CENTRAL RESEARCH

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Pfizer

MEMORANDUM

March 21, 1985
GWT-59

Ms. Evelyn R. Matson
Materials Licensing Section
United States Nuclear Regulatory Commission
Region III
799 Roosevelt Road
Glen Ellyn, Illinois 60137

Dear Ms. Matson:

SUBJECT: U.S. Nuclear Regulatory Commission Response Letter to License Number 13-10179-01 Application of May 21, 1984 - Control Number 17578

Your response letter to our application of May 21, 1984, has been received. Specific responses to the questions/comments raised in your letter are as follows:

"1. It is not clear if Dr. Daniel Farrington has actual hands on experience with the types and quantities of radioactive material on your license. It appears based on information submitted that the extent of his experience is to have supervised others who did the actual handling. In order to be authorized to use or supervise the use of material you must submit documentation specifying the experience he has had handling radioactive material."

Response - Dr. Farrington was added to the list of individuals who will use or directly supervise the use of licensed material because of his responsibility as Assistant Director of Development and his previous supervisory experience over experiments involving the radionuclide, carbon-14. The Development group, under Dr. Farrington's direction, will conduct most of the radiolabeled studies at Terre Haute as a part of their project activities.

"2. Item 14, waste disposal, of your application states all animal excrements and carcasses are buried in a designated burial site. Please note that current NRC regulation in Section 20 of 10 CFR do not authorize burial of radioactive material. If you wish to bury radioactive material, you may do so under the provisions of 10 CFR 20.302, or you may transfer waste to a licensed waste broker. In view of the above, describe your method for disposing of animal excrement and carcasses."

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Response - In reading through Section 20 of 10 CFR, I fail to find any specific reference to denial of authorization for burial of animal carcasses and excrements from radiotracer experiments. Section 20.301 does instruct that "No licensee shall dispose of licensed material except (a) By transfer to an authorized recipient ..., (b) As authorized pursuant to Section 20.302 or Part 61 of this chapter, or (c) As provided in Section 20.303, applicable to the disposal of licensed material by release into sanitary sewage systems or in Section 20.306 for disposal of specific wastes or in Section 20.106 (Radioactivity in effluents to unrestricted areas)..." In this regard, please note that our license application only requests burial of animal carcasses and excrements and does not request burial of licensed material, per se.

Our current license has been extended for more than 20 years through renewals of a license which was granted on July 17, 1964. Studies conducted under this license have been and will continue to be of short-term duration (usually 30 days or less) in which animals are dosed with minimal quantities of radiolabeled compounds. Following dosing, animals are maintained in metabolism cages for a few days during which time excrements (urine and feces) are collected. At the termination of each experiment, animals are sacrificed and blood and other tissues are collected. Most of the excrements and tissue samples are shipped to our Groton, Connecticut research laboratories where levels of radioactivity are measured. Samples of excrements and tissues shipped to Groton are disposed of under their license. The remaining parts of the animal carcasses and excrements are buried on location (See Exhibit 3a and 3b in our renewal letter of May 21, 1984). Such carcasses and excrements contain levels of radioactivity well below the level permitted in which any licensee may dispose of without regard to its radioactivity as described under Section 20.306(b); i.e., 0.05 microcuries or less of hydrogen -3 or carbon-14 per gram of animal tissue averaged over the weight of the entire animal. Therefore, we are requesting continued use of this burial site under Section 20.302 and as described in our license application of May 21, 1984.

"3. Describe your survey program to determine the radiation levels and radioactive surface contamination levels in all areas where radioactive materials are used or stored. Your description should include the type, methods, and frequency of surveys. Refer to Item 15 of the enclosed Regulatory Guide 10.7."

Response - Due to the infrequency and short-term duration of the radiolabeled studies at Terre Haute and the fact that radiolabeled materials are not permanently stored or prepared here, our survey program encompasses those activities which occur just prior to, during and immediately following these studies. Surveys for radioactivity are performed with the use of our survey meter and smear survey procedures (see Exhibit 1). These surveys are performed in all areas where radioactive materials are received, used and stored. These areas include our drug receiving and storage area, the laboratory where materials are finally prepared for dosing, animal study area, animal necropsy area, tissue storage area and burial site. Such areas are monitored for radioactivity just prior to the time of each study initiation to establish background levels and immediately following the completion of each study until levels of radioactivity reach levels described in the Guidelines for Decontamination of Facilities and Equipment for Beta-gamma emitters.

"4. Describe your limits for acceptable radiation levels and radioactive surface contamination levels. Describe what actions will be taken when these limits are exceeded. We suggest you establish limits similar to those in the enclosed Guidelines for Decontamination of Facilities and Equipment."

Response - As described in the response to question #3, surface contamination levels are measured with the survey meter and the smear survey procedure to establish background levels just prior to the usage of each area. Such procedures are also followed immediately following the completion of each study and the areas are cleaned up by washing down with detergents, degreasers, etc. and resurveyed until contamination levels reach levels described in the Guidelines for Decontamination of Facilities and Equipment for Beta-gamma emitters.

"5. Describe the instrumentation used to analyze removable surface contamination levels for H-3, S-35, and C-14. The instrument should be sensitive enough to measure the levels specified in the Guidelines for Decontamination of Facilities. (i.e., 1000 disintegration per minute). Describe the calibration of the instrument used."

Response - Swipe samples are shipped to our Groton research laboratories and counted in a Beckman 9000 Liquid Scintillation Counter that is manufacturer serviced and maintained. Counters are calibrated weekly with commercial sealed standards purchased from New England Nuclear. A log of calibration procedures is maintained. This liquid scintillation counter is capable of detecting less than 1000 disintegrations per minute.

"6. Describe your procedures for ordering and receiving radioactive material. Sample procedures are enclosed as Appendix E. These procedures, designed for a hospital, can be modified by you to fit your program."

Response - No radioactive materials are ordered and/or purchased outside of Pfizer Inc. All radioactive materials used in studies at Terre Haute are shipped from our Groton research laboratories immediately prior to the time of the initiation of the study and are normally used in their entirety in the short-term animal studies. Any unused radioactive material is immediately shipped back to our Groton research laboratories. Radioactive materials are received in accordance with the procedures described in "Appendix E - Procedures for Ordering and Accepting Delivery of Radioactive Material", U.S. Nuclear Regulatory Commission Regulatory Guide 10.8. A log of received radioactive materials is maintained.

"7. Describe your procedures for safely opening packages containing radioactive material. Sample procedures are enclosed in Appendix F. You may adopt those procedures or submit equivalent procedures covering each topic in Appendix F."

Response - We are planning to adopt these procedures described in "Appendix F - Procedures for Safely Opening Packages Containing Radioactive Material", U.S. Nuclear Regulatory Commission Regulatory Guide 10.8.

I trust that these responses will adequately answer the questions/comments you made in your letter of February 28, 1985. However, if you have any further questions about my responses, please feel free to call me at 812/299-2121, ext. 462.

Sincerely yours,

PFIZER INC.

George W. Thrasher

George W. Thrasher, Ph.D.
Director - Operations
Animal Health Research

GWT:jg
Attachment

EXHIBIT 1 - SMEAR SURVEY PROCEDURE

OBJECTIVE: To demonstrate the work areas used in radiotracer studies have been successfully decontaminated.

PROCEDURE:

1. Prepare a simple sketch of the work areas to be surveyed that shows room arrangement with pens, cabinets, tables, etc. The overall procedure should include areas that are likely to be contaminated as well as those that are not expected. Focus on the immediate work area as well as balances, door knobs, walls, etc. Number each sample to be surveyed consecutively or identify with a unique abbreviation.

2. Collect a box of 4.25 cm - 5.5 cm Whatman qualitative #2 filter paper or equivalent, plastic squirt bottle containing methanol and an appropriate number of scintillation counting vials.

3. Put on protective gloves.

4. Wet the filter paper with methanol and gently swipe an area approximately 2'x2'. Place the wet swipe directly into scintillation vial and screw on cap. Label the sample by marking on top of the cap the appropriate identification corresponding to the sketch. Depending on the size of the experiment, 20 to 50 swipes are normally sufficient.

5. In an area away from the work areas (other buildings), obtain two to four swipes for determining normal background radiation levels. Identify samples as background and note on the sketch where samples were taken.

6. Sign and date all papers related to survey procedures.

7. Send all the samples with a copy of sketch and a list of samples to the Radiation Safety Officer, Groton.