

MAY 03 1985

License No. 20-18423-01
Docket No. 030-15057
Control No. 17352

Eunice Kennedy Shriver Center for
Mental Retardation, Inc.
ATTN: Robert McCluer
Director of Bio Chemistry
Radiation Safety Officer
200 Trapelo Road
Waltham, Massachusetts 02254

Gentlemen:

This is in reference to your letter dated April 9, 1985 and attached application dated April 12, 1985 to renew License Nos. 20-18423-01 and 20-18423-02 as one license in reply to our letter dated February 20, 1985. In order to continue our review, we need the following additional information:

1. Item 6 of your April 9, 1985 letter does not include a survey at the package surface for radiation levels in the safe opening of Radioactive Packages" procedure. We assume that you are surveying the surface of the package by the statement in step 5, please confirm.
2. Regarding Item 8 or your combined application dated April 12, 1985;
 - A. Please confirm that in addition to the Harvard Course, your radiation workers will have a training session on the NRC regulations and radiation safety rules and procedures of your NRC license and license conditions; initially upon hiring and at least annually thereafter as refresher training.
3. Regarding Item 9, of your application
 - A. Please identify your survey instruments by manufacturer's name and model number, type of radiation detected (alpha, beta, gamma) the sensitivity range (mR/hr or cpm) and window thickness of the probe (mg/cm²). Eberline Model SK-1 is the model number of the audible speaker not the survey instrument. We assume the model no. is an Eberline E-120.
 - B. Please clarify who performs the calibration of your survey instruments and at what frequency at which such calibrations are performed. We assume Harvard University will perform these services at a six month frequency and provide you with a certificate of calibration, please confirm.

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- C. With regard to personnel monitoring devices, please specify:
- 1). Name of the supplier.
 - 2). Type of devices used (e.g., film badges, TLD; body, wrist, ring).
 - 3). Frequency of changing monitoring devices.
- D. Please specify the minimum flow rate of your hoods and at what frequency airflow measurements are taken to assure the minimum flowrate are maintained. We suggest that hood flow rates be measured, at least every six months or after any repair to the hood exhaust system.
4. Regarding Item 10 of your application;
- A. You state in point I. Introduction, that your program is under the supervision of Harvard University Radiation Protection Program. The NRC does not allow supervision of one licensee's radiation protection program by another licensee. Your program must be under your management's supervision since you are the licensee. Harvard University may provide consultation for your program and perform services such as training, contamination surveys, bioassays, air sample analysis, leak testing of sealed sources and instrument calibration, however, the supervision of your program including record keeping and assuring that Harvard University performs the services for which you have contracted is your responsibility. Please confirm that the management of Eunice Keddedy Shriver Center for Mental Retardation, Inc., will supervise and is responsible for the radiation protection program at your facility.
- B. In order to assure your control over your program we suggest that your Radiation Protection Officer perform an audit (once per calendar quarter) to assure that the services for which you have contracted Harvard University to provide, have been completed and that you have records at your facility documenting these services. Please clarify if you will perform audits.
- C. Please submit your typical laboratory safety procedures (e.g., wearing of lab coats, gloves, personnel dosimeters; pipetting by mouth; surveys at the end of day radionuclides are used; transfer of materials between labs; smoking, eating, drinking, storing of these materials; waste disposal instructions; records to be kept by the user, etc.).
- D. Your application states that radioactive materials are used in animals. Please submit:
- 1). A description of the animals' housing facilities,

- 2). A copy of the instructions provided to animal caretakers for handling of animals and animal waste carcasses,
 - 3). Instructions for cleaning and decontaminating animal cages, and
 - 4). Procedures for ensuring that animal rooms will be locked or otherwise secured unless attended by an authorized user of radioactive materials.
- E. In support of your request for 35 millicuries of phosphorus-32, you should develop and submit special safety instructions to be provided to individuals using millicurie quantities of P-32. We recommend that your procedures include, but not be limited to, the following:
- 1). The use of low density shielding (e.g., plexiglass) in order to keep Bremsstrahlung radiation at a minimum.
 - 2). A mandatory radiation survey and wipe test procedure after each use.
 - 3). The use of finger type extremity monitors for procedures that involve 1 millicurie or more.
 - 4). The use of a dry run prior to the performance of unfamiliar procedures in order to preclude unexpected complications. In addition, it is recommended that the radiation protection officer be present during new procedures.
 - 5). The use of eye protection for procedures that involve 10 millicuries or more.
- F. Describe special precautions to be used when handling your sealed sources.
- G. Describe your method for determining the radiation dose to the extremities of personnel handling sealed sources.
- H. Describe the equipment and shielding available for transporting the sealed sources from storage sites to place of use.
- I. Radium-226, a naturally occurring radionuclide, is not byproduct material as defined in Section 30.4 (d) of Title 10, Code of Federal Regulations, Part 30, and is not subject to licensing by the NRC. Therefore, you may procure and use it without amendment to your byproduct material license.

You should contact your State regulatory authorities to determine the State licensing or registration requirements for use of this radionuclide.

- J. Describe your bioassay program for individuals using millicurie quantities of tritium and radioactive iodine. You should include the type of bioassays (thyroid count, urine count, whole body count, etc.), the criteria and frequency for performing bioassays, and the type of action taken when positive results are obtained. For your assistance, we are enclosing tritium and iodine bioassay guides that contain criteria for performing bioassays that we find acceptable.
 - K. Please provide a copy of your emergency instructions to be posted in all laboratory areas where radioactive materials are used. These instructions should (1) describe immediate action to be taken in order to prevent contamination of personnel and work areas, e.g., turning off the ventilation, evacuation of the areas, containment of the spill, (2) state the telephone numbers of the responsible persons to be notified in case of an emergency, and (3) instruct personnel on appropriate methods for reentering, decontaminating, and recovering facilities that may have been accidentally contaminated.
 - L. Describe your procedures for complying with Section 20.1(c), Section 20.103, and Section 20.106 of 10 CFR Part 20, for procedures such as protein iodinations and tritium labeling experiments that may release volatile or gaseous radioactive materials to restricted and unrestricted areas. You should include a description of the type of surveys (e.g., environmental or breathing zone), frequency of surveys, and the individuals who will perform the surveys (e.g., radiation safety officer or investigator), equipment to be used, and the procedures for evaluating the results.
4. Regarding Item 11 of your application-Waste Management
- A. Harvard University is not authorized to be responsible for or provide waste packaging services to your facility. Such activities must be under your supervision and responsibility. If you intend to use Harvard personnel you must supervise such packaging to assure that the requirements of your commercial waste disposal broker are met.
 - B. Interex is no longer in the commercial waste disposal business, please specify your new waste disposal broker.

We will continue our review upon receipt of this information. Please reply in duplicate to my attention at the Region I office and refer to Mail Control No. 17352.

Sincerely,

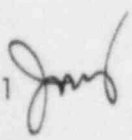
Original Signed By
Jenny M. Johansen

Jenny M. Johansen, M.S.
Nuclear Materials Safety Section B
Division of Radiation Safety
and Safeguards

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Enclosure: Regulatory Guides 10.7, 8.20 and
Applications of Bioassay for
Tritium, Task OP713-4, June 1983

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