

U.S. NUCLEAR REGULATORY COMMISSION  
OFFICE OF INSPECTION AND ENFORCEMENT

REGION I

Report No. 030-15048/85-01

Docket No. 030-15048

License No. 18-18420-01

Priority 3

Category E

Licensee: Foundation for Blood Research  
P. O. Box 190  
Scarborough, Maine 04074

Facility Name: Foundation for Blood Research

Inspection At: Scarborough, Maine 04074

Inspection Conducted: June 24, and July 1, 1985

Inspector: Thomas K. Thompson  
Thomas K. Thompson, Health Physicist

8/21/85  
date

Approved by: John E. Glenn  
John E. Glenn, Chief, Nuclear Materials  
Safety Section B

8/21/85  
date

Inspection Summary: Routine Safety Inspection/Conducted June 24 and July 1, 1985

Areas Inspected: Organization; Radiation Protection Procedures; Use of Materials; Storage of Materials; Facilities; Instruments; Receipt and Transfer of Material; Personnel Protection - External; Personnel Protection - Internal; Effluent Controls, Waste Disposal; Posting of Notices; Transportation. The inspection involved 4 staffhours by one NRC inspector. The inspection was performed during regular hours.

Results: Four apparent violations were identified: Release of byproduct material to the sewer system in excess of 10 CFR 20, Appendix B limits; failure to follow laboratory swipe survey frequencies; failure to follow laboratory procedures with respect to wearing laboratory coats; failure to package byproduct material as required by 10 CFR 71.5.

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## DETAILS

### 1. Persons Contacted

\*George J. Knight, Ph.D., Director, Radioimmunoassay Laboratory and  
Radiation Safety Officer  
June McCarthy, Technician  
Roberta Adams, Supervisor of Cellular Immunology

\*Exit Interview Attendees

### 2. Licensee Action on Previous Inspection Findings

No prior inspection history.

### 3. Organization

The Radiation Safety Officer (RSO) stated that the laboratory's primary use of byproduct material involved I-125. The RSO stated that iodinations were performed for the Foundation for Blood Research by Ventrex Laboratories, Incorporated, under NRC License No. 18-17303-01.

### 4. Radiation Protection Procedures

Interviews with a licensee technician and the RSO indicated security and operating procedures were being generally followed, except that laboratory coats were not always worn when handling byproduct material.

The finding that laboratory coats are not always worn is an apparent violation of License Condition 14.

### 5. Use of Materials

Procurement and use of materials records were reviewed and found to be in accordance with regulatory requirements.

No violations of NRC rules, regulations or license conditions were identified.

### 6. Storage of Materials

The inspector observed during laboratory visits that licensed materials were apparently secured when unattended. Licensed materials observed not to be in storage were under the licensee's constant surveillance and control.

No violations of NRC rules, regulations or licensee conditions were identified.

7. Facilities

The inspector observed that facilities appeared to be as described in the license application.

No violations of NRC rules, regulations or license conditions were identified.

8. Instruments

Appropriate, calibrated survey instruments were observed by the inspector.

No violations of NRC rules, regulations or license conditions were identified.

9. Receipt and Transfer of Material

The RSO stated that most byproduct material is obtained by transfer of labeled compounds prepared at Ventrex Laboratories, Inc., to the Foundation for Blood Research. The RSO stated that he transports the material himself.

No violations of NRC rules, regulations or license conditions were identified.

10. Personnel Protection - External

The inspector reviewed monthly film badge records and found exposures to be minimal. Film badges were being exchanged regularly as required.

No violations of NRC rules, regulations or license conditions were identified.

11. Personnel Protection - Internal

The inspector noted the licensee had not performed wipe test of the by-product materials laboratory on a monthly basis between February 28, 1985, and June 2, 1985.

The finding that wipe tests were not performed on a monthly basis from February 28, 1985 to June 2, 1985 is an apparent violation of License Condition 14 .

12. Effluent Controls, Waste Disposal

The licensee stated that decay in storage and release to the sanitary sewer are the primary means of waste disposal. The inspector noted discrepancies between the limits calculated for releases to the sanitary sewer, and the actual quantities released. Specifically, the licensee's records indicated that they frequently exceeded the daily release limit

specified in 10 CFR 20, Appendix B, for I-125, and in two instances by 10 times the limit specified in 10 CFR 20, Appendix C. The licensee's records for August 11, 1981, indicated they released 2200 microcuries that day. Records for August 30, 1984, indicated 1212 microcuries of I-125 were released to the sanitary sewer. The licensee's calculated maximum daily limit for release of I-125 was 120 microcuries.

Subsequent to this inspection and in response to NRC's letter dated June 26, 1985, (Enclosure 1) the licensee provided a revised set of calculations based on actual operating conditions at the facility (Enclosure 2). The revised calculations resulted in the determination that the August 11, 1981 release was only 1100 microcuries, after correcting for decay. Further, the maximum daily release limit was calculated to be 292 microcuries. As a result, it is apparent that concentrations of iodine-125 released have exceeded the daily release limits to the sanitary sewer by less than 5 times the limit. The licensee committed to limit all releases of I-125 to the sanitary sewer to the daily limits of 10 CFR 20.303(b).

The finding that licensed material (iodine-125) was released to the sanitary sewer in quantities which, when diluted by the average daily quantity of sewage released by the licensee, exceeded the concentration specified in 10 CFR Part 20, Appendix B, Table I, Column 2 and which exceeded ten times the activity listed in Appendix C of 10 CFR 20, is an apparent violation of 10 CFR 20.303(b).

### 13. Posting of Notices

All notices required to be posted were observed by the inspector to be posted.

No violations of NRC rules, regulations or license conditions were identified.

### 14. Transportation

The licensee transports I-125-labeled compounds in a private car. The inspector requested a copy of shipping papers for a typical shipment (Enclosure 4). The inspector noted that byproduct material intended for shipment appears to qualify for a limited quantity shipment as specified in 49 CFR 173.421-1. Limited quantities must have a notice forwarded with the package which includes the name of the consignor or consignee and the statement "This package conforms to the conditions and limitations specified in 49 CFR 173.421 for excepted radioactive material, limited quantity, N.O.S. UN2910." The licensee did not include the required statement and notice.

The finding that the licensee failed to properly prepare the shipping papers is an apparent violation of 10 CFR 71.5.

15. Exit Interview

The purpose, scope and results of the inspection were discussed with Dr. Knight.

At no time during the inspection was written material provided to the licensee by the inspector.