed source leak tests for five years which contain the signature of the RSO.

Contrary to the above, as of April 25, 1991, the licensee's records for annual accuracy tests, quarterly linearity tests, and geometrical dependence for the dose calibrator, and quarterly physical inventories, ambient dose rate surveys and leak tests of sealed sources did not contain the signature of the RSO, since April 25, 1988.

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

5. A. 10 CFR 20.203(f) requires that, except as provided by 10 CFR 20.203(f)(3), each container of specified amounts of licensed material bear a durable, clearly visible label identifying the radioactive contents.

Contrary to the above, on April 25, 1991, a container of radioactive waste in the nuclear medicine hot laboratory did not bear any label identifying its radioactive contents and the container was not excepted from such labeling.

B. 10 CFR 20.203(b) requires that each radiation area be conspicuously posted with a sign or signs bearing the radiation caution symbol and the words, "Caution Radiation Area."

Contrary to the above, on April 25, 1991, the radiation area in the nuclear medicine hot laboratory was not posted as required.

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

6. 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 April 25, 1991, the licensee did not measure the thyroid burden of Dr. Delia Garcia, who administered a dosage of iodine-131 for a patient receiving radiopharmaceutical therapy on January 7, 1991, 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).

7. 10 CFR 20.205(b)(1) requires, in part, that a licensee, upon receipt of any package containing radioactive material in excess of Type A quantities, monitor the external surfaces of the package for radioactive contamination caused by leakage of the radioactive contents.

   10 CFR 20.205(c)(1) requires, in part, that a licensee, upon receipt of any package containing radioactive material in excess of Type A quantities, monitor the radiation levels external to the package.

   10 CFR 20.401(b) requires, in part, that each licensee maintain records showing the results of monitoring of packages required by 10 CFR 20.205(b) and (c).

   Contrary to the above, the licensee did not monitor the external surfaces of a package received on April 25, 1990 for radioactive contamination caused by leakage of the radioactive contents. The licensee did not monitor the surface radiation levels external to packages received on April 25, 1990, October 16, 1990, and January 24, 1991, containing approximately ten curies of iridium-192, an amount in excess of a Type A quantity. The licensee did not maintain records showing the results of monitoring of a package received on April 8, 1991, containing approximately ten curies of iridium-192, an amount in excess of a Type A quantity.

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

8. 10 CFR 35.92(b) requires, in part, that a licensee retain records of disposal of byproduct material held for decay-in-storage for three years, and that the records include the survey instrument used and the background dose rate.

   Contrary to the above, as of April 25, 1991, the licensee's retained records of disposal of byproduct material held for decay-in-storage did not include the survey instrument used and the background dose rate, since April 25, 1988.

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

9. 10 CFR 35.22(a)(2) requires that the Radiation Safety Committee meet at least quarterly.

   10 CFR 35.22(a)(3) requires that to establish a quorum and conduct business, at least one-half of the Radiation Safety Committee's membership must be present, including the Radiation Safety Officer and the management's representative.

   Contrary to the above, the licensee's Radiation Safety Committee failed to meet during the first and fourth quarters of 1990. On October 29, 1989, December 18, 1989, and May 3, 1990, the licensee's Radiation Safety Committee met and conducted business and a quorum was not established in that the management's representative was not present.

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

10. 10 CFR 35.59(b)(2) requires, in part, that a licensee in possession of a sealed source, test the source for leakage at intervals not to exceed six months or at other intervals approved by the Commission or an Agreement State.

    Contrary to the above, the licensee did not test sealed sources containing 172 microcuries of cesium-137 and 183 microcuries of barium-133 for leakage from March 16, 1988 to October 28, 1988, October 28, 1988 to September 20, 1989, and from March 21, 1990 to December 27, 1990, all intervals which exceeded six months and no other interval was approved.

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

    This is a repeat violation as it was identified during our March 19 and 20, 1985 inspection.

11. 10 CFR 35.59(g) requires, in part, that a licensee in possession of a sealed source or brachytherapy source conduct a quarterly physical inventory of all such sources in its possession.

    Contrary to the above, the licensee did not conduct a physical inventory of sealed dose calibrator reference sources, containing 172 microcuries of cesium-137 and 183 microcuries of barium-133, from the date of previous inspection on January 29, 1988 to April 25, 1991, a period in excess of a calendar quarter. The licensee did not conduct a physical inventory of sealed cesium-137 brachytherapy sources during the fourth quarter of 1990.

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

12. License Condition No. 17.A.(ii) requires, in part, that subsequent to each source exchange for the MicroSelectron-HDR, radiation surveys and tests shall be performed in all areas adjacent to the treatment room with the source in the "irradiation" position to establish that (a) radiation levels in restricted areas are not likely to cause personnel exposure in excess of the limits specified in Section 20.101, Title 10, Part 20, Code of Federal Regulations, Chapter 1, "Standards for Protection Against Radiation", and that (b) quantities of radiation in unrestricted areas do not exceed the limits specified in Section 20.105(b) 10 CFR 20.

    Contrary to the above, the licensee did not perform radiation surveys and tests in all areas adjacent to the treatment room subsequent to each source exchange for the MicroSelectron-HDR as required. Specifically, radiation surveys and tests were not performed in all areas adjacent to the treatment room subsequent to source exchanges conducted since the initial installation of the MicroSelectron-HDR on September 13, 1988, including exchanges conducted in July 1989, October 1989, January 1990, April 1990, July 1990, October 1990, January 1991, and April 1991.

    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 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.

MAY 16 1991
Dated

William Sylla for
John A. Grobe, Chief
Nuclear Materials Safety Branch