From:	Laura T. Smith- Physics
To:	Jason Kelly
Subject:	[External_Sender] Fw: U.S. NRC Materials License #21-35657-01 - Request for Additional Information
Date:	Monday, March 9, 2026 11:30:52 AM
Attachments:	Amendment - Updated Procedure V2 091625.pdf

Jason,
Whoops I thought I sent this over the weekend. It is in regards to
U.S. NRC Materials License #21-35657-01 - Request for Additional Information

This document should have the information needed.
Ignore the first page, it was a draft for the doctor to review.

Thank you,
Laura Speer Smith

----- Forwarded Message -----
From: Chad Smith <csmith@fxmasse.com>
To: Laura T. Smith- Physics <lsphysics@att.net>
Cc: ddegner@comcast.net <ddegner@comcast.net>
Sent: Friday, March 6, 2026 at 10:04:24 AM EST
Subject: RE: U.S. NRC Materials License #21-35657-01 - Request for Additional Information

Hi Laura,

You should be able to just send the attached to Jason.

Let me know if you need anything else.

Chad

From: Jason Kelly <Jason.Kelly@nrc.gov>
Sent: Tuesday, March 3, 2026 6:20 PM
To: Laura T. Smith- Physics <lsphysics@att.net>
Cc: Chad Smith <csmith@fxmasse.com>; ddegner@comcast.net
Subject: U.S. NRC Materials License #21-35657-01 - Request for Additional Information

Ms. Smith:

I have reviewed the application dated December 21, 2025, and accompanying letter dated September 26, 2025, signed by Dan Degner, DVM, for an amendment to U.S. Nuclear Regulatory Commission (NRC) Materials License No. 21-35657-01. Upon review, I noted that the request referred to the following attachments:

- Technical Bulletin
- Updated Procedure of Use for Synovetin QA

I was unable to locate the referenced attachments. In fact, your request comprised of only two pages, including NRC Form 313, "Application for Materials License," dated December 21, 2025, signed by Laura T. Speer-Smith, RSO, and the cover letter dated September 26, 2025, dated Dan Degner, DVM.

Therefore, please resubmit your request including the referenced attachments within 15 calendar days. In your resubmission, please refer to your U.S. NRC Materials License No. 21-35657-01 and Control No. 654762.

Jason M. Kelly, MPH, CPH

Health Physicist

Materials Licensing Branch

U.S. Nuclear Regulatory Commission

Region III

2056 Westings Avenue, Suite 400

Naperville, IL 60563-2657

Office: (630) 829-9737

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September 16, 2025

United States Nuclear Regulatory Commission, Region III
2443 Warrenville Road Suite 210
Lisle, IL 60532-4352

License Number: 21-35657-01

At this time, The Animal Joint Care Company is requesting an amendment to the above radioactive materials license as described below.

We request that Item 9.A. read: “For use of Synovetin OA in veterinary medical procedures.” See NRC license number 34-35718-01 as precedent.

Further, we would like to update our procedures of use with a simplification of release instructions for “in-home” domestic companion animals (cats and dogs). The “in-home” domestic companion animal release criteria and restrictions will follow the attached updated procedure with simplifications of two categories of owner behavior instead of four (co-sleepers and all others). A technical bulletin is provided as justification for this amendment request.

The amendment has been combined into a single document for the ease of the reviewer and contains:

1. Cover letter (pages 1)
2. Technical Bulletin (pages 2-4)
3. Updated Procedure of Use for Synovetin OA (pages 5-12)
    a. Updated pre-screening questionnaire for in-home domestic animals.
    b. Updated release instructions for in-home domestic animals.

If there are any technical questions regarding the content attached, please do not hesitate to contact Chad Smith at csmith@fxmasse.com or 978-491-9810, Laura Speer Smith at lsphysics@att.net or 586-808-3058, and Dan Degner, DVM at ddegner@comcast.net or 810-671-0000

Sincerely,

_____
Dan Degner, DVM

4621 S. Cooper Street # 131-332
Arlington, TX 76017
www.foxfirescientific.com

(ph) 877-433-2029
(fax) 877-433-2492
info@foxfirescientific.com

Radiation safety for use of Synovetin OA in animals other than dogs
September 11, 2025
Prepared by Matthew Arno, PhD, CHP, PE

Introduction

In 2020, The US Nuclear Regulatory Commission (NRC) issued a Technical Evaluation Report (TER) detailing a method for releasing dogs treated with Synovetin OA in compliance with 10 CFR 20.1301, i.e., such that a member of the public does not get in excess of 100 mrem and there is not a dose rate in excess of 2 mrem in any one hour.[1] That evaluation took into consideration the nature of human-dog interactions and the geometries of those interactions and in particular the self-shielding provided by the dog's torso. The result of the evaluation were pre-screening questions to permit veterinary staff to categorize how an owner(s) interact with a treated dog and release instructions containing interaction limits dependent on that categorization. This TER was specific to injections of Synovetin OA in dog elbows.

The methodology from that TER was subsequently expanded and refined in a series of publications to apply to any synovial joint. The first one was a publication entitled "Anisotrophy of the Radiation Field Following Canine Sn-117m Treatment" issued in the August 2021 edition of the Health Physics Journal.[2] The purpose of this article was to present the authors' findings regarding how a dog's body, and especially its torso, impact the radiation field around a dog treated with Synovetin OA. This publication presented the original work done and submitted to the NRC in support of the TER that the NRC issued and expanded on that work to also address hips and stifles. The conclusion of the article was that the amount of self-shielding provided by the dog's body was essentially identical for elbows, stifles, and hips. In other words, variation in the injection location does not result in any net change in the radiation field surrounding the dog and thus the radiation safety instructions ("release instructions") for treating elbows would work for treating hips or stifles as well.

The second factor was investigated further in another publication, "Age-Dependent Radiation Dose Rates from Canine Sn-117m Treatments" in the November 2021 Health Physics Journal.[3] This article performed a detailed review of the variation in absorbed dose as a function of age for ages ranging from infants to adults. The primary reason for this study was to improve upon the previous calculations that had been performed using Microshield by updating the calculations using MCNP for greater precision.

The combination of these two papers was used as input to a third paper consolidating the most

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[1] US Nuclear Regulatory Commission 2018b. Response to Technical Assistance Request Dated 4/27/2018, Central Hospital for Veterinary Medicine, New Haven, CT. October 17, 2018. Available at https://adamswebsearch2.nrc.gov/webSearch2/main.jsp?AccessionNumber=ML1819A440. Accessed 27 November 2018.

[2] Arno MG, Simon J, Stevenson NR, Donecker J, *Anisotrophy of the Radiation Field Following Canine Sn-117m Treatment,* Health Phys Aug 2021: 121(2):150-155

[3] Arno MG, Smith C, *Age-Dependent Radiation Dose Rates from Canine Sn-117m Treatments*, Health Phys November 2021: 121(5):447-453.

recent evaluations into a single resource usable by a health physics practitioner. It took the release criteria and methodology endorsed by the NRC in their TER and combined with the two publications discussed above to provide new release criteria. This study entitled "Update and Extension of Release Criteria for Canine Sn-117m Treatments" was published in the May 2023 edition of the Health Physics Journal.[4] The text of the release criteria are essentially unchanged from those originally approved in the NRC TER. The primary update was to optimize the duration of the release instructions dependent on the age and nature of the interactions of the dog owner(s) with the treated dog.

Problem Statement

There are other animals for which Synovetin OA can be beneficial. Among these are household cats, horses, service animals, and zoo animals. This "technical memorandum" describes how to comply with the public dose limits for these other animals, making Synovetin OA available for all animals and all joints.

Cats

There is essentially no anatomic difference between a cat and a small dog with regard to the attenuation and shielding provided by a cat's body. Therefore, the original TER and the other publications discussed above establish the basis for the dose rates around a treated animal are also valid for a cat. Additionally, administered Synovetin OA activity is weight based, so cat doses would be substantially lower in most cases.

While specific behaviors of cats and dogs differ, the primary behaviors that need to be modified, such as whether the animal sleeps with its owner, lap-sitting, and similar are the same from a radiation safety perspective. The time limits at various distances and behavior restrictions developed to ensure the public dose limit is not exceeded for a dog equally apply to a cat. If those time limits and behavior restrictions are followed, the public dose limit will not be exceeded.

Zoo Animals

To date, some zoo animals have been treated. These include multiple komodo dragons and a tiger. No person is sleeping with a tiger, komodo dragon, or any other zoo animal for that matter. In these cases, the interactions of a staff member at a zoo do not differ significantly from the "dog groomer" scenario already evaluated. If anything, the interaction is at much longer distances and for much shorter times due to the dangerous nature of those animals. Thus, zoo animals can be treated without concern for approaching the public dose limit.

Service Animals

Service animals may include dogs such as hunting dogs that are treated more as "tools" than family pets. These animals are typically kenneled when not in active service and close-range interaction is significantly limited. Without the extended close range interaction, there is no exposure scenario that has a high enough dose rate for long enough to reasonably come close to

[4] Arno MG, Stevenson N, Smith C, Donecker J, *Update and Extension of Release Criteria for Canine Sn-117m Treatments,* Health Phys May 2023: 124(5): 391-396.

the public dose limit.

Horses

Horses, and in particular competitive race and show horses, are candidates for treatment with Synovetin OA. In particular the hooves and lower extremities are of interest. Radiation surveys during clinical trials reveal that the dose rate from horses is no more than that from treated dogs. And due to the lower position of the hooves, the radiation to a person's torso is lower. In addition, while riding the horse, the radiation dose rate is effectively zero due to the large mass of the horse's torso effectively attenuating all the radiation from the treated joint. The measured dose rate above the horse's back (effectively where the lower portion of a person's torso wound be) is background. Some radiation would be received by a rider's lower legs but this contributes little dose to the whole body dose as calculated in accordance with NRC Regulatory Guide 8.40.[5]

Conclusions

The above discussions demonstrate that it is possible to treat not only dogs but other animals with Synovetin OA in a manner that is in compliance with public dose limits. There are a few key factors that result in this conclusion. The first is that the radiation field around household pet is the same regardless of species due to the anatomic similarities. For other animals, the interaction scenarios are bounded by those evaluated for the dog in a conservative manner and due to the inherent nature of the animals. Second is that the other factors such as the interaction between a dog and its owner(s) are also unchanged since the relative position of these joints with respect to a person are effectively identical.

Therefore, the radiation safety precautions used for treating dogs in compliance with public dose limits may also be used for other household animals in compliance with those same public dose limits. For larger animals, the radiation exposure is self-limiting due to the size of the animals and the inherent nature of the interactions with them. The most important among these is that no person sleeps with them or has them sit on their lap

If you have any additional questions or need more information, please feel free to contact me at 817-995-6762 or arno@foxfirescientific.com.

[5] US Nuclear Regulatory Commission. Methods for Measuring Effective Dose Equivalent From External Exposure. Washington, DC: US Government Printing Office; Regulatory Guide 8.40; July, 2010.

Procedure for Use of Synovetin OA® *Rev Date: 08/29/25*

[*Note: Licensee to modify to match specific facility operations.*]

Scope

This procedure is designed to be used in conjunction with the veterinary hospital's normal operating procedures and addresses those aspects which are unique to Synovetin OA®.

A primary objective of this procedure is to ensure that pet owners understand and can comply with any post-treatment restrictions and instructions before treatment is initiated, and again before the pet is released. In this procedure, there are three interactions with veterinary personnel specifically trained in the use of unsealed sources. If, during any of these interactions compliance with instructions and restrictions cannot be confirmed, then treatment will not be administered, or the pet will not be released.

The following process is summarized in a flow chart in Appendix A

Procedure A: Identification of Pets for Treatment with Synovetin OA®.

The purpose of Procedure A is to:

1. Determine the common behavior patterns of the owner(s) with the pet,
2. Determine if those behavior patterns create any risk for any household member to exceed the public dose limits and,
3. If necessary, examine whether or not the owner(s) can modify certain behaviors necessary to comply with the public dose limits.

If the licensee concludes the owner is not willing or able to comply with any limitations necessary to preserve the public dose limits, then treatment will not be offered.

A1. The veterinarian will examine the pet and determine if Synovetin OA is medically appropriate.

A2. If so, the veterinarian will discuss Synovetin OA with the owner.

A3. The licensee will conduct the Pre-Screening Questionnaire (Appendix B) with the owner to determine the behavior patterns of the pet and owner(s). The owner will have full knowledge of household member's interaction with the proposed pet.

A3.1. The Pre-Screening Questionnaire is contained in Appendix B. Follow each prompt in the Pre-Screening Questionnaire with assistance from the content included in this Procedure (A3.2.-A3.9.).

A3.2. Collect information regarding the pet(s) and household members (anyone that shares the residence where the pet lives).

A3.3. Complete the questions on the remainder of the questionnaire.

A3.4. Determine which category of pet/owner distance behaviors is applicable and explain to owner. Determination should be conservatively based on each household member's interactions. This table will aid in the determination of the duration of the Release Instructions. Note that only one category will apply for the entire household.

Common Contact (Typical)
Up to 5 min/day direct contact (e.g., joint to torso) 15 min/day @ 1 ft 4 h/day @ 3 ft e.g., feeding, grooming, petting, pet walking
Prolonged Close and Intermediate Contact (Co-Sleeper)
Up to 5 min/day direct contact (e.g., joint to torso) 11 h/day @ 1ft e.g., pet sleeps in the owner's bed etc. 9 h/day @ 3 ft e.g., pet rests at the feet of the owner etc.

A3.5. If the licensee is confident the owner understands the need to comply with public dose limits and the household can comply with the Release Instructions, then proceed with scheduling the procedure, ordering Synovetin OA® and then continue with the following procedures. If the licensee is not confident the owner and other household members can comply with the Release Instructions as needed, exit this procedure and do not offer treatment with Synovetin OA®.

A3.6. If the procedure moves forward, the licensee will retain the signed copy of the Pre- Screening Questionnaire.

Procedure B: Review Release Instructions, Scheduling Treatment

The purpose of this procedure is to ensure that owners appreciate and understand the Release Instructions they would receive immediately after treatment (including any specific behavior limitations that may have been identified in Procedure A). The licensee will explain that pets cannot be released without a signed copy of the Release Instructions specific to each pet, so care is taken to ensure owners understand those Release Instructions and confirm their ability to comply before treatment is planned. Only if the owner gives that confirmation, will treatment be scheduled and Synovetin OA ordered.

B1. Review the Release Instructions with the owner. Confirm that the owner understands and will comply with all of the applicable instructions.

B2. Schedule treatment and then order Synovetin OA in accordance with manufacturer requirements and schedule treatment.

B3. When the Synovetin OA arrives, receive and handle the package in accordance with site shipping and receiving procedure and radiation safety program precautions.

Procedure C: Treatment and Release

In this procedure, the owners are reminded of the Release Instructions prior to treatment. After the pet is treated and the release measurements taken, the licensee completes the Release Instructions with the appropriate duration, and presents them to the owner for signature. The pet will not be released until the owner signs the Release Instructions. Upon release, the owner is given a copy of the signed Release Instructions for ongoing reference. The licensee will retain a copy of the signed Release Instructions. Additionally, the licensee should review the Release Instructions with the owner(s) should any follow up care be provided to ensure public dose limits are met.

C1. Treatment

C1.1. On the day of treatment, re-review the Release Instructions with the owner, discuss any behavior modifications that are required.

C1.2. Follow standard site personnel safety requirements.

C1.3. Prepare the injection in accordance with the directions on the package insert.

C1.4. The pet shall be injected by trained staff under the supervision of the AU.

C1.4.1. If the injection site is missed, the owner must be informed that re-treatment can be scheduled at the discretion of the AU and RSO providing additional calculations ensuring the public dose limit is met.

C1.5. After the procedure, perform contamination surveys in accordance with the site procedures. Check the treatment site for removable contamination and decontaminate as needed.

C2. Release

C2.1 Once the pet is recovered and medically stable for release, perform exposure rate surveys of the pet at a distance of 1 meter from the nearest treated joint (elbow e.g.). Surveys should be performed at the pet's joint (elbow e.g.) height anteriorly and left and right laterally. Record the highest reading.

C2.2 If the highest reading is greater than 0.45 mR/h, the pet must be held at the facility until such time as the highest reading is 0.45 mR/h or less. A decrease in the exposure rate reading of approximately 5% per day can be expected.

C2.2.1 If the pet must be held, kennel the pet in appropriate location at the facility.

C2.2.2 Resurvey the pet periodically (typically daily) until the release exposure rate criteria is met.

C2.2.3 Using the chart below, fill in the duration of time on the Release Instructions and present to the owner for signature.

	Weeks of Instructions			
	Co-Sleeper (age of person years)			**All Others**
mR/h @ 1 m	**5-9**	**10-14**	**15+**	
<= 0.20	2	2	2	2
0.3	4	3	2	
0.4	5	4	3	
0.45	5	5	4	

C2.2.4 After the owner signs the Release Instructions, release the pet and provide the owner with a copy of the signed Release Instructions. The licensee will retain a copy of the signed Release Instructions.

C2.2.5 Reinforce to the owner that they may return to their normal interactions with the pet after expiration of the written instruction but that they should continue to practice ALARA (time and distance moderation) for the next two weeks afterwards.

C2.2.6 Instruct owner that if the pet dies within 20 weeks to contact you. In the event that the pet dies, burial may proceed without restriction. Delay cremation until less than 10 μCi is present (e.g., approximately 20 weeks for largest pet from date of being treated with maximum activity).

C3. Post-Release

C3.1 Retain in the files a copy of the completed and signed Pre-Screening Questionnaire.

C3.2 Retain in the files a copy of the signed Release Instructions with the recorded release exposure rate.

C3.3 Follow up with the patient's owner approximately one week after the procedure. Remind the

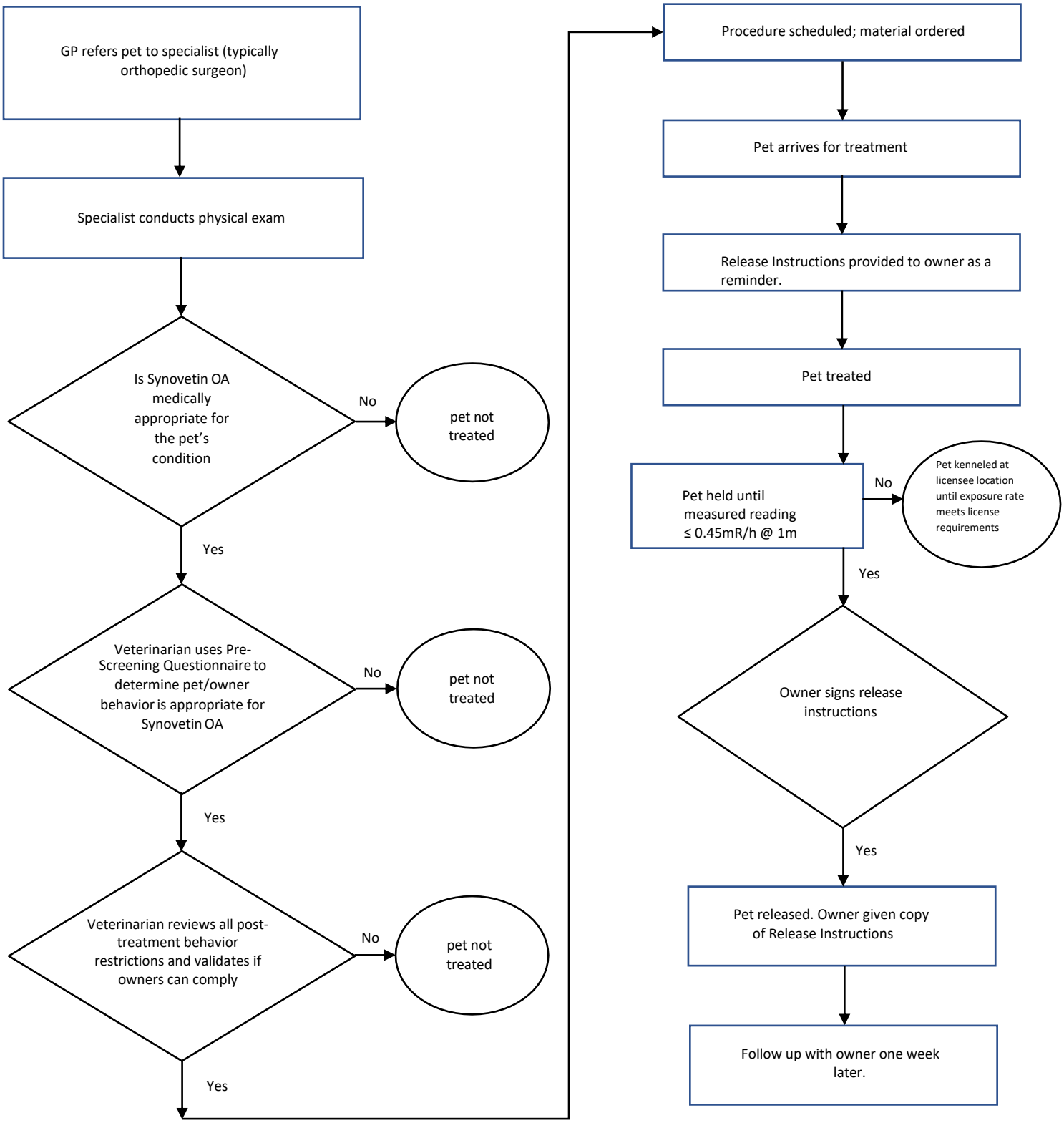
owner on how to keep doses ALARA and review compliance with the Release Instructions. Document in the files if follow up contact was successful or not and the date of follow up. If the owner indicates that the household has not complied with the written instructions, perform a dose assessment to determine the dose to date of the individual household members and formulate corrective actions for the household members to follow as necessary.

C3.4 Investigate any instances where public dose limits may have been exceeded including instances when owners have self-reported exceeding the limitations prescribed in the Release Instructions. If at any point, it is determined that the dose to a member of the public has exceeded 100 mrem in a year or 2 mrem in any one hour, send the appropriate regulatory agency (NRC or agreement state) a written report within 30 days as required by 10 CFR 20.2203 (or equivalent state regulation).

C3.5 Retreatment or additional joint treatment can be an option provided a public dose assessment is completed prior to retreatment.

Appendix A

Process Flow Chart



Synovetin OA® Screening Questionnaire

Your pet is being evaluated for treatment with Synovetin OA® (tin-117m). Synovetin OA®, provides mild therapeutic radiation that reduces inflammation within the joint that results in long-lasting pain relief. Synovetin OA stays in the joint and is not distributed systemically through the pet's body. Your pet's urine, feces, saliva, hair coat, and surroundings are not affected. The tin-117m naturally diminishes over a short period of time.

Owner Name: _____

Pet Name: _____

Following treatment, you and each member of your family should follow the home care instructions below for two (2) weeks (or potentially longer if you or your family members sleep with the pet in bed at night). These instructions apply to all members of the household. There are no restrictions regarding contact with other pets.

*measured from treated joint to center of person's torso

Do any household members sleep the entire night in bed with your pet? Adults: Y / N Children: Y / N Ages: _____

If yes, can arrangements be made to avoid this for a few weeks following treatment? Y / N

Notes/ALARA considerations:

_____

_____

By signing below, I acknowledge that I understand and agree to the treatment and to follow the home care instructions.

Veterinary Staff	Signature	Date
Pet Owner	Signature	Date

Revision date: 02/03/2025
Exubrion Therapeutics

Synovetin OA® Release Instructions for In-Home Domestic Animals

Total Dose Administered:_____ mCi Measured Exposure Rate:_____ mR/h at 1m

Your pet has been treated with Synovetin OA® (tin-117m) in one or more arthritic joints. Synovetin OA® is a treatment that emits mild therapeutic radiation within the joint to reduce inflammation. This results in long-lasting pain relief. Your pet's hair coat, waste, and surroundings will be unaffected, and the tin-117m will naturally decrease over several weeks. Please follow these recommendations for the next _____weeks. These instructions apply to all members of the household. Your pet can have normal contact with other pets.

Each member of the household may spend up to 15 minutes each day doing activities with your pet such as feeding, grooming, and hugging (within 1 foot, measured from your chest to the pet's treated joint), and up to 4 hours each day petting, playing, and sitting nearby (within 3 feet, measured from your chest to the pet's treated joint). Activities such as walking or jogging with your pet can continue as normal.

- Minimize touching the treated joint(s).
- Avoid sleeping with your pet for the designated time period.
- Remember to maintain your exposure as low as reasonably achievable (ALARA).

If your pet needs emergency care, please inform the provider about its treatment with Synovetin OA, and to contact _____with any questions.

Patient-specific instructions:

_____

_____

_____

Should your pet pass away for any reason within 20 weeks of treatment, contact:

_____

Veterinarian signature:_____Date:_____

I have received this information orally and in writing, and I understand it. I have had the opportunity to ask any questions.

Pet owner signature:_____Date:_____

Common Contact (Typical)
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From: Jason Kelly
To: Martha Pavon
Cc: Sandy Pavon; Tammy Tomczak
Subject: FW: Fw: U.S. NRC Materials License #21-35657-01 - Request for Additional Information
Date: Thursday, March 19, 2026 1:45:29 PM
Attachments: [External_Sender] Fw_ U.S. NRC Materials License #21-35657-01 - Request for Additional Information.pdf

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Martha,

Good afternoon. Attached is a Response to a Request for Additional Information E-mail dated March 9, 2026, for Materials License No. 21-35657-01 (Animal Joint Care Company), Docket No. 030-39291, for Control No. 654762.

Jason M. Kelly, MPH, CPH
Health Physicist
U.S. NRC Region III – DRSS MLB
Phone: (630) 829-9737
E-mail: Jason.Kelly@nrc.gov

From: Laura T. Smith- Physics <lsphysics@att.net>
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Hi Laura,

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Jason M. Kelly, MPH, CPH

Health Physicist

Materials Licensing Branch

U.S. Nuclear Regulatory Commission

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