U.S. NUCLEAR REGULATORY COMMISSION

REGION III

Report No. 030-01609/90001(DRSS)

Docket No. 030-01609

License No. 13-02752-03 Priority I Category G1

Licensee: Indiana University
541 Clinical Drive
Indianapolis, IN 46223

Inspection Conducted: November 14 and 15, 1990

Purpose of Inspection: Routine unannounced safety inspection to determine compliance with Commission rules, regulations and license conditions.

Inspector: Toye L. Simmons 12/21/90
Toye L. Simmons Date
Radiation Specialist

Approved By: William H. Schultz 12-21-90
William H. Schultz, Chief Date
Nuclear Materials Safety
Section 1

Inspection Summary

Inspection on November 14 and 15, 1990 (Report No. 030-01609/90001(DRSS))
Areas Inspected: Routine unannounced safety inspection which included a review of the organizational structure; program audits; materials; personnel radiation protection; waste disposal and independent inspection effort. This is inspection targeted the brachytherapy and research programs.
Results: Within the scope of this inspection, two apparent violations of NRC requirements were identified: (1) License Condition No. 11 - unauthorized Chairman of the Radionuclide Radiation Safety Committee; and (2) 10 CFR 19.11(a) and License Condition No. 29 - failure to post Parts 19 and 20, license and license documents in nine use labs.

DETAILS

1. Persons Contacted

*Robert Welty, Director of Planning, School of Medicine
*Mack Richard, Radiation Safety Officer
*Jeffery Mason, Assistant Radiation Safety Officer
Stephanie Frost, Physicist
Linda Pratt, Research Authorized User
Raoul Rosenthal, Research Permit Holder
Peter Roach, Research Permit Holder

*Denotes those present at the exit meeting held on November 14, 1990.

2. Inspection History

Indiana University was last inspected on February 15 and 16, 1989. One violation of NRC requirements was identified: 10 CFR 35.59(g) - calibration source inventory records did not contain the required information.

3. Organization

Dr. Gerald Bepko is the Vice President of Indiana University; Walter Daly, M.D. is Dean of the School of Medicine; Robert Welty is the Director of Planning, School of Medicine; Dr. Byron Batteiger serves as the Chairman of the Radionuclide Radiation Safety Committee (RRSC) and Mack Richard is the Radiation Safety Officer (RSO).

During the course of this inspection it was learned that the individual serving as Chairman of the Radionuclide Radiation Safety Committee was replaced after the February 1989 inspection and the license was not amended to reflect this change. This is in violation of License Condition No. 11 which specifically names the replaced individual as Chairman of the RRSO.

One violation of NRC requirements was identified.

3. Licensed Program

License No. 13-02752-03 authorizes the possession and use of any byproduct material identified in 10 CFR Part 35 and Atomic Nos. 3 to 83 for medical diagnostic, therapeutic and research purposes; and for pure research and development. Radiation Safety Office staff consists of three health physicists, one technician, and two secretaries. The RRSC has approved approximately 130 individuals as Permit Holders. This number includes physicians who staff the various hospital nuclear medicine and oncology departments associated with the University.

For research purposes, the most commonly used byproduct material is tritium, carbon-14, iodine-125, phosphorus-32 and sulfur-35 in low

millicurie or microcurie quantities. Iodinations are performed in designated fume hoods. The licensee has an active brachytherapy program which averages one and one half to two implants per week using primarily cesium-137.

No violations of NRC requirements were identified.

4. Internal Audits

The Radiation Safety staff performs quarterly audits of each research laboratory where radioactive materials are used. These audits include a series of swipe tests, direct radiation surveys, and reviews of required laboratory records. Identified violations are brought to the attention of the Permit Holder for resolution. Repeat violators are brought to the attention of the Radionuclide Radiation Safety Committee for corrective action and/ or discipline.

Monthly audits are performed in each nuclear medicine department.

A random review of 1990 records revealed that laboratory audits have been performed as required.

No violations of NRC requirements were identified.

5. Materials

The licensee's facilities appear to be as described in the applications and letters referenced in License Condition No. 29 and isotopes, chemical form, quantities, and use appear to be as authorized.

Radioactive Material Control: Requests for radioactive material are sent to the radiation safety office where they are verified and ordered. With the exception of molybdenum-99 generators which are delivered directly to the nuclear medicine departments, most other byproduct material is received by the radiation safety office where it is surveyed and/or swiped and logged into the Permit Holders inventory. A computerized inventory listing can be easily generated to assure that byproduct possession limits are not exceeded. However, all radioactive materials possessed have not been added to the inventory. For example, the inventory generated on November 14, 1990 did not list americium-241 (Am-241), during a tour of the lead storage area, it was learned that the licensee did possess a nominal 20 millicuries of Am-241. A complete inventory is expected once the licensee's new computer program is fully implemented.

As an additional method of control, a "waste day" has been established once each week. Each laboratory brings their waste to a central location where it is received and processed by members of the radiation safety staff.

Brachytherapy Program: The licensee conducts an active brachytherapy program averaging one to two implants per week utilizing primarily cesium-137. According to records and discussions with a physicist the inspector learned that prescriptions are written by a physician prior to

the start of treatment. The inspector noted a minor discrepancy in the prescription for a patient undergoing a vaginal implant. One physician prescribed the vaginal implant at 0.5 centimeters. Directly under the first prescription, a different physician prescribed a more precise treatment of 2000 Rads at 1.0 centimeter from the second source, however, this prescription was unsigned. The patient was treated according to the second prescription. The discrepancy in treatment depths and the lack of the prevailing physician's signature was discussed with the Radiation Safety Officer, oncology physicists and at the exit meeting. Based upon a review of other patient charts it appears that physicians routinely sign or initial prescriptions. Therefore, this does not appear to be a generic issue.

When afterloading devices are used, treatment planning is performed before the patient is implanted. Initial dose calculations are generally performed by a dosimetrist and independently checked by another dosimetrist or a physicist before treatment commences.

The program appears to be adequately staffed.

No violations of NRC requirements were identified.

6. Personnel Radiation Protection

A NVLAP accredited dosimetry vendor is used to monitor the exposures of nearly 1000 individuals at the University's various locations of use. Approximately 800 of those badged work with or around byproduct material. Film badges and extremity TLD's are exchanged monthly and reports are reviewed by the radiation safety staff monthly. Quarterly exposures are reviewed by the RRSC as required. The NRC inspector reviewed external exposure records for the periods of January 1989 through September 1990, the records disclosed that exposures were below 10 CFR Part 20 limits. The maximum 1989 whole body and extremity exposures noted were 700 millirem and 5150 millirem respectively. The maximum 1990 whole body and extremity exposures noted were 190 millirem and 5380 millirem respectively.

Potential for exposure to airborne radioactivity exists on a limited scale. Individuals handling millicurie amounts of iodine-131 receive a thyroid bioassays in accordance with methods and frequencies described in License Condition No. 29. Iodinations are performed by four individuals who generally use less than 10 millicuries per procedure. Thyroid bioassays performed on these individuals are commensurate with the frequency of the procedure. The inspector reviewed the records of thyroid bioassays performed on the most active user of iodine and the results were well within 10 CFR Part 20 and ALARA limits.

Laboratory fume hood flow rates are checked at least annually.

No violations of NRC requirements were identified.

7. Waste Disposal

The licensee disposes of radioactive waste by a variety of authorized

methods. Short-lived material is held for decay and surveyed prior to disposal into the normal trash. The radiation safety staff handles the disposal of liquid waste into the sanitary sewer via a designated sink in the waste room. Long-lived material and liquids not suitable for sewer disposal are transferred to a waste broker.

Incineration has not been used as a method of disposal since the last NRC inspection in 1989.

No violations of NRC requirements were identified.

8. Observations

The NRC inspector visited several laboratories, the brachytherapy preparation and storage room, the lead room, and the waste storage rooms. The inspector also visited two patient rooms, one patient had received 105 millicuries of iodine-131 and the second patient had been implanted with 40 mq Raeq (approximately 100 mCi) of cesium-137.

Room surveys had been performed as required and radiation levels in adjacent areas were within NRC and license limits.

The inspector toured eleven laboratories where radioactive material is used and/or stored. During the tour the inspector randomly reviewed survey and swipe records, checked survey instruments for operation, observed postings and interviewed personnel. The inspector observed that in nine of the eleven laboratories visited, 10 CFR Parts 19 and 20, the license and the license documents were not posted. License Condition No. 29 references application dated April 9, 1985, which states in Item 15 I.A. that all areas where radionuclides are used and stored will be posted in accordance with 10 CFR 19.11. 10 CFR 19.11(a) requires each licensee to post current copies of Parts 19 and 20 and the license, and the license documents. Failure to post the require documents is in violation with License Condition No. 29.

During a tour of the lead room, a room used to store mainly sealed sources, it was learned that the lock had been changed without the radiation safety staff's knowledge or consent. The room was posted as containing radioactive material. This matter was discussed during the exit meeting. It was suggested that the individuals such as the locksmiths and maintenance be reminded that the radioactive storage rooms in the Clinical Building are not to be changed, re-keyed or otherwise tampered with without the consent of the Radiation Safety Officer.

One violation of NRC requirements was identified.

9. Exit Meeting

At the conclusion of the inspection on November 15, 1990, the inspector met with the individuals identified in Section 1 of this report. A summary of the scope and findings of the inspection, recommendations, and observations were discussed. No information included in this report was identified as proprietary by the licensee.