

Licensing Guide for Veterinary Licenses

This guide is intended to assist applicants in the development of a radiation safety program for use of radiopharmaceuticals in animals. The applicant must submit complete, accurate and detailed information for each of the items listed below. RHB form 2050 is the application used for veterinary licensing. Copies of this guide are available on the internet at the [Radiologic Health Branch website at www.cdph.ca.gov/RHB](http://www.cdph.ca.gov/RHB).

Item 1:

- a) Name of Applicant: Specify the name of the company or business entity responsible for the radiation safety program.
- b) Mailing address: California only
- c) Phone number: California only

Item 2:

- a) Type of business: Sole proprietorship, group, corporation, university. Provide copy of Articles of Incorporation.
- b) Location of use: List all Radioactive Material (RAM) locations of use and include room numbers if applicable.

Generally each RAM license may have only one RAM use location. Exceptions will be evaluated by RHB staff.

Location(s) of use must have a letter from the landlord/building owner allowing use of RAM and unrestricted entry into facility to retrieve all RAM and decontaminate facility in case of disharmony between the parties.

- c) Application type: Self-Explanatory

Item 3:

- a) Nuclide(s): Specify isotopes to be used
- b) Form: Any for unsealed material and sealed sources with model numbers if applicable for sealed sources.
- c) Possession limit: State maximum possession limit to meet demand. The possession limit includes the material in storage and animal excreta.

Item 4:

- a) Proposed use: Select the proposed use(s) as follows:
 - 1) diagnostic imaging in animals
 - 2) hyperthyroidism and/or thyroid tumors in animals

- 3) Palliative treatment in animals
- 4) Marker and calibration sources for calibration of instruments
- 5) Brachytherapy
- 6) Other: (describe)

Item 5: Radiation Safety Officer and authorized user training requirements

- a) Submit a Duties and Responsibilities of the Radiation Safety Officer (RSO) and Delegation of Authority form. Form must be signed by the RSO designee and a senior member of management such as the CEO, COO, Vice-President, President or Owner.
- b) Submit a completed Training and Experience (T&E) form RH-2050A for the RSO and supervisory users. Supervisory users shall only be the Veterinarian. As the supervisory user, the Veterinarian must be intimately involved in the radiation safety program. Describe how the DVM will remain involved including number of hours per week the DVM is actually on site. Animals having undergone Iodine therapy may only be released to the owner by the DVM. The T&E requirements are as follows:
 - 1) The veterinarian shall be a board certified Radiologist prior to 1994 or Board Certified Radiation Oncologist after 1994 or;
 - 2) The veterinarian shall have completed training and experience for the total required hours:
 - a. For diagnostic procedure:
 1. 40 hours of didactic training and
 2. 40 hours of clinical training whose preceptor is qualified as in B.1. above. This clinical training must be pre-approved by the department.
 - b. For therapeutic procedures with isotopes:
 1. 40 hours of didactic training and
 2. 80 hours of clinical training whose preceptor is qualified as in B.1. above. This clinical training must be pre-approved by the department.
- c) Submit a training program, including annual refresher training program, provided to individuals who will act as the radiation workers supervised by the supervisory users listed in B. above. Provide an outline of the topics covered in their didactic training and describe their on-the-job training process. Commit to maintaining records of each radiation worker's training log and training completion certificate.

Item 6: Radiation Detection Instruments

Complete the table shown on form RH-2050. Survey instrumentation must include exposure rate instrumentation and wipe test instrumentation. Your wipe test instrumentation must be sensitive enough to detect the contamination action levels you use. Submit evidence that the Minimum Detectable Activity (MDA) of the instrument meets your action levels.

$$MDA = \frac{2.71 + 4.65\sqrt{B}}{Eff}$$

Where: B Background (cpm)

Eff detector efficiency

Contamination action levels: 2000 dpm/100 cm² (isotopes other than iodine)
200 dpm/100 cm² (iodine)

Suggested exposure action levels: 2.0 mR/hr (restricted areas)
0.05 R/hr (unrestricted)

Item 7: Method, frequency and standards used in calibrating instruments listed in item 6.

- a) Provide the name of the authorized service company who will be calibrating survey meters. You may commit to utilizing any other authorized service company in the future to avoid amendments involving such a change.
- b) If calibrated by the Licensee submit procedures including:
 - 1) Calibration standard (energy, activity, accuracy)
 - 2) Two point on each scale
 - 3) ± 10 percent
- c) The frequency shall be at least annually and following repair.
- d) Specify sources used for calibration of the liquid scintillation, NaI or gamma well counter. Indicate if these are received as exempt or should be included under Item 3 of the application.

Item 8: Personnel monitoring and bioassay procedures

Submit a description of personnel monitoring and frequency of exchange including:

- a) Whole body film badge or Thermoluminescence Dosimeter (TLD).
- b) Extremity film badge or TLD.
- c) NVLAP approved vendor.

Note: If using radiopharmaceutical human use grade Iodine-131 for therapy procedures then bioassays are not required.

Item 9: Facilities and Equipment

Provide a labeled facility diagram showing RAM use and storage locations in relation to the rest of the facility. Specify restricted versus unrestricted areas and describe shielding. Also include the following:

- a) Security identified/described
- b) Remote handling equipment
- c) Hot lab diagram
- d) Waste areas identified including decay-in-storage
- e) Generator storage areas identified, if applicable
- f) Isotope storage areas identified
- g) Commitment to post areas where RAM is used or stored
- h) RAM use injection areas identified.
- i) Animal holding areas identified

Item 10: Radiation Safety Program

Note: Please refer to NRC attachments (Appendix H, Considerations for Laboratory Animal and Veterinary Medicine Uses and Item 8.11, waste management) for additional information on Veterinary Radiation Safety Programs.

- a) Commit to conspicuous posting of form RH-2364 (Notice to Employees) which is supplied by the Department with the license. Also commit to posting the license, operating procedures, and regulations or if not practical, where these items may be found.
- b) Provide the "General Safety Rules" which will be followed by all users of RAM. Commit to providing initial and annual refresher training on these topics to keep the users informed (Section 30255 of Title 17). Commit to maintaining records for inspection. Include the following descriptions:

General Rules for the Safe Use of Radioactive Material

- 1) Instructions
- 2) Lab Coats
- 3) Gloves
- 4) Logbook and labels for doses
- 5) Monitoring hands
- 6) Syringe shields
- 7) No eating, drinking, smoking or storage in RAM use areas
- 8) Procedures on moving and/or transporting RAM
- 9) Personnel monitoring instructions
- 10) Description of contamination control and personnel monitoring surveys, after each procedure and at the end of the day.

Personnel Training Program:

- 1) Training frequency
 - 2) Before using RAM
 - 3) Before working in vicinity
 - 4) Annual refresher
 - 5) Training Procedures Submitted for staff and ancillary personnel
 - 6) Topics:
 - a. Licensees ALARA program
 - b. Annual dose limits
 - c. Identification of use locations
 - d. Potential Hazards
 - e. Safety precautions appropriate to duties (minimize exposure)
 - f. Pregnancy policy
 - g. Regulations
 - h. Duty to report unsafe conditions
 - i. Location of notices, copies of regulation and license
 - j. Properly documented
- c) Submit ordering, receipt, inventory control and sealed source leak test procedures. These procedures should be performed in accordance with 10CFR20 Section 1906.

Procedures for Ordering and Receiving:

- 1) Procedures for ordering and receiving
- 2) Procedures for whom can order materials
- 3) Procedures during working hours
- 4) Storage location for off-duty hours
 - a. Off-duty hour RAM receipt procedures

Radioactive Materials Package Opening Procedures:

- 1) Procedure for opening packages
- 2) Radiation level monitoring (10 mR/hr at one meter, 200 mR/hr at surface)
- 3) Wipes taken on the outer container (2,200 dpm/100 cm² limit)
- 4) Check packing material for contamination
- 5) Report excessive levels to RSO

Records of Possession and use of RAM

- 1) Procedure for maintaining records of RAM
- 2) Records of Unit dosage used
- 3) Records of Multi-Dose vial use

Sealed Source Leak Test

- 1) Vendor doing leak test
 - 2) Licensee doing leak test:
 - a. Frequency (every 6 months)
 - b. Minimum detectable activity (0.005 uCi or better)
 - c. Instrumentation
 - d. Specify procedures
- d) Provide area survey procedures. In general, daily surveys of work areas should be done (no record unless a positive result is found), and weekly

recorded surveys will be maintained for inspection. The following should be included:

- 1) Survey frequencies
 - 2) Daily - Elution, Preparation and injection areas
 - 3) Weekly - All other use areas
 - 4) Ion chamber or energy compensated probe required for surveys
 - 5) NaI detector or gamma well counter required for wipes
 - 6) Records (appropriate units)(dpm/100cm² and mR/hr)
 - 7) Exposure trigger levels identified
 - 8) Contamination action levels identified
 - 9) A keyed diagram of wipe/survey test locations
- e) Provide Emergency procedures including:
- 1) Emergency instructions
 - 2) Immediate actions listed (e.g. turn off ventilation, evacuation and containment)
 - 3) Notification of RSO
 - 4) Names and telephone numbers of responsible parties listed and posted
 - 5) Clean-Up Procedures (instructions for reentry, decontamination and recovery)
- f) Assure that containers, storage areas, rooms, stalls, pens, and equipment in which radioactive material are used are properly labeled in accordance with 10 CFR 20, sections 1801, 1802 and 1901.
- g) Submit a description of your animal release criteria and procedures. Members of the general public may not receive more than 100 mR/year. Your procedures must demonstrate how occupants of the residence or other members of the general public will not be exposed to greater than this exposure limit. **The Department recommends the animals be held for a minimum of 5 - 24 hour periods and not be released until the dose rate is 0.5 mrem / hr at 1 meter for I-131.** Should the licensee choose release guidance different than that described above justification and supporting data must be submitted.
- 1) Submit a sample of the animal owner instructions with signature/print name and date blocks for both the owner and the authorized user DVM. Date and times of injection and release must be included.
 - 2) Animal excreta is not exempt for disposal. Your procedures must include discussion of how you will deal with the animal excreta.

Item 11: Effluent and environmental monitoring

This item is generally not applicable except for sewer disposal of RAM which is covered in item 12.

Item 12: Waste disposal

- a) If using the sanitary sewer system, provide estimated monthly water usage by the facility and calculate expected concentrations for each proposed isotope. Compare these with Appendix B of 10 CFR 20.
- b) Describe procedures and equipment for containment of animal excreta. Specify how stall, cages, floors and facility ground will be decontaminated.
- c) For solid waste packaging, consult with a qualified radioactive waste broker for detailed information.
- d) To store for Decay in Storage (DIS)(isotopes with physical half lives less than 65 days), hold for 10 half-lives, survey with pancake probe prior to disposal to verify levels indistinguishable from background, and label removal or defacement. Retain records of surveys and items disposed of for inspection.
- e) Also include the following if applicable:
 - 1) Waste will be handled by:
 - a. Commercial waste broker contracted
 - b. Transfer to manufacturer or disposal facility
 - c. Decayed in Storage on premises
 1. DIS facility diagram
 2. DIS security

Item 13: Decommissioning and Decontamination Plans:

Commit to a thirty day prior notification of your intent to vacate and subsequent submittal of a clearance survey to the Department. You may contact the Radiologic Health Branch for clearance survey requirements.

Item 14: The application must be signed by an official who is legally and financially liable for the corporation.

REFERENCE:

1. Duties and Responsibilities of the Radiation Safety Officer and Delegation of Authority for Veterinary Facilities
2. U.S. Nuclear Regulatory Commission , NUREG-1556, Volume 7 "Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope (Final Report), Appendix H : Considerations for Laboratory Animal and Veterinary Medicine Uses, Section 8.11, Item 11: Waste Management