NOTICE OF VIOLATION

University of Michigan
Ann Arbor, Michigan

License No. 21-00215-04
Docket No. 030-01988
License No. 21-00215-06
Docket No. 030-06958
License No. SNM-1835
Docket No. 070-02864

As a result of the inspection conducted on March 12-22, 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:

License No. 21-00215-04

1. 10 CFR 20.301 requires that no licensee dispose of licensed material except by certain specified procedures.

   Contrary to the above, on February 14, 1990, March 6, 1990, and March 20, 1990, disposable diapers containing microcurie quantities of iodine-131 were sent for disposal to the normal trash, a method not authorized by 10 CFR 20.301.

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

2. 10 CFR 71.5(a) requires that licensees who transport licensed material outside the confines of their plants or deliver licensed material to a carrier for transport, comply with the applicable requirements of the regulations appropriate to the mode of transport, of the Department of Transportation (DOT) in 49 CFR Part 170-189.

   A. 49 CFR 172.200(a) requires that except as otherwise provided in this subpart, each person who offers a hazardous material for transportation shall describe the hazardous material on the shipping paper in the manner required by this subpart.

   B. 49 CFR 172.403 requires that each package of radioactive material, unless excepted from labeling by 173.421 or 173.422, be labeled, as appropriate, with a RADIOACTIVE WHITE-I, a RADIOACTIVE YELLOW-II, or a RADIOACTIVE YELLOW-III label.

      Contrary to the above, since at least 1988, the licensee has routinely transported iodine-131 and iodine-125 radiopharmaceuticals on public roads from the Phoenix Memorial Laboratory to University Hospital and did not properly label packages or prepare shipping papers for these transfers.

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

3. 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 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 the day of the inspection, the School of Public Health, Engineering Bay contained approximately 400 millicuries of carbon-14, which was not secured from unauthorized removal and was not under constant surveillance and immediate control of the licensee.

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

License No. 21-00215-06

4. License Condition No. 16 requires that licensed material be possessed and used in accordance with the statements, representations, and procedures contained in certain referenced documents.

   The referenced November 19, 1973 and March 27, 1979 letters require that the irradiator pool water be checked every six weeks for conductivity.

   Contrary to the above, since at least 1988, the irradiator pool water has not been checked for conductivity.

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

License No. SNM-1835

5. License Condition 12.A.(1) states that the source specified in Item 7.A. shall be tested for leakage and/or contamination at intervals not to exceed six months.

   Contrary to the above, the licensee failed to test a sealed source for leakage and/or contamination at intervals not to exceed six months. Specifically, between May 25, 1989 and March 8, 1990, a leak test of the sealed plutonium/beryllium neutron source was not performed.

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

With respect to Items 2 and 3, the inspection showed that actions had been taken to correct the identified apparent violations and to prevent recurrence. Consequently, no reply to these apparent violations is required and we have no further questions regarding these matters. With respect to Items 1, 4, and 5, 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.

Dated

Charles E. Norelius, Director
Division of Radiation Safety
and Safeguards

CONCERNS/RECOMMENDATIONS

As a result of the inspection conducted March 12-22, 1990, the following concerns/recommendations were identified as indicators of performance which, if unchecked, may lead to health and safety problems.

NRC Inspection Findings

Two general concerns were identified with regard to the University - wide radiation safety program. First, there appears to be an acute shortage of technically trained personnel in the Radiation Safety Service (RSS) group. It appears that RSS needs at least two additional technicians to maintain continued control over the program. Although the program is generally meeting regulatory requirements at this time, significant delays in processing wastes were identified.

The second concern pertains to the University's waste disposal future. By 1993, the Midwest Low-Level Waste Compact is required to construct a regional waste disposal facility, slated for Michigan. The licensee plans to build a waste handling facility on the North Campus. The inspectors recommended that this project should be expedited in the event storage of waste is required, pending completion of the Compact facility.

With respect to the individual licenses, the following findings were addressed at the exit interview:

License No. 21-00215-04: A number of concerns were identified: The dose calibrator used in the Phoenix Memorial Laboratory to verify doses prior to distribution should be calibrated in accordance with 10 CFR Part 35 and/or Regulatory Guide 10.8.

The licensee was informed that the broadscope license references at least three different (contradictory) frequencies for the implementation of the radioiodine bioassay program. The licensee was advised to evaluate the program with the NRC licensing staff (Section VI(A)(5)).

The licensee was asked to reevaluate their procedures and techniques for performing radiation surveys of unrestricted areas around patient rooms that contain patients with therapeutic quantities of iodine-131. This evaluation is requested to demonstrate that additional area surveys are not necessary due to room shielding (Section VI(A)(1)).

The licensee needs to reevaluate the incinerator air effluent waste streams to better define air quality around the incinerator building. An unrestricted area is claimed on the ground around the incinerator building and downwind from the building. The inspectors did not dispute this claim, but asked the licensee to perform air sampling to verify the air quality. A concern was also raised regarding the sharing of facilities with waste operations by University maintenance personnel (Section VI(A)(11)).

The water used for storage of two californium-252 sources at the Willow Run Labs has not been tested for water quality (conductivity, turbidity, chlorides, etc.) for several years. Poor water quality may lead to source degradation (Section VI(A)(1)).

An illuminated "Caution-Radiation" warning sign at the Willow Run Labs needs repair/replacement (Section VI(A)(8)).

Control of nuclear medicine doses in the radiopharmacy needs tighter controls. Prepared doses are currently left in the pickup window area which could lead to unauthorized removal (Section VI(A)(9)).

The waste drums maintained at the Willow Run storage facility show deterioration from exposure to the elements (Section VI(A)(11)).

License Condition No. 10.A should be updated to properly reflect the areas of use of licensed materials at the University. Specifically, Willow Run Labs is located in Belleville, Michigan, rather than Ypsilanti, 1919 Green Road should be added as a use area and the Environmental Research Institute should be deleted.

Licensee management was advised that a sludge sample was taken from the Ann Arbor Waste Water Treatment Plant and is being analyzed by the licensee for a determination of radionucide reconcentration. (See Section VI(A)(11)).

License No. 21-00215-05

One concern was identified: Audits of daily quality control checks should be instituted to ensure compliance with protocols (Section VI(B)).

License No. 21-00215-06

No concerns were identified.

License No. SUD-1398

One concern was identified: Observation of one uranium slug stored in the subcritical assembly showed it to be physically distorted. The slugs should all be thoroughly examined to determine cause and potential generic implications and the distorted slug should be isolated and disposed of (Section VI(D)).

License No. SNM-179

One concern was identified: In April 1985, a researcher may have ordered and received neptunium-237 in a form not authorized by the research protocol (Section VI(E)).

License No. SNM-1377

No concerns were identified.

License No. SNM-1529

One concern was identified: The closure ring on the plutonium/beryllium source drum needs replacement (Section VI(G)).

License No. SNM-1835

No concerns were identified.

Other Agency Findings

Two representatives from the U.S. Environmental Protection Agency (EPA) visited the campus on March 13, 1990, and reviewed the incineration procedures and practices at the North Campus pathological incinerator. This review addressed compliance with the agency's proposed rule changes in the EPA clean air standards. Their findings and recommendations were discussed with Mr. Mark Driscoll and his staff on March 13, 1990. The EPA is concerned that the University's North Campus incinerator may not meet requirements of proposed EPA radionuclide emission standards. A copy of their report is attached to this report (see Attachment 1).

A representative from the Michigan Department of Health, Division of Occupational Health toured the campus on March 13, 14, and 15, 1990, and reviewed various work place safety procedures and worker injury reports. His findings and recommendations were discussed with Mr. K. Schatzle and his staff on March 15, 1990. Their findings identify the need for a comprehensive emergency response plan for the University. A copy of this report is attached to this report (see Attachment 2).

A representative from the U.S. Food and Drug Administration (FDA) visited the Phoenix Lab on March 14 and 15, 1990, and reviewed the manufacturing and distribution procedures of two products (NP59 and NP292). The findings and recommendations of this inspection were discussed with Neil Petry, R.Ph., on March 15, 1990. A copy of the report is attached to this report (see Attachment 3).