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FOOD AND DRUG ADMINISTRATION
PHILADELPHIA DISTRICT
SCIENCE BRANCH (HFR-MA160)

UNITED STATES GOVERNMENT

MEMORANDUM

DATE: 7 December 1994

TO: US Nuclear Regulatory Commission, Region I
Attention: Eric Reber, Mail Control No. 120352

FROM: Richard Needham, Radiation Safety Officer

SUBJECT: Renewal of License 37-09752-01: Deficiency Letter

Enclosed find our response to the deficiency letter dated 11 October 1994. I apologize for the delay in responding, due to other duties. As noted in Item 14, we wish to remove 35-Sulfur from our application. We have not used this isotope previously and have no plans at present for its use. If this changes, we will submit an amendment. We have also clarified our use of 125-Iodine in our response. If you have any questions, please contact me at 215-597-2123.

Richard E. Needham

Richard E. Needham
Radiation Safety Officer

enclosure: response to Deficiency Letter

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1. 125-Iodine will be used only in the form of pre-packaged 125-I labeled in-vitro diagnostic kits, which are used for regulatory testing.

2. To clarify the role of Dr. Joseph A Feighan in our organization: Dr. Feighan is one of two Science Advisors to our organization. Science Advisors are appointed for a one year term as part-time employees, which may be renewed annually. The Science Advisors provide expertise in their areas of specialty to advance the scientific mission of our organization. Dr. Feighan was hired as a general Science Advisor for our organizations many science-based activities. As part of these duties, he will share in the responsibility for the Radiation Safety Program.

3. The duties of the on-site Radiation Safety Officer are detailed in part 10C of our application (**DUTIES OF THE ON-SITE RADIATION SAFETY OFFICER**), where twelve areas of responsibility are delineated.

We understand item number 9 of Part 10C to include the responsibility to ensure that the use of licensed materials is by or under the direct supervision of those individuals specifically listed on our license.

We hereby add under Part 10C a specific duty to ensure that licensed materials are properly secured against unauthorized removal at all times when not in use, and a specific duty to perform routine inspections of all laboratories using or storing licensed materials.

4,5. We will carry out initial training and will follow up annually on a refresher basis the following training sessions:

A. Annual Refresher Course for Employees Involved in Isotope Laboratory Work.

This will be an 8-10 hour workshop, given on-the-job to those employees currently involved with isotope work. It will consist of:

1. An update on new instrumentation or techniques available for the determination of activity levels of samples collected for regulatory testing, and a review of new analytical techniques involving licensed materials that may impact on FDA's mission and responsibilities.

2. An Update on Health Physics Issues and Dosimetry

3. A review of NRC Communications (new regulations, NRC Information Notices, Regulatory Guides, etc.) since the last refresher training.

4. Review of FDA internal lab procedures and health physics surveys, and discussion of any modifications to be made. Final approval for any modifications to existing procedures will be by the on-site Radiation Safety Officer, and will be submitted as NRC License Amendments as necessary.

B. Training for Science Employees (either new hires or those with a strong interest or background in this area)

This will be a 16-20 hour workshop which will cover the following areas:

1. Ionizing Radiation types and their properties

2. Decay equation, half-lives, decay chain equilibria, natural and artificial isotopes, units of activity and exposure.

3. Counting equipment, counting statistics, and methods: Geiger-Muller counters, scintillation detectors, solid-state detectors, ionization chambers, etc.

4.Health Physics: Units of absorbed and exposed dose; exposure limits, health hazards, detection and survey equipment, reporting records.

5. Analytical methods: neutron Activation analysis, tracer methods and spiking, isotope dilution analysis, radioimmunoassay.

C. Training for Ancillary Personnel, such as housekeeping, security and clerical workers.

This will be a 3 hour workshop which will cover the following areas:

1. Hazards of Radioactive Materials

2. Demonstration of counting methods for the detection of radioactivity.

3. Discussion of the essential 'invisibility' (can't see, taste, or smell) of radiation and the need to avoid areas that are posted with the Radiation Warning Symbol.

4. The need to confer with the Radiation Safety Officer or authorized users on any concerns or questions.

6. a. Our current radiation survey meter is a Ludlum Model 3 Survey Meter fitted with a model 44 9 GM (Alpha/Beta/Gamma) Detector. The instrument was factory calibrated in 1991 and contains a 137 Cs check source, which is used to verify the factory calibration before each use (operational check). The meter will be factory calibrated by the end of this calendar year and every two years thereafter, unless operational checks indicate otherwise. Therefore, there will be a factory calibration and an operational check of the calibration performed by the on-site Radiation Safety Officer.

b. Factory calibration will take place at Ludlum Measurements, Inc., Sweetwater TX Factory calibration will include a conversion table to convert meter readings (counts/minute) to units of exposed dose (mR/hr). Operational checks will be carried out before each use or at least once per quarter by the on-site RSO. The training of the on-site RSO is outlined in Section 7 of the application.

c. d. For the operational check, the batteries will first be tested using the battery check function of the meter. The GM detector will then be placed

directly at the face of the 1 microcurie 137-Cs check source mounted on the side of the meter, with the protective plate for the check source removed. The reading in counts/minute will be compared with the value obtained at the last factory calibration. If the reading differs by more than 100 counts/minute (approximately 3 standard deviations) from the factory calibration value, the factory will be contacted and if needed will be returned for repair or recalibration.

7, 8. The dosimetry processor that we use is Radiation Detection Company, Sunnyvale, CA, which is NVLAP-acrredited. Our TLDs are sent to our Off-Site RSO in Winchester, MA, who consolidates the badges from all of our FDA field laboratories and sends them out to the processor. We receive a copy of the report for our files each quarter. We will take action for any reported dose of 20 mRem or more in a quarter. The action will consist of a review of the material that the person has used during the last quarter, and a review of radiation protection measures that were used. The results of the review will be written, with a determination of whether the dose was avoidable or not, and if it was avoidable measures that will be taken to avoid any future dose.

9. Contamination surveys will consist of wipe tests and of surveys with the survey meter at the time that materials are being used. Wipe tests will consist of filter paper wipes of approximately 100 square centimeters, and their locations will be indicated on a copy of a floorplan of the area (similar to Attachment A of Part 9 of this application). The wipes will be counted by placing the wipes in close proximity to our thin end-window survey meter, with the meter selected for a fast response time and an audible output. Any positive readings (in counts/minute or cpm) will be corrected for background and the factory calibration value for 137-Cs will be used to convert cpm to disintegrations per minute (dpm). [The current calibration value is 12,000 cpm = one microcurie of 137-Cs]. An action threshold will be considered to be 1000 dpm per 100 square centimeters of removable contamination. This is sufficiently above the background count rate of our meter to be detectable. Action taken will depend on the situation, but at a minimum will include a review of recent history of usage of radionuclides.

10. Any planned disposal of radioactive waste into public sewers will be at the explicit consent of the on-site RSO. Before any radioactive waste is approved for disposal, the on-site RSO will:

a. Verify that the material is water-soluble or readily dispersable in water.

b. Determine the activity of the radionuclide to be discharged using appropriate counting equipment (liquid scintillation counter or single channel gamma-counter).

c. Calculate the dilution factor necessary to bring the concentration of the discharge below the limits set forth in Table 3 of Appendix B of paragraphs 20.1001-20.2401 of 10CFR.

d. Supervise the discharge, ensuring that adequate volumes of water are added to the discharge to meet the dilution criteria above.

e. Document the above in writing.

11. Leak testing is done on our 63-Ni Gas Chromatographic detectors, which are the only sealed sources we have (other than calibration check sources of 1 microcurie or less). The procedure for leak testing of these sources is given in Item I.9. of our application. Wipe tests on these detectors are counted at the facility of our off-site RSO, Edmond J. Baratta. The NRC License number for this facility is 20-08361-01 and the license expires on June 30, 1995.

12. The following measures will be taken to secure licensed material against unauthorized removal:

a. The laboratory area where licensed material will be used is controlled by a combination lock at the main entrance (see Attachment A to Item 9 of our application). This door is locked outside of normal working hours. Inner rooms 1,2,3,and 4 of this laboratory are considered to be restricted areas, and no materials will be used outside these areas. (see Part 9.A.1 and Part 9.a.2 of our application).

b. All calibration sources and all material held for decay in storage will be placed in the storage cabinet labeled "Rad Waste/Decay in Storage" in Room 4 (see Attachment A of Part 9 of our Application). This cabinet will be kept padlocked at all times, with access limited to the in-house RSO or his specific designee.

c. Records will be maintained which constitute surveillance over licensed materials. These records include a quarterly inventory of licensed materials (see Part 10.B.7.c of our application), and records for Radionuclide Receipt and Transfer.

13. The following procedure will be used to examine incoming packages for leakage, contamination, or damage:

a. The RSO or specific designee will be responsible for monitoring incoming packages. All packages will be monitored before release to the consignee.

b. For each incoming shipment, a Record of Radionuclide Receipt and Transfer will be filled out (see Attachment A to Item 10 of our Application). On this form will be recorded the specific isotope, chemical form and quantity. The radiation level at the exterior surface will be monitored and recorded in units of absorbed dose rate (mrads/hour) using the calibrated survey meter referred to in Item 6 above. The package will also be visually examined for damage at this time.

c. The package will then be opened, using gloves, and wipes will be taken of the surface of the immediate container using procedures outlined in Item 9 above. Any levels of removable contamination above 1000 dpm per 100 cm2 will be considered a cause for rejection of the shipment: the pacakage will be retained in the "Rad Waste/Decay in Storage" area in Room 4 (see Attachment A of Part 9 of our Application), and the shipper will be notified.

d. Packing material which surrounds the immediate container will be monitored either by a wipe test for removable contamination or by placing a survey meter in proximity to the material, as determined by the nature of the packing material.

e. After evaluation of all results, the in-house RSO will decide whether to transfer the radionulcide to the consignee. All results will be recorded on the Record of Radionuclide Receipt and Transfer (see Attachment A to Item 10 of our Application).

14. We would like to remove 35-Sulfur from our application, based on the small probability that it will be needed for our purposes. If our needs change, an amendment will be submitted. The only isotopes which will be held for decay in storage will therefore be 32-Phosphorus and 125-Iodine, which have half-lives of less than 65 days. 32-Phosphorus and 125-Iodine will be held separated from other radioactive materials as set forth in Part 11.D of our application. At the end of the decay-in-storage period for each disposal of an individual isotope, as set forth in Part 11.E of our application, the individual bag containing the isotope will be disposed of as ordinary trash. Disposal will be documented on the Record of Radionuclide Disposition form included in Appendix A to Part 10 of our application, and will take place only after monitoring and defacing of radiation statements as set forth in Part 11.E of our application have taken place.