ILLINOIS EMERGENCY MANAGEMENT AGENCY

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IEMA SUPPLEMENTAL GUIDANCE

SUBJECT: Guidance for Applicants Requesting Release of Animals treated with Radiopharmaceuticals

Purpose

This supplemental guidance specifies the minimum criteria the IEMA Radioactive Materials licensing unit staff will require for evaluation of public dose limits when animals are to be released after being administered radiopharmaceuticals for research or veterinary purposes. The criteria are meant to address the considerations brought forth in NUREG 1556 Vol. 7, Rev. 1, formulate a consistent basis for the evaluation of proposed use and are subject to change as is necessary to protect the public from unnecessary exposure to ionizing radiation.

Background

NUREG 1556 Vol. 7, Rev. 1 specifies that a licensee should develop criteria for assessing the release of animals that have received radioactive material for diagnostic, therapeutic or research purposes. The criteria need to ensure that the dose to members of the public will not exceed 1 millisievert (mSv) [0.1 rem or 100 millirem (mrem)] in a year and 0.02 mSv [0.002 rem or 2 mrem] in any one hour. A member of the public is any individual, except when that individual is receiving an occupational dose. Members of the public, therefore, include bystanders, pet owners, family members, or caretakers of the animal after the research or veterinarian has released it. Example criteria are provided for the release of cats having been administered I-131 for hyperthyroidism and set the baseline expectations IEMA will utilize in authorizing such activities:

- Cats are held not less than 4 complete days [96 hours] after administration, AND
- the dose rate is less than 0.01 mSv per hour (mSv/h) [1 milliroentgen (mR/h)] at 6 inches or 0.0025 mSv/h [0.25 mR/h] at 1 foot, AND
- written instructions are provided to the owners, AND
- the licensee can demonstrate that a member of the public would not receive a dose from the cat that would exceed 0.02 mSv [2 mrem] in any one hour or 1 mSv [100 mrem] in a year

NUREG 1556 Vol. 7, Rev. 1 acknowledges the regulator may accept alternative release criteria on a case-by-case basis, and recommends the following minimum factors in their evaluation:

- The instructions provided should provide a margin for dose reduction, but not be the primary means of keeping the dose to members of the public below the applicable limits.

- The release criteria should be based on patient and radiopharmaceutical-specific data.
- The instructions pertaining to the extent and duration of contact permitted with the animal should be easy for the owner to comply with
- The potential dose should be well below the 2 mrem in any one hour and 100 mrem in a year public dose limit.
- Additional consideration may be necessary when establishing the date for release of a pet treated with I-131 to a home with small children.

Notably, this guidance document did not recommend release criteria for cats above 0.5 mR/h at one foot due to concerns with exceeding the public dose limits. Additionally, cats released at higher radiation levels also may contain enough radioactive materials that I-131 contamination of the owner and home may be of concern.

Although historically, IEMA radioactive material licenses have authorized the veterinary treatment of cats with I-131 and utilized a release rate of 0.5 mR/hour at one meter; IEMA has aligned with the guidance and maximum release rates specified above. Should an applicant wish to deviate from the recommendations in NUREG 1556, Vol. 7, Rev. 1 or propose a use not specifically addressed in that guidance, this document provides the criteria IEMA will generally utilize to evaluate such a proposal.

Evaluation Criteria

Ideally, a standard set of conditions is preferable that governs the release of all animals administered radiopharmaceuticals and ensures compliance with the public dose limits specified in 32 Ill. Adm. Code 340.310. In order to be adequately encompassing of all potential exposure pathways, these criteria would need to account for contaminated excreta and owner/pet behaviors that would increase the likelihood of exceeding 2 mR in any one hour or 100 mR/year (for example, co-sleeping or lap-sitting). The assumptions therein may not be appropriate for all radiopharmaceutical administrations or pets – as is the case for Sn-117m in dogs when compared to I-131 treatment of cats.

The DNS-RAM Section concurs that the example release criteria provided in NUREG 1556 Vol. 7, Rev. 1 are conservative and adequately protective of the public dose limits when applied to the release of cats administered I-131. Although these should be the baseline expectations for the release of cats administered I-131, they are likely not applicable for any other animal or proposed radiopharmaceutical use. Therefore, if an applicant/licensee wishes to release a cat administered I-131 outside of the baseline parameters specified in NUREG 1556 Vol.7, or if the proposed use differs in radionuclide or animal; then tailored procedures will need to be submitted which include additional administrative controls (where appropriate) to ensure public dose limits are not exceeded. These procedures will need to address, at a minimum, the following:

1. Bioavailability and contamination potential from excreta. This should include total activity retained at the time of animal release, likely owner uptake (CDE), and handling of contaminated items. *Please note: Reg Guide 8.39, Appendix B, section B-3 provides a calculation methodology that may be appropriate for licensees to utilize in estimating the contribution to public dose from this exposure pathway.*

2. Proposed external exposure rate, measured from any point on the animal, under which the animal may be released. The maximum afforded exposure rate shall not exceed 0.05 mSv (0.005 rem) in 1 hour at 30 centimeters from the source of radiation or from any surface that the radiation penetrates (correlating to 0.45 mR/hour, measured at one meter.) Following NUREG 1556 Vol. 7, Rev. 1, the maximum exposure rate for release of cats administered radioiodine should not exceed 0.5 mR/hour, measured at one foot. The applicant's procedures should include an assessment of living conditions and pet/owner behavior and the resulting cumulative external dose over the remaining mean life of the radiopharmaceutical.

3. The total effective dose equivalent expected to the maximally exposed member of the public as a result of the animal release in accordance with the applicant's alternate procedures. EDE shall not exceed 2 mR in any one hour to any member of the public. CEDE + EDE shall not exceed 100 mR in a year to the maximally exposed individual. The applicant shall address any special considerations for mitigating exposure to young children in the house with the released animal.

4. If living conditions or pet/owner behavior is modified to meet the public dose limits specified in 32 Ill. Adm. Code 340.310, the following documentation is required:
    a. An analysis of how the modified conditions/behavior will result in compliance with the public dose limits.
    b. Description of the means by which the behavior or conditions are identified that would result in a public dose limit exceedance (i.e., a pre-screening questionnaire)
    c. Signed acknowledgement by the owner that behavior and/or conditions will be modified to meet public dose limits (i.e., no co-sleeping for 9 weeks)
    d. A copy of the instructions provided to the animal owner. Instructions should clearly specify the extent and duration of contact permitted with the animal and be reasonably able to be met by the owner. Instructions shall include address of any young children in the house with the released animal (if applicable).
    e. A commitment that the authorized user will state in writing that he or she is satisfied of the owner's willingness and ability to comply with necessary instructions, that the animal is suitable for release and the public dose limits specified in 32 Ill. Adm. Code 340.310 are not likely to be exceeded.
    f. A commitment that the licensee will evaluate compliance with the modified living conditions and pet/owner behaviors, at a minimum, one week after patient release. The means by which this evaluation will be conducted, the criteria that will be evaluated, and the manner in which the licensee will calculate compliance with public dose limits should be specified in the application.
    g. A commitment to report exposures, identified in (f), which exceed the limits for an individual member of the public in 32 Ill. Adm. Code 340.310; in accordance with the provisions of 32 Ill. Adm. Code 340.1230(a)(2).

Questions regarding this supplemental guidance may be directed to ema.speclic@illinois.gov or you contact the Radioactive Materials Section at (217) 785-9947.