EXUBRION™
THERAPEUTICS

Authorized User/Radiation Safety Officer Training for Synovetin OA®

Module 8: Waste, Decay in Storage, and Disposal

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Introduction

- This module focuses on the practical aspects of disposing of radioactive material. It provides several options for disposal of aqueous liquid waste and organic solid waste.
- Also included are some radiation safety basics, including the safe handling of unsealed radioactivity.
- Assigned reading:
  - Synovetin OA® Device Label
  - 10 CFR 20.2003
  - Waste Policy
  - Spill Procedure
  - Owner Precautions

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Outline

- **Radioactive Waste Regulations:**
  - 10 CFR 20.2003
- **Decay in Storage:**
  - Regulations
  - Surveys
  - Solid Waste
  - Liquid Waste
- **Liquid Waste Disposal**
- **License Conditions**
- **Organic Waste**
- **Radiation Safety Basics:**
  - Handling
  - Spill Procedure

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Radioactive Waste: The Basics

- Radioactive waste can be liquid or solid.
- Radioactive waste cannot be disposed of as regular waste.
- Radioactive waste must be segregated from non-radioactive waste, documented, and disposed of according to the conditions of your radioactive materials (RAM) license.
- Before you dispose of any radioactive waste, be sure to read your individual RAM license conditions and state or federal regulations.

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Review Your RAM License Conditions

- A template Waste Policy your facility may use can be found in the supplemental reading materials for this module.
  - If Exubrion initiated your license amendment to add Synovetin OA®, this policy can be adopted as part of the license amendment process.
  - If Exubrion was not contracted for your license amendment to add Synovetin OA®, this policy can be used as a valuable resource in conjunction with the knowledge gained during this training module series.

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RAM License Conditions: Waste Disposal

- Because most license conditions dictate that only a certain amount of radioactive material may be at a physical location at any point in time, an inventory must be kept of all radioactivity, including radioactive waste.
- When radioactive waste is disposed of, that disposal must be accounted for in the inventory and documented in a "waste log."
- Solid waste:
  - Long-lived—must be transferred for disposal.
  - Short-lived—can "decay in storage" and then be disposed of as regular waste.
    - Tin-117m (Synovetin OA®) has a half-life of 2 weeks and is categorized as "short-lived. " Therefore, all ^{117m}Sn can be disposed of as regular waste after 10 half-lives (140 days).
    - Short-lived solid waste can be further categorized as "sharps" and "non-sharps."
- Liquid waste:
  - Mixed liquid wastes must be transferred for disposal ($$$$).
  - Synovetin OA® is readily soluble in water, however, because Synovetin OA® contains a colloid which is nonbiological, it cannot be disposed of into the sanitary sewage system (down the sink).
- Refer to your RAM license or state/federal regulations for approved disposal methods.

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Solid Waste Disposal

- Solid waste can be kept in shielded waste containers.
  - Typically includes contaminated gloves, gauze, packaging, etc.
- Sharps waste should be kept in a segregated "hot" sharps container (a regular sharps container identified with a "Caution Radioactive Material" label) to prevent confusion with "cold" sharps containers.
- Radiation labels are not allowed to be disposed of in regular waste. Always deface them before placing into a waste stream.
- Lead cannot be disposed of in radioactive waste and must be held separately.
- Biohazardous or organic material cannot be placed into solid waste and must be held separately.
- Include waste containers in your daily closeout and weekly wipe test surveys.

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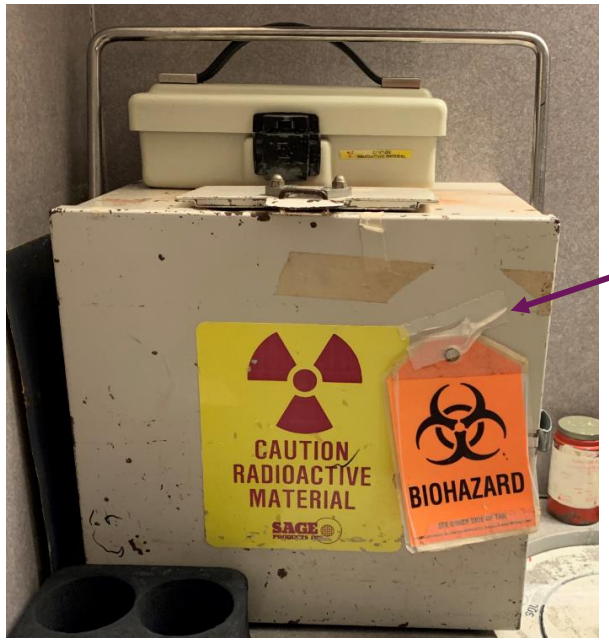
Examples of Radioactive Waste Sharps Containers



Shielded Sharps Container

Sharps Container

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Solid Waste: Decay in Storage

- Solid radioactive waste must be allowed to "decay in storage"—held until its radioactivity is not distinguishable from background radiation levels. The industry standard is to wait 10 half-lives before disposing of it in a regular waste stream.
- Typically a facility will have at least two solid radioactive waste containers—one to fill while the other is decaying.
- After filling a solid radioactive waste container, it is closed, dated, and left to decay.
- After the decay period is over, the waste is removed and surveyed to be sure that no radiation is detectable from the outside of the container. The survey is documented in the waste log, and the waste can be disposed of in the regular waste stream.
- The half-life of ^{117m}Sn (Synovetin OA®) is 14 days. After filling a container with ^{117m}Sn waste, close the container, date it, wait 140 days, survey with a GM counter, document the survey, then dispose as regular waste.

Above is a standard waste container labeled for radioactive waste. The solid waste from ^{117m}Sn contains such a small amount of radioactivity that the container is not required to be shielded.

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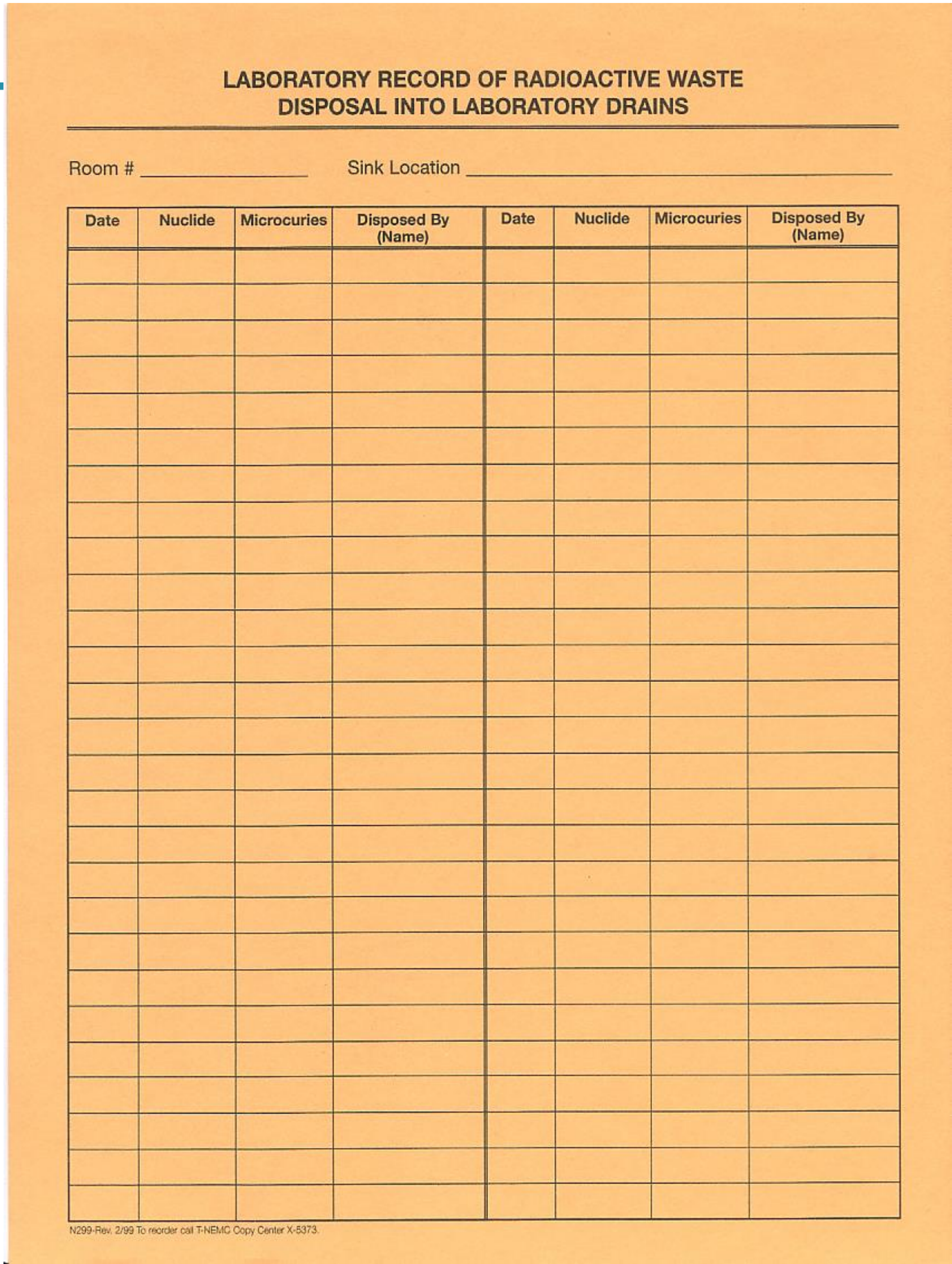
Liquid Waste: Sink Disposal

- Facilities must designate a “hot sink” for disposal of liquid radioactive waste.
- Liquid disposal activity, date, and nuclide must be documented on a disposal form or “sink log” to ensure compliance with disposal limits.
- Only water-soluble ***biologic*** radioactive solutions may be disposed of down the drain.
- Radioactive waste should never be disposed of without running the water in the sink to properly dilute/rinse the waste.
- Synovetin OA® (^{117m}Sn) does not come in a biologic aqueous form and can therefore **cannot** be disposed of in a hot sink.



LABORATORY RECORD OF RADIOACTIVE WASTE
DISPOSAL INTO LABORATORY DRAINS

Room # ______________ Sink Location ______________

Date	Nuclide	Microcuries	Disposed By (Name)	Date	Nuclide	Microcuries	Disposed By (Name)

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Organic Waste

- There is always a possibility that an animal treated with ^{117m}Sn could die from unrelated causes during the precautionary period post-treatment.
- If this were to occur, the animal must be returned to the licensee for decay in storage (DIS). The licensee would need to designate a freezer for DIS for the remainder of the decay period.
- After the decay period (total of 10 half-lives), the animal may be disposed of routinely.
  - Alternatively, the carcass can be measured with a calibrated GM counter. If the measurement is "not distinguishable from background" the carcass may be treated as regular waste.
- Note that the Synovetin OA® Owner Precautions document (see supplemental reading materials) instructs owners to bring their deceased animal back to the licensee for DIS if needed.

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Radiation Safety Program

A radiation safety program contains all of the below elements. The next few slides will focus on a routine spill procedure, some basic radiation safety practices, and the ALARA principle.

- Engineering Controls
- Administrative Controls
  - Specific Training from AU or RSO
  - All areas of use require daily closeout surveys and weekly wipe tests
  - Unsafe practices or conditions involving radiation should promptly be reported to the AU or RSO
- Work Practice Control
  - Techniques for contamination control and to minimize radiation exposure
- Personal Protective Equipment

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Spill Procedure

Should a spill occur:

- Notify others / AU / RSO
  - If necessary (spill is estimated to be greater than 1 mCi, contact Radiation Safety Officer
- Isolate spill
- Leave affected area
- Check for personal contamination
  - Decontaminate as appropriate
- Begin decontamination procedures when appropriate to do so
  - See supplemental material 8.4
  - Work from the perimeter inwards
  - Collect absorbent material as radioactive waste

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Spill Procedure *(continued)*

- Contamination clean-up is simple.
- Cleaning contamination from a surface can be done with any standard cleaning product. When cleaning, try to avoid spreading the contamination with high-pressure hoses or spray nozzles.
- Collect cleaning materials as radioactive waste.
- Personnel should wash their contaminated skin with warm water and soap.
- Survey the contaminated area after cleaning for removable and fixed contamination and rewash if necessary.
- See supplemental reading materials: "Spill Procedure."

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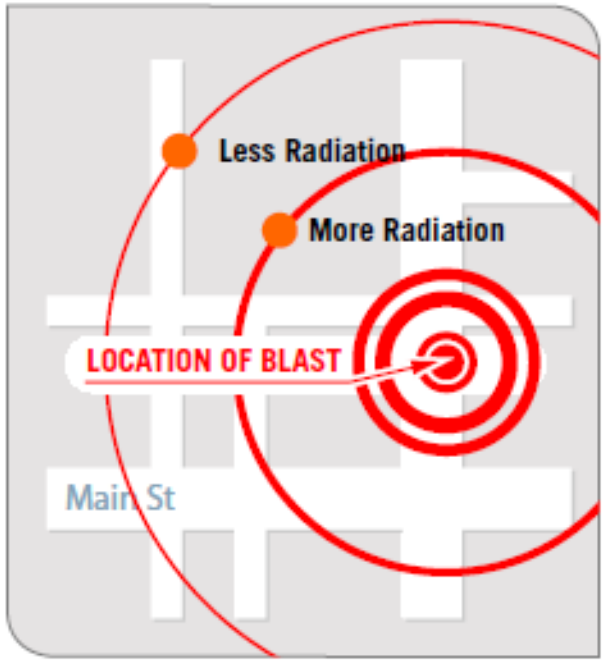
External Radiation Exposure Reduction

There are three ways to minimize radiation dose: time, distance and shielding.

Time: Minimizing time spent exposed will also reduce your risk.



Distance: The farther away you are from the radiation the lower your exposure.

Shielding: If you have a thick shield between yourself and the radioactive materials more of the radiation will be absorbed by the thick shield, and you will be exposed to less.

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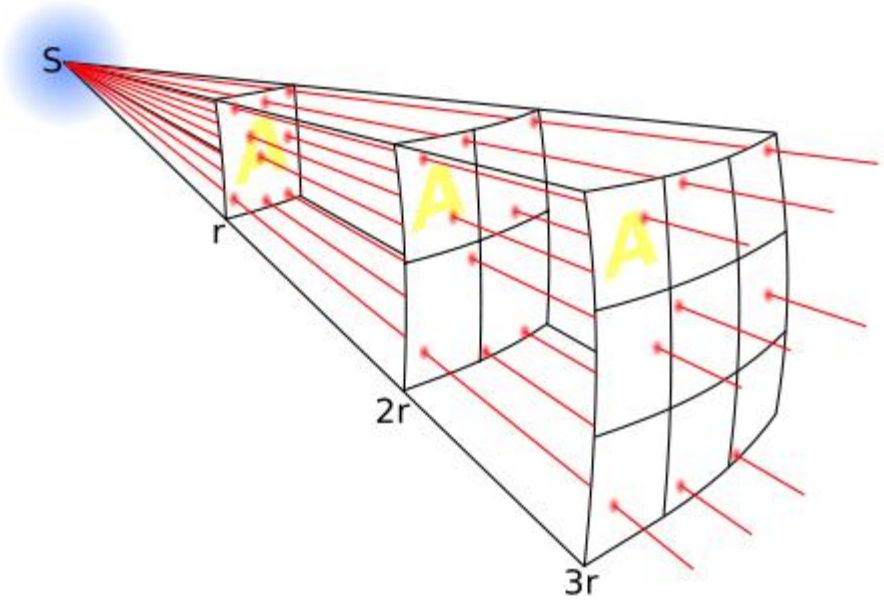
Exposure Reduction: Inverse Square Law

Radiation propagates through space following the inverse square law. So as you move further away from the source of radiation, your dose decreases by the distance you move away → squared.



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Handling

- Always use the basic radiation safety principles when handling radioactivity.
- When handling unit dose syringes for prolonged periods of time, it is always best to use shielding techniques such as a syringe shield.
  - If routine handling is sporadic and the handling time is short, a syringe shield is not necessary.
  - If the syringe shield impedes the delivery or extends the handling time, the AU can opt to handle the dose directly.
- Doses are typically measured in the hot lab and carried to the surgical suite where the patient is waiting.
  - Doses should be carried to the delivery location in a shielded container lined with absorbent material.
  - The shielded carrier should also be used to carry the spent syringe and contaminated tubing back to the hot lab for decay in storage.

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Syringe Shield and Shielded Carrier Examples

Shielded Carrier Examples:
https://www.alimed.com/shielded-syringe-carriers.html

Syringe Shield Examples:
https://m.biodex.com/nuclear-medicine/products/syringe-vial-shields

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As Low As Reasonably Achievable (ALARA)

- ALARA is the principle of maintaining exposure to ionizing radiation as far below the dose limits as practical, taking into account:
  - The state of technology
  - The economics of improvements in relation to the state of technology
  - The economics of improvements in relation to benefits to the public health and safety
  - Other societal and socioeconomic considerations in relation to utilization of nuclear energy and licensed materials in the public interest
- Requirement for all RAM licensees
- To comply, no person should conduct any operation that generates unnecessary radiation exposure

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Summary of Module 8: Waste, Decay in Storage, and Disposal

- Radioactive waste must be handled according to local and federal regulations.
- Liquid waste may be rinsed into a licensed "hot sink" for disposal. However, the disposal must be documented appropriately. Synovetin OA® shall not be disposed in liquid form in a hot sink.
- Solid ^{117m}Sn waste may be held to decay in storage, then disposed of in a regular waste stream.
- Owners of animals treated with Synovetin OA® are provided with instructions to return an animal who dies within 4 months of the treatment date to the licensee to DIS.
- Spills happen when working with unsealed radioactivity. Follow your license conditions and notify your RSO should a spill occur.
- When handling radioactivity or spending time near a radiation source, always follow the three basic principles of radiation safety:
    1. Minimize time
    2. Maximize distance
    3. Use shielding when practical

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Supplemental Reading Material

- Assigned reading material for Module 8:
  - Synovetin OA® Device Label
  - 10 CFR 20.2003
  - 10 CFR 20 Appendix B
  - Waste Policy
  - Spill Procedure
  - Owner Precautions
- Upon successful completion the Module 8 quiz, along with those of the other 7 modules, a certificate of completion will be sent to the email that was used to register for the training program. Retain this certificate for future licensing actions.
- For additional training, see the www.FXMasse.com website:
  - DOT training for shipping and receiving radioactivity
  - Synovetin OA® Practical Use and Radiation Safety

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