Authorized User / Radiation Safety Officer Training for Veterinary Users

Module 1: Regulatory Overview

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Introduction

- This training course is for veterinary facilities interested in establishing a radioactive materials license (RAM License), or adding radioisotopes to an existing license.

- The course consists of 9 modules related to the safe use of radioactive materials in veterinary applications. Each module includes training slides, supplemental reading material, and a short quiz. Completion of the quiz enables the trainee to move to the next module. All content is available for download.

- The first 8 modules cover generic aspects, with a few references to specific radioisotopes. Upon satisfactory completion of all 8 modules, a certificate will be generated and forwarded to the email address provided at registration.

- The last module, 'Practical Use', is specific to licensing and usage aspects of specific products, such as ^{90}Y IsoPet® for solid malignant tumor treatment, ^{117m}Sn Synovetin OA™ for canine arthritis treatment, or ^{131}I radioiodine for feline hyperthyroidism treatment. A separate certificate will be generated upon completion of this module.

- If this is your first time applying to be an Authorized User (AU) on a RAM license, you are required to complete all 9 modules, in succession. If you are already an AU, and are merely adding a new radioisotope to your existing license, you may skip modules 1-8, and complete only module 9. Supervised Individuals (SIs) are typically assigned all 9 modules as part of their training.

Flowchart of establishing a Radioisotope Therapy Program

Express interest in veterinary treatment for a particular modality

Sign up for the required training for Authorized Users and Supervised Individuals

Complete training modules 1-9, and obtain certification

Pick out a Radiation Safety Officer, Authorized User(s), location of use, and generate a floor plan

Get license application prepared (with F.X Masse Assoc.), and mail it with attachments, to your State's regulators. A license application fee may be involved.

Answer questions from application reviewers; the waiting time for license issuance can be weeks to months.

While waiting for license, get prep work done: Establish hot lab, signage, equipment, dosimetry badges and rings, and other paraphernalia. Have at least one person in the group complete **DOT/Hazmat training**

If necessary, arrange for hands-on **onboarding** training of AUs and SIs with consultants or drug manufacturer or RSO. This could involve practice runs using a non-radioactive practice solution (dye) injected into animal tissue (chicken breast). Performance evaluations and re-iterations done as necessary.

Once the license is issued, make arrangements with radioisotope supplier or drug manufacturer to ship doses.

If necessary, do **practice run**(s) on animal tissue with radioactive material. This will also help you get acquainted with package receipt, check-in and security procedures, aside from refining and fine tuning injection technique, area surveys and wipe tests, handling a possible spill, and decay-in-storage. Performance evaluations and re-iterations done as necessary.

Arrange for **initial treatment**(s), after picking out suitable candidate, owner interview, etc.

On the day(s) prior to treatment: receive, check-in and secure the radioisotope treatment package

Initial treatment may be done in the presence of the RSO or a trained expert. It may happen that **onboarding, practice tun** and **initial treatment** are done very close together (maybe a day apart). Additional hands-on training for more patients may be arranged as required, until the RSO or drug manufacturer determines proficiency of personnel.

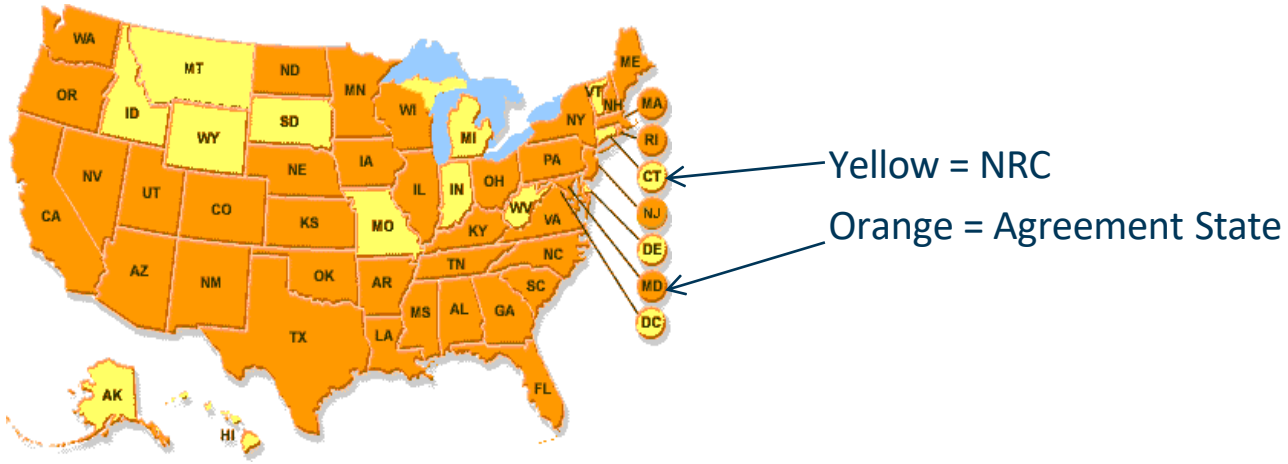
Outline

- Regulation of Radioactive Materials Use
- Radioactive Materials License
- Authorized Users and Radiation Safety Officers
- RAM License Amendment Process
- RAM License Conditions
- Licensee Inspections and Violations
- Supplemental Reading Material:
    1.1. FDA Package insert / Device Label from drug manufacturer
    1.2. NUREG 1556 Volume 7 (specifically, see Appendix D for veterinary users)
- Quiz

Who Regulates Use of Radioactive Materials?

- US Nuclear Regulatory Commission (NRC)
  - Federal parent organization that oversees safe use of radioactive material
  - Currently 13 states (+ DC) are regulated by the NRC

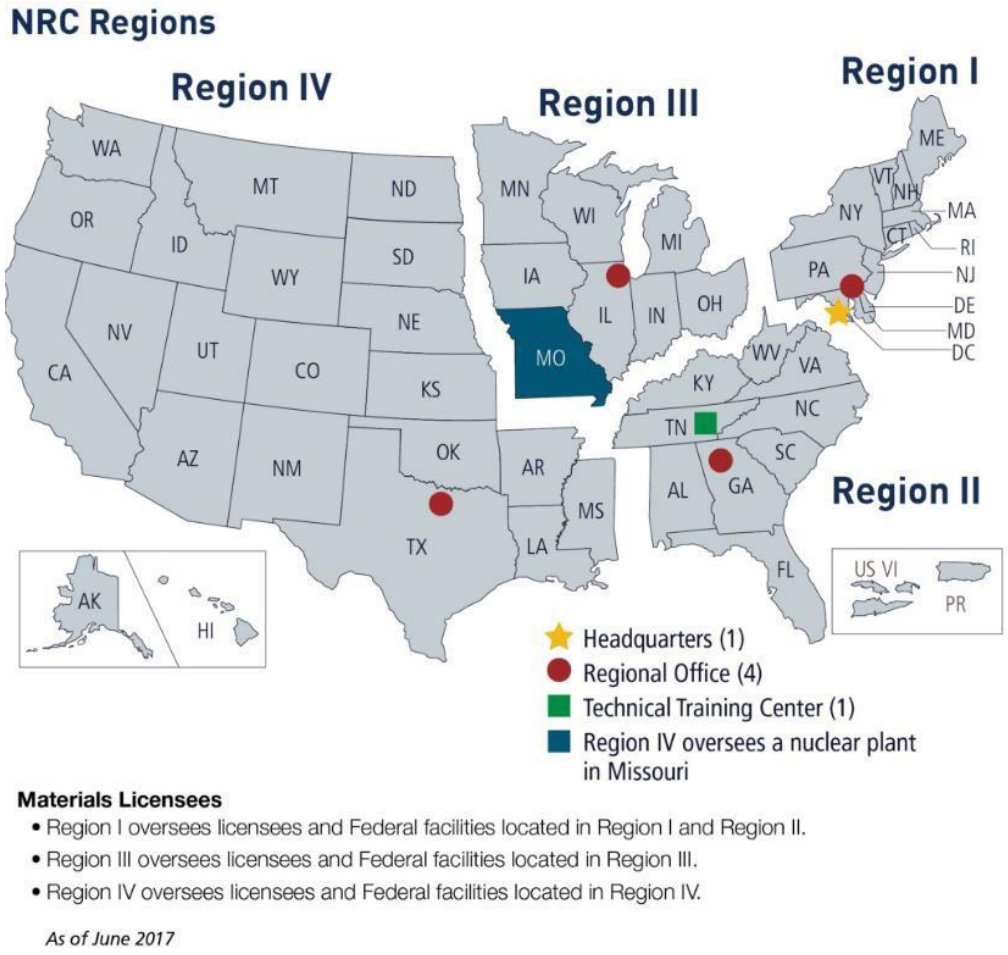
- Agreement States
  - The remaining 37 states have an agreement with the NRC to manage radioactive material use at the state rather than federal level
  - Agreement States have their own regulations which need to be equally stringent or more stringent than those of the NRC.



Who Regulates Your State?

- This link (https://www.crcpd.org/mpage/Map) takes you to the Council of Radiation Control Program Directors website page showing a map of the US and contact information for each state's radiation control program.

- The map to the right identifies the regions for NRC-regulated states, and contact information for each region can be found at this link: https://www.nrc.gov/about-nrc/locations.html.



Example of an Agreement State - California's Radiation Control Program: https://www.cdph.ca.gov/Programs/CEH/DRSEM/Pages/RHB.aspx

What Is a Radioactive Materials License?

- The US regulates the safe use of radioactive materials through the Nuclear Regulatory Commission (NRC) and Agreement States.
- A radioactive materials (RAM) license is the document that authorizes an entity to procure, possess, and manipulate sealed or unsealed radioactive materials.
- Specific regulations and procedures must be followed when handling radioactive materials, and the licensee is required to develop and maintain an approved radiation protection program.
- There are two specific roles identified on a radioactive materials license:
  - **Radiation Safety Officer (RSO)**
  - **Authorized User (AU)**

  The RSO and AU can be the same person.
- For more information, refer to supplemental reading: NUREG 1556 Volume 7.

Authorized Users (AU) and Radiation Safety Officer (RSO)

- **Authorized User:** Licensed veterinarian who is listed on a RAM license and is trained in the safe handling and use of unsealed and sealed radioactive materials. Qualified training includes one or more of the following:
  - Fellowship in radiology and / or nuclear medicine
  - Training course specific to the safe use of radioactive material
  - Preceptor attestation by an AU approved for the type of use requested
    - Authorized Users can also supervise other employees with specific, documented training. For example, a technologist could be trained to receive and check-in packages containing radioactivity, prepare a dose, and assist in injections. The technologist would be a **Supervised Individual (SI).**
- **Radiation Safety Officer:** Typically an AU or contracted consulting health or medical physicist who is trained in the state/federal regulations for the safe use of radioactive materials.
  - Responsible for the licensee's safe use of radioactive materials
  - Ensures the program is kept ALARA (staff and public radiation exposure is maintained "as low as reasonably achievable")
  - Serves as liaison with regulators

Amendments to Existing RAM Licenses

- Most existing veterinary RAM licensees are approved to use ^{131}I as radioiodine therapy for feline hyperthyroidism. Current licensees will already have many aspects of the radiation protection program in place.
- Before licensees are permitted to use any other radioactive material (such as yttrium-90 or tin-117m), they must submit an “amendment request” to their regulatory body for approval.
- The specific format of the amendment request will vary by state, but the content will be similar. In all cases, the most recent state-specific or federal guidance must be used.
- Amendment requests must be sent from the licensee on their letterhead and signed by a practice administrator or “responsible person” such as the RSO.

Amending an Existing RAM License to add another radioisotope

At a minimum, each amendment request must include:

1. Existing radioactive materials license number (if applicable)
2. Physical address of veterinary facility and name of contact person (RSO or practice administrator)
3. Type of radioactive material to be added
4. Description and purpose of use (e.g., brachytherapy for canine and feline sarcomas). Example of proposed wording for IsoPet® license amendment:

   "We are applying for an amendment for the use of yttrium-90 (specifically the brachytherapy device IsoPet®) to treat soft tissue sarcoma tumors in canine and feline patients. We request a possession limit of 50 millicuries (mCi) maximum per procedure and 200 millicuries (mCi) total. Unless the animal has to be hospitalized due to clinical indications, the treatment will be provided on an outpatient basis."

5. Training plan for staff members, both AU(s) and any SI(s) who will be working with RAM
7. Description of the hot lab and where the RAM will be used
6. Description of the radiation safety program (including release criteria)
8. Description of the radioactive waste management program

F.X. Massé Associates has been contracted to help initiate your RAM license amendment process. Contact us at http://www.fxmasse.com/; info@fxmasse.com; or 978-283-4888.

Device Label: Description of Purpose and Use

Each licensee should carefully review the Device Label or FDA Package Insert of the radioactive drug (see supplemental reading material) for important information about the product:

- Device or drug name
- Chemical form
- Product description
- Mechanism of action
- Intended use
- Maximum individual dosage
- Warnings and precautions
- Directions and preparations for use
- Adverse reactions
- Aftercare and owner instructions
- Storage instructions

Note: There is no specific FDA package insert for the use of ^{131}I for feline hyperthyroidism. The document is for human treatment in capsule form, but has valuable background information about the radioisotope.

License Conditions

- Licensees are required to safely receive and store radioactive materials in a secure location, typically using “two delay methods”, *i.e*., any unauthorized individual trying to gain access to sources should be challenged by at least two mechanical hindrances. This requirement can be satisfied by storing material (a) in a locked container / cabinet / drawer (b) Within a small locked room called a **hot lab**. The hot lab is considered a **restricted area**, and only personnel who have required training (repeated annually and documented) may have access to it.
- Licensees are required to maintain areas where unsealed radioactive material is used to the specific licensed exposure rate and contamination limits. Quantification of contamination and exposure will be covered in future modules, but those measurements are typically taken with a handheld GM (Geiger-Müller) ratemeter or survey meter.
- Licensees are required to maintain staff occupational radiation doses “as low as reasonably achievable” (ALARA). This can be managed by providing dosimetry (passive radiation detectors) to staff members who handle radioactive material to validate that their occupational doses do not exceed regulatory limits.
- All staff members who handle radioactive material, or are expected to exceed 100 mrem / year of whole body occupational dose, must be provided annual radiation safety training.

License Conditions (continued)

- Licensees are required to maintain their **public** radiation exposure as low as reasonably achievable (ALARA) by limiting the quantity of radioactive materials injected, providing specific instructions to the pet owners, and interviewing the owners to ensure they can comply with the instructions.

  The dose limit to members of the general public is 100 mrem/y, which is equivalent to about 10 chest x-rays or 100 days of natural background radiation in the US.

- Licensees are required to safely manage their radioactive waste, typically using a "**decay in storage**" (DIS) method where radioactive material is set aside for a specific amount of time in a secure, locked location, then disposed of as normal waste once its radiation level is no longer distinguishable from background radiation.
- Licensees are required to maintain radiation protection program records, develop spill procedures, and annually **audit** the program—called the Annual Radiation Safety Officer Audit.
- Future modules will address each condition in greater detail.

Licensee Facility Inspections

- The NRC and each Agreement State's regulators are obligated to inspect every RAM licensee. The duration between inspections varies from state to state based on the scope and type of license and the inspectors' workload.
- What to expect during a radiation control program inspection:
  - Inspections may be un-announced or pre-scheduled, typically on a three-to-five year rotation depending on previous inspection results.
  - Inspectors tour the facility, focusing on licensed areas of radioactive materials use. They typically bring their own radiation detectors and survey routine use areas such as the hot lab and injection table.
  - Inspectors review license conditions and the associated records proving compliance, such as dosimetry records, patient release records, RAM receipt records, RAM disposal records, daily ambient survey and weekly removable contamination survey records, and annual ALARA audits.
  - A pre-licensure inspection may also take place, wherein the regulators will tour the facility, interview the AUs proposed on the license application, in order to establish the legitimacy of the applicant before they issue the RAM license.

RAM License Violations

- Violations are broken down into five categories and five severity levels (I to V):
  a. Health Physics
  b. Transportation
  c. Materials Operations
  d. Miscellaneous Matters
  e. Emergency Preparedness

  Severity Levels I and II are the most severe and involve actual or high potential for impact to the public. Severity Level V reflects minor safety or environmental concerns.

  If items of non-compliance are discovered during a facility inspection, the licensee may face:
  - Immediate suspension of license
  - Denial, modification, limitation, revocation of, or refusal to renew their license
  - Monetary fines
  - Other actions that just make life difficult

RAM License Violations (continued)

- Notice of Violation (**NOV**)
  - This is a formal notification of a violation to the applicant, licensee, or registrant. It includes the specific violation, the provision of regulation relied upon, and a reasonable period-of-time for correction.
  - Within 10 days of receipt of the NOV, a clearly delineated plan of correction must be sent back to the state or federal regulatory body.
  - The plan of action and a reasonable period-of-time for correction is followed by a reinspection to close the loop on the corrective actions taken.
  - The NOV and its response must be **posted** (*i.e.*, displayed in a conspicuous location) within 5 working days of receipt and response, and must remain posted for at least 5 working days or until the action correcting the violation has been completed, whichever is later.
- Administrative Hearings
  - If the license were to be revoked, the licensee has the procedural right to an administrative hearing.
- Civil Penalties
  - If the licensee waives the administrative hearing process, the regulatory body can impose civil penalties.

See 10 CFR Part 35 or applicable State Regulation for more information

Conclusion

- The use of radioactive material is very heavily regulated by either the Nuclear Regulatory Commission or an Agreement State, depending upon facility location.
- RAM licensees are required to designate a **Radiation Safety Officer (RSO)** and one or more **Authorized Users (AUs)**. Additional personnel who handle radioactive materials are not specifically named on the license, but work under the supervision of an AU, and are called **Supervised Individuals**.
- RAM licensees must comply with the conditions listed on their license, which provide an outline for safe use of radioactive material.
- Regulators are obligated to inspect every RAM licensee to determine whether license conditions are being met.
- Although rare, violations can include civil penalties and suspension or revocation of the RAM license.

Supplemental Reading Material

Supplemental reading material for Module 1:

1.1 FDA Package Insert or Device Label

1.2. NUREG 1556 Volume 7

Upon successful completion of the Module 1 quiz, you may continue to Module 2.