Topics pertaining to the Radioisotope Safety Examination (RISE)

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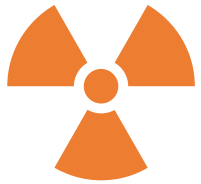
Topics



Radiation Protection Programs

Radiation protection program requirements

Types of licenses and RSO requirements

Radiation Area designations

Control of Radiation Areas

Regulatory Exposure Limits

Occupational

Public dose

Conditions requiring monitoring of external and internal occupational dose

The ALARA concept

Administrative Controls and Responsibilities

NRC/Agreement states

Personnel responsibilities

- Authorized Users (AU)
- Technologists

Topics (cont.)

Management of RAM

Receiving and opening packages

Shipping categories - Type A, Type B, Type C

Exempt, Limited Quantity, and Empty

Sealed Source regulations

Waste management/disposal

- ‘Cold trash’ surveys
- Decay-in-storage

Safety considerations for I-131 therapy greater than 33 mCi

Outpatient

- patient screening
- Public dose considerations

Inpatient

Outpatient

- Room set-up
- instructions

Radiation Protection Program Requirements
NUREG 1556 Vol 9, rev. 3 – model procedures

- RAM license and Radiation Safety Officer, or designee
- Radiation monitoring program (dosimetry or area monitoring)
- ALARA program
- Survey program
- Instrument calibration procedure
- Sealed Source inventory and leak test program
- SOPs and Emergency Procedures
- Waste disposal procedures
- Training program
- DOT approved shipping procedures

Radiation Protection Program – RAM licenses

<u>Broad Scope License</u> – (Type A, B, or C) is a specific license authorizing receipt, acquisition, ownership, possession, use, and transfer: Of any RAM (byproduct material) specified in the license

In amounts (activities) not exceeding quantities specified in the license

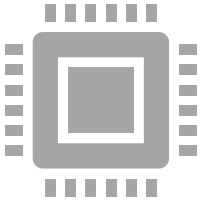
For the purposes authorized in the license.

Large diverse organizations, medical centers/teaching hospitals

The difference between A, B, and C has to do with what these types, quantities and uses are, type A being the least restrictive

<u>Specific license</u> – Licensee is qualified through training and experience to use RAM only for the purpose requested, in accordance with the regulations, in a manner to minimize danger to public health and safety or property:

Medical Use Only licenses



<u>General License</u> – Licensee may possess small amounts of material for use in certain devices

Laboratory use, environmental detection, non-human imaging (industrial radiography)

Radiation Safety Officer (RSO)

Depending on the license and the program, the RSO will need to be a degreed and certified individual in an appropriate field.

For medical programs, many times the RSO is a physician, with a limited role in the day-to-day radiation safety practices.

Regardless of the RSO's daily role, he will be responsible to ensure in some manner the following:

- General program radiological safety
- Compliance with:
  - U.S. Nuclear Regulatory Commission (NRC) or agreement state DOH regulations
  - U.S. Department of Transportation (DOT) regulations
  - The conditions of the license

RSO (or designee) General Program Radiological Safety oversight will ensure:

- All activities involving RAM are safe
- Emergency procedures are up to date, available, and followed
- Possession, use, and storage of licensed material are consistent with the limitations in the license
- All individuals are trained commensurate to their duties
- Provide and document dosimetry to all individuals likely to receive in excess of 10% of the limits
- All RAM is properly secured
- Notify authorities of incidents

Radiation Safety Program - RSO

Safety oversight should also include:

- Periodic audits (at least annually)
  - Transportation of material per DOT regs
  - Waste is disposed of properly
  - Sealed source leak testing is performed
  - Instrument calibrations
  - Exposures are ALARA (quarterly)
  - WDs
- Periodic supervision of surveys and decontamination procedures
- Maintain up to date copies of policies and SOPs
- RAM license is kept up to date

RAM and Radiation Area Designations

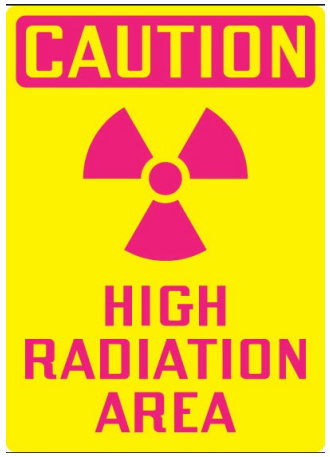
- Public Area – Any area that is accessible to the public, and will not result in a radiation dose to any individual of greater than the public dose limit. (100 mrem/yr)
- Restricted Area - Any area to which access is controlled for the protection of individuals from exposure to radiation and radioactive materials.
- Types of restricted area designations:
  - Caution (or Danger): Radioactive Materials
  - Radiation Area
  - High Radiation Area
  - Very High Radiation Area

Restricted Area - Radioactive Materials

A licensee is required post each area or room in which there is **used or stored** an amount of licensed material exceeding 10 times the quantity of such material specified in appendix C to CFR part 20* with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL(S)" or "DANGER, RADIOACTIVE MATERIAL(S)."

* https://www.nrc.gov/reading-rm/doc-collections/cfr/part020/part020-appc.html

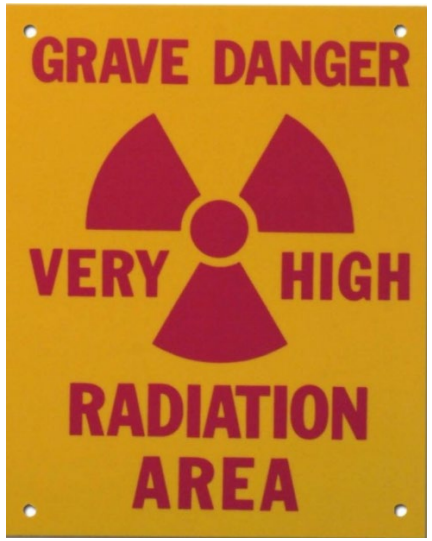
Restricted Area - Radiation Area Designations

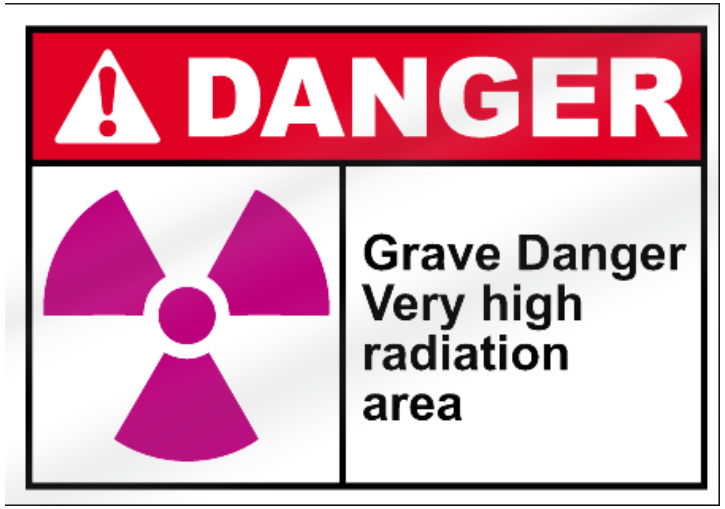


- Radiation Area - Any area with radiation levels greater than 5 millirem (0.05 millisievert) in one hour at 30 centimeters from the source or from any surface through which the radiation penetrates.

- High Radiation Area - an area, accessible to individuals, in which radiation levels from radiation sources external to the body could result in an individual receiving a dose equivalent in excess of 0.1 rem (100 mrem, 1 mSv) in 1 hour at 30 centimeters from the radiation source or 30 centimeters from any surface that the radiation penetrates.

Radiation Area Designations





- Very High Radiation Area - An area accessible to individuals, in which radiation levels exceed 500 rad (5 gray) in one hour at 1 meter from the source or from any surface that the radiation penetrates (see 10 CFR 20.1003).

Exceptions from posting and labeling requirements

A room or area is not required to be posted provided the radiation level 30 centimeters (1 ft.) from the surface of a sealed source does not exceed 0.05 mSv (5 mrem) per hour.

Rooms or other areas in hospitals that are occupied by patients containing RAM are not required to be posted with a caution sign if the patient could otherwise be released.

Caution signs are not required to be posted in areas or rooms that contain radioactive material for periods of less than eight hours if:

The material is constantly attended.

The area or room is under the licensee's control.

The area contains radioactive material being prepared for shipping and packaged according to DOT rules.

Controlling Access to Restricted Areas

- ‘Badge access only’ controlled doors
- Door interlocks
  - Open door, radiation source shuts off

- Door interlocks that include warning lights and alarms
  - Radiation source still present but entry alerts with lights and an alarm
- Physical barriers
  - Barricades
- Surveillance
  - Cameras
  - Attendant/guard

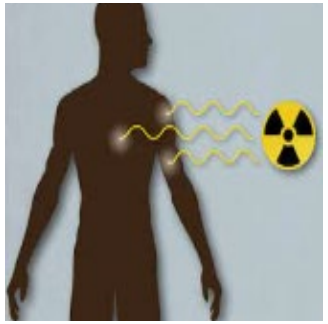
Monitoring Requirements & Radiation Dosimetry

Annual Radiation Dose Limits

- Occupational Dose Limit
  - Whole body 5000 mrem (50 mSv)
  - Extremity or individual organ 50,000 mrem (500 mSv)
  - Lens of Eye 15,000 mrem (150 mSv)
- Public Dose Limit
  - 100 mrem (1 mSv)
- Fetal Dose Limit
  - 500 mrem during the pregnancy (5 mSv)

Conditions requiring monitoring of radiation exposure

External exposure



Dosimetry must be provided if:

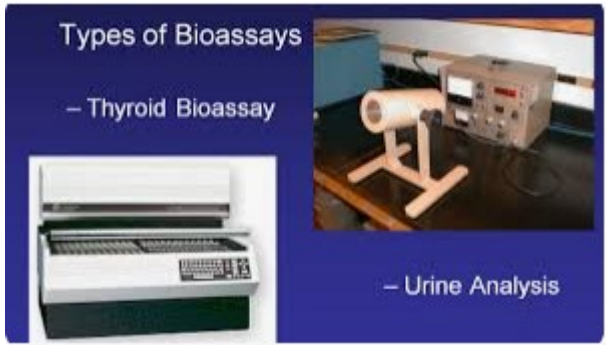
an individual is likely to receive more than 10% of the annual dose limits (WB deep dose or extremity)

a declared pregnant women is likely to receive during the entire pregnancy, a deep dose equivalent in excess of 0.1 rem (100 mrem, 1 mSv)

an individual is entering a high or very high radiation area.

Conditions requiring monitoring of radiation exposure

Internal exposure



Monitoring must be provided to:

Adults likely to receive, in 1 year, an intake greater than 10% of the ALI(s) (Annual Limit on Intake)

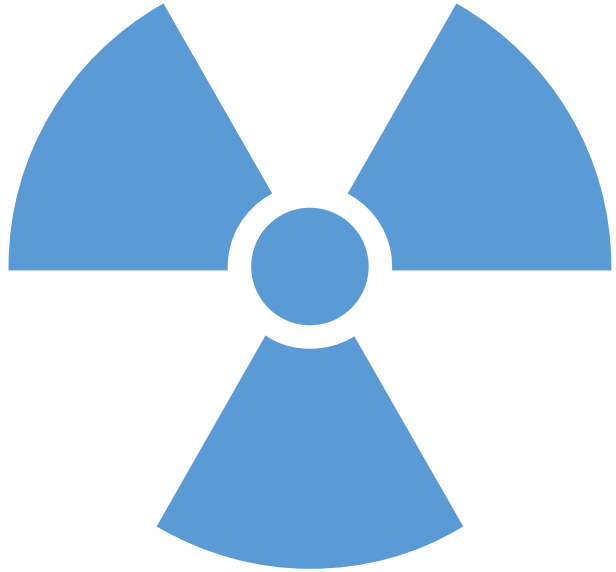
Declared pregnant women likely to receive, during the entire pregnancy, a committed effective dose equivalent in excess of 0.1 rem (100 mrem, 1 mSv).

“ALARA” program - required

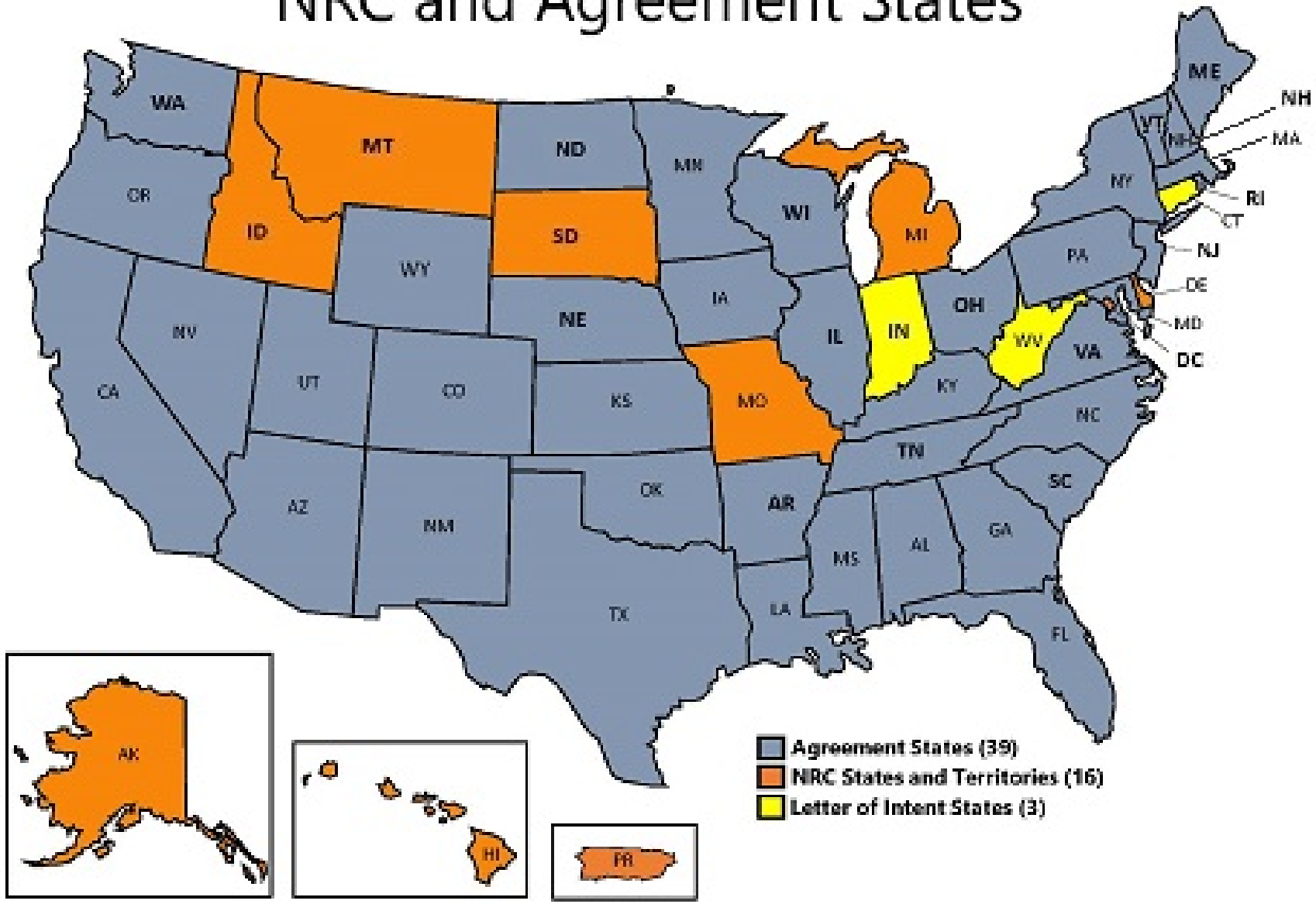
ALARA (acronym for "as low as reasonably achievable") means making every reasonable effort to maintain exposures to radiation as far below the dose limits as is practical, taking into account:

- The available technology
- The cost (expense) of any improvement
- The balance of the cost of improvements in relation to benefits to the public health and safety

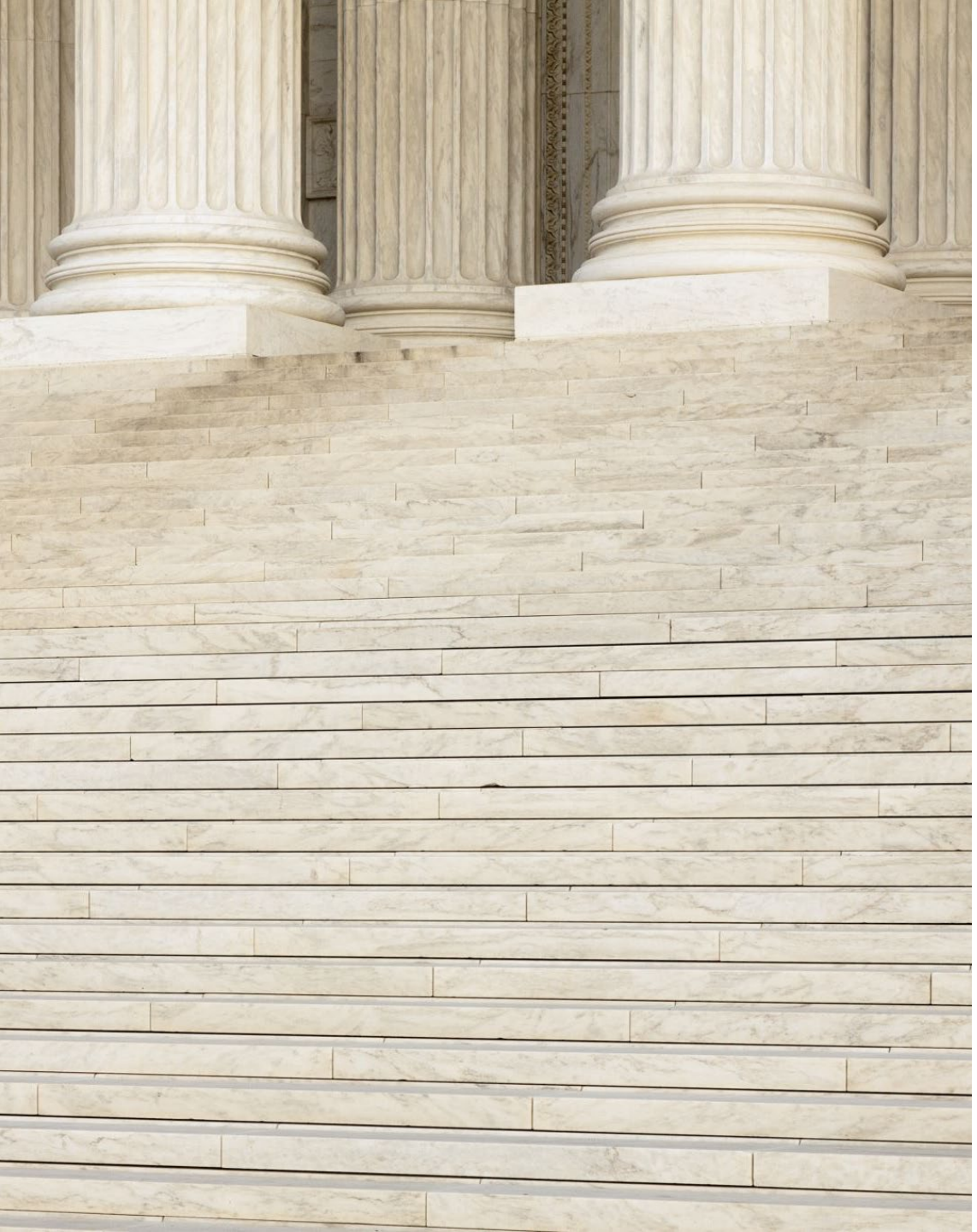
The goal is to keep as many people as possible at <10% of the annual dose limits.



NRC and Agreement States



Agreement States, have entered into agreements with NRC that give them the authority to license and inspect byproduct, source, or special nuclear materials used or possessed within their borders.



NRC State vs Agreement States

- NRC State - Governed exclusively by the Nuclear Regulatory Commission (NRC), and are regulated by 10 CFR part 35.
- Agreement State - Authorities (for example, the WA DOH) have the authority to regulate RAM licenses and programs MORE STRICTLY than the NRC, but not less strictly.
- Agreement State authorities act as a liaison and report to the NRC.
- Most Agreement States have adopted the 10 CFR 35 regulations to be consistent with the NRC.
- If a state doesn’t adopt 10 CFR 35 exactly, they must have comparable regulations.
- The state of WA has adopted 10 CFR 35, mostly verbatim.

Authorized User- AU

An Authorized User (AU) is someone designated under a RAM license to be able to perform certain activities, either human use or other uses.

In being granted this status they must ensure that:

- Licensed (radioactive) materials are handled and used safely in accordance with NRC or State regulations and under the terms and conditions of the license.
- For all activities involving "human use" of licensed material, the person must be a physician (10 CFR 35.3).
- Other properly trained individuals may be designated under an AU to perform certain activities, human or otherwise, (technologists).

Personnel Responsibilities - Authorized User- Physician

- Set up the clinical parameters to be used by the personnel being supervised with regard to patients, doses, interpretations of studies
- Closely review the radiation safety procedures and requirements
- Supervise the diagnostic and/or therapeutic procedures performed by physician trainees (residents)
- Be present on the licensee’s premises for ongoing and reasonable periods of time, especially for procedures requiring a WD.
  - or should be available by telephone and should be able to get to the licensee's facility within a short time to handle any emergency.

Personnel Responsibilities
Radiological Technologists

- Technologists are not technically (legally) responsible for anything, if they are acting under the direct supervision of an Authorized User.
- They should follow all WD, and departmental procedures, but the AU is ultimately responsible to make sure that they are adequately provided with instruction and guidance.
- The AU can get in trouble if the lack of supervision or instruction leads to mistakes that result in medical events.

Management of RAM
Receiving and opening packages

Receiving and Opening Packages – contamination survey

After a package is received and within 3 hours:

Monitor for radioactive contamination the external surfaces of any package labeled with a Radioactive White I, Yellow II or Yellow III label unless the package contains only radioactive material in the form of gas or in special form.

- Wipe/smear survey
- Meter survey (or LSC/gamma counter)
- Removable contamination must not exceed 22 dpm/cm^2 (beta, gamma emitters); 2.2 dpm/cm^2 (alpha emitters)

+

Receiving and opening packages
Dose rate survey

Monitor the radiation levels of the external surfaces of any package labeled with a **Radioactive White I, Yellow II or Yellow III label** unless the package contains quantities of radioactive material that are less than or equal to the Type A quantity.

Proper instrument:
Ionization Chamber

- Dose rate survey at the package surface
- Must not exceed 200 mR/hr (2 mSv/hr)

Receiving and opening packages
damaged goods

Monitor all wet or crushed packages if they are known to contain RAM, even if they are not labeled.

Items could be out of their shielded container

Items could be out of their shielded container AND leaking

- If contamination above the acceptable levels is discovered, or if the dose rate is above 200 mR/hr at the package surface, you must immediately:
  - Notify the final carrier – (Fed-Ex etc.)
  - Notify the Agreement State Authority or the NRC
  - 1-800-NUCLEAR

Management of RAM- Shipping

Type A Package – UN2915

- Higher amounts of materials (varies by radioisotope)
- Radiopharmaceuticals often
- shipping papers required

- Type B Package
  - Life-endangering amounts of materials
  - Spent nuclear fuel, e.g.
  - Can be TONS of material
  - Shipping papers, vehicle survey, may be route controlled

- Type C package
  - An overpack for transport of large amounts of RAM
  - Must maintain containment upon impact at 90 m/s

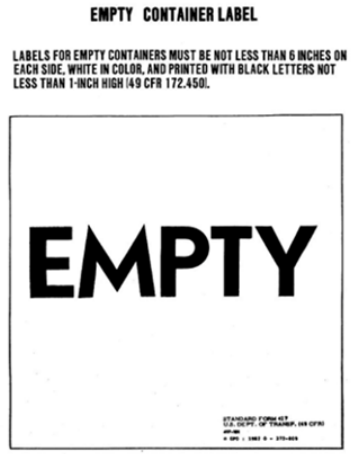
Management of RAM- Shipping

Limited Quantity – UN2910

- Also known as “excepted” package
- No shipping papers required

- Exempt
  - Quantities below Limited Quantity limits, but not “empty”
  - No shipping papers required
  - Survey required

- Empty
  - Packages emptied of their contents “as far as practical” but may still contain regulated amounts of internal contamination
  - No shipping papers, external survey required
  - “Empty” sticker on outside


EMPTY CONTAINER LABEL

LABELS FOR EMPTY CONTAINERS MUST BE NOT LESS THAN 6 INCHES ON EACH SIDE, WHITE IN COLOR, AND PRINTED WITH BLACK LETTERS NOT LESS THAN 1-INCH HIGH (49 CFR 172.450).

EMPTY

Labeled Packages

Allowed Radiation levels for labeled packages:

0-0.5 mR/hr at the surface
No Transport Index (TI)*

0.6-50 mR/hr at the surface
Transport Index (TI) </=1

51-200 mR/hr at the surface
Transport Index (TI) </=10

* Transport Index (TI) = measured dose at 1 meter

Sealed Source Regulations

Sealed Source- means any radioactive material that is encased in a capsule designed to prevent leakage or the escape of the radioactive material. (Some vary, and definition is somewhat loose in some cases)

Each sealed source greater than 100 uCi must be

- Inventoried every 6 months
- Leak tested every 6 months

Leaking sealed sources must be taken out of service immediately.

All sources, even < 100 uCi will likely be inventoried, but it is not required.

Waste disposal

- Most waste in a Nuclear Medicine department is short-lived and can be decayed in storage as the preferred method of waste disposal.
- Decaying waste should be kept in a remote or shielded location so as to not disrupt daily area surveys.
- Decay in storage waste is generally stored for 10 half-lives and then surveyed prior to release into the regular waste stream.
- If decay in storage waste is found to be non-radioactive before 10 half-lives has elapsed, it may be released at that time.
- If decay in storage waste is still radioactive after 10 half lives has elapsed, then it likely contains a long-lived contaminant. This may or may not decay in storage in a timely manner.

Waste disposal – ‘cold trash’ survey

- All trash in a radioactive materials use area should be considered “hot” until it is surveyed.
- If trash is found to be hot, you may secure it until it is no longer radioactive and then release it into the normal waste stream.
- All radioactive markings must be removed or defaced prior to being thrown in the trash.

I-131 therapy > 33 mCi – Patient Release Criteria

- Outpatient – preferred method
  - all I -131 patients who are not likely to give a member of the public > 0.5 rem effective dose during the course of the therapy may be released:
    - With instructions/precautions to allow this (including interruption or discontinuation of breast-feeding)
    - If they can follow the instructions/precautions
- Inpatient – when is it required?
  - Patient must be an inpatient if:
    - Dose too high (> 220 mCi, with standard occupancy factor of 0.25) to assure < 0.5 rem
    - Home too crowded or contains young children who are unable to follow instructions
    - Patient is the only caregiver for young children
    - Only option for sleeping arrangement is same the bed, (one bathroom not ideal but OK for adult only homes)
    - Patient is incontinent
    - Patient is unable to follow instructions

Radiation Safety during Inpatient I-131 therapy > 33 mCi

- Patient is sequestered in a lead-lined hospital room
- Room is prepared by covering appropriate areas and items with paper and plastic
- Dose is administered in the room
- Patient stays in the room until radiation dose levels are at or below the acceptable level, (7 mR/hr @ 1 m)
  - This dose rate is accepted as the dose rate that would be measured if the patient had received 33 mCi or less
- Patient is given verbal instructions to minimize any potential exposure to sensitive individuals
- Room is decontaminated until contamination levels are indistinguishable from background
- Staff directly caring for the patient are given training and given dosimetry when necessary