Appendix

NOTICE OF VIOLATION

University Hospitals of Cleveland License No. 34-05469-01

As a result of the inspection conducted on August 9 and 10, 1982, and in accordance with the NRC Enforcement Policy, 47 FR 9987 (March 9, 1982), the following violations were identified:

1. License Condition No. 20 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 letter dated June 23, 1978, with enclosed application dated August 26, 1977, states in the Radiation Safety Program manual, Section F that:

   a. The Radiation Safety Officer will conduct surveys at least twice per year of all areas where radioisotopes are received and used.

   b. All elution, preparation and injection areas will be surveyed daily.

   Contrary to the above, these surveys were not conducted as required. Specifically:

   a. The R.S.O. has not surveyed at least twice per year all laboratories using radioactive material. For examples, room 471, Rainbow Babies and Children, and rooms 312 and 201, Pathology have not been surveyed since September 1981.

   b. The radioisotope laboratory for Nuclear Medicine which is used for elution, preparation and injection of radioactive material was not surveyed on the following occasions, July 5, 8, 12-15, 20, 23, 27, and 28-30, 1982, in addition to many other occasions.

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

2. 10 CFR 20.301 states no licensee shall dispose of licensed material except:

   a. By transfer to an authorized recipient as provided in the regulations in Parts 30, 40, 60, 70 or 72 of this chapter, whichever may be applicable; or

b. As authorized pursuant to 20.302; or

c. As provided in 20.303, applicable to the disposal of licensed material by release into sanitary sewerage systems, or in 20.306 for disposal of specific wastes, or in 20.106 (radioactivity in effluents to unrestricted areas).

Contrary to the above, the licensee has allowed its users of radioactive material to dispose of licensed material in a dry trash compactor with limits of 14 microcuries per box for iodine-125 and 25 microcuries per box for hydrogen-3. This method of disposal is not authorized under the above referenced regulations.

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

3. License Condition No. 20 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 letter dated June 23, 1978, with enclosed application dated August 26, 1977, states in the Radiation Safety Program manual, Section D, Page D-A2, Item C.3 requires wearing personnel monitoring devices (film and ring badges) provided.

Contrary to the above, on August 10, 1982, an individual, who was not wearing an assigned finger badge, was observed handling and preparing radiopharmaceuticals.

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

4. License Condition No. 14.B states each sealed source containing licensed material, other than hydrogen-3, with a half-life greater than thirty days and in any form other than gas shall be tested for leakage and/or contamination at intervals not to exceed six months.

Contrary to the above, a 14 millicurie americium-241 sealed source as not been leak tested since its receipt in April 1981.

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

5. License Condition No. 20 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 letter dated June 23, 1978, with enclosed application dated August 26, 1977, states in the Radiation Safety Program manual that air flow rates in xenon use areas will be checked and recorded every six months.

Contrary to the above, air flow rates have not been measured in xenon use areas since July 31, 1981.

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 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.

Dated 8/26/82

D. J. Sreniawski

D. J. Sreniawski, Chief
Materials Radiation Protection
Section 2