



ENZON, Inc.

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August 25, 1998

Control No. 125865

U.S. Nuclear Regulatory Commission
Region I
475 Allendale Road
King of Prussia, PA 19406-1415

Attention: James M. Bondick
Health Physicist
Nuclear Materials Safety Branch 2

✓ BY FACSIMILE: 610-337-5393 8/25/98 (original copies enclosed)

Dear Mr Bondick,

As you requested during our telephone conversation today, I am providing a description of our procedures for the use of radioisotopes in animals at Enzon, Inc. for inclusion in our license under review for renewal. The location of all animal work will be in the Radioisotope Laboratory which is Room 32 and is highlighted on the facility map on page 29 of the Enzon Radioisotope User Manual.

Please contact me if any additional information is needed.

Sincerely,

David Filpula, Ph.D.
Director, Molecular Genetics
Tel: 732-980-4941
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The Use of Radioisotopes in Animals

Description of Animal Housing Facility

Experimental mice are ordered through and housed at the UMDNJ-Robert Wood Johnson Medical School Vivarium. This vivarium has AAALAC, NIH and USDA certification. Twenty-four hours prior to experimentation, the mice are transported to Enzon's radioisotope room and remain on study for no longer than 72 hours.

Care and Handling of Animals at Enzon

Animals are housed in plastic metabolism cages sized in accordance with the "Guide for the Care and Use of Laboratory Animals of the Institute of Laboratory Animal Resource, National Research Council. Commercially available mouse chow diet is provided ad libitum in feeders designed to reduce soiling, bridging and scattering. Fresh tap water is also provided ad libitum via water bottles. The light cycle is set at 12 hours light : 12 hours dark. Temperature is maintained at 18°C to 29°C and the relative humidity controlled at between 30% to 70%.

Administration of radioisotopes occurs in restrained conscious mice either via a route of i.v. (tail vein) or i.p. injection using a 25 g. needle. At specific time points, animals are sacrificed (exsanguination) and their tissues removed. The bench where the radioisotopes are used is covered both with a Teflon coated bench cover and plastic backed absorbent paper. The radioisotope itself is shielded with Lucite. At a minimum, the researchers wear safety goggles, a lab coat and two pairs of disposable latex gloves.

Carcass Disposal

Carcasses are placed in sealed containers and stored in a designated -20 °C freezer within the radioisotope room until removed by a contract radiation waste disposal service.

Cleaning and Decontamination of Cages

Cages are washed three times thoroughly with either Rad-Con radioactive decontaminant spray (Nuclear Associates) or Radiacwash (Biodex). Each decontamination wash is followed by a soap/water scrub and a rinse. These cages are stored within the radioisotope room and at no time leave its confines.

Animal Caretakers

While in Enzon's radioisotope room, animals are cared for by members of the pharmacology and toxicology group. Members of this group have extension experience in the handling and use of radioisotopes for animal research and have attended semiannual training sessions at both Enzon and UMDNJ.

DRAWING 1

