

RECEIVED REGION 1

05 JAN 26 M2 :49

January 21, 2004 mm

U.S. Nuclear Regulatory Commission Region 1 Office Attn: Elizabeth Ulrich Senior Health Physicist Commercial and R&D Branch Division of Nuclear Materials Safety 475 Allendale Road King of Prussia, PA 19406-1415 MS 16 L-7

Dear Ms. Ulrich:

This letter is in response to your letter dated December 28, 2004 requesting additional information regarding our license renewal application for NRC Materials License Number 37-28218-01; Docket Number 030-30602; Mail Control No. 135937. The responses below refer directly to the points listed in your letter:

- 1a. Once an animal is administered a radioisotope at Calvert, only trained personnel under the direction of an authorized user are permitted to work with or take care of the animal. Ancillary personnel are precluded at this point from further interaction with the animals through their in-life existence, termination procedures and disposal procedures. In the event of an emergency medical condition requiring veterinary treatment, the treatment will be administered by a trained individual under the direction of a veterinarian.
- 1b. Attached with this letter are the instructions provided to the trained workers regarding animal handling, cleaning and decontamination and waste procedures.
- 2. A description of the radiation safety training which will be provided ancillary personnel is attached with this letter and will be inserted into the license application in section 8.
- 3. Radiation surveys performed at the conclusion of each study or room usage are contamination surveys. The survey records will include the following information: a diagram of the area surveyed, a list of the items/equipment surveyed, specific locations on the survey diagram where the wipe test was taken, contamination levels with appropriate units, make and model number

Laboratory Scott Technology Park 100 Discovery Drive Olyphant, PA 18447 Tel: 570.586.2411 Fax: 570.586.3450 Corporate 1225 Crescent Green Suite 106 Cary, NC 27511 Tel: 919.854.4402 Fax: 919.854.2860

135937 NMSS/RGNI MATERIALS-002

E. Elrich U.S. Nuclear Regulatory Commission

of the instruments used, the background radiation levels, and the initials of the person performing the survey. The personnel performing these surveys are trained personnel who have worked on the specific study and have undergone the previously described (section 8 of the license application) radiation safety training program at Calvert. The personnel are instructed in the procedures for performing wipe tests, including the use of scintillation and gamma counters. Where applicable for the radioisotope used, personnel are instructed in the use of portable survey meters.

The decontamination limit of 200 DPM referenced in the license application applies to an area of  $100 \text{ cm}^2$ .

In addition to the survey performed following the conclusion of each study, a monthly survey is also performed under the directive of the RSO to verify proper decontamination procedures in areas where radioisotopes were used during that month. As part of this monthly survey, we will monitor possible contamination in unrestricted areas by selecting locations on a random basis.

If you have any questions or need additional information regarding this license renewal, please contact me at 570-585-2222.

Sincerely,

in St. human

William G. Tuman, M.S. Radiation Safety Officer Calvert Laboratories, Inc.

cc: J. Chapdelaine, Ph.D., Vice President, Immunology S. Brozena, President of Operations

# 8. Training For Ancillary Personnel Who May Work in the Vicinity of Radioactive Materials

Ancillary personnel at Calvert who may work in the vicinity of radioactive materials includes laboratory animal resource personnel, the shipping and receiving clerk and maintenance/engineering personnel. Although ancillary personnel at Calvert are not exposed to an annual occupational radiation dose of 100 mrem, they will be provided training which will include the following topics:

- Definition of radiation, its sources and background radiation
- Types of radiation
- Biological effects of radiation
- Description of the radioisotopes used at Calvert and the purposes for which they are used
- Dose minimization including ALARA and the concepts of time, distance and shielding
- Laboratory specific procedures when radioisotopes are used
- Labeling/sign posting of restricted areas when working with radioisotopes
- Emergency procedures

Ancillary personnel will be provided initial safety training and refresher training on an annual basis. Training is typically provided by the Calvert Radiation Safety Officer in the form of a lecture or via a training video. Periodically, qualified non-Calvert personnel (i.e. consultants) are contracted by Calvert to provide radiation safety training.

## IN VIVO STUDY PROCEDURES

Gloves, labcoats and safety goggles must be worn at all times when working with animals administered radioisotopes. In addition, other precautions should be observed for all *in vivo* studies:

### In-Life Study Component:

- At the start of each experiment, the "Caution Radioactive Materials" sign will be installed on the treatment room door.
- Upon study initiation, all animal care, feeding and clinical observation duties will be performed by trained radiation worker personnel. Ancillary personnel access to the study room will be limited to recording of temperature and humidity readings.
- During dosing, extreme care must be exercised as the radioisotopes are in their most concentrated form. Measures should be taken to prevent contamination of the tables, floor and the area surrounding the cages during dose administration including the use of absorbent paper.
- When handling animals dosed with radioisotopes, care should be taken to prevent contamination of the tables, floor and area surrounding cages by the animal's excreta (urine and feces). Absorbent paper should be used where practical.
- All radioactive waste generated during this study will be stored in appropriately labeled radioactive waste bag liners which will be maintained in the study room until completion of the study, or if deemed necessary, will be transferred to the Radioactive Waste Storage room in the basement of Building #1 (see "Waste Handling" below).

### Completion of Study:

- Animal cages, tables and lab equipment which may have come in contact with or been contaminated by the study animals are surveyed via a wipe test (and survey meter if applicable) at the completion of the study. Equipment will be released back to laboratory animal resources and the general lab population if the survey results are <200 DPM per 100 cm<sup>2</sup>.
- Representative areas of the room floor as well as the door/doorknob and other areas of the room deemed appropriate will be surveyed. The room will be released back to the general lab population if the survey results are <200 DPM per 100 cm<sup>2</sup>.
- Following successful decontamination and clean-up procedures, the investigator(s) will inform the appropriate ancillary personnel that they may again access the laboratory/animal room.

#### Waste Handling:

At the conclusion of the study, the trained personnel, under the direction of an authorized user and/or the RSO, will store all radioactive waste in the Radioactive Waste Storage room on the basement floor of Building #1 as per the following criteria:

Short half-life isotopes (<120 days): All waste generated from studies using short half-life isotopes will be labeled with the isotope and receipt number, the estimated activity, the day it was placed in storage and the date of 10 half-lives. All biological waste and liquid waste should be stored frozen in the Radiation Waste Storage room. Dry waste may be stored in appropriately labeled boxes in the Radiation Waste Storage room. All waste is stored for a minimum of 10 halflives. Following this interval, the waste is surveyed, and if equivalent to background readings, the waste can be disposed of following the normal procedures for non-radioactive waste.

Long half-life isotopes (>120 days): If the animal was dosed with <sup>3</sup>H or <sup>14</sup>C at a dose level less than 0.05  $\mu$ Ci/g (50  $\mu$ Ci/kg) the carcasses/biological waste can be disposed of as non-radioactive waste. All other waste generated with long half-life isotopes is separated into either dry, liquid or biological waste, labeled with the isotope and receipt number, the estimated activity and the date in storage and is stored in the Radiation Waste Storage room. Biological and liquid waste is stored frozen. Dry waste may be stored in appropriately labeled boxes.