



Veterans
Administration

In Reply Refer To: 115

March 4, 1983

Mr. Rod Mason
Material Licensing Branch
Division of Fuel Cycle and Material Safety
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555

Thru: James J. Smith, M.D.
Director, Nuclear Medicine
VA Central Office

Docket No. 030-03273
License No. 43-03299-01
Control No. 00407

Dear Mr. Mason

Thank you for reviewing our broad license application. As you requested we are submitting the following revisions to our application: 1) We are adding pages 12, 13, and 14 to item 11. These pages describe the facilities in the new Nuclear Medicine wing. 2) We are re-submitting item 22 in total (pages 1 through 4 replace the previous pages 1 through 5). The procedures for disposing of animal waste are now consistent with other waste disposal procedures described in item 18. 3) We are submitting a new page 4 which replaces the old page 4 of item 23. A sentence has been added to this page, indicating that the Radioactive Drug Research Committee at the University of Utah will be used to review non-routine human uses of radioactive materials whenever appropriate under FDA guidelines.

The additional information regarding the use of radioactive xenon gas will be sent under separate cover, both to you and to Mr. St. Mary.

Sincerely

R.E. LINDSEY, Jr.
Medical Center Director

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FACILITIES AND EQUIPMENT

The Nuclear Medicine Department has moved into a newly constructed wing on the first floor of building 1. On page 1 of item 11 (April 1982), Building 1, 1st floor, Rooms 1304 and 1306 are no longer used as described. The new Nuclear Medicine area, including the hot lab is described below.

Building 1, 1st Floor, Nuclear Medicine Wing

No. on Diagram	Room Use	Equipment Available	Radiation Type and Levels
1	dark room		bkgnd
2	conference room		bkgnd
3	imaging lab	GE rotating camera Elscint camera	High level gamma
4	office		bkgnd
5	staff lockers		bkgnd
6	stress lab	Pickier portable camera	high level gamma
7	staff lounge		bkgnd
8	counting lab	Thyroid probe/sealar Ibrinitor (portable scintillation probe)	low level gamma
9	invitro lab	Gamma counter	low level gamma
10	invitro lab	Bone mineral analyzer	low level gamma
11	imaging lab	Pickier large field camera	high level gamma
12	computer room		bkgnd
13	dose preparation lab	G-M survey meter G-M area monitor Dose calibrator "L" shield and lead bricks Brick lined storage area Syringe shields Xenon delivery system and trap	high level gamma

No. on Diagram	Room Use	Equipment Available	Radiation Type and Levels
14	waste storage	Lead lined waste containers No Tc-99m generators	high level gamma
15	patient toilet		bkgnd
16	counting lab	no equipment yet	bkgnd
17	office		bkgnd
18	radiation safety office	G-M Survey Meter Cutie-Pie Pocket dosimeters and charger Decontamination Kit	bkgnd
19	waiting room		bkgnd
20	office		bkgnd
21	office		bkgnd
22	office		bkgnd
23	office		bkgnd

first floor

[illegible]

item 11
page 14
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PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL IN ANIMALS

A. The Animal House Facilities are located in Building 7 of the Veterans Administration Medical Center. The animal facilities utilize the northern wing of the building. The southern wing consists of the warehouse and hospital laundry. The facility is totally isolated from patient care facilities and is totally self sufficient with laboratory areas, surgical suites and accommodations for both large and small animals. A complete floor plan is attached.

B. The areas where radioactivity will be used in the animal facility are shown on the accompanying floor plan.

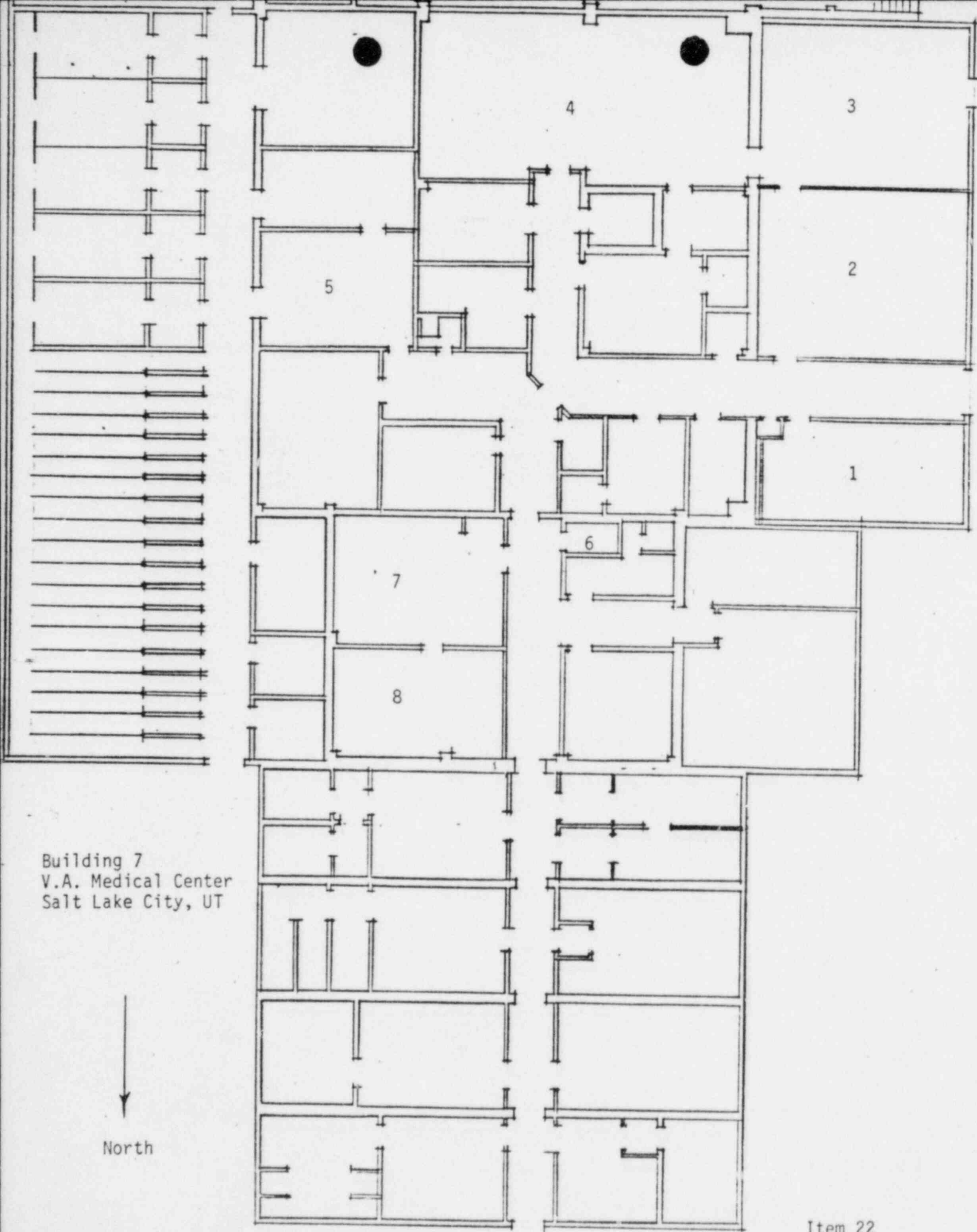
<u>Room</u>	<u>Description</u>
1	bio-chemistry lab
2	imaging lab
3	imaging lab
4	animal surgery
5	surgical prep area
6	lead lined storage area
7 and 8	cardiovascular research lab

C. Animal groups available for study include non-human primates, horses, sheep, goats, calves, dogs, cats, snakes, and rodents such as rats, mice, hamsters, guinea pigs and gerbils. The animal facility has accommodations for all these groups available.

D. Procedures using radioactivity in animals must be evaluated and approved by the Medical Radioisotope Committee. Evaluation of the study will determine if any special precautions and instructions are needed, as determined by the Radiation Safety Officer who will issue written special instructions.

E. The special instructions will be in addition to the instructions for handling of animals, animal waste and carcasses (attached).

F. The Investigator and the animal area supervisor have the responsibility to inform all personnel working in the area of necessary safety procedures.



Building 7
V.A. Medical Center
Salt Lake City, UT

North

INSTRUCTIONS FOR HANDLING ANIMALS, ANIMAL WASTE, AND CARCASSES

A. Injecting Animals

All injections of radioactive materials into animals shall be done in such a manner as to control and minimize accidental spillage and contamination. Protective gloves and clothing shall be worn.

B. Labeling Cages

All cages housing animals containing radioisotopes shall be clearly labeled with a tag which can be obtained from the Radiation Safety Office or the Supervisor of the animal facility. The tag will contain the following information:

1. Name and amount of radioisotope.
2. Date of administration.
3. Principal investigator's name and phone.
4. Mr/hour at the surface of the animal and at a distance of three feet.
5. "Excreta to be Collected" or "No Excreta Collected".

The investigator is responsible for determining when ten effective half lives have elapsed and removing the tag from animal cage at that time. Before removing the tag, a survey must be performed to ensure that the activity at the surface of the animal and everywhere in the cage is at background level.

It is the responsibility of the investigator to label radioactive animals in a clear manner. Any questions regarding this tagging procedure should be directed to the Radiation Safety Office. Radioactive animals kept in rooms by other than the animal facility shall also be tagged in the above manner.

C. Segregation

Animals containing radioactive materials shall not share cages with non-contaminated animals.

D. Animal Waste

Radioactive animal waste will be disposed of along with other radioactive waste generated at the medical center as described in Item 18. Excreta can be discharged into the sanitary sewer if the Radiation

Safety Officer gives written permission before hand, and the limits and other conditions described in Section A of Item 18, are all met.

Excreta that are not discharged into the sewer, and other contaminated material, such as bedding, must be collected and stored in leak-proof containers. This material will be either decayed or released to a commercial waste disposal service as described in Item 18.

E. Cleaning Cages

These procedures for cleaning cages must be observed as long as the cage is tagged as radioactive.

If the cage is labeled: "No Excreta Collected", wash the cage as usual. Do not collect wash water. However, any bedding, or other material removed from the cage, must be saved in a leak-proof container for disposal as radioactive waste, according to the procedures in Item 18.

If the cage is labeled: "Excreta to be Collected", no waste may be discharged into the sanitary sewer. All excreta, wash water, and bedding, must be saved in a leak-proof container for disposal as radioactive waste, according to the procedures in Item 18.

It is the responsibility of the investigator to include the information about excreta collection on the tag affixed to the cage. It is also the responsibility of the investigator to secure from the Radiation Safety Office, prior written permission to discharge radioactive waste into the sanitary sewer.

F. Carcasses

The total activity and isotope(s) contained in each animal carcass shall be determined before disposal by direct monitoring or by other means. For example, inventory of activity given to the animal or case history of the animal.

1. If the carcass contains no isotopes with half lives longer than 15 days, it may be frozen for decay to background with the following conditions:
 - a. The carcass will be labeled with the isotope(s), amounts, and the date.
 - b. It will be kept for at least ten half lives.
 - c. It will be monitored with a low level G-M survey meter and must be decayed to background before release.
2. Carcasses that are not frozen for decay to background will be disposed of via a commercial waste disposal service.

D. Human Use of Radioactive Material

Any human use of byproduct or cyclotron produced material must be carried out by or under the supervision of a physician. The standards presented in Appendix A to NRC Regulatory Guide 10.8 will be adopted by the Medical Radioisotope Committee as acceptable standards for physicians who direct procedures with radioactive material. Physicians who wish to direct procedures with radioactive material must submit forms NRC-313M-Supplement A, and NRC-313M-Supplement B to the Medical Radioisotope Committee. Only those physicians approved by the Medical Radioisotope Committee can direct procedures with radioactive material. Furthermore, only those procedures approved by the Medical Radioisotope Committee can be undertaken. A list of "Established Medical Uses of Radioisotopes" is attached. The Medical Radioisotope Committee may add to or delete items from this list by consensus of the members present at any meeting. Other human uses of radioactive material must be approved by the Medical Radioisotope Committee on an individual basis. The "Radioactive Drug Research Committee" at the University of Utah will be used to review non-routine human uses of radioactive material whenever appropriate under FDA guidelines.