



CONVERSATION RECORD

NAME OF PERSON(S)/TITLE CONTACTED OR IN CONTACT WITH YOU James Speiser, D.V.M. Radiation Safety Officer (RSO)		DATE OF CONTACT 10/26/2018	TYPE OF CONVERSATION <input type="checkbox"/> E-MAIL <input checked="" type="checkbox"/> TELEPHONE <input type="checkbox"/> INCOMING <input checked="" type="checkbox"/> OUTGOING	
E-MAIL ADDRESS jspeiser@indyvet.com		TELEPHONE NUMBER (317) 782-4484		
ORGANIZATION IndyVet Emergency & Specialty Hospital 5425 Victory Dr., Indianapolis, IN 46203		DOCKET NUMBER(S) 030-37823		
LICENSE NAME AND NUMBER(S) 13-32698-01		MAIL CONTROL NUMBER(S) 609384		

SUBJECT
Additional Information Request concerning the licensee's request to renew the referenced U.S. NRC radioactive materials license, including to allow continued 25 millicurie possession limit for sodium iodide I-131 liquid for treatment of thyroid disease in felines.

SUMMARY AND ACTION REQUIRED (IF ANY)

This record concerns the licensee's July 11, 2018 application (NRC Accession No. ML18198A220) requesting renewal of the above-listed radioactive materials license for veterinary use of sodium iodide I-131 in felines.

Upon review, we have noted that the application omits information requested in the NRC's NUREG 1556 Vol. 7, rev. 1, "Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope, Including Electron Capture Devices and X-Ray Fluorescence Analyzers," guidance volume. As discussed, please see attached for information needed to complete our review of your request.

As agreed during our phone call, please provide the requested information within 28 days of this message (on or before November 23, 2018). Include a signed and dated cover letter transmitting your response. Submission of your response as a pdf file attached to an email or via facsimile to 630-515-1078 will allow for the quickest processing. Please call or email me with any questions you may have, or if you are unable to respond by the date suggested above. Thank you for your prompt attention to this matter.

NAME OF PERSON DOCUMENTING CONVERSATION
Sara A. Forster, M.S., Health Physicist, Materials Licensing Branch, DNMS, RIII office, sara.forster@nrc.gov

SIGNATURE <i>Sara A. Forster</i>	DATE OF SIGNATURE 10/26/2018
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CONVERSATION RECORD (continued)

LICENSE NAME AND NUMBER(S)

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SUMMARY AND ACTION REQUIRED (IF ANY) (Continued)

ADDITIONAL INFORMATION NEEDED FOR CONTINUED REVIEW

I. For general resubmission of the renewal application:

- (1) Please resubmit the NRC Form 313, signed and dated by you or by other Senior Management official from IndyVet or other individual designated to sign on that official's behalf;
- (2) Please confirm that the licensee name has changed to IndyVet, or provide the correct name; and
- (3) Please include the licensee's mailing address as submitted in the July 11, 2018 application.

II. For the authorization for veterinary use of sodium iodide I-131 (liquid) for treatment of thyroid disease in cats:

Please resubmit the request for radionuclide (iodine-131), form (sodium iodide liquid), possession limit (25 millicuries), and authorized use (for treatment of thyroid disease in felines). No revision to information provided in your application is needed.

III. For listing Individual(s) Responsible for Radiation Safety Program and their Training and Experience:

- (1) Please confirm that the Radiation Safety Officer (RSO) for this license is James R. Speiser, D.V.M., or otherwise list the name and experience of the RSO to be listed on the license. Sample RSO training criteria may be found in NRC's NUREG 1556 Vol. 7, rev. 1, Section 8.7.1, pp. 8-13 to 8-16.
- (2) Please provide a copy of a Memorandum of Understanding/Delegation of Authority (MOU/DOA) document, signed and dated by both the licensee's Management Representative (if other than Dr. Speiser) and the RSO. At a minimum, the MOU/DOA should indicate the RSO's responsibilities and authority for the licensed program and that RSO's acceptance of those duties. Sample RSO duties together with a sample MOU/DOA form may be found in NRC's NUREG 1556 Vol. 7, rev. 1, Appendix E, pp. E-1 to E-3. A copy of this appendix is attached for your reference.
- (3) Please confirm that the sole Authorized User (AU) for this license is James R. Speiser, D.V.M., or otherwise list the name and experience of the AU to be listed on the license. Sample AU training criteria may be found in NRC's NUREG 1556 Vol. 7, rev. 1, Section 8.7.2, pp. 8-16 to 8-18.

CONVERSATION RECORD (continued)

LICENSE NAME AND NUMBER(S)

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SUMMARY AND ACTION REQUIRED (IF ANY) (Continued)

IV. For Individual(s) working in or Frequenting Restricted Areas (Occupationally Exposed Individuals and Ancillary Personnel):

Please refer to NRC's NUREG 1556, Vol. 7, rev. 1, Section 8.8, pp. 8-18 to 8-19, Appendix D, p. D-2, and Appendix F, pp. F-1 to F-4 to prepare and submit a description of the above-referenced licensee's radiation safety training program, including:

- (1) groups of workers (e.g. animal caretaker, veterinary technician, housekeeping, security, etc.);
- (2) frequency of training (e.g. before assuming duties, when duties change, annually, etc.);
- (3) topics covered, for each group of worker;
- (4) training method (e.g. lecture, demonstrations, videotape, self-study, etc.);
- (5) instructor qualifications (e.g. Radiation Safety Officer, Authorized User, etc.); and
- (6) how training is assessed.

V. For authorizing use and storage of byproduct material at the licensee's 5425 Victory Dr., Indianapolis, IN, 45203, location:

- (1) Please provide a description for the area where licensed material will be used or stored in accordance with NRC's NUREG 1556 Vol. 7, rev. 1, (a) Section 8.9, pp. 8-19 to 8-21, (b) Appendix D, pp. D-2 to D-3, and/or (c) Appendix G, pp. G-1 to G-3, as applicable;
- (2) Your response should include a diagram of the area where the material will be used or stored, showing street address, room number, any physical barriers (doors, walls, windows, shielding, etc.), and dimensions or scale of each area of use highlighted in the submitted facility diagrams;

NOTE: Diagrams should be drawn to fit on an 8 1/2" x 11" sheet of paper.

- (3) Your response should include any areas where materials are received, used, stored, measured, or disposed;

NOTE: Animal use areas should also be shown, to include controls used to minimize contamination.

- (4) Please describe how the area is secured (key, keycard, code, etc.), with a description of individuals (Radiation Safety Officer (RSO), Authorized Users (AUs), housekeeping, etc.) who will be able to access, or who will routinely access, the requested area; and
- (5) Finally, please describe any safety features (handling equipment, spill containment, etc.) available at the location where radioactive material will be used and stored.

CONVERSATION RECORD (continued)

LICENSE NAME AND NUMBER(S)

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SUMMARY AND ACTION REQUIRED (IF ANY) (Continued)

ADDITIONAL INFORMATION NEEDED FOR CONTINUED REVIEW

VI. For Updates to your Radiation Safety program, in accordance with guidance provided in NUREG 1556, Vol. 7, rev. 1, Items 8.10.2 through 8.10.7, pp. 8-22 through 8-45:

(1) As discussed, please clearly state any change that is being requested. In the alternative, please confirm that - other than the expiration date - no changes to your radiation safety program are being requested.

(2) Concerning Item 8.10.2 - Radiation Monitoring Instruments:

(a) Please describe instrumentation that will be used to perform required surveys.

(b) Concerning surveys, please confirm the statement:

"We will use instruments that meet the radiation monitoring instrument specifications published in Appendix I in NUREG -1556, Volume 7, Revision 1, 'Program-Specific Guidance 8-25 about Academic, Research and Development, and Other Licenses of Limited Scope.' We reserve the right to upgrade our survey instruments as necessary."

(c) Please confirm that instruments required for the program will be calibrated before first use, at least annually thereafter, and after any repair, by a vendor that the NRC or an Agreement State has licensed to perform instrument calibration.

(d) In the alternative, if the licensee will be performing its own instrument calibrations for instruments used in required surveys, please either (i) confirm the statement:

"We will implement the model radiation survey meter calibration program published in Appendix I in NUREG 1556, Volume 7, Revision 1, 'Program-Specific Guidance about Academic, Research and Development, and Other Licenses of Limited Scope.'" or

(ii) Submit equivalent procedures for instrument calibration.

(3) Concerning Item 8.10.3 - Material Receipt and Accountability, please confirm the statement:

"We will develop, implement, and maintain procedures for ensuring accountability of licensed materials at all times."

CONVERSATION RECORD (continued)

LICENSE NAME AND NUMBER(S)

13-32698-01

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SUMMARY AND ACTION REQUIRED (IF ANY) (Continued)

VI. For Updates to your Radiation Safety program, in accordance with guidance provided in NUREG 1556, Vol. 7, rev. 1, Items 8.10.2 through 8.10.7, pp. 8-22 through 8-45 (continued):

(4) Concerning Item 8.10.4 - Occupational Dose - please:

(a) Confirm the statement:

"We will maintain, for inspection by the NRC, documentation demonstrating that unmonitored individuals are not likely to receive a radiation dose in excess of the limits in 10 CFR 20.1502." or

(b) Confirm the statement:

"We will monitor individuals in accordance with the guidance in the section titled, 'Radiation Safety Program -Occupational Dose' in NUREG -1556, Volume 7, Revision 1, 'Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Academic, Research and Other Licenses of Limited Scope.'" or, in lieu of these statements,

(c) Provide a description of an alternative method for demonstrating compliance with 10 CFR 20.1502.

(5) Concerning Item 8.10.6 - Safe Use of Radionuclides, Security, and emergency procedures - please:

(a) Either, confirm the statement:

"We will develop, implement, and maintain procedures for safe use, security and emergencies." or

(b) Confirm the statement:

"We will adopt the procedures for the safe use of radionuclides, security and emergencies as published in Appendix L in NUREG -1556, Volume 7, Revision 1, 'Program-Specific Guidance about Academic, Research and Development, and Other Licenses of Limited Scope.'" or

(c) Provide procedures for safe use of radionuclides, security of materials and emergencies.

(6) Concerning Item 8.10.7 - Surveys and Leak Tests, either:

(a) Concerning surveys, please confirm the statement:

"We will survey our facility and maintain contamination levels in accordance with the survey frequencies and contamination levels published in Appendix M in NUREG -1556, Volume 7, Revision 1, 'Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope.'" or

CONVERSATION RECORD (continued)

LICENSE NAME AND NUMBER(S)

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SUMMARY AND ACTION REQUIRED (IF ANY) (Continued)

ADDITIONAL INFORMATION NEEDED FOR CONTINUED REVIEW (continued)

VI. For Updates to your Radiation Safety program, in accordance with guidance provided in NUREG 1556, Vol. 7, rev. 1, Items 8.10.2 through 8.10.7, pp. 8-22 through 8-45 (continued):

(6) Concerning Item 8.10.7 - Surveys and Leak Tests (continued),

(b) Concerning surveys, please submit a description of an alternate radiation survey program, including survey frequencies and contamination levels, to evaluate a radiological hazard.

VII. For Updates to your waste management program, in accordance with guidance provided in NUREG 1556, Vol. 7, rev. 1, Item 8.11, pp. 8-48 through 8-54:

(1) Please confirm the statement:

"We will use the model waste procedures published in Appendix P in NUREG 1556, vol. 7, rev. 1, NUREG -1556, Vol. 7, rev. 1, 'Program-Specific Guidance about Academic, Research and Development, and Other Licenses of Limited Scope.' or

(2) If the applicant wishes to use only selected model procedures, please confirm the statement:

"We will use the [specify either (i) decay-in-storage or (ii) disposal of liquids into sanitary sewerage] model waste procedures that are published in Appendix P in NUREG -1556, Volume 7, Revision 1, 'Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope.'"

CONVERSATION RECORD (continued)

from NUREG 1556, Vol. 7 rev. 1, Appendix E

Radiation Safety Officer Duties and Responsibilities

The radiation safety officer's (RSO's) duties and responsibilities include ensuring radiological safety, security, and compliance with both U.S. Nuclear Regulatory Commission (NRC) and U.S. Department of Transportation (DOT) regulations and the conditions of the license (see Figure 8-5). Typically, these duties and responsibilities include the following:

- Ensure that licensed material that the licensee possesses is limited to the types and quantities of byproduct material listed on the license.
- Maintain documentation demonstrating that the dose to individual members of the public does not exceed the limit specified in Title 10 of the *Code of Federal Regulations* (10 CFR) 10 CFR 20.1301.
- Ensure security of radioactive material.
- Post documents as required by 10 CFR Parts 19.11, "Posting of notice to workers," and 10 CFR 21.6, "Posting requirements."
- Ensure that licensed material is transported in accordance with applicable NRC and DOT requirements.
- Ensure that radiation exposures are "as low as is reasonably achievable" (ALARA).
- Oversee all activities involving radioactive material, including monitoring and surveys of all areas in which radioactive material is used.
- Act as liaison with the NRC and other regulatory authorities.
- Provide necessary information on all aspects of radiation protection to personnel at all levels of responsibility, pursuant to 10 CFR Parts 19 and 20, and any other applicable regulations.
- Oversee proper delivery, receipt, and conduct of radiation surveys for all shipments of radioactive material arriving at or leaving from the institution, as well as packaging and labeling all radioactive material leaving the institution.
- Determine the need for personnel monitoring, distribute and collect personnel radiation monitoring devices, evaluate bioassays, monitor personnel radiation exposure and bioassay records for trends and high exposures, notify individuals and their supervisors of radiation exposures approaching the limits, and recommend appropriate remedial action.
- Conduct training programs and otherwise instruct personnel in the proper procedures for handling radioactive material before use, at periodic intervals (refresher training), and as required by changes in procedures, equipment, regulations, etc.
- Supervise and coordinate the radioactive waste disposal program, including effluent monitoring and recordkeeping of waste storage and disposal records.
- Oversee the storage of radioactive material not in current use, including waste.

- Perform or arrange for leak tests on all sealed sources and calibration of radiation survey instruments.
- Maintain an inventory of all radionuclides possessed under the license, and limit the quantity to the amounts that the license authorizes.
- Immediately terminate any unsafe condition or activity found to be a threat to public health and safety or property.
- Supervise decontamination and recovery operations.
- Maintain other records not specifically designated above, for example, records of receipts, transfers, and surveys as required by 10 CFR 30.51, "Records," and 10 CFR Part 20, Subpart L, "Records."
- Hold periodic meetings with, and provide reports to, licensee management.
- Ensure that all radioactive materials users are properly trained.
- Perform periodic audits of the radiation safety program to ensure that the licensee is complying with all applicable NRC regulations and the terms and conditions of the license (e.g., leak tests; inventories; use limited to trained, approved users); the content and implementation of the radiation safety program to achieve occupational doses and doses to members of the public that are ALARA, in accordance with 10 CFR 20.1101; and required records are maintained.
- Ensure that the results of audits, identification of deficiencies, and recommendations for change, are documented (and maintained for at least 3 years) and provided to management for review; ensure that prompt action is taken to correct deficiencies.
- Ensure that the audit results and corrective actions are communicated to all radiation workers, including ancillary personnel.
- Ensure that all incidents, accidents, and personnel exposure to radiation in excess of ALARA or 10 CFR Part 20 limits are investigated and reported to the NRC and other appropriate authorities, if required, within the required time limits.
- Maintain understanding of and keep up-to-date copies of NRC regulations, the license, revised licensee procedures, and ensure that the license is amended whenever there are changes in licensed activities, responsible individuals, or information or commitments provided to NRC during the licensing process.
- Develop, implement, maintain, and distribute, as appropriate, up-to-date operating, emergency, and security procedures.

Model Delegation of Authority for Radiation Safety Officer

Memo To: Radiation Safety Officer
From: Chief Executive Officer
Subject: Delegation of Authority

You, _____, have been appointed radiation safety officer and are responsible for ensuring the safe and secure use of radiation. You are responsible for managing the Radiation Protection Program, identifying radiation protection problems, initiating, recommending, or providing corrective actions, verifying implementation of corrective actions, stopping unsafe activities, and ensuring compliance with regulations. You are hereby delegated the authority necessary to meet those responsibilities, including prohibiting the use of byproduct material by employees who do not meet the necessary requirements and shutting down operations, when justified, to maintain radiation safety. You are required to notify management if staff does not cooperate and does not address radiation safety issues. In addition, you are free to raise issues with the U.S. Nuclear Regulatory Commission at any time. It is estimated that you will spend _____ hours per week conducting radiation protection activities.

Signature of Management Representative

Date

I accept the above responsibilities,

Signature of Radiation Safety Officer

Date

cc: Affected department heads

Song, Taehoon

From: Forster, Sara
Sent: Friday, October 26, 2018 8:53 AM
To: Sandrik, Lauren; Pavon, Sandy; Song, Taehoon
Subject: FW: Additional Information Request re IndyVet renewal, NRC Lic. No. 13-32698-01, CN609384
Attachments: 02400.609384.13-32698-01 etc. RFAI via NRC 699 signed.pdf

Please scan in the attached record and update ADAMS profile as noted on attached NRC Form 665. Thank you!

Sara
630-829-9892

From: Forster, Sara
Sent: Friday, October 26, 2018 8:50 AM
To: 'jspeiser@indyvet.com' <jspeiser@indyvet.com>
Subject: Additional Information Request re IndyVet renewal, NRC Lic. No. 13-32698-01, CN609384

Dear Dr. Speiser:

We have reviewed your July 11, 2018 application (NRC Accession No. ML18198A220) requesting renewal of the above-listed radioactive materials license, for use of sodium iodide I-131 in cats.

Upon review, we have noted that the application omits details requested in the NRC's NUREG 1556 Vol. 7, rev. 1, "Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope, Including Electron Capture Devices and X-Ray Fluorescence Analyzers," guidance volume. I will attempt to call you in the next 1 to 3 business days to follow up with this request. As we will discuss, please see attached for information needed to complete our review of your request.

To facilitate our continued review of your request, please provide additional information – via a signed and dated cover letter and resubmitted supporting information - as noted in the attached record.

Please provide the requested information within 28 days of this message (on or before November 23, 2018). Include a signed and dated cover letter transmitting your response. Submission of your response as a pdf file attached to an email or via facsimile will allow for the quickest processing. Please call or email me with any questions you may have, or if you are unable to respond by the date suggested above. Thank you for your prompt attention to this matter.

Sincerely yours,

Sara A. Forster, Health Physicist Licensing Reviewer
U.S. Nuclear Regulatory Commission - Region III
Division of Nuclear Materials Safety
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