U.S. NUCLEAR REGULATORY COMMISSION
REGION I

INSPECTION REPORT

Report No. 030-04544/97-001 Program Code 03610

Docket No. 030-04544

License No. 19-07538-01 Priority 2 Category E1A

Licensee: Department of Health & Human Services
Food & Drug Administration
Center for Devices and Radiological Health
1350 Piccard Drive
Rockville, Maryland 20850

Inspection At: 1350 Piccard Drive
12709 Twinbrook Parkway
12720 Twinbrook Parkway, Buildings 1 and 2
1220 Wilkins Avenue
Rockville, Maryland

Inspection Conducted: January 6-7, 21 and February 6, 1997

Inspector: Pamela J. Henderson 2/20/97
Pamela J. Henderson date
Senior Health Physicist

Approved By: John D. Kinneman 2.20.97
John D. Kinneman, Chief date
Nuclear Materials Safety Branch 2
Division of Nuclear Materials Safety

Inspection Summary: Routine, unannounced inspection conducted on January 6-7, 21 and February 6, 1997. (Inspection Report No. 030-04544/97-001)

Areas Inspected: Organization and scope of program; management oversight; equipment and instrumentation; materials receipt and control; training; surveys and contamination control; leak tests and inventories; radiation protection; radioactive waste management; posting and labeling.

Results: Within the scope of this inspection, seven (7) apparent violations were identified:

1. Failure of the Radiation Safety Committee to meet on a scheduled basis not exceeding 3-month intervals.

2. Failure of the Radiation Safety Officer to conduct an annual audit of each approved project.

3. Failure to conduct fixed and removable contamination surveys at least once each month in laboratories where radionuclides are used.

4. Failure to provide one hour of annual training to each individual working with radioactive material.

5. Failure to review the radiation protection program content and implementation at least annually.

6. Failure to conduct a physical inventory every six months to account for all sealed sources and devices containing licensed material.

7. Failure to label each container of licensed material with a label bearing the words "CAUTION, RADIOACTIVE MATERIAL," or "DANGER, RADIOACTIVE MATERIAL."

DETAILS

1. Persons Contacted

*Elizabeth Jacobson, Ph.D., Deputy Director for Science
*Orhan Suleiman, Ph.D., Chief, Radiation Protection Branch
#*Don Thompson, Ph.D., Chair, Radiation Safety Committee
#*Edward Tupin, Radiation Safety Officer
Petro Shandruk, Consumer Safety Officer
Larry Cress, Authorized User
Russell Owen, Authorized User
Larry Bockstahler, Authorized User
Peter Goering, Authorized User
Barbara Zmudska, Authorized User
Frank Cerra, Authorized User
Abiy Desta, Biologist

Individuals present at entrance meeting
* Individuals present at exit meeting

2. Organization and Scope of Licensed Activities

The Center for Devices and Radiological Health (CDRH) is a very small Type-A broad-scope research and development licensee with multiple locations of use. CDRH has a Radiation Safety Committee (RSC) and a Radiation Safety Officer (RSO). The RSO commits 50% of his time to radiation safety duties including those asociated with radiation producing machines. Radiation producing machines make up a much larger portion of the radiation safety program than radioactive materials. The materials program has been shrinking for the past several years due to cuts in funding and alternative research modalities. A reorganization of the radiation safety staff took place in May 1995 when the Director of Health Physics retired. Prior to that time, health physics was a separate office at CDRH. It is now incorporated into the existing Radiation Programs Branch.

Authorized uses for the broad-scope license encompass research and development, standardizing, testing and calibration of instruments and storage. Currently, there are approximately 12 authorized users of which about 6-8 are actively using radioactive material. Research and development at CDRH includes the use of licensed material to test the interaction of devices with tissue. CDRH also does basic research with licensed material on radiation effects and UV activation of HIV. The most commonly used isotopes are P-32, S-35, H-3, and C-14. Iodinations are not performed.

3. Management Oversight

In their letter dated November 4, 1994, the licensee stated that their RSC would meet on a scheduled basis not exceeding 3-month intervals. The RSC met as required in 1995 (3/31/95, 6/30/95, 9/29/95, 12/15/95). However, the RSC only met twice in 1996 (3/29/96 and 10/2/96).

Failure of the Radiation Safety Committee to meet on a scheduled basis not exceeding 3-month intervals is an apparent violation of the license.

In their letter dated November 4, 1994, the licensee stated that an audit of each approved project and the individuals working on that project would be conducted annually by the RSO or his designee. The audit was to include, but not be limited to: inventory records, user survey records, evaluation of training needs, independent work area surveys and authorization terms compliance. The inspector determined that an audit of each approved project and the individuals working on that project was not conducted annually by the RSO in 1995 and 1996.

Failure of the Radiation Safety Officer to conduct an annual audit of each approved project is an apparent violation of the license.

The licensee did not review the radiation protection program content and implementation at least annually. Specifically, a review of the radiation protection program content and implementation for 1995 had not been completed at the time of the inspection.

10 CFR 20.1101(c) requires that the licensee shall periodically (at least annually) review the radiation protection program and implementation.

Failure to conduct an annual review of the content and implementation of the radiation protection program is an apparent violation of 10 CFR 20.1101.

The oversight of the program by the RSO has been an on-going concern mentioned in the NRC inspection field notes of the prior two inspections. The inspector remarked in the 1995 inspection field notes: "The RSO should take more oversight responsibility for surveys to ensure that conditions of license are met." The inspector remarked in the 1993 inspection field notes: "Items of non-compliance identified during inspection could have been easily identified with more involvement by the RSO."

4. Facilities

The licensee has four locations of use listed on their license. Unsealed isotopes are in use only at 12709 Twinbrook Parkway. Sealed sources are used at 12200 Wilkins Avenue and in Buildings 1 and 2 at 12720 Twinbrook Parkway. The RSO's office is located at 1350 Piccard Drive in Rockville and is remote from all locations of use.

No violations were identified.

5. Equipment and Instrumentation

The licensee possesses appropriate and operable survey instrumentation. The instruments were calibrated as required and calibration records were maintained.

No violations were identified.

6. Materials Receipt and Control

Packages containing licensed material are received by the receptionist at 12709 Twinbrook Parkway. The receptionist contacts an individual authorized to receive packages. The individual surveys and wipes each package and records the results on the shipping invoice. The invoices are maintained in well-organized notebooks by the receptionist.

Access to 12709 Twinbrook Parkway and Buildings 1 and 2 of 12720 Twinbrook Parkway is by electronic combination. Combinations are changed frequently as personnel terminate employment with the organization. In addition, many labs inside the buildings are secured by combination locks.

No violations were identified.

7. Training

Initial and annual refresher training are required. Applicants to use licensed materials are required to have 40 hours of initial academic and hands-on experience prior to authorization. The licensee sends applicants to the National Institutes for Health for radiation safety training if needed.

In their letter dated November 4, 1994, the licensee stated that annual refresher training is expected to be at least one hour and may be met through attending short courses, seminars, briefings or topical presentations, on subjects relevant to radiation safety, given by the RSO or other individuals knowledgeable in radiation safety. The inspector determined that this training was not provided in 1995 or 1996. Despite the lack of refresher training, users appeared to be knowledgeable of requirements.

Failure to provide one hour of annual training to each individual working with radioactive material is an apparent violation of the license.

8. Surveys and Contamination Control

In their letter dated November 4, 1994, the licensee stated that users should survey after each use for contamination, but at least once a month. Laboratories are required to maintain records of surveys on both positive and negative results. The RSO is not required by license commitment to do any independent contamination surveys of the laboratories. The inspector determined that radionuclides were used by radiation users at the 12709 Twinbrook facility in Room 23 in September, October, and December 1996; in Room 37 in November 1996; and in Room 4C in March, July, September, November 1995 and February 1996 and contamination wipe surveys were not performed in these laboratories. Failure to maintain records of monthly contamination surveys was also identified during the previous inspection conducted on February 9-10, 1995.

Failure to conduct fixed and removable contamination surveys at least once each month in laboratories where radionuclides are used is an apparent violation of the license.

9. Leak Tests and Inventories

There is a large shielded storage container/safe in Building 2 of the 12720 Twinbrook Parkway building that contains a significant number of aged sealed sources. Many of these sources have decayed beyond their useful life and none of the sources in the safe have been used by the licensee in years. Leak testing of sealed sources was performed as required. A physical inventory every six months to account for all sealed sources and devices containing licensed material had not been conducted in 1995 or 1996. Failure to perform a physical inventory every six months was also identified during the previous inspection conducted on February 9-10, 1995.

Failure to conduct a physical inventory every six months to account for all sealed sources and devices containing licensed material is an apparent violation of the license.

10. Radiation Protection

Personal dosimetry reports are reviewed by the Consumer Safety Officer rather than the RSO. The CDRH badges approximately 100 staff. The vast majority of these staff work with radiation producing machines. The licensee does not attempt to obtain records of prior occupational dose. However, prior records are not required since no one in the licensed materials program is likely to exceed 10% of the exposure limits.

No violations were identified.

11. Radioactive Waste Management

The licensee has a waste storage area at the loading dock of the 12709 Twinbrook Parkway building. There are two flammable liquid storage cabinets containing liquid waste. One cabinet has a nominal capacity of 60 gallons and the second has 80 gallon capacity. There is also a 40 square foot caged area for solid-dry waste storage. All waste storage areas are currently filled to capacity with both decay-in-storage waste and long-lived waste that will eventually be commercially disposed. Some of the solid dry waste was overflowing it's containers. It was apparent that waste which had long since completed decay-in-storage had not been emptied in some time.

Since the last inspection, the licensee has shipped liquid scintillation vials to Perma-Fix (formerly Quadrex) on 3/9/95, 8/10/95 and 7/11/96. Manifests were prepared as required. No other shipments of radioactive waste have occurred.

No violations were identified.

12. Posting and labelling

NRC Form 3 "Notice to Employees" was posted as required in each facility where licensed material was used.

Six containers of liquid licensed material stored in the radioactive waste storage area did not bear labels that identified the radionuclides or the quantity of radioactivity and one container of liquid waste did not identify the radionuclide, nor did these containers otherwise bear sufficient information to permit individuals handling or using the container, or working in the vicinity of the containers, to take precautions to avoid or minimize exposure.

10 CFR 20.1904(a) requires that each container of licensed material bears a durable, clearly visible label bearing the words "CAUTION, RADIOACTIVE MATERIAL," or "DANGER, RADIOACTIVE MATERIAL."

Failure to label each container of licensed material with a label bearing the words "CAUTION, RADIOACTIVE MATERIAL," or "DANGER, RADIOACTIVE MATERIAL" is an apparent violation of 10 CFR 20.1904(a).

13. Exit Conference

The inspector and the Branch Chief of the Nuclear Materials Safety Branch 2 met on February 6, 1997 with individuals specified in Section 1 of this report to discuss the purpose, scope and findings of the inspection and NRC enforcement policy.

At the exit meeting, the licensee addressed the status of each of the apparent violations identified during the inspection as follows:

1. A Radiation Safety Committee meeting was held on January 24, 1997 and a special meeting is scheduled for February 27, 1997. Quarterly meetings have been scheduled for the remainder of 1997.

2. The RSO performed an inventory of all sealed sources on January 23, 1997.

3. Retraining was performed on February 4, 1997 and a second session was scheduled for February 13, 1997.

4. The RSO was scheduled to begin audits of laboratories the week of February 10, 1997. The audits are expected to take two weeks and will include a check for monthly contamination surveys.

5. The annual review of the radiation safety program was scheduled to be addressed at the February 27, 1997 meeting of the RSC.

6. The RSO labelled the unlabeled containers identified during the inspection.

The licensee assured NRC representatives that the items identified in the inspection had been brought to the attention of the appropriate level of upper management. The licensee stated that there will be more direct interaction with management in the future and more management control of the program.

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