



**UNITED STATES
NUCLEAR REGULATORY COMMISSION**
REGION I
2100 RENAISSANCE BLVD.
KING OF PRUSSIA, PA 19406-2713

October 18, 2021

Eli Port, CHP, P.E. (Safety Engineering)
Radiocat, LLC
32A Mellor Avenue
Baltimore, MD 21228

SUBJECT: RADIOCAT, LLC, REQUEST FOR ADDITIONAL INFORMATION, MAIL CONTROL NO. 625737

Dear Mr. Port:

This is in reference to your letter dated April 28, 2021, requesting to amend NRC License No. 45-25330-01. In order to continue our review, we need the following additional information:

1. The request provides no justification that the public dose limit of 2 mrem limit per any one hour as required by 10 CFR 20.1301(a)(2) will not be exceeded. Using the inverse square law, the exposure rate at the time of release at 1 foot would be 5.38 mR/hr and even higher on contact, such as a cat sitting in an owners lap. Therefore, additional justification is necessary to demonstrate this limit would not be exceeded following release.
2. The request states that a member of the public would receive 3.5 mrem or less from a cat released with an exposure rate of 0.5 mR at a meter if the individual limits time near the cat in accordance with instructions (i.e. half hour a day at 1 foot [30 cm] and 2 hours a day at 3 feet [90 cm]). However, using a point source and no decay for the first day, the calculated dose is approximately 4 mrem. Please update the value or provide further information (i.e. calculation) on how 3.5 mrem was determined.
3. The request should ensure all assumptions are justified or that the procedure includes controls to ensure assumptions are appropriate for each released cat. For example:
 - a. After the 14 day period, the applicants calculated TEDE assumes the cat will only sit on a person's lap for 1 hour a day. Either update this assumption to a conservative timeframe to capture all cats or describe how licensees will ensure they will only release treated cats with this type of typical behavior. In addition, provide justification for the 30 cm distance used.
 - b. After the 14 day period, the applicant calculated TEDE using the exposure rate at a distance of 30 cm. In this calculation, only dose to the gonads is considered. Provide updated values considering dose to the whole body or provide justification as to why only dose to the gonads is considered. In addition, provide justification for the 30 cm distance.
 - c. For all quantitative assumptions, provide a range of typical cat values and justify that the values chosen in the calculation are appropriate. For example, the

application assumes a feline patient receives a dose of 5 mCi and has an uptake of approximately 20%. What is the range of normal administration activities and uptake fractions? In addition, the application assumes a member of the public ingests up to 0.1% of free iodine. Provide general justification for this value.

- d. The request assumes renal excretion rate from cats is the same as it is for humans to estimate excretion activity. Provide justification for that assumption using data from cats. As the application is currently using radiological half-life in external dose assessments, this justification does not need to justify the biological half-life but should provide evidence of assumed excretion activity after 48 hours.
 - e. The request ignores external exposure from excreted material. Provide an estimate of external exposure from excretion or provide justification for why this can be ignored.
 - f. The request assumes the typical dose rates at 48 hours following administration will be less than 0.5 mrem/hr at 1 meter. Provide general information of typical dose rates at 48 hours post administration to provide justification for this assumption.
4. As stated in NUREG-1556, Volume 7, Revision 1, Appendix D, instructions should provide a margin for dose reduction but should not be relied upon as the primary way of keeping the dose to members of the public below the 1 mSv [0.1 rem or 100 mrem] public dose limit. However, your request uses instructions to ensure dose to members of the public does not exceed the public dose limit. While the procedure has the owner sign a statement saying they have been given the instructions, Radiocat's procedure does not provide a mechanism which shows that the licensee will verify that the owner will be able to meet the restrictions described in the instructions. To ensure the public dose limit will not be exceeded, the procedure must have steps which allow the licensee to ensure the owner of each released cat can and will meet instructions. Examples include a screening questionnaire and personalized instructions based on normal cat behavior and follow-up with the owner. The purpose of a follow-up after release allows the licensee to reenforce the importance of the instructions with the owner after some time has passed and to allow the licensee to learn if cat owners are able to follow instructions, allowing adjustments if necessary to the procedure and reporting if the public dose limit is expected to have been exceeded.
 5. Please provide a dose estimate of the highest, realistic dose an individual could receive if they did not follow the instructions. This can be over the public dose limit but the release procedure should demonstrate how the licensee will prevent this scenario from happening.

We will continue our review upon receipt of this information. Please reply to my attention at:

Janice Nguyen
Mail Control No. 625737
USNRC, Region I
Division of Radiological Safety and Security
2100 Renaissance Boulevard, Suite 100
King of Prussia, PA 19406

Or

R1DRSSMail.Resource@nrc.gov

Reference – Janice Nguyen

Mail Control No. 625737

In order to continue prompt review of your application, we request that you submit your response to this letter within 30 calendar days from the date of this letter.

An electronic version of the NRC's regulations is available on the NRC Web Site at: www.nrc.gov. Additional information regarding use of radioactive materials may be obtained on the NRC Web Site at: <http://www.nrc.gov/materials/miau/mat-toolkits.html>. This site also provides the link to the toolbox for updated information on the revised regulations for naturally-occurring and accelerator-produced radioactive materials (NARM).

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter will be available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS). ADAMS is accessible from the NRC Web Site at: <http://www.nrc.gov/reading-rm/adams.html>. Please be aware that you may request that certain portions of your submittal to NRC be withheld from public disclosure as proprietary information. To do this, you must execute an affidavit as specified in 10 CFR 2.390. You must list all portions that you wish to be held proprietary, along with your reasoning as to why that is appropriate. While it is allowable, please refrain from submitting proprietary information in support of a license unless necessary. Keep in mind that all NRC licenses are considered to be in the public domain, and therefore may be viewed by any member of the public who requests to see them.

If you have any questions regarding this request for additional information, please contact me at 610-337-5006 or via electronic mail at Janice.Nguyen@nrc.gov.

Thank you for your cooperation.

Sincerely,

Janice Nguyen, Senior Health Physicist
Medical and Licensing Assistance Branch
Division of Radiological Safety and Security
Region I

License No. 45-25330-01

Docket No. 03033825

Mail Control No. 625737

cc: Rand Wachsstock, DVM, RSO

RADIOCAT, LLC, REQUEST FOR ADDITIONAL INFORMATION, MAIL CONTROL NO. 625737 DATED OCTOBER 18, 2021

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SUNSI Review Complete: ETindle-Engelmann

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