

U. S. NUCLEAR REGULATORY COMMISSION

REGION III

Report No. 030-18286/90001(DRSS)

Docket No. 030-18286

License No. 48-11805-02

Category Ela

Priority II

Licensee: Hazelton Laboratories America, Inc.
3301 Kinsman Blvd.
Madison, Wisconsin 53707

Inspection Conducted: August 27-29, 1990

Purpose of Inspection: Routine, announced safety inspection to determine compliance with Commission rules, regulations, and license conditions, and to review the circumstances surrounding a reported loss/theft of a nominal 20 millicuries of carbon-14.

Inspector:

T. L. Simmons
T. L. Simmons
Radiation Specialist

October 3, 1990
Date

Approved By:

William H. Schultz
William H. Schultz, Chief
Nuclear Materials Safety
Section 1

10-12-90
Date

Inspection Summary

Inspection on August 27-29, 1990 (Report No. 030-18286/90001[DRSS])

Areas Inspected: This routine safety inspection included a review of the licensee's organizational structure; scope of program; audits; training programs; materials; facilities; receipt and transfer of byproduct materials; personnel radiation protection - internal; personnel radiation protection - external; waste disposal; posting and labeling; and independent measurements. In addition to the routine program, the inspector reviewed the circumstances surrounding the loss/theft of 20 millicuries of carbon-14 as reported to the NRC in licensee letter dated July 18, 1990.

Results: Within the scope of this inspection, no violations of NRC requirements were identified:

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DETAILS

1. Persons Contacted

- *Robert Conway, General Manager
- *Robert Daun, Chairmen, Radiation Safety Committee
- *Dee Ann Kaiser, Radiation Safety Officer
- *Deborah Keller, Manager - Quality Assurance Unit
- Mark Johnson, Assistant Radiation Safety Officer
- William Hamilton, Facilities Planning and Development Manager
- R. James Puhl, Authorized User
- Dale Sharp, Authorized User
- Mary Jane Bull, Research Associate
- Sue Payne, Research Associate
- Greg Puent, Senior Laboratory Assistant

*Present at exit meeting on August 29, 1990.

2. Inspection History

The license was last inspected in February 1989. Two violations were identified: (1) failure to monitor incinerator ash prior to disposal; and (2) failure to maintain fumehood face velocity up to a minimum of 100 FPM.

3. Organizational Structure

Robert E. Conway is the Corporate Vice President and General Manager; Robert J. Daun serves as Chairman of the Radiation Safety Committee (RSC) and Dee Ann Kaiser serves as the Radiation Safety Officer (RSO).

No violations of NRC requirements were identified.

4. Licensed Program

The license authorizes any byproduct material with Atomic Nos. 1 to 83 for use in research and development as defined by 10 CFR 30.4(q) and for human and animal research. The RSC has currently approved 17 individuals as authorized users.

Ninety percent of all byproduct material received by the licensee is supplied by clients as radiolabeled product. Investigation and/or testing of the product is performed in accordance with standard protocols or procedures established and approved by the client, the testing department, and the radiation safety committee.

All research and testing conducted on humans is performed under the direction of a medical physician and may entail the use of a radiolabeled product or pharmaceutical which may be ingested, injected, or applied. The licensee maintains facilities to house human subjects while fluids are collected and analyzed and examinations are performed.

No violations of NRC requirements were identified.

5. Audits

Independent confirmatory surveys for removable contamination and radiation levels of all use and storage areas have been conducted by the Radiation Safety Staff at least quarterly. Required signs, labels and postings are checked and replaced as necessary. Violations identified during these and other inspections were reported to the appropriate unit manager. The Radiation Safety Committee reviews the program on an annual basis. The review includes an examination of all records, RSO reports, written safety procedures, and management control adequacy. The 1989 annual program review results were presented to the RSC membership during their March 1990 meeting.

No violations of NRC requirements were identified.

6. Training

The Radiation Safety Staff conduct training sessions for technical and ancillary staff at least semi-annually. The last ancillary training program was held in August 1990. The RSC reviews, with the assistance of the RSO, applicant authorized users' training and experience in accordance with the requirements for a TYPE A broad-scope program.

No violations of NRC requirements were identified.

7. Materials

As stated in Section 4 of this report, at least 90% of all byproduct materials received are client-supplied radiolabeled product. In-vitro kits and nickel-63 foil sources are received directly from the supplied radiolabeled product. In-vitro kits and nickel-63 foil sources are received directly from the suppliers. According to the August 28, 1990 inventory of unsealed material, the licensee possessed 3.3 curies of carbon 14, which is the most commonly used nuclide. The combined total of all other unsealed byproduct material on hand was less than 95 millicuries. In addition, the licensee possesses a total of 900 millicuries of nickel-63 in the form of 8 to 15 millicurie gas chromatograph foil sources. Based upon a review of the 1989 and 1990 records, leak tests have been performed as required and the results were within NRC limits.

No violations of NRC requirements were identified.

8. Facilities

The licensee facilities are as stated in License Conditions No. 10 and No. 27 with the following exceptions: (a) The eighth floor tower of Meriter - Madison Hospital is no longer used for clinical research and has been released for hospital use. The appropriate close-out surveys were performed. (b) Radioactive material is no longer used in outdoor enclosures as described in section 10.6.3 in referenced application dated January 25, 1989.

No violations of NRC requirements were required.

9. Receipt and Transfer

All radioactive material received is delivered to the 3301 Kinsman Blvd. facility with one exception; radiolabeled plant materials are sent directly to the user facility. The RSO is notified before the procurement of any radioactive materials occurs. Clients and other suppliers have been instructed to send radioactive materials to the attention of the RSO. Upon arrival, the receiving department visually inspects incoming packages for signs of damage and delivers them to the Radiation Safety Office. Radiation safety personnel verify the contents, enter the material into the users' inventory and perform the appropriate surveys for potential contamination. Radiolabeled human use product is transported to the clinical research facility via a company vehicle under the supervision of the RSO.

The inspector conducted a sample review of 1989 and 1990 receipt, transfer, and survey records; the results were within NRC limits.

No violations of NRC requirements were identified.

10. Personnel Radiation Protection - Internal

The licensee does not normally use radioactive materials in sufficient quantities to require analysis for internal deposition. Since the last NRC inspection, one thyroid bioassay has been performed on an individual who used one millicurie of iodine-125. The results, in units of counts per minute, indicated that the individual did not receive an uptake. The inspector suggested that the record should include type of equipment used, reference source used, percent unit efficiency, and the final results should be in units of microcuries.

No violations of NRC requirements were identified.

11. Personnel Radiation Protection - External

The licensee provides approximately 15 employees with personnel dosimetry supplied by a NVLAP approved vendor. Whole body and TLD ring badges are exchanged monthly. A review of records from January 1989 through June 1990 revealed exposures to radiation workers well within 10 CFR Part 20 limits.

No violations of NRC requirements were identified.

12. Waste Disposal

Solid hydrogen-3 and carbon-14 waste as well as animal carcasses are disposed of by incineration. The licensee averages one burn per month and the ash residue is analysed prior to disposal in the normal trash. Carcasses and solid waste containing all other nuclides used are burned separately. The ash is held for disposal by a waste broker. The licensee decays short-lived material for 10 half-lives and conducts the appropriate surveys prior to disposal in the normal trash.

Radioactive wastes disposed to the sanitary sewer appear to satisfy the requirements of 10 CFR 20.303.

13. Independent Measurements

Radiation level measurements made by the inspector were performed with a Ludlum 14C, NRC No. 013158, calibrated May 3, 1990. Radiation levels were found to be well within 10 CFR Part 20 limits for restricted and unrestricted areas.

14. Carbon-14 Incident

In addition to the routine program, the inspector reviewed the licensee's actions concerning the reported loss of 20 millicuries of carbon-14 labeled product (see attached licensee report dated July 18, 1990).

In summary, the licensee received two shipments of carbon-14 labeled product, 8.49 millicuries on June 28, 1989 and 12.30 millicuries on March 7, 1990. The material was discovered missing on June 4, 1990. According to the departmental supervisor, the material was last accounted for in April 1990. To date the material has not been recovered.

The licensee's actions included an intensive search of all laboratories, swipe tests of areas where material is used and stored, interviews with personnel, a comprehensive physical inventory and a press release in two local newspapers. There was no response to the press release and no new information has been learned. Due to circumstances which occurred just before June 1990, it appears that the material was stolen as retaliatory action against the licensee by someone who knew that testing was scheduled to begin. The licensee has notified the local police.

The material was stored in a restricted area which was properly posted and with no access to the general public.

No violations of NRC requirements were identified.

15. Exit Meeting

At the conclusion of the inspection on August 29, 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. In addition, the inspector addressed the new regulation 10 CFR 30.35, which requires the licensee to submit a decommissioning funding plan. To date the licensee has not submitted the required plan; however, according to the RSO their plan is currently waiting for corporate office approval.

No information included in this report was identified as proprietary by the licensee.

Attachment: Licensee Incident Report
dated July 18, 1990