Requests for Additional Information for the Review of the Hypothetical License Amendment Application for Treatment of Dogs with Synovetin OA™ Containing Sn-117m

Requests for Additional Information (RAIs) specific to the NRC Form 313 Supplement

1. Item 8, "Training," of the NRC Form 313 Supplement states that employees preparing the administration will be users authorized on the license or appropriately trained staff members. Please confirm that anyone preparing the administration will be a user authorized on the license (authorized user), or under the supervision of an authorized user.

2. Item 9, "Facilities and Equipment," of the NRC Form 313 Supplement states that a survey instrument with a pancake GM detector with a minimum detectable activity (MDA) of less than 2,000 disintegrations per minute (dpm) per 100 square centimeters area (100 sq-cm) will be used for contamination analysis.

    a. Appendix M of NUREG-1556, Volume 7, "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," states that acceptable removable concentration levels are 1,000 dpm per 100 sq-cm and total contamination levels are 5,000 dpm per 100 sq-cm. Confirm that you will update the procedure to ensure that the contamination levels meet the requirements of NUREG-1556, Volume 7 and that the MDA will be less than the 1,000 dpm per 100 sq-cm.

    b. The package insert section titled "Facility Contamination Assessment" also states that a ratemeter may be used to count wipes used to perform surveys for removable contamination. Confirm if it is intended that wipes be counted using a survey instrument in "ratemeter mode" or "scaler mode". If the detector will be used in ratemeter mode, explain how the MDA for Sn117m is determined.

    c. Confirm that surveys for total contamination will be performed, in addition to surveys for removable contamination in accordance with Title 10 of the *Code of Federal Regulations* (10 CFR) 20.1501.

3. Item 9, "Facilities and Equipment," of the NRC Form 313 Supplement states that surveys will be conducted and documented after administration if the location of the administration is outside of the currently licensed controlled area. "Controlled area" has a specific definition in Part 20, so this statement indicates that licensed material would be used in an unrestricted area. Please confirm if that is intended. If so, provide procedures for performing activities with licensed materials in unrestricted areas that address security and control of licensed materials, and surveys that will ensure no residual radioactive materials remain in the area above levels that would exceed public dose limits. If you were using the phrase "controlled area" differently than as defined in Part 20, provide an alternate explanation of your intention.

4. Item 10, “Radiation Safety Program,” of the NRC Form 313 Supplement states that the existing Area Survey Procedures will be followed. Based on the cover letter dated December 4, 2019, this section is applicable only if the person requesting the license amendment already is treating cats with iodine-131 (I-131) and that the survey procedures for I-131 are adequate for Sn-117m. Please confirm that Area Survey Procedures will be provided by licensees or applicants who do not currently have a license to work with radioactive materials or update the procedures to state that a licensee will provide this for review with their applications as necessary.

5. Item 10, “Radiation Safety Program,” of the NRC Form 313 Supplement states that the existing Radiation Safety Program and Radioactive Spill Procedures will be followed. Provide any modifications that would be expected for the routine program and/or emergencies (incidents/events) that may be required due to the differences between I-131 and Sn-117m. Please note that the procedures listed in package inserts are generic, and we would expect the licensee to develop site-specific procedures.

6. Item 10, “Radiation Safety Program,” of the NRC Form 313 Supplement states that the existing personnel monitoring program would be followed, and that routine bioassay of personnel is not required. Provide instructions for dose evaluation in the event of personnel contamination due to a needle-stick or update to state licensees will provide this for review with their applications as necessary. Follow-up for such an incident would be different for Sn-117m than for I-131.

7. Item 11, “Waste Management,” states that radioactive waste may be held for decay-in-storage for 10 half-lives or until the contact exposure rates are indistinguishable from background. The NRC license condition for decay-in-storage states that:

    i. “Before disposal as ordinary trash, the waste shall be surveyed at the container surface with the appropriate survey instrument set on its most sensitive scale and with no interposed shielding to determine that its radioactivity cannot be distinguished from background. All radiation labels shall be removed or obliterated, except for radiation labels on materials that are within containers and that will be managed as biomedical waste after they have been released from the licensee.

    ii. A record of each such disposal permitted under this license condition shall be retained for 3 years. The record must include the date of disposal, the date on which the byproduct material was placed in storage, the radionuclides disposed, the survey instrument used, the background dose rate, the dose rate measured at the surface of each waste container, and the name of the individual who performed the disposal.”

    Please note that while the NRC no longer requires the waste to be held for 10 half-lives, some Agreement States maintain this requirement. Please confirm that you will revise your statement to require that waste be surveyed, and records maintained as required in the license condition. Also note that page 2 of the product insert states that the vial will be placed in the lead container and stored for 5 months before disposal. The vial

should be removed from the lead container before the waste container and its contents are surveyed.

8. Attachment A, “Synovetin OA Training Outline” includes a discussion of decay-in-storage and sanitary sewer disposal. In accordance with 10 CFR 20.2003, confirm that the sanitary sewer disposal training will PROHIBIT the disposal of the tin oxide material by release to the sanitary sewer, because it is NOT readily soluble in water, and is NOT readily dispersible biological material.

9. Provide the amount of time that is expected to be needed to cover the training described very briefly in Attachment A, “Synovetin OA Training Outline”. In accordance with NUREG-1556, Volume 7, submit a description of the assessment of training, a description of the qualifications of the instructors, and the method and frequency of training.

10. The Safety Data Sheet (SDS) and package inserts have inconsistencies and omissions that conflict with regulations in 10 CFR Part 20 or make it difficult for a licensee to determine the necessary protections necessary for an appropriate radiation protection program required per 10 CFR 20.1101.

    a. The chemical formula for hydrated tin(IV) oxide as “$Sn_xO_y(OH)_z$.” The *CRC Handbook of Chemistry and Physics* lists a number of compounds as tin(IV) oxides including tin dioxide, SnO_2; stannic acid (tin oxide di-hydrate or alpha-stannic acid) SnO_2-xH_2O; and beta-stannic acid, SnO_2-xH_20. Please confirm if Synovetin OA is actually a mixture of tin oxide and stannic acid compounds or if another more accurate chemical formula is applicable.

    b. The SDS does not list any potential routes of entry. In the case of any material that is injected, entry by needle is a potential route of entry and should be addressed in the SDS.

    c. The SDS requires additional information. The SDS does not include hazards identified for non-radioactive tin oxides on Material Safety Data Sheets readily available on the internet. Tin(IV) oxide is listed as hazardous in case of inhalation, and slightly hazardous (irritant) in the event of skin contact, eye contact, or ingestion. It is listed as toxic to mucous membranes and may be toxic to lungs and the upper respiratory tract.

    d. The SDS chronic health hazard statement is not consistent with the U.S. system of regulatory protection. The system is based on linear no threshold. There is no threshold below which no stochastic effects may be induced. The text must be changed accordingly. Also, remove genetic effects as a potential chronic health hazard in Section 11 of the SDS.

    e. The SDS section for protective clothing or equipment should include shielded containers for handling and storage of the radioactive material.

f. The SDS states that the molecular weight is “N/A (polymeric).” This is not a polymer; molecular weight can be known, without hydration if hydration is unknown. Please confirm that the SDS will be revised to include the molecular weight.

g. Section 12 of the SDS states that, because this product is intended for use by a veterinary hospital or clinic patients, it is expected to be treated by standard wastewater treatment facilities. This statement must be corrected because 10 CFR 20.2003 prohibits disposal to the sanitary sewerage system unless the material is readily soluble or is in readily dispersible biological material. Tin oxide hydrate is a solid in colloidal suspension; the solid is not readily soluble in water and is not a readily dispersible biological material.

h. In the package insert, section “Preparation for Use” states that the prescribed dose should be administered on the date noted on the accompanying certificate; however, it could be administered the day before or after if circumstances require. This may not make much difference for doses below the 3 mCi maximum but injecting a day earlier may require the dog be held if radiation levels exceed the release criteria. Please confirm that a reminder of the need for a survey will be added to the procedure to ensure that the maximum activity is not exceeded. Also note that there is no statement on the vial regarding the concentration of radioisotope (e.g., mCi per mL). Without this information, how will the veterinarian know how much solution should be withdrawn for the appropriate dose? Update the procedure or package insert to ensure the veterinarian knows how much solution should be withdrawn.

i. The package insert does not address the use of dosimetry or shielding for radiation. Step 5 of the preparation for use states “Where practical, use a syringe shield...”. Add use of syringe shield, as well as whole body and extremity dosimeters for the persons administering the dose and handling the animal, to procedure.

j. The package insert instructions for owners states that “The dog will, however, retain a low level of radioactivity in the treated joint(s) for a short period of time.” This is misleading, as 10 half-lives is 136 days (more than 4 months). Based on our calculations using point sources for dogs receiving 3 mCi and released at measuring 0.45 mR/h at a distance of 1 meter from the elbow, the radioactivity in the dog could be measurable for at about 1 mR/h at 1 cm from the elbow at approximately 5.5 months after administration, dropping to about 0.02 mR/h after 8 months. Update the package insert, licensee’s procedure, and instructions to clearly define a duration (e.g., 4 to 5 months) that the dog will contain measurable/detectable radioactive material to ensure this is not misleading.

RAIs specific to the Procedure for Use of Synovetin OA™

11. The entire procedure is difficult to follow. As strict adherence to the procedure is necessary to ensure public dose limits are not exceeded, the procedure should be updated to ensure each step in the procedure, including the use of the table in Appendix B, is easily understood to minimize mistakes in its use. The following are just some examples of items that should be clarified, but staff recommends the entire procedure be evaluated and updated to ensure those without detailed knowledge of the technical basis can follow it without mistakes.

    a. The statement "Determine which of the four categories of contact is applicable and explain to owner" in Section A3.6 is difficult to understand and leaves a lot up to the user for interpretation, some of which would not align with the technical basis and could lead to overexposures. Instructions on how to use the table are necessary. In addition to including steps, providing a few examples in an appendix might help. In the instructions, ensure to:

        i. Describe if it is possible that multiple contact categories would be applicable to an owner? Please clarify what the licensee should do if the animal falls into multiple categories or in-between two categories.

        ii. Please clarify that licensees must round down to the nearest distance if the distances described by the owner does not match those used in the table.

        iii. Please clarify terms like "most common," "extended intermediate contact," and "extended close contact" as it is not clear what they encompass. Explain the activities that they typically involve and distances to avoid confusion.

    b. It is not easily understandable that Step A3.1 is walking the licensee through each step of the pre-screening questionnaire. Clarification that this step is intended to help the questionnaire would avoid misuse. Possible options would be to include which item number in the questionnaire each step is referring to or at least specify that the licensee should record the information in the questionnaire.

    c. Step A3.7 states to flag any asterisked question where the answer is yes; however, it does not reference which questions this is referring to and there are no asterisked questions in the pre-screening questionnaire. Clarify this step.

    d. The note in Step A3.7 states to reduce interactions to fit into one of the categories listed in the table. However, two of the categories (prolong close and intermediate contact categories) would exceed the public dose limit. Please revise this note.

e. Step A3.3.4 provides four separate questions (i.e., what activity, who, duration, and distance), but the table in item II only has two blanks (i.e., activity and duration). Therefore, it is unclear how the licensee is meant to fill out this table. The questions in the step should match the table. The table should include distances. Also, please clarify if the licensees should document exposure to different individuals in the household (i.e., whether or not they fill out two tables).

f. Revise Section C2.1 to add "If both elbows were treated, measurements should be made for each treated elbow."

g. The language in the flow chart step "Veterinarian reviews all post-treated behavior restrictions can pet owners comply" is confusing. Revise as appropriate.

h. The flow chart should include a step to hold the animal if the dog measures above 0.45 mrem/hr at 1 meter.

i. Appendix A includes a possibility "Patient not released" in the event that an owner will not sign the release instructions after the dog is treated. Please submit contingency actions if a dog cannot be released.

12. The procedure should include all limitations necessary to ensure public dose limits are not exceeded, such as the maximum activity per joint and per dog and that only one animal should be treated with radioactive material per household per year.

13. As instructions are necessary to ensure public dose limits are not exceeded, the procedure should be updated to ensure all individuals who have the potential to exceed the public dose limits are given instructions. In addition, as the procedure relies on a person's interactions with the animal, the procedure needs to be updated to explain what a licensee should do if more than one individual is exposed to the dog on a daily basis. For example, if one individual co-sleeps with a dog but another individual lets the dog sit on their lap, how would the licensee provide conservative instructions? Please ensure the procedure is updated to clarify how licensees develop instructions when multiple individuals will be exposed to the dog.

14. The procedure does not discuss modifications that should be changed if there are children in the home. Young children, such as toddlers, are unlikely to follow instructions and also would have shorter distances when interacting with an animal in similar situations. Please describe how the licensees should ensure that the public dose limit will be not be exceeded when children, or other individuals who may have difficulty following instructions, are present in the home where the animal resides.

15. The items below are for the pre-screening questionnaire found in Appendix B.

    a. Ensure situations where individuals who do not have the ability to follow instructions, such as children, cannot be kept away from the dog on a daily basis should clearly preclude treatment in the questionnaire and procedure.

b. The technical basis relies on an individual not spending any time within 6 inches and an average of 1 minute a day between a foot and 6 inches from the dogs' elbows for months following the procedure. Include an overarching screening question to see if modifications are needed to meet these criteria. The procedure should prohibit release when close contact is necessary, and these criteria cannot be met.

c. The cover paragraph on the pre-screening questionnaire makes it appear that there is no emission outside the dog's elbow joint. Revise to add that there are radiation emissions that leave the dog's joint and can lead to public exposure. The phrase "very low" and the word "energy" should be removed in the phrase "very low amounts of radiation energy" as the maximum dose rate almost classifies as a radiation area and that terminology could lead to non-compliance with instructions.

d. Add a question to the pre-screening questionnaire to determine if dogs spend significant time outside the home, including at a daily boarding facility or dog park. Provide instructions to the licensee on how to respond if a dog does spend a significant amount of time in public facilities. For boarding facilities, either include in instructions that boarding facilities cannot be used for a specified number of weeks or provide additional justification in the technical basis how public doses at the boarding facility would be kept as low as reasonably achievable (ALARA) and below limits.

e. Add a question to ensure dogs are not working service animals whose close contact with individuals would likely cause exposure exceeding public dose limits.

f. The pre-screening questionnaire has a space for another person besides the owner to be interviewed. Clarify in the procedure that the person being interviewed should have full knowledge of the dog's behavior and should be able to control behaviors after the procedure as necessary to ensure public dose limit is not exceeded.

g. At the end of the questionnaire, the application states that any "no" checkmark may contraindicate the procedure. However, the application allows for modifications in many cases. Update this statement to clearly state when a licensee will consider a procedure contraindicated due to radiation safety, such as the procedure would be contraindicated if modifications appear not to be able to be made to ensure members of the public will receive less than public dose limits or the licensee is not confident the public dose limits would not be exceeded following treatment of the animal.

h. Clearly explain in the procedure how the table at the end of Appendix B is intended to be used and ensure this is consistent with the technical basis. Currently, if more than one category is applicable, it appears that each category may be viewed individually. For example, an owner might restrict direct contact during common activities to 1 minute each day for 2 weeks, restrict direct contact

for holding the animal in direct contact on the lap to 1 minute each day for 5 weeks, and limit direct contact to 1 minute each day while sleeping in the owner's bed for 9 weeks. As this does not align with the technical basis, additional instructions are necessary.

16. The items below are specific to the instructions.

    a. The instructions do not match the technical basis assumptions used to demonstrate the public dose limit is not exceeded. Please update the procedure and instructions to include all necessary limitations described in the technical basis to ensure the public dose limit and doses are ALARA if the instructions are followed. For example, the technical basis assumes the closest distance between the dog and an individual is not less than 6 inches; however, the instructions do not prohibit contact under 6 inches. It should be noted in the procedure and instructions that instances where distances less than 6 inches to the dog's elbow should be minimized or avoided for a specified timeframe. The timeframe should be justified in the technical basis.

    b. To demonstrate that public dose limits are not exceeded, the technical basis assumes limitations on interactions well beyond the proposed duration of the instructions. The procedure and instructions should be modified to ensure instructions and necessary limitations on interactions are maintained as long as necessary to ensure the public dose limits are not exceeded and to ensure doses are ALARA. Note, there can be multiple sets of instructions with different durations, if necessary.

    c. Define "direct contact," "close contact," and "intermediate contact" in the instructions. These definitions should include the distances meant by these terms. Also, the term "direct contact" could be easily confused to mean actual touching of the animal, but the instructions are using this term to mean a distance of 6 inches. Ensure the terms are clearly understood as to what behaviors usually assume to fall under these terms.

    d. Without strict adherence to instructions, staff's analysis indicates that the exposure to members of the public could potentially exceed public dose limits. Therefore, the instructions need to clearly articulate the following:

        i. The phrase "very low" and the word "energy" should be removed in the phrase "very low amounts of radiation energy" as the maximum dose rate almost classifies as a radiation area and that terminology could lead to non-compliance with instructions.

        ii. The instructions should prohibit having a dog lying directly next to you as well as holding a dog on the lap as one would expect a large dog to lay next to someone instead of directly on their lap.

iii. The instructions state that walking and playing with your dog can continue as usual. However, this would not be the case if the owner plays with an animal in close contact or in another manner that could result in public dose limits to be exceeded. Therefore, this statement needs to be revised.

iv. The instructions state to avoid boarding of an animal. Either specifically state long term/daily boarding is prohibited, or provide the information requested above.

v. Commercial grooming could result in an exposure of greater than 2 mrem in any 1 hour to a member of the public who does not know about the dog's treatment. Therefore, instructions for limitations on grooming for a specified period of time should be included. The timeframe should be justified in the technical basis document.

e. More instructions are needed in the case of a death of an animal. Specifically, the instruction regarding cremation needs to discuss where and how the animal carcass would be stored to ensure doses are ALARA if it is not immediately able to be cremated. In addition, justification for allowing cremation at 4 months should be added to the technical basis document as a dog injected with 6 mCi would still contain approximately 12 microcuries at 4 months.

f. Please describe how the instructions will be used to ensure public dose is maintained ALARA. Specifically, describe how the statement on page 13 of the technical basis document which states "the minimum possible change to normal behavior for each dog is required" would be considered ALARA. Update instructions as necessary to ensure public doses will be maintained ALARA.

g. If follow-ups are expected to be conducted by the licensee before the duration of the instructions ends, update the procedure to ensure the licensee re-enforces the need to follow instructions for the entire instructional period during this follow-up to ensure the public dose limit is not exceeded.

h. 10 CFR 20.2203(a)(2)(iv) requires the licensee to report if public dose limits are exceeded. Update the procedure to ensure the licensee appropriately reports if they find the public dose limit has been exceeded. Include a description of how the licensee may determine if the public dose limit has been exceeded based on discussions with the owner or individuals close to the animal following treatment.

i. Throughout the application, including in the instructions, Synovetin is referred to as a device. Synovetin is not considered a device for the purposes of NRC regulations. Please use a more appropriate term for owners such as "medical treatment" or "solutions" throughout the application. However, the term "device" can be used in the package insert if necessary for classification by the U.S. Food and Drug Administration.

RAIs specific to the Technical Basis Document, "Evaluation of potential dose to members of the public from treatment of dogs with Synovetin OA™ containing Sn-117m"

17. The technical basis uses many assumptions based on an average dog which would not be applicable for all dogs. Ensure all assumptions would be met using the pre-screening questionnaire and instructions for all animals released to demonstrate the public dose limit will not be exceeded. Provide a description in the technical basis of how the pre-screening questionnaire and instructions will be used to ensure that all assumptions in the technical basis are met.

18. The technical basis assumes the center of the human torso as the point on the body which is used to calculate exposure. However, 10 CFR Part 20 defines the whole body, for the purposes of external exposure, to include the head, trunk, arms above the elbow, or legs above the knee. Explain your rationale for using this methodology versus a more conservative method such as assessing exposure to the maximally exposed portion of the body.

19. Average shielding factors cannot always be assumed. For example, a dog sitting or lying across a person's lap, who has direct contact with a person's leg such as shown in Figure 6, or dogs who lay on their side with their legs extended and elbows up cannot have credit for torso/body shielding in the exposure to the legs. In addition, one would expect that close contact activities, such as carrying, petting, and feeding, would be done in a similar geometry every day, especially when the time is limited to less than 15 minutes a day. Therefore, the use of average shielding factors is not justified in all geometries. Therefore, average shielding factors cannot be conservatively applied in these scenarios and close contact doses and criteria must also be revised.

20. The statement that the dog's leg joints are much lower than the dog's torso is not acceptable for the elbow joint, which is very close to the base of the dog's torso. This statement is used to consider additional distance between the dog's elbow and the human torso (whole body). Although this may be true for lower joints such as the knee, it is not true for the elbow. Instead, the paper "Canine Torso Attenuation from Elbows Treated with Synovetin OA (Sn 117m)" states that the "Canine anatomy is such that the dog's elbows are approximately at the same height as the lower extent of the dog's torso when in a standing position." If distances used to support the calculations were based on locations much lower than the elbow, please revise those calculations. If not, revise the statement saying that dog's leg joints are much lower than the dog's torso to avoid future licensee confusion.

21. The technical basis states that for a child or small adult, the distance from the human torso to the dog's torso can easily be a foot or more than the distance from the human's leg to the dog's torso even for a child or small adult. Small children or small adults standing next to an animal will be much closer to the dog's elbow than an average-sized adult and can easily be within a foot distance. This statement should be revised, and more consideration is needed in the technical basis and instructions to ensure children or small adults do not exceed the public dose limit.

22. As 2 mrem can be exceeded within minutes at close distances, such as 1 inch, justification is needed to demonstrate that short-term close-distance encounters, such as young child coming up to pet the dog during a walk, would not exceed the public dose limit of 2 mrem in any 1 hour. As doses at close distances are not uniform, use of non-uniform dosimetry such as that described in Regulatory Guide 8.40, "Methods for Measuring Effective Dose Equivalent from External Exposure," could be considered in this calculation. In addition, stronger instructions are necessary to ensure that members of the public do not have close contact with the animal, specifically spelling out activities, distances, and timeframes which should be prohibited.

23. Routine veterinarian exams could result in an exposure of greater than 2 mrem in any on 1 hour if the examination is performed by an individual who does not know about the radioactive material. Describe any limitations, or instructions, that would be given to the dog's primary veterinarian if they are not associated with the licensee.

24. The technical basis states that the worst-case scenario for evaluating whether a person could receive 2 mrem in any 1 hour, from a dog released at 0.45 mR/h measured at 1 meter from the dog's elbow, is that for a person that spends 1 minute at 6 inches from the dog's elbow, plus 15 minutes at 1 foot away, plus the remaining 44 minutes at 3 feet away. However, the NRC does not believe this is the worst-case scenario, but rather the maximum dose that would be received by owners performing only the activities allowed by the instructions. Please confirm that our understanding is correct or provide an explanation that clarifies the statement.

25. In a published presentation, there was a note of a past unintentional misadministration where the material was administered outside the elbow. Please describe if the material could be excreted or end up migrating if it is administered outside the elbow. Update the licensee release procedure as necessary to instruct licensees of what they should do if the treatment is injected somewhere other than the elbow.

26. Please describe common interactions that owners might have with dogs with osteoarthritis that are not common with other dogs. For example, is massaging recommended for some dogs with osteoarthritis and if so, describe the dose one would get from a conservative massage? If massaging needs to be halted to meet public dose limit, could it be and what would be the consequences to the dog? Include in the instructions if necessary. In addition, do dogs with osteoarthritis need help up-stairs or in other normal interactions? If so, describe how 1 minute a day would cover those who need to help a dog up and down flights of stairs on a daily basis.

27. Regulations in 10 CFR Part 20 require licensees to maintain doses ALARA. Principles of ALARA include time, distance and shielding. Describe the feasibility to include shielding to minimize public exposure, such as use a small elbow shield.

RAIs specific to the Contact Does Modeling Document, "Contact Doses from Dogs That Have Been Treated with Sn-117m Radiosynoviorthesis"

28. Please describe how this information is being used to develop instructions and the technical basis for release. For example, the paper suggests limiting touching the dog's elbow for 34 days, but the minimum duration for instructions is 2 weeks.

29. As the technical basis states that it is not reasonable to treat dose rates found in this report as applicable to calculating a whole-body dose, provide calculations or a model that is applicable to calculating whole dose on contact or at close distances as requested above.

RAIs specific to the Torso Shielding Evaluation Document, "Canine Torso Attenuation from Elbows Treated with Synovetin OA (Sn-177m)"

30. Explain how the following terms are used in this paper:

    a. Anterior – the paper states that anterior measurements of 1 foot are under or within the body of the dog, and therefore 1-foot anterior measurements were taken at the rump of the dog regardless of the distance. However, "anterior" in other common documents use "anterior" to be towards the front of the dog, in which case anterior measurements of the elbow would not be in the body of the dog at all. Explain how your anterior measurement locations are different from your "posterior" and "dorsal" measurements.

    b. Explain the difference in locations between upper anterior, upper posterior, and dorsal.

31. In 2 of the 10 dogs measured, the anterior and lateral measurements were not the highest at 1 meter. Update the release procedure to ensure all geometries which have the potential for having the highest dose rate are measured.

32. One would expect the dorsal or posterior positions to have the lowest dose rate due to having the most shielding through the dogs' body. As these shielding factors are used to demonstrate public dose limit is not exceeded, provide an explanation on how the dorsal and posterior measurements had either the maximum or close to the maximum dose rate in several of the measurements.