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Paper

Update and Extension of Release Criteria for Canine ^{117m}Sn Treatments

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Abstract—**Tin-117 m (^{117m}Sn) is used to treat dogs with osteoarthritic joints by radiosynoviorthesis. The internal conversion and Auger electrons emitted by the ^{117m}Sn provide the therapeutic effect. Sn-117 m also emits x rays and gamma rays, of which the most significant is 158.6 keV. Accurate information regarding the interactions of a person with a treated dog is needed to determine the person's total dose and thus regulatory compliance; i.e., a time and motion study. Prior studies have characterized the radiation field emitted by a treated dog, determined the effective dose rates to a person based on those radiation fields, and evaluated dog-human interactions. These studies have been tied together to calculate the prospective dose to the owner of a treated dog. The behavior modifications needed to comply with public dose limits were identified, and a template for written instructions limiting dose was developed. Further calculations based on the written instructions were made to determine the necessary duration of the instructions. The result is guidance that may be used by veterinary practitioners to release treated dogs in accordance with the public dose limits.**
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Key words: dose assessment; dogs; medical radiation; x rays

INTRODUCTION

RADIOSYNOVIORTHESIS IS used to treat chronic pain and inflammation of osteoarthritis (OA) in dogs. Veterinarians turn to radiosynoviorthesis in cases where the primary and secondary line of treatments are found to be inadequate, and there is a lack of other treatment options. Synovetin OA is a colloid containing tin-117 m (^{117m}Sn) that can be used to treat osteoarthritic dog joints such as the elbow, the stifle (the equivalent of the human knee), and hip.

The use of ^{117m}Sn radiosynoviorthesis in veterinary medicine is relatively new. As a new therapeutic modality, there are some safety concerns that need to be addressed. The patient safety aspects have previously been addressed (Srivastava 2007; Doerr et al. 2015; Stevenson et al. 2015; Aashish 2018; Lattimer et al. 2019). For commercial use, radiation safety for members of the public must be addressed to ensure compliance with regulatory requirements of those persons sharing a household with the treated dog (the critical group). Veterinary medicine is regulated under 10 CFR 30 rather than 10 CFR 35, and thus the public dose limits in 10 CFR 20 (US NRC 1991) or the Agreement State equivalents apply to veterinary medicine in all states except Texas which regulates veterinary medicine under Title 25 Texas Administrative Code Chapter 289 Rule 256 (Texas 2018)—the Texas equivalent of 10 CFR 35. There are two criteria that must be met for release of a dog (US NRC 1991):

- 10 CFR 20.1301(a)(1): The total effective dose equivalent to a member of the public shall not exceed 1 mSv in 1 year; and
- 10 CFR 20.1301(a)(2): The dose to a member of the public shall not exceed 0.02 mSv in any 1 hour.

This paper expands on earlier work that has been done on this subject to present a consistent framework that can be used to specify release for canine ^{117m}Sn treatment sufficient to ensure compliance with public dose limits for an expanded range of release dose rates and for different joints.

Background

In the last 2 y, the non-broad scope facilities licensed for canine ^{117m}Sn treatment have expanded into all four US NRC regions and most Agreement States. The US NRC was the first regulatory agency to license canine ^{117m}Sn treatment as described in more detail below. Subsequently, most Agreement States have since licensed canine ^{117m}Sn treatment or are in the process of doing so. While generally the same, each regulatory jurisdiction has different license requirements and conditions tied to the license and different scopes of allowed treatments.

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The original licensing approved by the US NRC was based on simplistic and conservative external dose and dose rate modeling techniques and was limited to treatment of canine elbows up to a specified maximum measured external dose rate at 1 m. Since then, the external dose and dose rate modeling techniques have been refined, the modeling has been extended to explicitly model different ages (infant through adult) of members of the public, and evaluation of joints other than elbows has been conducted. What remains is to use this new data to update the actual release criteria used by veterinary practitioners. Each of these revised inputs, the analyses pulling them together, and the updated release criteria are described below.

INPUTS AND METHODS

Original analysis

A review of interactions between osteoarthritic dogs and their owners was conducted by Arno (2020) based on a study of dog-human interactions by Westgarth et al. (2008) and Patel et al. (2017). The review evaluated common interactions such as carrying, feeding, walking, petting, lap-sitting, sleeping, etc., and developed four categories of overall interaction types based on the length of time spent at various distances. These categories and the associated typical times and distances are summarized in Table 1 in increasing order of the amount of time spent in proximity to the dog. The distances and time were conservatively selected to encompass specific likely behaviors while being generic enough to allow for other behaviors that fit into the specified time and distance categories.

Dogs with osteoarthritis, and thus candidates for ^{117m}Sn radiosynviorthesis treatment, usually fall into the *common category* because they do not spend prolonged time in close contact (touching) with their owner(s) as they are older and larger with painful joints that are sensitive to the touch and have mobility limitations. A typical behavior for the *extended close category* is a dog that interacts closely with the owner but for limited periods, such as only in the evenings when the owner is home from work. The *extended intermediate category* is typified by a dog that spends a considerable portion of the day at the feet of an owner that works from home or is otherwise relatively sedentary. The *prolonged close & intermediate category* is for dogs that spend significant portions of the day in direct contact with their owner, such as sleeping with their owner.

Table 1. Behavior categories and times.

Scenario	On-contact	30 cm	1 m
Common	≤5 min	>15 min	≤4 h
Extended Close	≤5 min	<3 h	≤4 h
Extended Intermediate	≤5 min	>15 min	≤12 h
Prolonged Close & Intermediate	≤5 min	<11 h	≤9 h

Simplistic dose rate calculations performed using Microshield (Grove Software, Lynchburg, VA) were used to convert these times and distances into prospective dose rates. Those dose rates served as the basis for determining the maximum allowable exposure durations consistent with compliance with the public dose limits, which in turn led to the development of written instructions for the dog's owner (s) to implement those limits. The written instructions were patterned after those contained in NUREG-1556 Volume 7 Revision 1 Appendix D (US NRC 2018) and NCRP 148 (NCRP 2004) for ^{131}I treatment of cats but altered to address the specific characteristics of ^{117m}Sn. Fig. 1 provides a template of the written instructions. Maximum allowed activity times of 1 min, 15 min, and 4 h are used for distances of <30 cm, 30 cm, and 1 m, respectively, over the duration of the written instructions. These same written instructions form the basis for this update and extension with the variable being the required duration of the instructions.

Update of age-dependent dose rates

Arno and Smith (2021) re-evaluated the dose rate from a treated joint to individuals based on the radiation field interaction with the receptor using Monte Carlo N-Particle Transport (MCNP). It is common to refer to the distance between an individual and a radiation source based on the minimum separation. However, this "closest point of approach" method is not suitable for determining an overall effective dose rate. Simple geometric attenuation or point source approximations are not appropriate given the significant variations in distance that may occur. As an example, the treated joint of a dog standing beside its owner may be "in contact" with the owner's leg, yet 0.5 m removed from the individual's torso and further still from the individual's head. Thus, the dose rate to the person's leg, torso, and head are all substantially different and the inverse square law does not apply.

The effective dose rate received by a person interacting at close distances with a treated dog is needed to determine the person's total effective dose and thus regulatory compliance. The US Nuclear Regulatory Commission provides guidance on how to calculate a quantity described as the Effective Dose Equivalent eXternal (EDEX) in non-uniform radiation fields in their Regulatory Guide 8.40 (US NRC 2010). MCNP models of the interactions for five ages (1, 5, 10, and 15 y old, and adult) of humans at three distances ("on-contact," 30 cm, and 1 m) were created to determine the effective dose rates using the methodology from US NRC Regulatory Guide 8.40. Ratios of the effective dose rate to the person in Sv h^{-1} to the measured dose rate in Gy h^{-1} at 1 m from the same source were calculated and are given in Table 2 taken from Arno and Smith (2021).

To maintain overall exposure below regulatory limits, follow these recommendations for the next_____weeks.

- ✓ Remember to maintain your exposure as low as reasonably achievable (ALARA).
- ✓ Do not sleep with the dog or hold the dog in or near your lap.
- ✓ Each member of the household should avoid direct contact with the treated joint(s) as much as possible. Daily direct contact should be limited to _<1_ minute. **Direct** activities are those that are <1ft from the dog's treated elbow to the owner's torso (e.g., carrying the dog where the elbow is in contact or lap sitting where the elbow is directly on the torso).
- ✓ Each member of the household should limit close contact to _15_ minutes and should limit intermediate contact to _4_ hours. Activities such as walking or playing with your dog can continue with distance limitations maintained. **Close** activities are at 1ft (e.g., feeding, grooming, sleeping, and routine lap-sitting) and **Intermediate** activities are at 3ft (e.g., walking, jogging, and officing).
- ✓ Minimize the time that children and pregnant women spend in close contact with the dog.
- ✓ Avoid long term/daily boarding or commercial grooming of your dog for two weeks or traveling with it by air or across any international borders or very large, organized events (professional sporting events, parades, etc.). Provide a copy of this document should any questions arise.
- ✓ Minimize use of public transportation and staying in public accommodations (e.g., hotels). Transport your dog in its carrier and/or as far from passengers as is reasonable and safe for the dog.
- ✓ Follow up care is recommended where your dog received this treatment. If your dog needs emergency care, please inform the provider about its treatment with radiotherapy, and to contact (*insert contact information here*) with any questions.

Fig. 1. Generic release instruction template.

Extension to hips and stifles

The radiation field around a treated dog is significantly anisotropic. The dog's torso attenuates the radiation being emitted toward the opposite side of the dog's body, whereas the radiation emitted on the same side as a treated joint is attenuated only by the tissue around the treated joint itself. Arno et al. (2021) evaluated this anisotrophy for canine hips and stifles by comparing the radiation dose rate in various directions around a dog with the maximum dose rate measured at the same distances of 30 cm and 1 m. This study built upon earlier work (Arno 2020) that performed the same measurements for canine elbows.

The maximum dose rate at a given distance will typically be measured either in the cranial or lateral direction with respect to the dog and at a height corresponding to the dog's treated joint(s). However, this height is quite low, corresponding to a human's knee height or less. The actual effective dose rate experienced by a person will be modified by the height difference between the dog's joint and the center of the person's torso and the interposition of the mass of the dog's torso, upper leg, and other bony and soft tissues. In general terms, there are nine basic geometries that may be encountered and described in terms of cardinal directions:

- Anterior, posterior, left lateral, and right lateral at treated joint height;
- Anterior, posterior, left lateral, and right lateral at standing torso center height; and
- Dorsal (above).

These nine measurements at each distance were averaged to determine the average dose rate around the dog that is most representative of the average dose rate to a person interacting with the dog at that distance. The percent reduction in average dose rate compared to the maximum dose rate at each distance can then be calculated. From a radiation safety perspective, the important factor is the minimum percent reduction in the average compared to the maximum that can be expected. A reasonable measure for this value is the 5th percentile of the dose rate reduction. The 5th percentile dose rate reductions were determined to be 27% at 0.3 m and 21% at 1.0 m (Arno et al. 2021).

Table 2. Normalized dose rates, Sv h^{-1} at each distance per measured Gy h^{-1} at 1 m.

Distance	Adult	15-y-old	10-y-old	5-y-old	1-y-old
Contact	11.8	13.2	19.8	28.4	30.2
0.3 m	2.8	3.0	3.6	4.2	5.1
1.0 m	0.52	0.53	0.58	0.62	0.68

Calculations

When a dog is ready to be released from the veterinary facility, the dog is surveyed at a distance of 1 m from the nearest treated joint to find the maximum dose rate in μGy h^{-1}. Determining the maximum dose rate at this distance is a familiar process to the facility staff since the same procedure is commonly used when receiving a shipment of radioactive material. This dose rate is used as the input to the calculations.

The effective dose to a member of the public is then calculated by assuming that a person is around their dog for the maximum period of time allowed by the written

Table 3a. Adult instruction durations, weeks.

	Release dose rate at 1 m, μGy h^{-1}									
Scenario	1	2	3	4	5	6	7	8	9	10
Common	2	2	2	2	2	2	2	2	2	2
Extended Close	2	2	2	2	2	2	3	3	4	4
Extended Intermediate	2	2	2	2	2	2	2	2	2	3
Prolonged Both	2	2	2	3	4	5	6	6	7	7

Table 3b. 15-y-old instruction durations, weeks.

	Release dose rate at 1 m, μGy h^{-1}									
Scenario	1	2	3	4	5	6	7	8	9	10
Common	2	2	2	2	2	2	2	2	2	2
Extended Close	2	2	2	2	2	2	3	3	4	5
Extended Intermediate	2	2	2	2	2	2	2	2	2	3
Prolonged Both	2	2	2	3	4	5	6	6	7	8

Table 3c. 10-y-old instruction durations, weeks.

	Release dose rate at 1 m, μGy h^{-1}									
Scenario	1	2	3	4	5	6	7	8	9	10
Common	2	2	2	2	2	2	2	2	2	2
Extended Close	2	2	2	2	2	3	4	4	5	6
Extended Intermediate	2	2	2	2	2	2	2	2	3	4
Prolonged Both	2	2	3	4	5	6	7	7	8	9

Table 3d. 5-y-old instruction durations, weeks.

	Release dose rate at 1 m, μGy h^{-1}									
Scenario	1	2	3	4	5	6	7	8	9	10
Common	2	2	2	2	2	2	2	2	2	2
Extended Close	2	2	2	2	3	4	4	5	6	7
Extended Intermediate	2	2	2	2	2	2	2	3	4	5
Prolonged Both	2	2	4	5	6	6	7	8	9	10

Table 3e. 1-y-old instruction durations, weeks.

	Release dose rate at 1 m, μGy h^{-1}									
Scenario	1	2	3	4	5	6	7	8	9	10
b	2	2	2	2	2	2	2	2	2	3
Extended Intermediate	2	2	2	2	2	2	3	4	5	7

instructions for the duration of those instructions. It is assumed that after expiration of the written instructions, the family will return to its prior behaviors with the treated dog as categorized in Table 1. With regard to the treated dog, the pain relief and increase in activity provided by the injection is not instantaneous (Aulakh et al. 2021). The improvement is gradual with time, and thus the dog's behavioral activity can be expected to initially remain the same. Therefore, their effective dose is based on the maximum times and distances allowed by that categorization.

The measured maximum dose rate at release is multiplied by the anisotrophy reduction factors (the Sv h^{-1} per Gy h^{-1} at 1 m ratios and the respective allowed daily interaction times for on-contact, 30-cm, and 1-m distances) and integrated to account for radioactive decay over the entire respective time intervals. The variable in this calculation is the duration of the written instructions. The duration is selected based on the minimum whole week increment that will result in an effective dose of less than 0.95 mSv and using a minimum of 2 wk; 0.95 mSv was selected rather than 1 mSv to provide a margin of conservatism. The minimum instruction duration has been set to 2 wk even where not strictly necessary as an ALARA measure.

All calculations were performed using the following equation:

$$[eq]D_X = \frac{D_0}{\lambda}\left[\left(1 - e^{-\lambda T_i}\right)\sum\nolimits_d \left(Y_{x,d} An_d T_d\right) + e^{-\lambda T_i}\sum\nolimits_{dinf}\left(Y_{x,dinf} An_{dinf} T_{dinf}\right)\right], \quad (1)$$

where:

$Y_{x,d}$ or Y_x

D_x = Total effective dose to a member of the public age X, mSv;

λ = Sn-117 m decay constant, 0.05097 d^{-1};

D_0 = Maximum dose rate at a distance of 1 m at release, mGy h^{-1};

T_i = Duration of release instructions in days;

d or dinf = distances of on-contact, 30 cm and 90 cm;

$Y_{x,d}$ or $Y_{x,dinf}$ = age-dependent dose rate adjustment factor for age X and distance d or dinf;

An_d or An_{dinf} = (1 − aniostrophy reduction factor) at distance d or dinf; and

T_d or T_{dinf} = h d^{-1} during duration of release instructions (T_d) or after the end of the release instructions (T_{inf}) at distance d or dinf.

RESULTS AND DISCUSSION

This evaluation considers dogs released with a dose rate of up to 0.01 mGy h^{-1} at 1 m. The required written instruction duration for the various dose rates at release, interaction category, and individual age are provided in Table 3a through 3e. The veterinary hospital conducts pre-screening prior to ordering ^{117m}Sn radiosynviorthesis treatment to identify the behavior and interaction patterns of the dog with its owner(s) and categorize it into one of these categories. Each person in a household can be separately categorized based on the nature of their particular interactions with the dog; however, for a household, the longest duration required for any individual in that household is then inserted into the duration blank on the written instructions template.

When evaluating the effective dose to members of the public, the dog's owners are the most exposed group, especially with respect to the 1 mSv annual effective dose limit. The effective dose to other individuals such as friends, neighbors, and other people at a dog park are much lower due to the much shorter durations of exposure and longer separation distances from the treated dog.

Unrestricted dose to owners

The maximum evaluated dose rate at which a dog may be released is 0.01 mGy h^{-1} at 1 m. Based on this maximum dose rate, these conservatively estimated contact times result in an effective dose of 0.6 mSv to an adult owner if the dog does not co-sleep with the owner, sit in its owner's lap, or lie at the feet of someone who offices at home—well below the 1 mSv y^{-1} public dose limit. For a 1-y-old child, the effective dose under the same scenario is 0.93 mSv—still below the 1 mSv y^{-1} public dose limit. Further, it is unlikely that such a young child would be around a large dog for that length of time. If all three of those behaviors occur, the effective dose to an adult could be as high as 5.5 mSv for the largest dogs. The effective dose to a 5-y-old under the same scenario is 8.1 mSv. The effective dose to a 1-y-old child is not calculated for this scenario because it is unreasonable to conceive of any size dog sleeping in a crib with a 1-y-old. This behavior is credible with a 5-y-old. For the same reason, a 5-y-old is used as the youngest age for the extended close contact scenario. The doses resulting from smaller dogs would scale approximately linearly with the dog's weight due to the reduced activity used to treat smaller dogs.

The worst-case scenario for evaluating whether a person could receive 0.02 mSv in any 1 h during the duration of the written instructions is a person that spends 1 min on contact, 15 min at 30 cm, and the remainder of the hour (44 minutes) at 1 m. Under this scenario, the maximum effective dose would be 0.011 mSv for an adult and 0.019 mSv for a 1-y-old. Two weeks after the procedure, the minimum duration for the written instructions, the worst-case scenario is 5 min on contact and 55 min at 30 cm. Under this scenario, the maximum effective dose would be 0.009 mSv for an adult and 0.013 mSv for a 1-y-old.

For the common contact scenario and dogs released with a dose rate at 1 m of up to 0.005 mGy h^{-1}, the maximum calculated effective dose is below 0.05 mSv to a 1-y-old and even less to an adult. This would allow for multiple treatments during a single year without exceeding the public dose limit. If it is expected that multiple treatments will be needed within a single year, these calculations can be modified to allow a maximum effective dose per treatment of no more than 0.05 mSv, although in some cases more modification than only the release instruction duration may be needed. In particular, it is necessary to limit the contact duration at 1 m in some instances.

Real-world validation

Smith and Krimins (2022) conducted a study of the actual dose to owners from following these instructions. External radiation doses to owners were measured by providing optically stimulated luminescent dosimeters (OSLD) for up to 30 d post-treatment of the pet. Twelve owners were measured over various time frames at two licensed locations independent of each other. In one location, the average OSLD measured 0.029 mSv over a 14-d wear period. In the second location, the average OSLD measured 0.057 mSv over a 30-d wear period; both values were well below the recommended annual public dose. The overall average extrapolated external radiation effective dose was estimated at 0.092 mSv, while the maximum effective dose estimate was 0.25 mSv. The dosimeters measured deep dose equivalent, and it was assumed that the measured dose was the greatest of any whole body part and further assumed that deep dose equivalent was roughly equivalent to the total whole-body effective dose equivalent. The OSLD results and extrapolated owner doses provide reasonable assurance that the public dose limits were met.

CONCLUSION

Treatment of OA in dogs with ^{117m}Sn radiosynoviorthesis is performed after the pain associated with OA has significantly impacted the dog's quality of life and other conservative treatments have failed to provide satisfactory results. Calculations of the prospective dose to an owner were performed that determined that for the vast majority of treated dogs that do not co-sleep or lap-sit, the effective dose from an ^{117m}Sn radiosynoviorthesis treatment would result in no more than 0.93 mSv to a child and 0.60 mSv to an adult from the largest dogs and proportionately less for smaller dogs. For dogs that do sleep in its owner's bed, sit in its owner's lap, or lie by its owner's chair most of the day, written instructions prohibiting these behaviors are necessary to ensure that the effective dose to the owner remains less than 1 mSv. In determining the necessary duration of the written instructions, the durations were selected to result in an effective dose of less than 0.95 mSv to provide a margin of safety.

These instructions and precautions for ^{117m}Sn treatment of dogs are consistent with the established instructions and precautions and do not result in a dose to a member of the public of greater than 1 mSv. The behavior modification of the dogs is limited, most routine daily behaviors are unmodified, and the time period for which modification is needed is limited, making compliance straightforward and manageable.

These written instructions can form part of the basis for licensure and demonstration of regulatory compliance for a veterinary facility wishing to offer this treatment.

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