MEMORANDUM TO: James M. Trapp, Director  
Division of Nuclear Materials Safety  
Region I

FROM: Daniel S. Collins, Director  
Division of Materials Safety, Security, State /RA/  
and Tribal Programs  
Office of Nuclear Material Safety  
and Safeguards

SUBJECT: RESPONSE TO TECHNICAL ASSISTANCE REQUEST DATED 4/27/2018, CENTRAL HOSPITAL FOR VETERINARY MEDICINE, NEW HAVEN, CT

I am responding to your technical assistance request (TAR) dated April 27, 2018 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML18122A140). In the TAR, you are requesting (1) an evaluation of Central Hospital for Veterinary Medicine’s proposed release criteria for dogs treated with radioactive Tin-117m (Sn-117m) for radiation synovioarthrosis of the elbow as part of their license amendment application requesting authorization for such treatment, (2) guidance on acceptable release criteria for dogs treated with Sn-117m, and (3) clarification of whether the licensee can take credit for specific verbal instructions in developing their release criteria.

Issue:

NUREG-1556, Volume 7, Rev. 1, “Consolidated Guidance About Materials Licenses: Program Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope, Including Electron Capture Devices and X-ray Fluorescence Analyzers” provides generic guidance for veterinary release of animals that receive radioactive material for diagnostic, therapeutic, or research purposes; however, it only includes specific guidance for release of cats following radioactive sodium iodine (I-131) therapy. Due to the differences in the radiation profile, half-life, and retention of Sn-117m colloid as compared to sodium I-131 and the different behavior patterns of cats and dogs, the specific guidance for release of cats following sodium I-131 treatment is not appropriate for dogs following Sn-117m colloid treatment. Therefore, Region I requested the Office of Nuclear Material Safety and Safeguards (NMSS) evaluate Central Hospital for Veterinary Medicine’s proposed release criteria for dogs treated with Sn-117m.

CONTACT: Katie Tapp, NMSS/MSST  
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Background:

Any animal that has been administered a radioactive compound cannot be released until the licensee ensures that the dose that members of the public will receive from the animal is within limits of Title 10 of the Code of Federal Regulations (10 CFR) 20.1301, “Dose limits for individual members of the public.” Regulations in 10 CFR 20.1301 require that the total effective dose equivalent to an individual member of the public from the licensed operation does not exceed 1 millisievert (mSv) [0.1 rem or 100 millirem (mrem)] in a year and that the dose in any unrestricted area from external sources does not exceed 0.02 mSv [0.002 rem or 2 mrem] in any 1 hour. As defined in 10 CFR 20.1003, 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 other caretakers of the animal who are not occupational workers.

Discussion:

Evaluation of Licensee’s Release Criteria Request using Dose Rate

As detailed in the license amendment request, the licensee requests authorization to immediately release dogs following Sn-117m radiation synoviorthesis if the dog’s dose rate is below 0.5 mR/hr at 1 meter (m). As described earlier, 10 CFR 20.1301 provides that doses to members of the public not exceed 100 mrem in a year. As a dog is likely to get treatment in both elbows, a 50 mrem limit per release is suggested by the licensee.

The dose to a person from a dog released can be calculated from the released dose rate:

\[
D = D_r \frac{T_{\text{eff}}}{\ln 2} \sum_n E_n \left(\frac{d_o}{d_n}\right)^2
\]

where D is total dose; \(D_r\) is the dose rate measured at a distance from the dog, \(d_o\); \(T_{\text{eff}}\) is the effective half-life; and E is the occupancy factor which the person is at a specific distance, \(d_n\), from the dog. Since over 99 percent of the Sn-117m colloid stays in the joint, the \(T_{\text{eff}}\) is approximately equivalent to the physical half-life of Sn-117m, which is 14 days. By using the equation above, the number of hours in a day it would take for an individual to receive 50 mrem at different combinations of distances can be determined. A limit of 50 mrem was used instead of 100 mrem since dogs would likely need to receive treatment on both elbows.

Using the equation above with the licensee’s proposed dose rate of 0.5 mR/hr at 1 m, an individual would only be able to spend 6.6 minutes a day (\(E_n = 0.005\)) at a distance of 0.15 m (approximately 6 inches) from a dog, assuming the individual had no other exposure to the dog, to receive a yearly dose of 50 mrem. Similarly, an individual would only be allowed to spend a total of 27 minutes a day (\(E_n = 0.05\)) at a 0.3 m (1 foot) or 5.0 hours a day (\(E_n = 0.21\)) at 1 m (3.3 feet) before the individual would exceed the 50 mrem limit. As it would be unlikely that most human interactions with a treated dog would be limited to and below these times, the licensee’s request to use a release criteria of 0.5 mR/hr at 1 m is determined to be inadequate to ensure compliance with 10 CFR 20.1301.

To show the possible consequence of releasing a dog with a measured dose rate of 0.5 mR/hr measured at 1 m following Sn-117m treatment, the dose that a person might receive if they were next to the dog at two different distances for 8 hours a day, such as a person who slept
next to a dog, was calculated. If one assumed that a person did not follow the instructions and that that person was at 0.3 m from the dog for 8 hours a day, the calculated dose would be 897 mrem in a year. If a person was 1 m from the dog for 8 hours a day, the calculated dose would be 80.7 mrem in a year. Additionally, if one assumed a person followed instructions for one month and received no exposure during that time, but then decided to sleep next to or be close to his dog, that person’s dose would be 215 mrem for 8 hours a day at 0.3 m and 19.4 mrem at 1 m. This information is additionally displayed in the table below, where an occupancy factor of 0.33 is equivalent to 8 hours per day.

<table>
<thead>
<tr>
<th>Occupancy Factor for first month at specified distance</th>
<th>Occupancy Factor after first month at specified distance</th>
<th>Calculated Dose (mrem/year) at 0.3 m</th>
<th>Calculated Dose (mrem/year) at 1 m</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.33</td>
<td>0.33</td>
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<tr>
<td>0</td>
<td>0.33</td>
<td>215</td>
<td>19.4</td>
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These scenarios show that the possible dose an individual might receive from a common dog-human interaction scenario exceeds the 100 mrem dose limit from a single treatment. The dose might be even higher if the dog has even closer or more frequent interaction with the owner, such as a dog that is near an owner during the day and sleeps next to an owner at night. If a release criteria is to be developed for any dog, further evaluation would need to be completed to determine conservative occupancy factors based on typical human interaction with dogs.

**Evaluation of Licensee’s Request for Outpatient Sn-117m Radiation Synoviothesis**

In a study provided in the license application entitled, “Release from Radiation Safety Quarantine of Canine Patients that have been treated with Sn-117m-Synoviothesis,” dated October 4, 2015, a Monte Carlo model was used to simulate the expected dose rate from the elbow of a dog. The simulated dose rate, 143 uR/mCi-hr at 1 m, is slightly higher than the average measurement of 133.3 uR/mCi-hr measured among 5 treated dogs. Both the simulated and measured dose rates were lower than the expected dose rate from a bare source in air, which is 169 uR/mCi-hr. Using the simulated dose rate and assuming a dog gets the highest therapeutic dose of 3.3 mCi, the highest radiation dose rate expected at 1 m would be approximately 0.5 mR/hr. As this was shown unacceptable above, the licensee’s request to immediately release the dog following this treatment protocol would not be acceptable.

In addition to evaluating the licensee’s proposed release criteria, the TAR additionally requests generic guidance on acceptable release criteria for dogs treated with Sn-117m using the treatment dosages specified in the veterinary procedures. It was determined by NMSS that the development of such guidance could not be created in response to a TAR and would need to be developed in a guidance document, such as a Regulatory Guide. NMSS staff plans to initiate an effort, in coordination with the Agreement States and the Regions, to publish such guidance in the future.

**Use of Written Instructions to Ensure Compliance with Public Dose Limit**

While NUREG-1556, Vol. 7, Rev. 1 only has specific guidance regarding the release of cats following radioactive sodium I-131 treatment, it does have general guidance regarding use of instructions following veterinary treatment. As stated in NUREG-1556, instructions can be used to provide some degree of dose reduction but should not be relied upon as the primary way of keeping the dose to members of the public below 1 mSv [0.1 rem or 100 mrem] in a year. Any instructions that are used to provide a margin of dose reduction should be evaluated by
licensees and license reviewers with respect to the ease with which owners can comply and the
degree and duration of compliance needed to ensure that the maximum dose to a member of
the public does not exceed the dose limit. To ensure owners can understand and comply with
instructions, they should be given in writing and verbally prior to treatment. NUREG-1556,
Volume 7, Rev. 1, provides more guidance on information that should be listed in instructions.

In developing release criteria and instructions for a new veterinary treatment using radioactive
materials, one needs to consider how the radiological properties of the radiopharmaceutical
would affect the dose to humans around the animals. As Sn-117m has a Teff of 14 days, the
dose rate around a treated dog will remain relatively high for several months following
treatment. Therefore, the licensee would need to have extremely high confidence that the
owner could maintain the behavior listed in the instruction and should not rely on instructions
that significantly change the way the dog interacts with humans. For example, if a dog typically
sits next to its owner for several hours a day, the licensee cannot assume that the dog will not
sit next to its owner following treatment because the licensee provided the owner with generic
instructions saying the owner should minimize proximity to the pet whenever possible for the
first month. If a licensee wishes to create specific release criteria based on the animal’s typical
behavior, the licensee should provide the U.S. Nuclear Regulatory Commission (NRC) with the
criteria used in the screening and subsequent evaluation and should ensure there is adequate
safety margin to ensure compliance with 10 CFR 20.1301. The licensee should still provide the
owner with instructions even if they use the dog’s typical behavior to create the specific release
criteria to ensure the owner understands that the dog needs to maintain this behavior for a
specified time as it was used in the evaluation to support the release.

As shown, the licensee’s proposed instructions do not include specific guidance on the type of
permissible contact and the duration of contact by individuals with the animal. Therefore, these
instructions cannot be evaluated to determine the ease to which owners could comply or how
they will be used to ensure that the maximum dose to a member of the public will not exceed
the dose limit. Further, instructions would likely significantly change the way the treated dog
interacts with its owner because it would have to direct potential behavior changes by
minimizing proximity to the treated dog as the maximum amount of time a dog could be near an
individual would be short. Therefore, the licensee’s proposal to use instructions to ensure the
public dose limit of 100 mrem per year is met is not adequate to support release of the dogs for
any release criteria

Conclusion

In responding to the TAR submitted by Region I, NMSS staff reviewed the instructions for
release, dose rate release criteria, and outpatient release of dogs treated with Sn-117m for
radiation synoviorthesis of the elbow. After evaluation, NMSS staff found that a release criteria
of 0.5 mR/hr measured at 1 m is unacceptable as it would, in common dog-human interactions,
result in doses greater than the public dose limit of 100 mrem/year found in 10 CFR 20.1301.
Additionally, NMSS staff also found that the licensee’s proposed instructions to be inadequate
as they do not include guidance on the type of permissible contact and the duration of contact
by individuals with the animal.
SUBJECT: RESPONSE TO TECHNICAL ASSISTANCE REQUEST DATED 4/27/2018,
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