

*Notes to License Reviewers Evaluating License Applications to Treat Dogs with Synovetin OA®*

NRC license reviewers should accept Exubrion's release procedure contained in their application dated June 1, 2020 (ADAMs Accession Number ML20282A513) as part of an individual license application to treat dogs with up to 222 MBq (6 mCi) of Sn-117m as part of Synovetin OA® treatment. The veterinarian requesting authorization to use Sn-117m for veterinary treatment of dogs should submit this procedure along with all other pertinent information requested in the most recent revision of NUREG-1556, Volume 7. Particular attention should be given to the guidance in NUREG-1556, Volume 7, Appendix D, "Guidance for Laboratory Animal and Veterinary Medicine Uses."

In addition to the guidance in NUREG-1556, Volume 7, Revision 1, the staff recommends that license reviewers obtain the following:

- Acknowledgement from the licensee that the licensee is responsible for ensuring that dogs are released with instructions that will not cause a member of the public to exceed dose limits.
- A commitment that the licensee will not use this procedure to release a dog whose typical behavior patterns, without instructions, do not fit into the time and distance limitations listed for one of the categories described in the procedure as these categories are the only ones evaluated.
- A commitment that the licensee will not release a dog if a child is in the house under the age of 5 who fits into the "Extended Duration at Close Contact" or "Prolonged Close and Intermediate Contact" categories. The dog can be released if the overall category for the dog is either of these categories based on the behavior of an individual over the age of 5. A request to amend the license to approve such a release may be submitted to the NRC with additional, specific calculations that demonstrate the public dose limits will not be exceeded based on the expected dog-child behavior.
- A commitment that there will only be one release per household each year, although a request to amend the license to approve additional releases of the same animal treated multiple times or release of an additional dog to the same household may be submitted, with the additional calculations provided to the NRC that demonstrate that the public limits will not be exceeded; if approved, the license would be amended to authorize the additional release to the same household.
- A commitment that all individuals who conduct the prescreening interviews using the prescreening questionnaire or provide instructions to the staff or clients/owners, will be trained on basic radiation safety principles and the importance of adherence to the procedure and instructions.
- A commitment to retain a copy of prescreening questionnaires and household instructions.
- A commitment to document and retain dose assessments made if household members indicate they have not followed written instructions per 10 CFR 20.2107.