

From: [Lanzisera, Penny](#)
To: eport@rssi.us
Cc: [Nguyen, Janice](#); [Elliott, Robin](#)
Subject: License Renewal for Radiocat
Date: Friday, October 23, 2015 3:17:23 PM

Licensee: Radiocat, LLC
License No: 45-25330-01
Docket No: 030-33825
Control No: 587133

Dear Mr. Port,

Could you please reply back to Ms. Nguyen to confirm receipt?

This is in reference to your application dated May 28, 2015, requesting to renew Nuclear Regulatory Commission License No. 45-25330-01. In order to continue our review, we need the following additional information:

1. Regarding your organization, please provide the following:
 - a. Please confirm if the licensee name should be Radiocat, LLC (as currently listed on the license) or Radiocat PC (as listed on the license application). Please indicate if the company has been restructured or if a change of ownership has occurred in accordance with NUREG-1556, Volume 15, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Changes of Control and About Bankruptcy Involving Byproduct, Source, or Special Nuclear Material Licenses."
 - b. Please confirm if the address of the New Castle, Delaware facility is 290 New Churchman's Road (as currently listed on the license) or 290 Churchmans Road (as listed on the license application).
 - c. In order to facilitate future communications, please provide business fax numbers and business email addresses (if you use them) for both you and Rand Wachsstock.
 - d. In your application, it is not clear whether or not the locations of use are controlled by an entity other than yourself. If so, please describe the relationship between Radiocat and the facility owner(s), concerning access to your location of use for the purpose of decontamination or removal of licensed material from the location of use in the event of disharmony between you and the owner entity. Additionally, please confirm that Radiocat will be responsible for decommissioning the facility should service be discontinued.
2. Regarding your facilities and equipment, please provide the following:
 - a. Please include a description of the area(s) assigned for the receipt, storage,

preparation and measurement of radioactive materials, including a description of how the areas are secured to prevent unauthorized removal of materials. On your facility diagrams, please show the locations and amount of shielding (e.g., shielding in walls, shielding of cage areas, shielded waste storage areas, etc.), the proximity of radiation sources to unrestricted areas, and other items related to radiation safety. The diagrams should contain schematic descriptions of the ventilation systems, with pertinent airflow rates, pressures, filtration equipment, and monitoring systems. Diagrams should be drawn to a specified scale, or dimensions should be indicated. Please also indicate what areas are located above and below the areas of use.

- b. Confirm that you will maintain the required air flow rate in each facility permitted to release radioactive effluent to unrestricted areas. Indicate what measures you have in place to assure that you maintain this flow rate; i.e. testing and equipment redundancy.
 - c. Please provide trash compactor procedures to control airborne releases in all facilities. In addition, please describe any filtration provided on the compactor. If filtration is not present, describe air sampling performed to determine the exposure to personnel from releases during compaction of waste.
 - d. In order to minimize the spread of contamination, please confirm that animals used in studies or treated with licensed material will be housed in cages or stalls separate from other animals.
3. Please confirm the following statement: "We will use instruments that meet the radiation monitoring instrument specifications published in Appendix M to NUREG-1556, Vol. 7, 'Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope,' dated December 1999. We reserve the right to upgrade our survey instruments as necessary." In addition, please confirm that meters not calibrated will be tagged "Do not use."
4. Please provide written procedures for ensuring material accountability.
5. With regards to your receiving procedures,
 - a. It states that a package will be not moved until instructions are received by the RSO if the package appears leaking or damaged. Please describe how this notification occurs and what is done with the package in the interim (e.g., storage until RSO decision, transported to the RSO, etc.).
 - b. Please confirm that all radioactive material will be under direct surveillance if not placed in a secured location.
 - c. Indicate who is responsible for receiving the packages and performing the required surveys.

- d. Indicate the designated licensed material receipt area on the facility descriptions provided in response to Item 2.
6. Please provide a list of all check sources currently possessed. In addition, confirm that physical inventories will be conducted at intervals not to exceed 6 months, to account for all sealed sources received and possessed under the license as applicable
7. Please confirm the following statement: "We have done a prospective evaluation and determined that unmonitored individuals are not likely to receive, in one year, a radiation dose in excess of 10% of the allowable limits in 10 CFR Part 20," or "we will monitor individuals in accordance with the criteria in the section entitled, 'Radiation Safety Program – Occupational Dose' in NUREG-1556, Vol. 7, 'Consolidated Guidance about Materials Licenses: Program-Specific Guidance about Academic, Research and Development, and Other Licenses of Limited Scope,'" dated December 1999."
8. Please confirm the following statement: "We will survey our facility and maintain contamination levels in accordance with the survey frequencies and contamination levels published in Appendix Q to NUREG-1556, Vol. 7, 'Program-Specific Guidance about Academic, Research and Development, and Other Licenses of Limited Scope,' dated December 1999."
9. Please confirm the following statement: "We will use the model waste procedures published in Appendix T to NUREG-1556, Vol. 7, 'Program-Specific Guidance about Academic, Research and Development, and Other Licenses of Limited Scope,'" dated December 1999."
10. Please provide procedures for the disposal of an animal that dies during its treatment of feline hyperthyroidism.
11. The renewal application dated May 28, 2015 should have been signed by a senior management representative of Radiocat. Please submit the following requested additional information in a letter signed by a senior management representative, and have them confirm that they have reviewed the application dated May 28, 2015, and concur in the statements and representations contained therein. We have a current delegation on file dated November 28, 2000, that allows you and Jennifer Allore to sign for all licensing requests. Please provide a current delegation of this authority.
12. It appears your Radiation Safety Officer (RSO), Rand Wachsstock, DVM, is based in Springfield, Virginia, although you have facilities in Indiana, Connecticut, and Delaware. Please indicate how often he is expected to be on-site at each facility, how he will respond to emergencies as necessary (including the maximum amount of time it will take him to arrive at the satellite facilities), how audits/records will be conducted/reviewed, etc., and provide a point of contact for each facility.

13. You indicated that if the RSO is not available for an extended period of time, the RSO's authority will be delegated to another individual. Please clarify what is meant by an extended period of time, and indicate what the maximum amount of time would be before amending the NRC license to change RSO.
14. Provide more information regarding the calibration process for the equipment used for conducting bioassay measurements and wipe analysis. In particular, what instrument is used and how is the efficiency calculated? Please also provide the efficiency determination for the probe used for wipe analysis.
15. Please confirm the following changes:
 - a. You are requesting to reduce your current total license possession limit of I-131 from 480 mCi to 240 mCi.
 - b. You are requesting the removal of the following authorized users: Douglas Aspros, DVM, James Beebe, DVM, William Blevins, DVM, MS, DACVR, Nancy R. Gustafson, DVM, and Robert M. Naum, DVM.
16. With regard to the training program, please confirm that the proper use of survey equipment is covered in the training. Additionally, please confirm that all training is provided prior to personnel being subjected to work in restricted areas.
17. The following items do not require a response and will be reviewed during inspection:
 - a. You were not required to submit the responsibilities of the RSO; however, in reviewing the list you provided there are some important duties missing, such as the authority to terminate any unsafe act, ensuring exposures are ALARA, ensuring the security of radioactive material, maintaining documentation that demonstrates that the dose to individual members of the public does not exceed the limit specified in 10 CFR 20.1301, etc. It is recommended that you review the complete list of typical RSO duties in Appendix I of NUREG 1556 Vol. 7, 'Program Specific Guidance About Academic, Research and Development, and Other Licensees of Limited Scope,' and revise your RSO duties accordingly.
 - b. With regard to your Procedure for Opening Radioactive Material Packages, please note that it did not include conducting a survey of the radiation levels of the exterior of the package. Please refer to Appendix N of NUREG 1556 Vol. 7, 'Program Specific Guidance About Academic, Research and Development, and Other Licensees of Limited Scope,' for model procedures for opening packages.
 - c. Please review item 9 of E. "General Rules for the Safe Use of Radioactive Material" on page 5 of 14 of your application. It appears as though the "should"

in the first sentence was meant to be a “must” and the must in the second sentence should not be present.

Current NRC regulations and guidance are included on the NRC's website at www.nrc.gov<<http://www.nrc.gov>>; select Nuclear Materials; Med, Ind, & Academic Uses; then Licensee Toolkits, see our toolkit index page. You may also obtain these documents by contacting the Government Printing Office (GPO) toll-free at 1-866-512-1800. The GPO is open from 8:00 a.m. to 5:30 p.m. EST, Monday through Friday (except Federal holidays).

You may respond to my attention in writing by letter, email (if letter is signed by senior management and scanned into a pdf format), or fax (610-337-5269), referencing mail control number 587133.

Please feel free to contact Ms. Nguyen or Ms. Elliott with any questions you may have. Ms. Nguyen may be contacted at: phone (610) 337-5006 or FAX (610) 337-5269.

The NRC's Safety Culture Policy Statement became effective in June 2011. While a policy statement and not a regulation, it sets forth the agency's *expectations* for individuals and organizations to establish and maintain a positive safety culture. You can access the policy statement and supporting material that may benefit your organization on NRC's safety culture Web site at <http://www.nrc.gov/about-nrc/safety-culture.html>. We strongly encourage you to review this material and adapt it to your particular needs in order to develop and maintain a positive safety culture as you engage in NRC-regulated activities.

Thank you in advance for your assistance.

Penny Lanzisera
Senior Health Physicist
US NRC, Region I