

U.S. NUCLEAR REGULATORY COMMISSION

REGION II

Docket No.: 030-04001

License No.: 10-06772-01

Report No.: 10-06772-01/97-01

Licensee: U. S. Department of Health and Human Services
Public Health Service
Centers for Disease Control

Location: Atlanta, Georgia

Date: ~~March~~ ^{May} 21-23, and 27, and June 2, 1997

Inspectors: Orysia Masnyk Bailey, Radiation Specialist
Lee Franklin, Radiation Specialist

Approved by: John P. Potter, Chief
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Division of Nuclear Materials Safety

Enclosure 1

EXECUTIVE SUMMARY

U. S. Department of Health and Human Services
Public Health Service, Centers for Disease Control
NRC Inspection Report No. 10-06772-01/97-01

This routine, unannounced inspection was conducted to evaluate the Centers for Disease Control's radiation safety program. The inspection included discussions with licensee representatives, reviews of documents, and direct observations of licensed activities. The inspection included a review of management oversight, organization and scope of the program, facilities, equipment and instrumentation, materials, training, area radiation and contamination control, radiation protection, waste management, transportation, and posting and labeling. The report covers operations conducted by the licensee between April 1, 1995 and May 23, 1997. Several apparent violations of regulatory requirements and/or licensee procedures were identified.

Management Oversight

The licensee's radiation safety function is organized within the Occupational Health and Safety organization. The licensee recently added an Occupational Health and Safety Specialist to the staff. A contractor employee is also available to the staff. The licensee has been cited for recurring violations over the past several years. Corrective measures for these violations seem to be inadequate in that they fail to address the root causes and the lack of internal controls to ensure adherence to license conditions. This appears to be indicative of a lack of management oversight of the radiation safety program.

Organization and Scope of the Licensee Program

The licensee utilizes licensed materials in various laboratories located throughout several buildings at two separate facilities. The material is used for research and development. This is a broad scope license allowing for multiple uses and users of various radionuclides and amounts. The licensee relies on the Radiation Safety Committee to grant authorization for material use and approved authorized users. The licensee authorizes persons to possess licensed material via authorized user forms, which list amounts that can be purchased and total amounts that may be kept. If the total authorized amounts to be kept on hand are summed, they exceed the license possession limits. However, at the time of the inspection, the licensee was within license material limits.

Facilities

The licensee conducts licensed activities in various laboratories located in buildings at both the Clifton Road and Chamblee locations. The facilities were found to be as described in the license application.

Equipment and Instrumentation

The licensee was previously cited violations, in 1993 and 1995, for failing to ensure that all survey meters were calibrated annually. During this inspection, the inspector observed instruments out of calibration in two laboratories. This was identified as an apparent violation, the third consecutive repeat.

Materials

There were two apparent violations identified in this area. The licensee, in its Radiation Safety Manual (RSM), requires an inventory of the radioactive materials on hand every four months. The licensee failed to perform this inventory for the past two years, in that it does not sum the total materials on hand and does not inventory the radioactive waste. In August 1993, a violation was issued for failure to perform inventory of various materials. The second apparent violation involves the security of licensed material. The inspector found several examples where licensed material was not secured from unauthorized removal or use.

Training, Retraining, and Instructions to Workers

Licensee personnel were trained in accordance with license conditions. They receive training commensurate with their involvement in licensed activities. There is no requirement for annual refresher training. Ancillary staff receive radiation safety training prior to working in controlled areas.

Area Radiation and Contamination Control

Authorized users are responsible for performing weekly area radiation surveys and contamination smears. Surveys are also performed after the completion of any experiment involving the use of radionuclides. A contractor performs quarterly surveys and smears. There is a weakness in this area in that it is possible for persons to "take over" a previous radiation work zone without adequate surveys having been accomplished. The quarterly surveys may not be timely enough to detect radioactivity prior to turning an area over for unrestricted use.

Personnel Radiation Protection

The licensee's monitoring program was found to be adequate. No overexposures were identified, and the licensee's As Low As Reasonably Achievable (ALARA) practices were observed by the inspector and appeared to be effective in reducing radiation exposure to personnel.

Radioactive Waste Management

The inspector found that the licensee adequately maintained radioactive material waste for decay-in-storage and/or properly disposed of waste in accordance with NRC regulatory requirements.

Transportation

The inspector found that transportation activities involving licensed materials, specifically radioactive waste, were conducted in accordance with NRC and Department of Transportation (DOT) regulatory requirements.

Posting and Labeling

Radioactive material use areas were observed by the inspector and were found to be properly posted/labeled with radiation hazards clearly identified. The licensee's RSM requires that radiation warning labels and signs be removed when no longer required. The inspector found areas posted where licensed materials had not been stored or used for two to three years. This issue is identified as an apparent violation of the licensee's procedures.

Attachment:

1. List of Persons Contacted
2. Inspection Procedures Used
3. List of Acronyms

REPORT DETAILS

01. Management Oversight (87110)

a. Scope

The inspector reviewed the licensee's organization and management oversight to determine whether the organization and staffing were as required by the license.

b. Observations and Findings

Through discussions with cognizant licensee representatives and review of records, the inspector was able to determine the following: The radiation Safety function is included within the Health and Safety Organization. The Radiation Safety Officer (RSO) reports to the Chemical and Physical Hazards Branch Chief. In addition to the RSO, the radiation safety staff consists of a Safety Technician and an Occupational Health and Safety Specialist. A contractor from Bionomics is also available to assist with the radiological waste and performs quarterly surveys of the laboratories. The licensee has a Radiation Safety Committee (RSC) consisting of representatives from the Office of Health and Safety and authorized users. The RSC reviews and approves authorized users and material usage applications. Additionally, it evaluates the adequacy of laboratories where radionuclides are used and reviews and investigates incidents as necessary.

The licensee has received recurring violations over the past several years, some of them repetitive. The licensee's corrective actions seem to be inadequate in that these violations are narrowly addressed, without the root cause being ascertained and corrected. This prevents the licensee from implementing generic controls programs to ensure adherence to license conditions and other regulatory requirements. The inventory and licensed material control problems discussed in Paragraph 05 below are demonstrative of this, as is the third consecutive repeat of the violation in Paragraph 04 below.

c. Conclusions

The licensee's organization was as described in the license application but there appears to be a lack of effective oversight of the radiation safety program.

02. Organization and Scope of the Licensee Program (87110)

a. Scope

The inspector reviewed the licensee's activities to determine whether the quantities of materials possessed and activities were as authorized in the license. NRC License No. 10-06772-01 authorizes the Centers for Disease Control (CDC) to possess: 100 millicuries of each radionuclide with atomic numbers 3-83, with a total possession limit of 5 curies, with the following exceptions:

The licensee may possess 150 millicuries of hydrogen 3, 60 millicuries of carbon 14, 120 millicuries of: iodine 125, 250 millicuries of phosphorous 32, 250 millicuries of sulphur 35, 120 millicuries of chromium 51, and 300 millicuries of nickel 63. The material can be in any chemical and/or physical form, except that the nickel 63 shall be plated sources or foil. The material is for possession and use in research and development as defined in 10 CFR Part 30.4

b. Observations and Findings

The licensee limits and controls the use of licensed materials by way of the RSC. An Authorized User Form is used to facilitate this. This form lists, among other information, the maximum amount of material that can be ordered by the user and the maximum amount of material that may be kept on hand. When the maximum amount of material that can be kept on hand for the current authorized users was totalled by the inspector, in some cases, that total exceeded the license possession limit. This was compounded by a failure to conduct an adequate inventory of licensed material. (This is discussed in Paragraph 05 below.) The Safety Technician, when informed of this, reviewed existing laboratory inventories and purchase orders and was able to demonstrate that the actual license limits were not currently exceeded. The licensee received a violation in August of 1993, for possessing 2 curies and 350 millicuries of hydrogen 3 and nickel 63, respectively, exceeding the license limits. In April 1995, the licensee received a violation for possessing 186 millicuries of hydrogen 3, exceeding the license limit.

c. Conclusions

The licensee did not have a program in place to ensure that they did not exceed license material possession limits. The corrective measures for previous violations failed to address the root cause and prevent recurrence of the violations. However, at the time of the inspection, the licensee's possession of licensed material was in accordance with the limits set in the license.

03. Training, Retraining, and Instructions to Workers (87110)a. Scope

During the inspection, the inspector discussed with licensee representatives the radiation safety training program and reviewed training records to determine if they met regulatory and license requirements.

b. Observations and Findings

The licensee's RSM discusses the need for radiation safety training for authorized users and for personnel who work under their supervision with radioisotopes. Also, the licensee provides training as required for personnel who "frequent" restricted areas, such as janitorial workers, security staff, etc... Personnel must complete the radiation safety course or have received equivalent instruction before beginning work with radioisotopes. Personnel observed during the inspection were knowledgeable of license requirements as they applied to laboratory radiation safety and use of radioisotopes. At the licensee's Chamblee facility, there are radiation work stations adjacent to non-radiation work stations within the same laboratory, i.e., there are restricted "islands" within a laboratory. Thus, the licensee must be alert to the required level of training for those personnel in adjacent areas. 10 CFR 19.12 requires training for personnel who may receive 100 mrem in the course of their employment. The licensee does not appear to violate this requirement at this time, but must remain alert to what "frequenting" a restricted area may mean. The licensee may eventually find itself in violation of the RSM since some of the staff (beyond those currently considered) may be found to "frequent" the restricted areas. The RSM states that training is provided at least twice a year, but there is no requirement for annual refresher training.

c. Conclusions

The licensee's training program is currently in accordance with license commitments, but will continue to require close monitoring of changing conditions.

04. Facilities, Equipment, and Instrumentation (87110)a. Scope

The inspector reviewed the licensee's facilities and operability and calibration of the licensee's equipment and instrumentation to determine conformance with regulatory and license requirements.

b. Observations and Findings

The inspector toured the facilities and found them as described in the license application. The Webb Gin House Road facility was not visited since the Safety Technician advised that licensed material was not used or stored there.

The inspector checked the calibration stickers on the survey instruments available for use within the laboratories and found several out of calibration. Ludlum Model 2, Serial No. 69507, was due for calibration on April 18, 1997, but was available for use in Room 2814. In Room 244, three instruments were found out of calibration, all due on April 18, 1997, and all Ludlum Model 2s, Serial Nos. 43155, 1144226, and 55591, respectively. One Ludlum Model 2 that was properly calibrated was also available in Room 244. The licensee has previously received violations in August 1993, and in April 1995, for failing to ensure that radiation meters were calibrated annually.

The licensee, in its August 17, 1992 letter to the NRC, at page 4, states that portable radiation meters are calibrated annually. This failure to ensure that all meters were properly calibrated is an apparent violation of License Condition 24.C. (EEI 10-06772-01 /97-01-01). It is the third consecutive instance of this apparent violation.

The licensee had Liquid Scintillation counters available for counting swipes for low level energy contamination. The licensee properly tested and maintained its fume hoods.

c. Conclusions

The inspector identified an apparent violation of License Condition 24.C, in that the licensee failed to ensure that survey meters were calibrated annually. This is a repeat of similar violations issued during the past two inspections.

05. Materials (87110)

a. Scope

The inspector reviewed the licensee's use and control of licensed material to determine if the licensee met regulatory requirements.

b. Observations and Findings

As discussed in Paragraph 02 above, the licensee controls the use of licensed material via the RSC, facilitated by the Authorized User Form. Authorized users must complete and submit this form to the Office of Health and Safety, for approval by the RSC. This form discusses, among other topics, the following: user's and alternate's name, location where material will be used, how security of materials will be maintained, chemical and physical

form of the radioisotope, maximum order and maximum on hand, use and disposal procedures, training of applicant, and survey procedures.

Orders for materials must be signed by an authorized user or alternate and forwarded to the Office of Health and Safety for approval. These orders are processed by Purchasing after approval. The Authorized User Form is used to verify approval. As previously mentioned, these forms could potentially allow the licensee to exceed the license limits if all authorized users were allowed to maintain the "maximum on hand" totals. Packages are surveyed after receipt to check for contamination or leakage. Receipt is logged in the radioactive logbook.

The commitments for inventory of the material are delineated in the RSM and the letter dated August 17, 1997.

The RSM, Part 1, II, F, Inventory and Records, page 11, states "An authorized user and/or designee must keep records of all radioactive materials ordered, received and disposed. These records must be reported on form CDC 0.1003 entitled "Radioisotope Inventory Report" (Appendix E). Authorized Users will forward a copy of the radioisotope inventory report form to the RSO March 1, July 1, and November 1 of each year. Attached to the inventory report form will be a copy of all the user's packing slips associated with all incoming radioactive material packages. The name and telephone number of the preparer and his/her telephone number must be clearly indicated on the form.

NOTE: Packing slips must be strictly maintained to assist in keeping an accurate inventory. To keep track of the amount of radioactive material on hand, a Radioactive Material Tally Sheet (see CDC Form 0.1159, Appendix F) should be utilized.

Inventory reports submitted on Form CDC 0.1003 must include the name of the physical/chemical form of the radioactive material, the amount (in millicuries) of radioactive waste and the net quantity (in millicuries) of the radioisotopes on hand in the laboratory. The date of the assay is required for accurately determining the exact activity on hand at that time. Authorized Users can either use the date of assay on the original container, or they can "decay correct" the material to the date of the inventory."

The RSM section above is expanded in a letter dated August 17, 1992, as follows. "The record management program for the inventories of radioactive materials on hand including receipts and disposal consists of the following components:

1. Recording data for all incoming radiation packages
2. Maintenance of the Radioisotope Inventory Report

3. Updating of the Office of Health and Safety (OHS)
Radioisotope Inventory Report...

Upon receipt of the inventory reports, the RSO verifies the activity (in millicuries) of each new radioisotope received by the radiation worker via the OHS Radioisotope Inventory Data Base. The activities of the radioisotopes on hand are verified for each worker. The activity of the disposed radioactive waste is then entered into the OHS Radioisotope Inventory Data Base. The computer program calculates the net activity of the radioisotopes on hand by subtracting the waste disposed from the laboratories."

The inspector reviewed inventory records and discussed them with the radiation safety staff and determined that the licensee does not accomplish the inventory as described. Each laboratory user completes the individual inventory forms, but the licensee does not sum all the totals for a facility total. Additionally, the licensee does not inventory the waste maintained by the radiation safety staff prior to disposal after it has left the laboratories. There is no Inventory Data Base at this time. The licensee does sum the total purchases at each four month inventory reporting period, but this does not reflect an accurate inventory of material on hand. This failure to perform an inventory of material is identified as an apparent violation of License Condition 24.B and C (EEI 10-06772-01/97-01-02). The licensee received a similar violation in August of 1993 for failing to inventory a portion of its licensed materials.

The inspector reviewed the licensee's method of securing licensed material. 10 CFR 20.1801 requires the licensee to secure from unauthorized removal or access licensed materials that are stored in controlled or unrestricted areas. 10 CFR 20.1802 requires the licensee to control and maintain constant surveillance of licensed material that is in a controlled or unrestricted area and that is not in storage. The licensee discusses the security requirements for licensed material in its RSM in Part 1, Section II, I, No. 20, page 17, as follows "Secure all radioactive materials when not under the constant surveillance and immediate control of authorized personnel." In the August 17, 1992 letter, the licensee states "Radioactive material at CDC is normally stored in refrigerators and freezers when not under the constant surveillance and immediate control of authorized personnel. These storage containers are secured with some kind of locking mechanism to ensure limited access and the proper signage as approved by the RSO is affixed."

The inspector toured the facilities, accompanied by the Safety Technician, to evaluate the security of licensed material, after reviewing the security measures listed in the authorized user form. The inspector found several examples of failure to secure licensed material from unauthorized removal as described below. This was not an exhaustive review of all material use areas.

The material log in Room 1323, Building 1, indicated that approximately 5.25 millicuries of phosphorous 32 were stored in the room. The material was in an unlocked refrigerator, in an unlocked room. The authorized user was not present, but a passerby, another authorized user, was able to locate the material in the refrigerator. The authorized user form for the authorized user indicated that the material would be in a locked refrigerator and that the room would be locked when unattended.

The material log in Room 331, Building 7, indicated that approximately 12 millicuries of chromium 51 were stored in the room. The material was in an unlocked cabinet, in an unlocked room. An individual was present in the outer room; she advised that the doors at the end of the halls were kept locked. When the inspector and technician passed through the hall, the hall door 303 (cardreader 80), was standing open. One other door, that leading to hall 236 (cardreader 166), was also found to be malfunctioning. The technician advised that the door should be locked.

The authorized user in Room B14, Building 7, was present. The inventory for that room showed a little under 5 millicuries of iodine 125. The authorized user form listed a locked refrigerator as a security measure, but no lock was provided for the refrigerator. The authorized user stated that he did not lock the laboratory door when he left during the day.

The inspector also toured Building 17 at the Chamblee facility. Observations of the storage refrigerators and discussions with workers there disclosed that the material was not stored in locked cabinets and that doors at the facility were not locked. The inventory for this building, provided by the Safety Technician, indicates 0.2 millicuries of sulphur 35 and 0.2 millicuries of iodine 125 (in kits). In some areas, radiation work stations are adjacent to clean work stations within the same laboratory.

The buildings at the CDC facilities are kept locked, the facilities are fenced, and a security force is in place to secure the perimeter. The licensee feels that these security measures, along with the disciplined work force, are adequate to provide security of the licensed materials. The work force is disciplined in that CDC personnel also work with biological and chemical hazards.

This failure to secure licensed material is an apparent violation of 10 CFR 20.1802. (EEI 10-06772-01/97-01-03). The licensee received a violation for failure to secure licensed material in April 1995.

c. Conclusion

The inspector identified two apparent violations in this area. The licensee failed to inventory the licensed material on hand

every four months as required by License Condition 24.B. and C., and failed to secure licensed material from unauthorized use or removal as required by 10 CFR 20.1801 and 1802.

06. Area Radiation Survey and Contamination Control (87110)

a. Scope

The inspector reviewed the records of radiation area surveys and contamination surveys, and discussed survey requirements with cognizant licensee and contractor personnel to determine if the licensee met regulatory and license requirements.

b. Observations and Findings

The inspector found that the licensee had used the appropriate survey instruments to perform surveys (with the exception of the instruments discussed in Paragraph 04 above) and that the surveys were performed in the manner and at the frequency described in the license application and as required by regulations. The authorized users and their staff perform surveys weekly and after experiments utilizing radionuclides. A contract employee performs the quarterly surveys of the laboratories. There is one potential weakness in this area. Discussions with radiation safety staff disclosed that the staff performs quarterly surveys "one or two times" after material use is discontinued in an area. It is possible for an individual to take over an area or piece of equipment that had previously been a restricted area without the type of survey required prior to release for unrestricted use. For example, in Building 17, at the Chamblee facility, an individual had "inherited" two refrigerators that were posted with Radioactive Materials signs. The individual said that the refrigerators had been under his control for approximately two years, and that he was not an authorized user at this time. There was no documentation to show that the refrigerators had been completely surveyed and released for unrestricted use.

c. Conclusions

The licensee was performing area surveys and contamination surveys in accordance with its license application.

07. Personnel Radiation Protection (87110)

a. Scope

The inspector reviewed the licensee's program for monitoring workers' doses to determine whether it met regulatory and license requirements.

b. Observations and Findings

The inspector reviewed licensee personnel dosimetry records for the period May 1995 to March 1997, and discussed those records with cognizant licensee personnel. Licensee personnel are issued whole body dosimetry badges that are exchanged quarterly. The inspector observed licensee personnel wearing dosimetry appropriately to detect radiation exposures from the handling and use of radioactive materials at the licensee's facilities.

c. Conclusions

The licensee was maintaining personnel radiation exposure ALARA and no NRC regulatory radiation exposure limit had been exceeded for licensee personnel.

08. Posting and Labeling (87110)

a. Scope

The inspector reviewed the licensee's program for posting warning signs and notices to workers to determine whether they met regulatory and license requirements.

b. Observations and Findings

In the RSM, Part 1, Section II, L, page 23, the licensee requires: "Authorized Users must also remove signs that are no longer needed or that have become incorrect or inappropriate for their laboratories." As discussed in Paragraph 06 above, the inspector observed an individual using two refrigerators that were posted with Radioactive Materials signs that were no longer required. This is an apparent violation of License Condition 24.B. (EEI-10-06772-01/97-01-04. The inspector observed other examples during the tour of the laboratories. Based on discussion with the technician in the area, the inspector determined that Room 11A was still posted, and that licensed material had not been used there for two to three years. An authorized user had moved from the second to the third floor in Building Seven two to three years ago and the old laboratories were still posted.

c. Conclusions

The inspector identified an apparent violation in that the licensee does not remove radiation warning signs after they are no longer needed.

09. Waste Management (87110)

a. Scope

The inspector reviewed the licensee's waste management program to determine if it met regulatory and license requirements.

b. Observations and Findings

Authorized users separate waste by isotope in the laboratories; this waste is picked up by radiation safety staff weekly or as needed. The licensee has been storing waste for decay, but recently, the waste was packaged and shipped by Bionomics personnel. The waste storage facility is a separate concrete building. Waste is protected from fire and the elements. The licensee is authorized to dispose of appropriate waste by sewer but does not do so at this time. The licensee does not incinerate waste.

c. Conclusions

The licensee maintains its waste management program in accordance with license commitments and regulatory requirements.

10. Transportation(87110)

a. Scope

The inspector reviewed the licensee's transportation practices to ensure that they were conducted in accordance with regulatory requirements.

b. Observations and Findings

The inspector reviewed shipping papers and interviewed the contractor personnel used to transport waste. The inspector was able to determine that shipping papers were completely and accurately filled out and that the contractor was cognizant of applicable transportation regulations.

c. Conclusions

The licensee conducts its waste transportation program in accordance with regulatory requirements.

EXIT MEETING SUMMARY

An exit meeting was held with licensee representatives on June 2, 1997. The overall findings from the inspection, including the apparent violations were discussed. The licensee took exception to the apparent violation involving the failure to secure licensed material from unauthorized removable or use. The licensee believed that the existing industrial security measures and disciplined population provided adequate security for the material. The licensee did not specify any information reviewed during the inspection as proprietary in nature.

ATTACHMENT

1. PERSONS CONTACTED

Centers for Disease Control

- *Thomasina M. Hargrave, Safety Technician
- *Robert Hill, Jr., Ph.D., Branch Chief, Chemical and Physical Hazards Branch
- *Janice Knight, Microbiologist Researcher
- *Sam Moye, Safety and Occupational Health Specialist
- *Antoinette Odoms, Intern
- *Nora Passmore, Contractor
- *Jonathan Richmond, Ph.D., Director, Occupational Health and Safety
- *Paul Simpson, Radiation Safety Officer
- *David Taylor, Ph.D., Deputy Director, Occupational Health and Safety

Bionomics, Inc.

Paul Nipper, Quality Assurance Manager

*Attended June 2, 1997 Exit Meeting

In addition, various laboratory staff were interviewed during laboratory tours.

2. INSPECTION PROCEDURE USED

IP 87110 Industrial/Academic/Research Programs

3. LIST OF ITEMS OPENED, CLOSED, AND DISCUSSED

<u>Item Number</u>	<u>Status</u>	<u>Description</u>
10-6772-01/97-01-01	Open	EEI - Failure to secure licensed material from unauthorized removal or use.
10-6772-01/97-01-02	Open	EEI - Failure to calibrate all portable survey instruments annually. This is a repeat violation.
10-6772-01/97-01-03	Open	EEI - Failure to perform periodic inventory.
10-6772-01/97-01-04	Open	EEI - Failure to remove unneeded signs from previously restricted areas.

4. LIST OF ACRONYMS

ALARA	As Low As Reasonably Achievable
CDC	Centers for Disease Control
DOT	Department of Transportation
RSC	Radiation Safety Committee
RSM	Radiation Safety Manual
RSO	Radiation Safety Officer
VIO	Violation