



UNITED STATES
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Dear Dr. Feeney:

This refers to your letter dated January 24, 2002, and to our subsequent telephone conversation on February 1, 2002, between you, John Madera, Branch Chief, Materials Licensing Branch and myself concerning unrestricted release of feline hyperthyroid cats treated with iodine-131. The following summarizes current NRC guidance concerning release criteria.

Before releasing a cat treated with iodine-131 for unrestricted control to the general public (family members) the licensee needs to demonstrate compliance with 10 CFR Part 20 radiation limits. Specifically, the licensee must assure the radiation dose to individual members of the general public (including family members) will not exceed 100 millirem in a year as required by 10 CFR 20.1301 and to not create radiation levels in unrestricted areas in excess of 2 millirem in an hour as required by 10 CFR 20.1302. Once compliance with these requirements has been established, the next objective should be to keep exposure to members of the general public ALARA (As Low As Reasonably Achievable). To help accomplish ALARA, owners should be given instructions on how to handle contaminated litter, bedding and other objects the cat comes into contact with. The instructions should also address the extent and duration of contact by individuals with the cat. These instructions should be clear and concise so that the cat owner can comply with them throughout the duration of the implementation period. Enclosed is a sample instruction sheet from NRC NUREG 1556, Volume 7 for your review.

The release of a treated cat can be calculated by determining the effective half-life. Since effective half-life, radiation profile, typical behavior pattern, and living situation for each cat are different, the actual release date will vary and needs to be established for each individual cat. This determination may be based upon 2 two consecutive daily radiation measurements made at the same time of day and at the same distance to determine effective half-life. Release date and time can then be calculated and the owner's instruction sheet can be completed to help keep exposure ALARA.

As an example of the variability of effective half life, a certain treated cat may have a dose rate of 0.5 mR/hr at one foot from the neck and an iodine-131 effective half-life of 4 days. This cat may need to be held for an extra day or two while another treated cat with the same dose rate reading but with an iodine-131 effective half-life of 1 to 1.5 days could be released earlier.

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The following has been acceptable for cat release and is based upon a minimum number of days after iodine-131 treatment, normally not less than 4 days after treatment, and maximum dose rate, normally not more than 0.25 mR/hour at 1 foot. Regardless of the release level used, the licensee will need to demonstrate compliance with 10 CFR 20.1301 and 20.1302.

I hope this guidance helps you in future feline hyperthyroid treatments. Please feel free to call if you have any questions.

Sincerely,

James R. Mullauer, M.H.S.
Health Physicist
Materials Licensing Branch

Enclosures: Appendix H, NUREG - 1556, Vol. 7

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Appendix H

Considerations for Laboratory Animal and Veterinary Medicine Uses

Considerations for Laboratory Animal and Veterinary Medicine Uses

This Appendix provides additional information on the use of byproduct materials in laboratory animals, in animals used for research in the environment, and by veterinarians.

Laboratory Animals

Training

Before allowing an individual to care for animals used in studies with or treated with licensed material, the Radiation Safety Officer (RSO), Authorized User (AU), and/or veterinarian must ensure that he or she has sufficient training and experience to maintain doses ALARA, control contamination, handle waste appropriately, etc.

Classroom training may be in the form of lecture, videotape, or self-study and should cover the following subject areas:

- Principles and practices of radiation protection
- Radioactivity measurements, monitoring techniques, and using instruments
- Mathematics and calculations basic to using and measuring radioactivity
- Biological effects of radiation.

Appropriate on-the-job-training should consist of:

- Observing authorized personnel using survey equipment, using proper contamination control techniques, and proper disposal of radioactive material
- Using survey equipment, proper contamination control techniques, and proper disposal of radioactive material procedures under the supervision of, and in the physical presence of, an individual authorized to handle animals treated with licensed material or otherwise containing licensed material.

Contamination Control and Waste Handling

In order to minimize the spread of contamination, animals used in studies with or treated with licensed material should be housed in cages or stalls separate from other animals. The facilities, stalls, or cages shall be secured to prevent unauthorized access to the animals. Individuals caring for these animals should reduce the chance of personal contamination by wearing gloves, lab coat, and eye protection, as appropriate.

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Special care should be observed when cleaning the cage or stall. The cage or stall, the bedding, and waste from the animal may contain radioactive material. Any radioactive material should be properly disposed of as described in Section 8.11, "Waste Management."

Disposal of laboratory animals that contain radioactive material require special procedures. Animal carcasses that contain less than 1.85 kBq/gram (0.05 microcuries/gram) of carbon-14 or hydrogen-3 may be disposed of by the same method as non-radioactive animal carcasses. Animal carcasses that contain byproduct material with a half-life of less than 120 days may be allowed to decay-in-storage in a freezer dedicated for radioactive material. Animal carcasses must be held for a minimum of 10 half-lives of the longest lived isotope. After 10 half-lives, the animal carcasses may be disposed as non-radioactive, if radiation surveys (performed in a low background area and without any interposed shielding) of the carcasses at the end of the holding period indicate that radiation levels are indistinguishable from background (See section 8.11, "Waste Management").

Animals Used for Research in the Environment

Before a researcher releases an animal that has been injected with a radiopharmaceutical or has had radioactive seeds implanted, the researcher will ensure that the dose that members of the public will receive from the animal is within limits of 10 CFR 20.1301. 10 CFR 20.1301 requires that the total effective dose equivalent to an individual member of the public from the licensed operation does not exceed 1 mSv (0.1 rem) in a year and that the dose in any unrestricted area from external sources does not exceed 0.02 mSv (0.002 rem) in any one hour. Further, the researcher may be required to perform an assessment of the impact the byproduct material will have on the environment (See section "Purpose(s) for Which Licensed Material Will Be Used").

Veterinary Use

Training

NRC believes that to demonstrate adequate training and experience, the veterinarian should have training and experience commensurate with the scope of proposed activities. Training should include the following subjects:

- Radiation Protection Principles
- Characteristics of Ionizing Radiation
- Units of Radiation Dose and Quantities
- Radiation Detection Instrumentation

- Biological Hazards of Exposure to Radiation (appropriate to the types and forms of byproduct material to be used)
- Hands-on Use of Radioactive Materials.

The length of the training (usually 40 hours) will depend upon the type, form, quantity and proposed use of the licensed material requested, but training shall cover the subjects stated.

Contamination Control and Waste Handling

See above section, "Laboratory Animals."

Release of Animals

Before a veterinarian releases an animal that has been injected with a radiopharmaceutical or has had radioactive seeds implanted, the veterinarian must ensure that the dose that members of the public (including the animal's caretaker) will receive from the animal is within limits of 10 CFR 20.1301. 10 CFR 20.1301 requires that the total effective dose equivalent to an individual member of the public from the licensed operation does not exceed 1 mSv (0.1 rem) in a year and the dose in any unrestricted area from external sources does not exceed 0.02 mSv (0.002 rem) in any one hour. Furthermore, licensees should provide instructions to the animal's caretaker to keep doses ALARA.

Instructions to Animal Caretaker Upon Release

The instructions should be specific to the type of treatment given, such as permanent implants or radioiodine for hyperthyroidism or thyroid carcinoma, and they may include additional information for individual situations. The instructions should not, however, interfere with or contradict the best medical judgment of the veterinarian. The instructions should include the name of a knowledgeable person to contact and that person's telephone number, in case the caretaker has any questions. Additional instructions appropriate for each modality, as shown in examples below, may be provided.

Sample Instructions to Caretakers of Animals Administered Radiopharmaceuticals or Other Unsealed Materials

Radiopharmaceutical instructions, to the caretaker, should include the following topics:

- Maintaining distance from people
- Minimizing time in public places (e.g., walks on public sidewalk, parks, beaches, grooming salon)
- Precautions to reduce the spread of radioactive contamination, including animal excreta (which may need to be held for decay)⁴.
- The length of time each of the precautions should be in effect.

Example Radiopharmaceutical Instructions

The animal has been treated with radioactive material (isotope) and still possesses a low level of radioactivity. The present level of radioactivity is below the regulatory agency level necessary for isolating the animal from humans. Because some radioactivity will be present for the next few days, it is necessary that the following safety precautions be exercised for the next _____ days:

1. The animal should be kept inside or in his cage/stall following hospital discharge.
2. The animal should not be permitted to have prolonged contact with children under the age of 12 for ____ days following hospital discharge. Close contact should be limited to less than ____ minutes per day.
3. Pregnant women should avoid ANY contact with the animal or its urine and/or feces for at least ____ days after discharge.
4. Family members should not be permitted to sleep with the animal for ____ days after discharge. They also should limit close contact with the animal (being within 1 meter or 3 feet of the animal) for the next ____ day(s) to no more than ____ minutes a day. Preferably, contact with the animal should be kept to a distance of more than 1 meter or 3 feet for this period.
5. Use a plastic litter pan liners and a scoopable litter (for cats).
6. Disposable gloves should be worn whenever changing the litter box for the next _____ days after discharge.
7. Wash hands after contact with the animal or the litter.
8. Call _____ to discuss any other radiation safety concerns.

⁴ Many solid waste disposal facilities have installed radiation detectors, at the entrance, to prevent the disposal of byproduct material at landfills. If the detectors indicate that there is radioactive material in the waste truck, the waste disposal facility staff or a contractor must search the truck and remove the radioactive material, which is a costly and time-consuming process. Although it is proper to dispose of animal excreta in a landfill, caretakers should consider storing animal excreta in a remote location to allow the radioactive material to decay. If applicable, caretakers should contact the veterinarian for further information about the length of time that animal excreta should be held for decay.