



Robert Packer Hospital
One Guthrie Square
Sayre, PA 18840-1698
Tel 570.888.6666

January 24, 2006

Shirley S. Xu
Health Physicist
Division of Nuclear Materials Safety
Region I
475 Allendale Road
King of Prussia, PA 19406

MS6
Q-8

RECEIVED
REGION I
2007 JAN 25 PM 12:17

RE: Control #139715, License number: 37-01893-01, Docket number: 030-03013

Dear Ms. Xu:

This is in reference to your email dated December 26, 2006 requesting the following information.

- a. a description of the animal housing facilities

Animal housing facility information is under the part III-A of Protocol: Housing, cleaning of radioactive animal room.

- b. a description of the training that will be provided to individuals caring for animals containing licensed materials, and

Description of the training is under specific training requirements section of the attached document, Protocol: Use of Radioactivity with live animals.

- c. a copy of the instructions provided to animal caretakers for handling of animals, animal waste carcasses, and cleaning and decontamination of animal cages.

Instruction to animal care takers for safe handling of animals, animal waste carcasses, and cleaning and decontamination of animal cages information is under the part III-A, III-B and III-C of Protocol: Housing, cleaning of radioactive animal room.

Please find attached documents supporting practice standards. Should you have any questions or require any additional information, please do not hesitate to contact me directly at (570) 882-4992.

Sincerely,

Bimal Patel
Administrative Director
Procedural & Ancillary Services
Robert Packer Hospital

BP/sc
DEP/NRC

139715

NMCC/ROIN MATERIALS-002

Guthrie Foundation Research		
Section: Animal Care	Next review Date:	December 2007
Protocol: Housing, cleaning of radioactive animal room	Last Review Date:	December 2006
Protocol Number: AnC-02	Last Revision:	December 2006
ISO 17025 Clause: NRC: NUREG-1556, v 7, Append. H. Refer also to USDA requirements and/or regulations.	Authorization:	

I. SCOPE

This protocol details the selection of a site to house animals exposed to radioactive isotopes and the handling of animal waste, carcasses and cleaning of cages and equipment. Some of the following items are based on recommendations from the NRC regulation NUREG-1556, volume 7, appendix H.

II. TRAINING REQUIREMENTS

Personnel who will be caring for animals exposed to radioactivity and the cleaning of their area must first have attended in-service training in the following areas: Radiation safety, and blood borne pathogens. These in-services are available to all employees and required on a yearly basis. Attendance records for these in-services are kept by RPH.

III-A. PROCEDURE SELCTION OF HOUSING SITE FOR ANIMALS EXPOSED TO RADIOACTIVITY.

STEP	ACTION	COMMENTS
1	Animals shall be housed in cages of appropriate size and in appropriate numbers as designated by USDA regulations. Before animals are placed in the room the steps below should be implemented.	All USDA regulations for housing of animals shall be followed. The animal care vivarian and/or veterinarian should know the regulations.
2	A designated room of adequate size to house the expected number of animals. The room should also meet the following criteria:	Room GF 2036 is 108 sq ft..
3	Security, access to the room shall be limited to authorized personnel only. All access to the room shall be documented with a sign up sheet.	Door(s) should be locked with access limited. Key would be kept by authorized personnel only.
4	Signage: The room will be appropriately labeled with a "Radioactive" sticker to inform personnel that radioactive material is present in the area. Also Instructions for precautions will be posted on animal room door	Placed on entrance door(s) to the room. Reference to the isotope in use should also be provided. Instructions include the need for gloves, gowns, shoe covers, etc.
5	Pre-use radiation survey (swipe test). Map of swipe area will be recorded. Placement of radiation badge on wall.	Swipe tests on areas of the room indicating radiation levels found in the room prior to the introduction of isotope.
6	"Isolation" of the room. The room chosen should be away from areas of high foot traffic.	Limits the possible exposure and spread of isotopes throughout the facility.
7	Flow to and from the room should be directional. One entrance into the room and exit through a second door.	Again limits the spread of isotope to "clean" areas.

8	Equipment used should be labeled and designated for that room only. This includes such items as tabletop work areas, scale, freezer for carcasses.	Prevents the use in other animal rooms by other animals. Limits the possibility of spreading isotope around.
9	Charcoal filter will be placed over the air inlet vent if isotope can become volatile.	Traps unbound or "free" volatile isotopes.
Post Study Procedures		
1	Upon termination of the study and removal of all animals, the room should be swiped for the presence of radioactive isotopes before cleaning begins.	Results of the swipe test will be sent to our radiation safety department for their okay that the room is safe for everyday use.
2	Once area is deemed to be contamination free, radioactive decals can be removed and the room opened for the housing of other animals.	Removal of other precautions signs may also be done.

III-B. HANDLING WASTE FROM RADIOACTIVE ANIMALS, CARCASSES AND DISPOSABLE PROTECTIVE GEAR .

STEP	ACTION	COMMENTS
1	Bedding from the animals will be collected into plastic bags and sealed (tying into a knot, etc) to prevent spillage.	Remove as much air as possible before sealing to minimize space requirements.
2	A plastic bag will be placed in the room for the collection of gloves and masks and other disposable protective gear, used while caring for the animals.	* See below.
3	If sharps are to be used in the animal room a separate sharps container will be provided and appropriately labeled.	
4	Carcasses will be collected into a plastic bag and stored in a freezer (in the room) until safe for disposal.	*All waste and disposable protective gear should be kept for time equaling 10 half lives of the isotope. If this is not possible, then the waste should be stored until it can be safely removed from the premises by a certified service.
5.	All waste bags will have stickers placed on them denoting that they are radioactive. The estimated activity and the date of storage will also be written on the bag.	Waste will be stored in the Foundation building in the space designated.

III-C. MONITORING RADIOACTIVITY IN ENVIRONMENT OF ANIMAL FACILITY

STEP	ACTION	COMMENTS
1	When in use the room housing the animals will be monitored on a regular basis for the presence of radioactive contamination. Monitoring will be carried out by swipe tests (Geiger counter scans when appropriate) to locate any radioactive hot spots.	The same time interval used to monitor radiation use in the lab will be used. (Weekly).

2	Areas will be selected for monitoring. These should include the floor by the exit door, the door handle, any surface such as a cabinet top where radioactivity may be used. Other areas that are prone to handling should also be monitored.	Water bottles, areas of cages where handled.
3	In addition to the weekly monitoring of the area, the area should be monitored immediately after the use of isotopes in the room. A Geiger counter survey will suffice if the isotope is strong enough to be detected, i.e. I ¹³¹ .	If animals injected with isotope then the areas should be monitored that same day, after the injections are complete.

IV. ADDITIONAL INFORMATION

SAFETY: Normal laboratory safety; working personnel should adhere to standard laboratory practices. Wear snug fitting gloves when handling mice, lab coats and nose mask. Gloves and mask can be disposed of into a designated waste container for contaminated material.

INSTRUMENT AND ACCESSORIES/EQUIPMENT: Equipment used to house animals includes cages, and racks for holding the cages, and water bottles. Feeders, card holders.

REAGENTS/SUPPLIES: Bedding and food pellets.

STANDARDS:N/A

INSTRUMENT PROCEDURE: N/A

CALCULATIONS/SPECIFICATIONS: N/A

INTERFERENCES/SPECIAL HANDLING/TROUBLE-SHOOTING--MISC.:

QUALITY CONTROL INFORMATION: All USDA regulations for animal care and NRC regulations for use of radioactive materials shall be followed and supersede this protocol.

Revision:	Date:
First write.	12-27-06

Guthrie Foundation Research		
Section: Animal Care	Next review Date:	December 2007
Protocol: Use of radioactivity with live animals	Last Review Date:	December 2006
Protocol Number: AnC-01	Last Revision:	December 2006
ISO 17025 Clause: Refer to USDA and NRC requirements and/or regulations.	Authorization:	

Purpose: The purpose of this protocol is to outline the additional steps for the care and handling of research animals that will be exposed to radioactive materials.

Background. All animal protocols will be reviewed by the animal care committee and approved before being implemented. Thus this protocol will be implemented only after the approval of the animal care committee.

Procedure

General Animal Training.

Authorized personnel to care for or handle animals. Prior to handling animals for this protocol, all personnel who are to have contact with the animals must first have been trained to work with animals, or work under the direct supervision of someone who has been trained and has their training documented. These include the Veterinarian, the animal care vivarian and those trained by the vivarian to care for the animals. Others authorized to care for the animals shall have their authorization status documented. This information shall be kept by the animal care vivarian.

Specific training requirements.

The specific requirements for this protocol are the documentation of (1) Radiation Safety in service, (2) documentation of blood born pathogens in service, and (3) protocol specific presentation of the investigator.

1. Radiation safety in-service is required to acquaint the individual with the different isotopes used, types of emitters, biological significance and effects of the different types of emitters, and half lives of the isotopes. This in-service is required of all individuals in the research area and their yearly training should be documented. The records are maintained by the RPH Health Physics department.
2. Blood born pathogen in-service. This in-service is required of all individuals contacting patient samples and should be required for all research personnel that handle animals as well, since they can also transmit infectious agents to personnel. Also personnel handling animals exposed to radioactive isotopes will use the same techniques and precautions for preventing the contamination and spread of isotopes that are used to prevent the contact and spread of infectious agents.
3. Protocol specific presentation of investigator. This presentation should provide the following information: Why the study is being done, and how it is to be done, with expected results and methods for determining those results. It should include information on the isotope to be used in the study, how it is to be introduced into

the animal (IP injection, tail vein injections, etc), and how it will be monitored (i.e. harvesting of specific organs and scintillation analysis of cell lysates). Additional information such as the biological significance of the isotope and half life should also be provided. The investigator should also provide answers to any questions personnel may have about the protocol and/or the special handling of animals.

Reference documents.

This protocol is subject to the provisions of both the USDA (animal handling) and NRC (isotope handling).

Revision:	Date:
First Write	12-2006