Radioisotope Safety Content (RISC) Study Guide 2025

This document contains the interpretation and opinions of the RISC study guide committee. Any errors in interpretation of NRC policies or procedures are the responsibility of the authors and are not to be interpreted as official NRC policies or guidelines. The purpose of this document is to aid candidates in preparing for the ABR qualifying, certifying, and subspecialty exams. It is not intended to be a legal document. The information contained herein is valid through the 2025 cycle and may be modified for future exams.

2024 RISC Study Guide Committee

- Ephraim Parent, MD, PhD – Chair
- Elizabeth Oates, MD
- Umesh D. Oza, MD
- Sam Brady, PhD
- Jesus Diaz, MD
- Arti Gupta, MD
- Justin Peacock, MD, PhD
- Terri New, BS – Staff coordinator

ABR | American Board of Radiology

Table of Contents

Radioisotope Safety Content (RISC) Study Guide

Introduction

Radioisotope Safety Content (RISC) is an integral part of the domain of diagnostic radiology and interventional radiology. Questions about RISC are included on the Qualifying (Core) Exam (25 questions) and in the essentials module on the Certifying Exam (10 questions). RISC questions count toward the overall exam score and are not scored separately.

These questions assess the candidate's understanding and knowledge related to the safe use of radioactive materials in the clinical practice of diagnostic or interventional radiology. The domain encompasses but is not limited to the Nuclear Regulatory Commission (NRC) requirements found in Part 35 of the Code of Federal Regulations (CFR): Medical Use of Byproduct Material. The NRC defines byproduct material as radioactive material yielded in or made radioactive by exposure to the radiation incident to the process of producing or using special nuclear material. The RISC elements on the Certifying Exam are devoted to clinically oriented practice scenarios, which emphasize evaluation of practical knowledge of radioisotope safety and handling, as well as regulatory compliance.

A short practice domain document on the ABR website lists the domain critical concepts and scope and provides an overview of the blueprint with estimated percentages of specific content. Much of the information necessary to prepare for the exams, however, is spread across multiple CFR reports and NRC documents. Reviewing this content can be a daunting task for candidates preparing for the ABR Qualifying and Certifying exams. Given the scope of expected knowledge and varied classroom/laboratory training and experience in radiology departments, an in-depth study guide for candidates that would supplement their NRC/authorized user (AU) training and experience during residency was identified as a needed document.

All RISC questions on diagnostic radiology and interventional radiology exams will be based on information that is covered in this document. This document will be maintained on an ongoing basis to ensure the information continues to reflect current practice models and regulatory requirements.

Please note: Some aspects of radiation safety and biology on the diagnostic radiology and interventional radiology exams are from the physics section and are not covered in this document.

1. Radiation protection

1.1 ALARA program

The annual average effective dose to the United States (U.S.) population from all sources of radiation including background is 500 to 600 mrem (5 to 6 mSv).

The ALARA acronym stands for "as low as reasonably achievable," referring to the judicious use of nuclear radiology imaging such that the level of radiation exposure to patients and personnel is as low as possible to yield a diagnosis. The Nuclear Regulatory Commission

(NRC) mandates annual review of the ALARA program by the Radiation Safety Officer (RSO).

1.1.1 Radiation protection program

Licensees must ensure that the highest dose to the public shall not exceed 100 mrem/year (1 mSv/yr). This dose also applies to hospital staff working outside of a radiology/imaging department including but not limited to administration, support, nursing, engineering, or transport personnel.

Time, shielding, and distance are the three main measures to decrease radiation exposure to personnel.

Training and experience of authorized users, inventory of sealed sources and leak testing, and a record of administered activity for diagnostic and therapeutic procedures are required in a radiation protection program.

All personnel dosimeters (except for direct and indirect reading pocket ionization chambers and those dosimeters used to measure the dose to the extremities) to determine the radiation dose and that are used by licensees must be processed and evaluated by a dosimetry processor. Personnel dosimetry records should be reviewed quarterly by the RSO. The Radiation Safety Committee (RSC) must review dosimetry records every 3 months.

Individual dosimeters are required if personnel exposures are expected to exceed greater than 10% of the annual occupational dose in a year.

1.1.2 Audit program

Periodic, planned audits must be carried out at least every 12 months to verify compliance with all aspects of the radiation protection program. These audits must be performed by trained personnel not having direct responsibilities in the department/facility being audited. Results from audits, including follow-up actions, must be documented and reviewed by hospital/facility administration.

1.2 Radiation areas

In nuclear radiology and radiation oncology departments, there are restricted and unrestricted areas depending on the exposure rates and/or the presence of radioactive materials.

1.2.1. Restricted areas

Examples of activities in radiation **restricted areas** include radiopharmaceutical preparation, radiopharmaceutical administration, radiopharmaceutical storage, and imaging.

Signage required for various areas depending on radiation levels is shown in Figure 1.

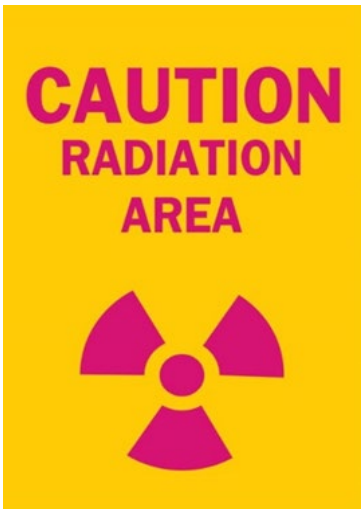
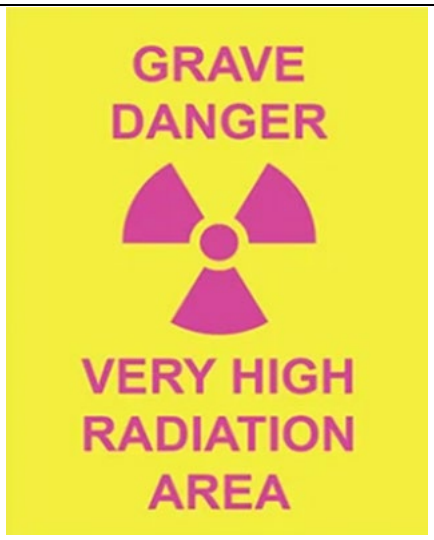
 **"Radiation area"** is where the effective dose could result in an excess of 5 mrem (0.05 mSv) in 1 hour at 30 cm from a radiation source.	 "**High radiation area**" is where the effective dose is up to 100 mrem (1 mSv) in 1 hour at 30 cm from the source. A visible or audible alarm is required to control access to a high radiation area.
 "**Very high radiation area**" is where the absorbed dose levels could exceed 500 rad (5 Gy) in 1 hour at 1 m from the source or from any surface.	 Areas where licensed radioactive material is used or stored must have a "caution radioactive materials" sign posted.

Figure 1. Radiation area warning signs and their significance

1.2.2. Public area

Unrestricted areas include reception, waiting areas, office spaces, and reading rooms. These areas must have dose rates less than 2 mrem in any 1 hour (20 µSv/h) or less than 100

mrem/yr (1 mSv/yr), excluding dose contributions from patients administered radioactive material and from patients being released.

Rooms or other areas in hospitals/facilities that are occupied by patients with administered radioactive material are not required to be posted with caution signs provided that the patients meet criteria for release (see section 6.5.1.3).

A room or area is not required to be posted with a caution sign in the presence of a sealed source if the radiation level at 30 cm from the source surface container or housing does not exceed 5 mrem (0.05 mSv) per hour.

1.2.3. Caution signs

The standard radiation symbol authorized by the NRC uses the colors magenta, purple, or black on a yellow background. Licensees are authorized to label sources, source holders, or other device components without a color requirement. Refer to 1.2.1 for examples of caution signage.

2 Radiation biology

There are four different but interrelated ways to measure radiation: **R**adioactivity, **E**xposure, **A**bsorbed dose, and **D**ose equivalent. These can be remembered by the mnemonic R-E-A-D.

2.1. Radioactivity

Radioactivity is a process by which an unstable atomic nucleus transitions to a stable configuration by emitting radiation. The emitted radiation can be in the form of alpha or beta particles, gamma rays, x-rays, or neutrons. A quantity of radioactive material is expressed in terms of its radioactivity (or simply its activity), which represents how many atoms in the material decay in a given time period. The units of measure for radioactivity are the curie (Ci) or becquerel (Bq); note: 1 mCi = 37 MBq.

- **Alpha particles** are positively charged particles consisting of two protons and two neutrons (a helium nucleus). They do not travel far in tissue (on average only 10-100 μm) and have a high linear energy transfer (LET), causing substantial radiobiological effect to surrounding tissue if ingested, inhaled, or used for medical therapeutic purposes.
- **Beta particles** are electrons (beta-minus) or positrons (beta-plus) emitted from a decaying nucleus. Beta particles have greater penetration ability than alpha particles (e.g., ^{131}I beta-minus [negatron] travels 0.5-3.0 mm) but can be stopped by a few millimeters of plastic. Beta-minus particles (electrons) have a moderate LET and can be used for medical therapeutic purposes. Beta-plus particles (positrons) are highly reactive and only travel a very short distance before combining in an annihilation event with a beta-minus particle. The resulting annihilation event ejects two 511 keV gamma rays in opposite directions. Annihilation photons are the foundation for PET imaging.

- **Gamma rays** are electromagnetic waves (i.e., photons that do not have any mass) emitted from the nucleus. Gamma rays have low LET and high penetration ability and can pass through several centimeters of lead and are principally used for imaging in general nuclear radiology studies.
- **X-rays** are electromagnetic waves (i.e., photons that do not have any mass) created by beta-minus particles that interact with atomic nuclei and undergo Bremsstrahlung radiation. As a beta-minus particle passes a high atomic mass nucleus (e.g., lead or tungsten), its path is deflected, resulting in low energy x-ray emission.
- **Neutron radiation** is free neutrons emitted from the breaking apart of an atomic nucleus. Neutron radiation can penetrate most materials and can cause nuclear reactions in other materials (called chain reactions).

2.1.1 Half-life

In determining radiation risk, it is important to understand the concept of half-life. The different concepts of half-life that are important to remember are:

- The **physical half-life (T_p)** of a radionuclide is defined as the time it takes for 50% of the radionuclide nuclei to decay.
- The **biological half-life (T_b)** of a radionuclide or radiopharmaceutical is defined as the time it takes for the radionuclide or radiopharmaceutical concentration within the body to reduce to 50% of the original concentration.
- The **effective half-life (T_e)** of a radionuclide or radiopharmaceutical takes into account the physical and biological half-life values and represents the combined effects of physical nuclear decay and biological excretion.

$$\frac{1}{T_e} = \frac{1}{T_p} + \frac{1}{T_b}, \text{ which can be rearranged to } T_e = \frac{T_p \times T_b}{T_p + T_b}$$

2.2 Radiation dose

Exposure describes the amount of radiation present in the air. The units for exposure are the Roentgen (R) or coulomb/kilogram (C/kg). Typical measuring instruments are Geiger-Mueller (GM) counters or ionization chambers and are measured in milliRoentgen (mR). The exposure equivalent to one chest radiograph is ~10 mR.

2.2.1 Absorbed dose

Absorbed dose describes the amount of radiation absorbed by tissue (that is, the amount of energy that is deposited while passing through the tissue). Absorbed dose is scaled by the mass of the tissue; thus, for the same amount of absorbed radiation, a smaller organ (e.g., kidneys) will have a greater absorbed dose value than a larger organ (e.g., liver). The units for radiation absorbed dose are Gray (Gy) or (rad). 100 rads is the equivalent of 1 Gy (SI unit).

2.2.2 Dose equivalent

Linear Energy Transfer (LET) is a term that describes the rate of energy transferred by radiation to a medium per unit of length. Radiation with higher LET (alpha or neutron) releases a higher rate of energy to tissue than radiation with lower LET (beta, gamma, or x-ray). Historically, when calculating the **dose equivalent**, quality factors termed Q(L) were calculated, which corresponded with the differences in radiation LET in tissue. After 1990, the International Commission on Radiological Protection (ICRP) proposed a different framework for calculating **dose equivalent** that incorporated dose over an organ or tissue (T). For the radiation quality factor, they developed a radiation weighting factor (w_R) that replaced Q(L) and that was based on the Biological Effects of Ionizing Radiation (BEIR) VII report.

Dose equivalent is a measure used to quantify the relative biological effectiveness (RBE) of the different types of emitted radiation on human tissue. Radiation with higher LET (i.e., alpha particles and neutrons) causes greater tissue damage than lower LET radiation (i.e., beta particles, x-rays, and gamma rays), and therefore correlates with higher RBE. When calculating the dose equivalent, the absorbed dose of an organ/tissue is multiplied by a quality factor (w_R). The w_R is a dimensionless factor that compares a radiation's RBE to a standard, such as the RBE of gamma rays. Quality factors are listed in Table 1. When weighted for the average dose to an organ or tissue, the resultant weighted dose is called the organ- or tissue-equivalent dose (H_T). Units for **dose equivalent** are the Sievert (Sv) or Roentgen equivalent man (rem); dose equivalent values in diagnostic medicine are commonly low and are therefore given in units of millisieverts (mSv) or millirem (mrem).

Table 1. Radiation weighting (quality) factors

Type of Radiation	Weighting Factor, w_R
X-rays	1
Gamma (g) rays	1
Beta (b) particles	1
Slow neutrons	5
Fast neutrons	10
Alpha (a) particles	20

2.2.3 Effective dose

Effective Dose Equivalent

The **dose equivalent** can further be scaled by a tissue weighting factor (w_T) that considers the relative sensitivity of different organs/tissues to radiation risk of radiocarcinogenesis. **Effective dose** is the multiplication of organ- or tissue-equivalent dose (H_T) with w_T. Therefore, the effective dose is the sum of the products of the dose equivalent to the organ or tissue (H_T) and the weighting factors (w_T) applicable to each of the body organs or tissues that are irradiated ($HE = \Sigma WTHT$). Tissue weighting factors for different tissues are listed in Table 2.

Table 2. Tissue weighting factors

Organ/Tissue Type	w_T
Colon, lung, red bone marrow, stomach, breast	0.12
Gonads	0.08
Bladder, liver, esophagus, thyroid	0.04
Bone surface, brain, salivary glands, skin	0.01

Total Effective Dose Equivalent

The Total Effective Dose Equivalent (TEDE) is a radiation dosimetry quantity defined by the NRC to monitor and control human exposure to ionizing radiation. It is defined differently in the NRC regulations and NRC glossary. According to NRC regulations, TEDE is the sum of effective dose equivalent from external exposure and from internal exposure (termed **committed effective dose equivalent)**, thereby taking into account all known exposures. However, the NRC glossary defines it as the sum of the deep-dose equivalent and committed effective dose equivalent, which would appear to exclude the effective dose to the skin and eyes from nonpenetrating radiation such as beta. These surface doses are included in the NRC's shallow dose equivalent, along with contributions from penetrating (gamma) radiation.

- Units for effective dose and TEDE are the Sv or rem (typically mSv or mrem).

Note: A measure given in Ci or Bq indicates the radioactivity of a substance, while a measure in mSv indicates the amount of energy that a radioactive source deposits in living tissue and gives a relative scale of risk. Effective dose scales linearly, thus, a PET/CT examination has a higher relative risk than a mammogram. (Note, cancer risk is too small to observe below 100 mSv.)

On average, U.S. inhabitants receive a radiation dose of about 3.1 mSv each year. This dose comes from natural background radiation. Most of this background exposure comes from radon in the air, with smaller amounts from cosmic rays and the Earth itself. An additional 2.2 mSv comes from man-made sources of radiation (mostly exposure from medical procedures, and some commercial and industrial sources). In general, a yearly dose of 5.3 mSv from all radiation sources has not been shown to cause humans any harm. Figure 2 breaks down sources of background radiation as discussed in NCRP report #184. Figure 3 shows specific examples of common radiation exposures.

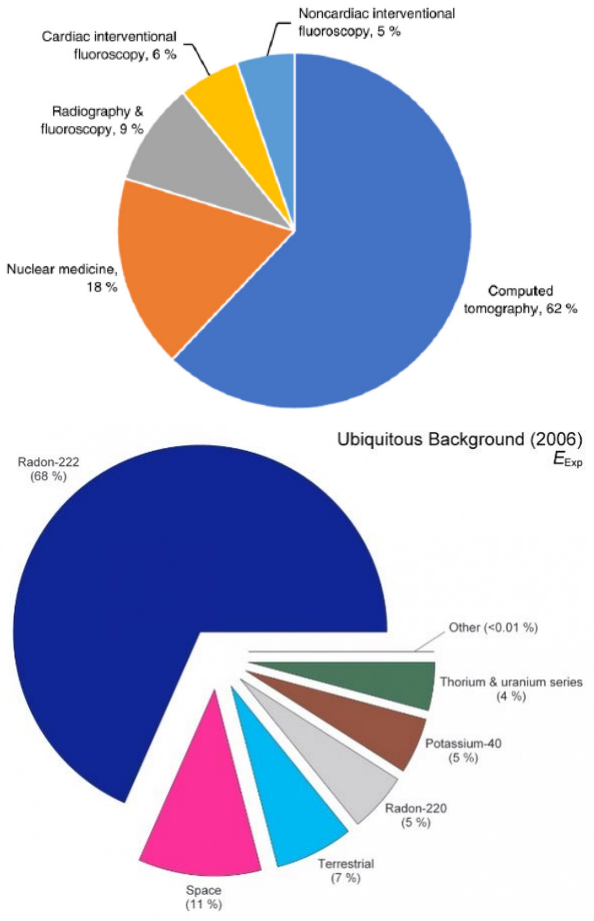


Figure 2. NCRP report #184: Medical Radiation Exposure of Patients in the United States, 11/15/2019

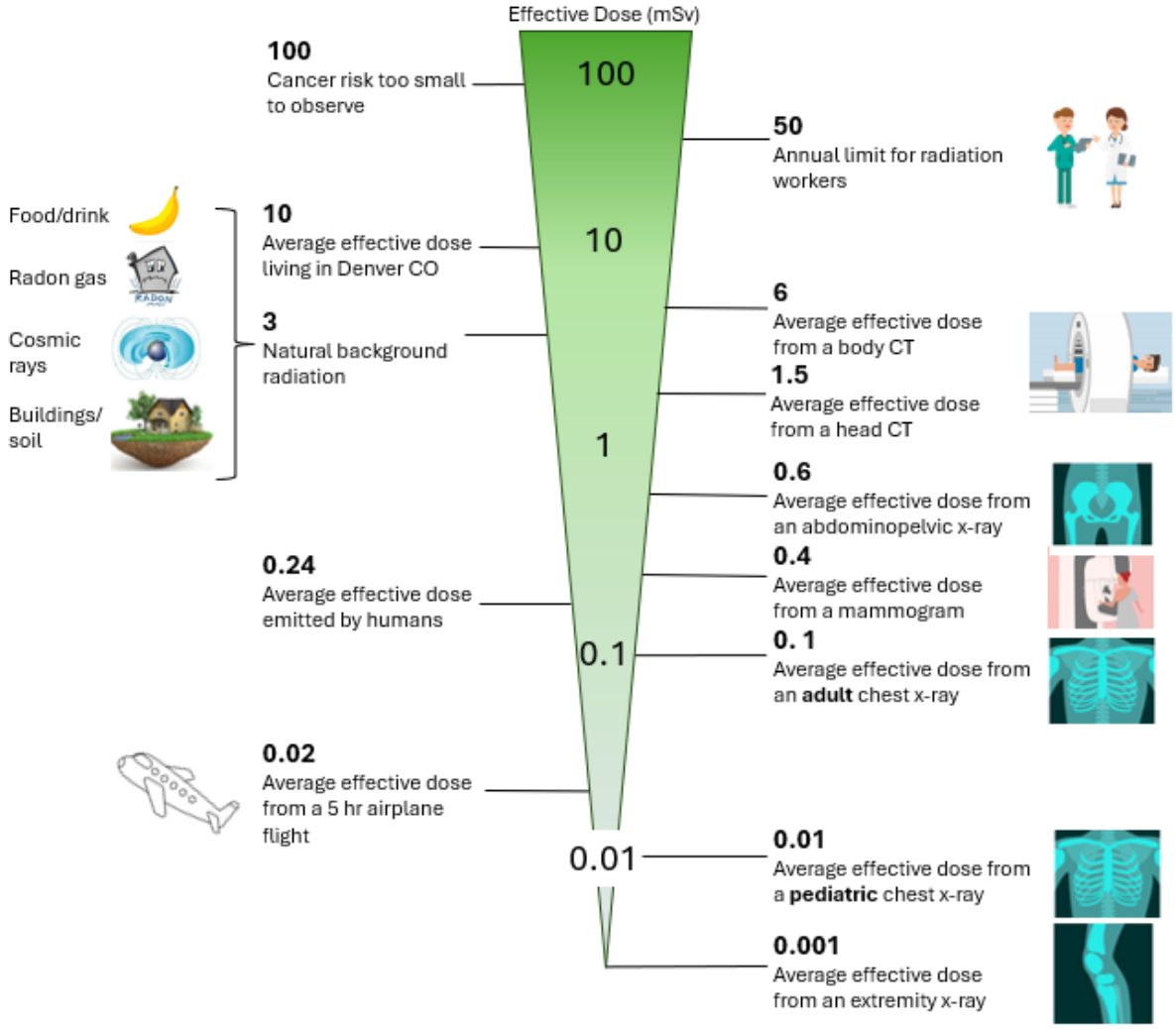


Figure 3. Examples and levels of common radiation exposures

2.3 Radiobiology

There are three general categories of effects resulting from exposure to radiation:

(1) Genetic or hereditary effects are passed on to the progeny of the exposed individual(s).

(2) Somatic radiation effects refer to the biological effects of radiation exposure on the cells and tissues of the exposed individual. These effects are further classified into two categories: tissue (deterministic) and stochastic.

(3) Teratogenic effects refer to the developmental abnormalities or birth defects that occur in a fetus as a result of *in utero* radiation exposure during pregnancy.

Radiation destroys cells and tissues through two general pathways, which has implications for when and where cells and tissues are most sensitive to radiation:

(1) **Direct pathway** - radiation induces single-stranded or double-stranded DNA (ssDNA or dsDNA) breaks that lead to cell death.

   a. Higher LET radiation leads to more dsDNA breaks as well as higher frequency ssDNA breaks.

b. During the cell cycle, cells are most sensitive to radiation during G2/M when the DNA is clumped in tighter bundles and DNA repair mechanisms are not active and cannot access the DNA. Contrastingly, cells in late S phase are the most radioresistant because of active DNA repair mechanisms.
c. Cells that are actively dividing are more radiosensitive, while those that are not actively dividing are more radioresistant.
    i. Radiosensitive cells include hematopoietic cells (particularly lymphocytes), spermatogonia cells, and gastrointestinal stem cells.
    ii. Radioresistant cells include nerve and muscle cells.

(2) **Indirect pathway** - radiation induces the development of reactive oxygen species that can damage proteins, DNA, and lipids resulting in cell death.
a. Water is an abundant source of oxygen for radiation injury due to indirect effects.
b. Cells in an oxygen-rich environment are more at risk for the indirect effects of radiation.

2.3.1 Tissue reactions (deterministic effects)

Deterministic effects are those for which the severity increases with the dose and for which there is a threshold below which no effects are observed. These effects are typically observed soon after exposure when the dose exceeds a certain threshold (Table 3).

Typical tissue effects during medical imaging/radiation therapy include:

- Skin burns: High doses of radiation can cause erythema (redness), hair loss, blistering, and ulceration of the skin.
- Opacifications and cataracts: Exposure to high doses of radiation can lead to clouding of the lens in the eye with delayed onset of years depending on dose and fractionation.

Table 3. Summary of deterministic effects

Effects	Threshold dose levels (Gy)	Time of onset
Transient erythema/epilation	2	~24 hours
Dry desquamation	8	4 weeks
Moist desquamation	15	4 weeks
Opacification (single acute exposure)	0.5-2	
Opacification (fractionated)	5	
Cataract (single acute)	5	
Cataract (fractionated)	8	

2.3.2. Linear no-threshold effects (stochastic)/Risks of radiation-induced cancer

Stochastic effects are those for which the probability of occurrence increases with the dose, but the severity of the effect does not depend on the dose. There is no threshold dose for

stochastic effects; this concept is called the linear no-threshold (LNT) model. The primary type of stochastic effect is carcinogenesis and genetic effects.

3. Transport and management of radioactive materials

Materials Transportation

About 3 million packages of radioactive materials are shipped each year in the U.S., either by highway, rail, air, or water. Regulating the safety of these shipments is the joint responsibility of the NRC and the Department of Transportation (DOT). The NRC establishes requirements for the design and manufacture of packages for radioactive materials. The DOT, which has type A and B package requirements, regulates the shipments while they are in transit and sets standards for labeling and smaller quantity packages.

The NRC oversees the safety of the transportation of nuclear materials through a combination of regulatory requirements, transportation package certification, inspections, and a system of monitoring to ensure that safety requirements are being met.

Obtaining a Radioactive Material Package Certificate of Compliance

The NRC must approve type A and B packages used for shipping nuclear material before shipment. If the package meets NRC requirements, the NRC issues a Radioactive Material Package Certificate of Compliance (CoC) to the organization requesting approval of a package. Organizations are authorized to ship radioactive material in a package approved for use under the general license provisions.

For a transportation package to be certified by the NRC, it must be shown by actual test or computer analysis to withstand a series of accident conditions. The tests are performed in sequence to determine their cumulative effects on the package. The application must address the safety and operational characteristics of the package, including design analysis for structural and thermal integrity, radiation shielding, nuclear criticality, material content confinement, and the conditions listed. In addition, the application must contain operational guidance, such as any testing and maintenance requirements, operating procedures, and conditions for package use.

Type A containers are designed to survive normal transportation handling and minor accidents. The Type A package is defined as the container and radioactive contents, and most radioactive materials in clinical use will be transported in Type A packages. Type B packaging is designed to survive severe accidents.

3.1. Managing packages

Colored labels are used to indicate the type and level of hazard contained in a radioactive package. Labels rely principally on symbols to indicate the hazard.

Although the package required for transporting radioactive material is based on the activity **INSIDE** the package, the label required on the package is based on the radiation hazard **OUTSIDE** the package. Radioactive material is the only hazardous material that has multiple possible labels, depending on the relative radiation levels external to the package, with White I, Yellow II, and Yellow III being the most common. Also, labels for radioactive material are the only ones that require the shipper to write information on the label. The information is a number called the transport index (TI), which is the highest radiation level at 1 meter from the surface of the package expressed in mrem/hr. Only the White I label does not have a transport index.

The three labels are commonly called White I, Yellow II, and Yellow III, referring to the color of the label and the Roman numeral prominently displayed. A specific label is required if the surface radiation limit and the limit at 1 meter satisfy the following requirements (Table 4):

Table 4. Transportation labels

Label	Surface Radiation Level		Radiation Level at 1 Meter
White I 	≤ 0.5 mrem/hr		≤ 0.5 mrem/hr
Yellow II 	> 0.5 mrem/hr but ≤ 50 mrem/hr	AND	≤ 1 mrem/hr
Yellow III 	> 50 mrem/hr and ≤ 200 mrem/h	OR	> 1 mrem/hr and ≤ 10 mrem/hr

Since the TI is the radiation level at 1 meter, a Yellow II must have a TI no greater than 1, and a Yellow III may have a TI greater than 1 but not more than 10.

The maximum TI for nonexclusive use vehicles (common carriers) and for exclusive use (contract carriers) *open* vehicles is 10. The radiation level at 1 meter from the surface of a package can exceed 10 mrem/hr only if the package is transported in an exclusive use (contract carrier) *closed* vehicle.

3.1.1. Hazard levels and labeling

The licensee shall ensure that each container of licensed material bears a durable, clearly visible label with the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL." The label must also include:

- Radionuclide(s) present.
- Quantity of radioactivity.
- Radioactivity date.
- Radiation levels.
- Kinds of materials.
- Mass enrichment.

Each licensee shall, prior to removal or disposal of empty uncontaminated containers to unrestricted areas, remove or deface the radioactive material label or otherwise clearly indicate that the container no longer contains radioactive material.

3.1.2. Receipt of radioactive material shipments

The NRC requires the following procedures when radioactive packages are received and opened:

1. Each licensee should be able to receive the package or receive notification of the arrival of the package at the carrier's terminal and to take possession of the package expeditiously.
2. Each licensee must monitor the external surfaces of a labeled package for radioactive contamination, unless the package contains only radioactive material in the form of a gas or is designated as an excepted package.
3. Each licensee must monitor all packages known to contain radioactive material for radioactive contamination and radiation levels with a Geiger-Mueller detector, and for evidence of degradation of package integrity, such as packages that are crushed, wet, or damaged. The licensee shall perform the monitoring as soon as practical after receipt of the package, but not later than: 3 hours after the package is received at the licensee's facility if it is received during the licensee's normal working hours, or not later than 3 hours from the beginning of the next working day if it is received after working hours.

4. The licensee shall immediately notify the final delivery carrier and the NRC Headquarters Operations Center by telephone if the removable radioactive surface contamination exceeds the limits or external radiation levels exceed the limits.
6. Each licensee shall establish, maintain, and retain written procedures for safely opening packages in which radioactive material is received, and ensure that the procedures are followed and that due consideration is given to special instructions for the type of package being opened.
7. Licensees transferring special form sources in licensee-owned or licensee-operated vehicles to and from a work site are exempt from the contamination monitoring requirements but are not exempt from the survey requirement for measuring radiation levels that is required to ensure that the source is still properly lodged in its shield.

3.2. Sealed sources

The NRC and the Agreement States (AS) perform engineering and radiation safety evaluations of the ability of sealed sources and devices to safely contain radioactivity under the conditions of their possession and use. Sealed sources are radioactive sources that are permanently or completely contained either by being bonded to a surface or encased in a metal capsule. Sealed sources reduce the risk of dispersion of radioactive material but must be monitored in case of damage. Both the NRC and AS issue registration certificates for distributors and manufacturers within their jurisdiction. However, only the NRC is responsible for devices distributed as exempt products (i.e., smoke detectors, gun sights, etc.) and issues those registration certificates.

Each sealed source must be tested at intervals not to exceed 6 months. In the absence of a certificate from a transferor that a test has been made within the 6 months before the transfer, the sealed source may not be used until tested. If a sealed source has leaked, a licensee shall file a report within 5 days if a required leak test reveals the presence of 185 Bq (0.005 μCi) or more of removable contamination. The report must be filed with the appropriate NRC Regional Office with a copy to the Director, Office of Nuclear Material Safety and Safeguards. The written report must include the model number and serial number, if assigned, of the leaking source, the radionuclide and its estimated activity, the results of the test, the date of the test, and the corrective action taken.

Training for use of sealed sources and medical devices for diagnosis requires the authorized user of a diagnostic sealed source or a device authorized to be a physician, dentist, or podiatrist who is certified by a specialty board whose certification process is recognized by the NRC or AS or is an AU. Alternatively, the AU must have completed 8 hours of classroom and laboratory training in basic radionuclide handling techniques specifically applicable to the use of the device. The training must include radiation physics and instrumentation, radiation protection, mathematics pertaining to the use and measurement of radioactivity, and radiation biology and has completed training in the use of the device for the uses requested.

3.3. Exempt quantities

Examples of exempt quantities include the following:

- Natural material and ores containing naturally occurring radionuclides in their natural state, which are not intended to be processed for the use of these radionuclides.

- Byproduct material used in products such as electron tubes, self-luminous watches, or radiation measuring instruments for standardization or calibration purposes.

- Small quantities of byproduct material such as in check sources and calibration standards for commercial distribution.

- Use in self-luminous products such as gunsights and exit signs, which contain tiny glass vials filled with a radioactive gas such as tritium (hydrogen-3).

- Use of byproduct material in gas and aerosol detector products such as smoke detectors and chemical agent detectors. These products contain tiny foils that provide a steady source of ions in analytical chambers. The foils are coated with byproduct material such as Am-241 or Ni-63.

- Capsules containing 1 μCi carbon-14 urea each, for "in vivo" diagnostic use for humans.

3.4. Use records

Each licensee shall maintain records showing the results of surveys, calibrations, and sealed source leak checks. The licensee shall retain these records for 3 years after the record is made.

The following records are retained for the duration of the license:

- Results of surveys to determine the dose from external sources and used, in the absence of or in combination with individual monitoring data, in the assessment of individual dose equivalents.

- Results of measurements and calculations used to determine individual intakes of radioactive material and used in the assessment of internal dose.

- Results of air sampling, surveys, and required bioassays.

- Results of measurements and calculations used to evaluate the release of radioactive effluents to the environment.

3.5. Area surveys

Each licensee shall make or cause to be made surveys of areas, including the subsurface, that may be necessary for the licensee to comply with the regulations to evaluate the magnitude and extent of radiation levels and the potential radiological hazards of the radiation levels and residual radioactivity detected. Records from surveys describing the location and amount of subsurface residual radioactivity identified at the site must be kept with records important for decommissioning, and such records must be retained. The licensee shall ensure that instruments and equipment used for quantitative radiation measurements (e.g., dose rate and effluent monitoring) are calibrated periodically for the radiation measured.

The licensee shall survey with a radiation detection survey instrument (Geiger-Mueller meter) at the end of each day of use. A licensee must survey all areas where unsealed byproduct material requiring a written directive was prepared for use or administered. A licensee must retain a record of each survey required for 3 years. The record must include the survey date, the results, the instrument used to make it, and the name of the person who performed it.

3.6. Waste management/disposal

A licensee shall dispose of licensed material only by transfer to an authorized recipient, by decay in storage, or by release in effluents within the authorized limits. A person must be specifically licensed to receive waste containing licensed material from other persons for treatment prior to disposal, treatment or disposal by incineration, or decay in storage, or disposal at a land disposal facility.

A licensee may discharge licensed material into sanitary sewerage if each of the following conditions is satisfied: The material is readily soluble (or is readily dispersible biological material) in water and the quantity of radioactive material released into the sewer in 1 month divided by the average monthly volume of water released into the sewer by the licensee does not exceed predefined concentration. The total quantity of licensed and other radioactive material that the licensee releases into the sanitary sewerage system in a year must not exceed 5 curies (185 GBq) of hydrogen-3, 1 curie (37 GBq) of carbon-14, and 1 curie (37 GBq) of all other radioactive materials combined.

Patient excreta from individuals undergoing medical diagnosis or therapy with radioactive material are <u>not</u> subject to the limitations.

Any licensee shipping radioactive waste intended for ultimate disposal at a licensed land disposal facility must document the information required on NRC's Uniform Low-Level Radioactive Waste Manifest and transfer this recorded manifest information to the intended consignee. Each shipment manifest must include a certification by the waste generator.

A licensee may hold byproduct material with a physical half-life of less than or equal to 120 days for **decay-in-storage** before disposal without regard to its radioactivity if they monitor byproduct material with a Geiger-Mueller meter at the surface before disposal and

determine that its radioactivity cannot be distinguished from the background radiation level with an appropriate radiation detection survey meter set on its most sensitive scale and with no interposed shielding; and if they remove or obliterate all radiation labels, except for radiation labels on materials that are within containers and that will be managed as biomedical waste after they have been released from the licensee. A licensee shall maintain records of the disposal of licensed materials for 3 years. The record must include the date of the disposal, the survey instrument used, the background radiation level, the radiation level measured at the surface of each waste container, and the name of the individual who performed the survey.

4. Regulatory exposure limits to radioactive materials

4.1. Occupational dose limits

All individuals who, in the course of their employment, are likely to receive a dose of more than 100 mrem (1 mSv)/year must receive adequate training to protect themselves against radiation. Also, these individuals have the right to know the amount of radiation to which they have been exposed. In addition, radiation workers have the right to ask the NRC to conduct an inspection if they believe their working environment has safety problems.

The maximum allowable radiation doses for radiation workers are shown in Table 5 and Figure 4.

Table 5. Maximum allowable radiation doses for radiation workers

	Adults/year	**Minors (< 18 years[**])/year**
Whole body	5 rem (0.05 Sv)[*]	0.5 rem (0.005 Sv)
Individual organ	50 rem (0.5 Sv)	5 rem (0.05 Sv)
Skin or extremity (distal to knee or elbow)	50 rem (0.5 Sv)	5 rem (0.05 Sv)
Eye lens	15 rem (0.15 Sv)	1.5 rem (0.015 Sv)

[*]If an adult radiation worker exceeds the dose of 5 rem in less than a year – employed at one or multiple places – the individual will not be allowed in the radiation zone until the next calendar year.
[**]Minors – such as students working in a lab – have a dose limit that is 10% of the adult dose.

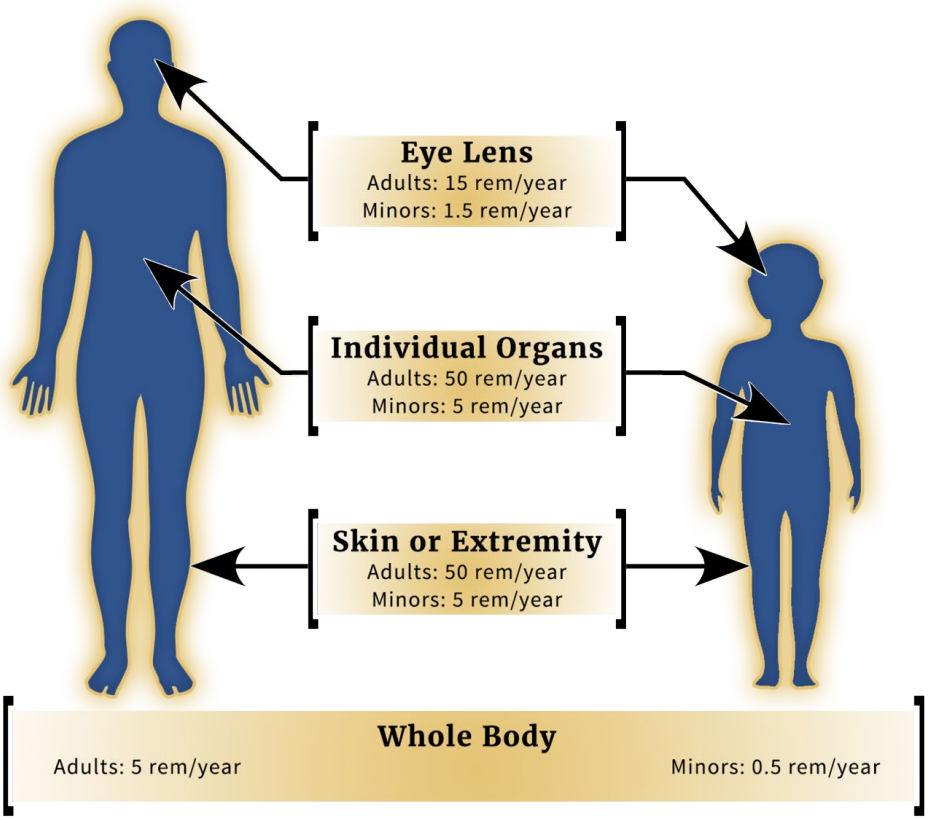


Figure 4. Maximum allowable radiation doses for radiation workers

Doses received in excess of the annual limits, including doses received during accidents, emergencies, and planned special exposures, must be subtracted from the limits for planned special exposures that the individual may receive during the current year and during the individual's lifetime.

The assigned deep-dose equivalent must be for the part of the body receiving the highest exposure. The assigned shallow-dose equivalent must be the dose averaged over the contiguous 10 square centimeters of skin receiving the highest exposure. The deep-dose equivalent, lens-dose equivalent, and shallow-dose equivalent may be assessed from surveys or other radiation measurements for the purpose of demonstrating compliance with the occupational dose limits.

Licensees are required to provide the NRC with an annual report of their workers' individual exposures. The NRC, in turn, maintains such radiation exposure data in its Radiation Exposure Information and Reporting System (REIRS). Thus, the REIRS database represents a resource for use in responding to workers' requests for exposure information and dose histories.

Organizations and individuals may request dose histories from REIRS and may submit requests for up to 10 individuals at a time. The requestor is required to enter their name, title,

and contact information, and the identification number, name, and birth date of the monitored individual(s).

4.1.1. Occupational dose limits for minors

The annual occupational dose limits for minors are 10 percent of the annual dose limits specified for adult workers (see 4.1.).

4.2. Pregnant workers

Other dose limits (additional notes):

Table 6. Other maximum allowable doses

Group	Maximum Allowable Dose
Pregnant workers (embryo/fetus)	0.5 rem (5 mSv) for entire gestation
Members of the public*	0.1 rem (1 mSv)/year
Visitor/caregiver/family member	0.5 rem (5 mSv) for duration of contact

*A patient is not considered a "member of the public."

If the dose equivalent to an embryo/fetus is found to have exceeded 0.5 rem (5 mSv) or is within 0.05 rem (0.5 mSv) of this dose by the time the worker declares the pregnancy to the licensee, the licensee shall be deemed to be in compliance. Additionally, if the additional dose equivalent to the embryo/fetus does not exceed 0.05 rem (0.5 mSv) during the remainder of the pregnancy, the licensee shall be deemed to be in compliance.

A declared pregnant worker is one who has voluntarily informed their employer, in writing, of the pregnancy and the estimated date of conception. A separate written declaration should be submitted for each pregnancy. A pregnant worker can decide not to declare the pregnancy and can de-declare the pregnancy at any time (e.g., in case the fetal dose may exceed limits and the worker does not want to change the place of work or stop work).

4.3. Public (including family and caregivers)

The total effective dose equivalent to individual members of the public from the licensed operation must not exceed 100 mrem (1 mSv) in a year, exclusive of the dose contributions from background radiation, any administration the individual has received, exposure to individuals administered with radioactive material, and voluntary participation in medical research programs.

If the licensee permits members of the public to have access to controlled areas, the limits for members of the public continue to apply to those individuals. A licensee may permit visitors to an individual who cannot be released to receive a radiation dose greater than 0.1 rem (1

mSv) if the radiation dose received does not exceed 0.5 rem (5 mSv) and the authorizer user has determined before the visit that it is appropriate.

A licensee or license applicant may apply for prior NRC authorization to operate up to an annual dose limit for an individual member of the public of 50 mrem (5 mSv)/year.

To protect the public, the dose in any unrestricted area from external sources does not exceed 2 mrem (0.02 mSv)/hour and 50 mrem (0.5 mSv)/year.

4.4. Embryo/fetus (radiation worker)

See 4.2.

4.5. Individual monitoring

Each licensee shall monitor exposures to radiation and radioactive material at levels sufficient to demonstrate compliance with the occupational dose limits including:

1) Adults likely to receive >10% dose limits in 1 year from external sources.
2) Minors likely to receive > 100 mrem (1 mSv), a lens dose equivalent in excess of 150 mrem (1.5 mSv), or a shallow dose equivalent to the skin or to the extremities in excess of 500 mrem (5 mSv) in 1 year from external radiation sources.
3) A declared pregnant worker likely to receive > 100 mrem (1 mSv) during the entire pregnancy from external radiation sources.
4) Individuals entering a high or very high radiation area.

Each licensee shall maintain records of doses received by all individuals for whom monitoring was required. These records must include: the deep-dose equivalent to the whole body, lens dose equivalent, shallow-dose equivalent to the skin, shallow-dose equivalent to the extremities, the estimated intake of radionuclides, and the effective whole body and organ dose.

The licensee shall make entries of the records at least annually and maintain clear and legible records containing all the information. The records required should be protected from public disclosure because of their personal privacy nature. The licensee shall maintain the records of dose to an embryo/fetus with the records of dose to the declared pregnant worker. The declaration of pregnancy shall also be kept on file but may be maintained separately from the dose records.

An RSO monitors readings from radiation badges such that when a radiation worker exceeds 10% of the occupational exposure in a quarter, an investigation is conducted to determine the cause of the higher exposure. This investigation would include evaluation of adherence to the principles of ALARA and proper badge placement.

5. Radiopharmaceutical administration

Radiopharmaceuticals emit radiation and are used in diagnostic or therapeutic medical procedures. Radioisotopes that have short half-lives are generally preferred to minimize the radiation dose to the patient and the risk of prolonged exposure. In most cases, these short-lived radioisotopes decay to stable elements within minutes, hours, or days, allowing patients to be released from the hospital in a relatively short time. The FDA oversees clinical administration of radiopharmaceuticals to humans either through an approved New Drug Application (NDA) or Abbreviated New Drug Application (ANDA). Investigational drugs must also be approved by the FDA for research purposes with an Investigational New Drug (IND) application.

An application for a specific license to manufacture, prepare, or transfer for commercial distribution radioactive drugs containing byproduct material for use by persons authorized pursuant will be approved if: The manufacturer is registered with the FDA, registered or licensed with a state agency as a drug manufacturer, licensed as a pharmacy by a state board of pharmacy, or is a PET drug production facility registered with a state agency.

5.1. Confirming dosage

5.1.1. Labeling

Each syringe or vial containing unsealed radioactive byproduct material must be labeled to identify the radiopharmaceutical. Syringe/vial shields must also be labeled unless the label on the syringe/vial is visible when shielded.

In addition to the above labeling requirements for radioactive materials, radiopharmaceutical dosage labels require:

- The radiopharmaceutical radionuclide.
- The radiopharmaceutical chemical form.
- The amount of radiopharmaceutical and the date/time of measurement.
- The radiopharmaceutical expiration date and time.
- The quantity of the radiopharmaceutical, including the volume of liquids, the capsule number/weight of solids, or the ampules/vials/syringes of gases.
- The name, address, and telephone number of the dispensing nuclear pharmacy.
- The prescription or lot number.
- The name of the radiopharmaceutical.

When dispensing radiopharmaceuticals, the following must be present:

- Labels for radiolabeled blood components and radiotherapies must contain the patient’s name.
- A tamper-evident seal must be affixed to the delivery container.

When the patient's name is not available at the time of dispensing for diagnostic dosing, a 72-hour exemption is allowed to obtain the name of the patient. No later than 72 hours after dispensing the radiopharmaceutical, the patient's name must be associated with the prescription in a readily retrievable manner and retained for 3 years.

The following items must also be included for administered radiopharmaceuticals:

- Name and address of the nuclear pharmacy.
- Name of the end authorized user, who is also a prescriber.
- Lot number of the preparation.

5.1.2. Outside of prescribed range for diagnostic and therapeutic dosage

Before medical use, radiopharmaceutical activities need to be determined and recorded. Unit dosages need to be determined by direct measurement of radioactivity or a decay correction from a predetermined activity or activity concentration. Other dosages need to be determined by direct measurement of radioactivity, measurement of radioactivity and mathematical calculations, or a combination of volumetric measurements and mathematical calculations from the manufacturers.

Authorized users can prescribe a diagnostic or therapeutic dosage or dosage range for medical use. The administered dosage is permitted to vary from the prescribed dosage by ±20%. If the licensee is aware that the administered dosage differs from the prescribed dosage by more than 20% and administers it anyway, then the licensee would be cited. However, the authorized user can direct the administered dosage to be more than 20% outside the prescribed dosage range for medical purposes. In such a situation, the authorized user must modify the prescription from one prescribed dosage/dosage range to a revised prescribed dosage/dosage range that encompasses the dosage to be administered.

For a unit dosage, this determination must be made by direct measurement of radioactivity or decay correction based on the initial activity determined by a licensed manufacturer. For other than unit dosages, this determination must be made by direct measurement of radioactivity or a combination of measurement of radioactivity and mathematical calculations or volumetric measurements. A licensee shall retain a record of the dosage determination.

5.2 Patient identity

Before any radiopharmaceutical administration, the patient’s identity needs to be confirmed with two patient identifiers. Examples of approved patient identifiers include:

- Individual’s name.
- Assigned identification number.
- Telephone number.
- Date of birth.

- Person-specific identifier.
- Electronic identification technology coding, such as bar coding or RFID, that includes two or more person-specific identifiers.

In cases where a patient's identity cannot be verified, a temporary means of identification must be used. Formal identification of the patient should occur as soon as possible. When obtained, the new identifying information should be used. No standards exist for the use of an alias to protect anonymity. Organizations should evaluate risks and utilize two identifiers regardless of the alias.

5.3. Fetal dose (patient)

Licensees shall notify the NRC Operations Center by telephone no later than the next calendar day after discovery of a dose to an embryo/fetus or nursing child in the following situations:

- Licensees must report any dose to an embryo/fetus if it is greater than 5 rem (50 mSv) dose equivalent that results from byproduct administration to a pregnant individual, unless it was specifically approved, in advance, by the authorized user.
- Licensees must report any dose to a nursing child that is a result of administration of byproduct material to a breast-feeding individual that is greater than 5 rem (50 mSv) total effective dose equivalent or has resulted in unintended permanent functional damage to an organ or a physiological system of the child, as determined by a physician.

Licensees shall also submit a written report to the NRC Regional Office within 15 days of discovery of dose administration. The written report must include:

- The licensee's name.
- The prescribing physician's name.
- A brief description of the event.
- Why the event occurred.
- The effect, if any, on the embryo/fetus or the nursing child.
- What actions, if any, have been taken or are planned to prevent recurrence.
- Certification that the licensee notified the pregnant individual or mother (or the mother's or child's responsible relative or guardian) and if not, why not.

The report must not include the individual's or child's name or any other identifying information for the individual or child.

The licensee shall provide notification of the event to the referring provider and also notify the pregnant individual or mother no later than 24 hours after discovery of an event that would require reporting, unless the referring provider personally informs the licensee either that they will inform the mother or that, based on medical judgment, telling the mother would be harmful. The licensee is not required to notify the mother without first consulting with the

referring provider. If the referring provider or mother cannot be reached within 24 hours, the licensee shall make the appropriate notifications as soon as possible thereafter.

The licensee may not delay any appropriate medical care for the embryo/fetus or for the nursing child, including any necessary remedial care as a result of the event, because of any delay in notification. The notification may be made to the mother's or child's responsible relative or guardian instead of the mother. If a verbal notification is made, the licensee shall inform the mother, or the mother's or child's responsible relative or guardian, that a written description of the event can be obtained from the licensee upon request. The licensee shall provide such a written description if requested.

5.4. Breastfeeding/lactation (patient)

Breastfeeding mothers may need diagnostic or therapeutic radiopharmaceuticals, leading to concerns about radiation exposure to both the mother and child. Radiopharmaceuticals can appear in breast milk, causing internal exposure to the child and external exposure from the mother.

Radiation Safety Guidelines

The ALARA (as low as reasonably achievable) principle is emphasized to minimize radiation exposure. Breastfeeding interruption or cessation may be recommended based on the radiopharmaceutical and dosage. A nursing mother who has received unsealed byproduct can be released if the total effective dose equivalent to any other individual, including the nursing child, is projected to not exceed 500 mrem (5 mSv). If the nursing mother continues to breastfeed after receiving a radiopharmaceutical and the nursing child’s radiation exposure could exceed an effective dose equivalent of 100 mrem (1 mSv), written instructions must be given to the mother regarding the potential adverse consequences if breastfeeding is not interrupted or ceased as well as guidance on the discontinuation of breastfeeding.

Before radioiodine therapy, oral and written radiation precaution instructions **must** be provided to the nursing mother and, as needed, to the appropriate family and/or caretakers. All concerns and questions should be addressed. The information should be given in a sufficient time frame for safety preparation, and **at least six weeks** prior to the radioiodine procedure to allow the necessary time for lactation cessation.

Recommendations for Specific Radiopharmaceuticals/Radionuclides

- ^{18}F: 4-hour interruption
- ^{67}Ga: 28-day interruption
- ^{68}Ga: No interruption
- ^{123}I-NaI: 3-day interruption
- ^{131}I-NaI and ^{124}I-NaI: **Permanent cessation** for current child. Breastfeeding should be stopped six weeks prior to therapy to minimize radiation dose to the breast.
- ^{111}In-labeled white blood cells: 6-day interruption

- ^{177}Lu-dotatate: **Permanent cessation** for current child
- ^{13}N: No interruption
- ^{82}Rb: No interruption
- ^{99m}Tc-labeled radiopharmaceuticals (all): 24-hour interruption
- ^{201}Tl-chloride: 4-day interruption

Brachytherapy and Other Procedures

Brachytherapy and radioactive seed localization procedures generally require suspension of breastfeeding while radioactive seeds are in place, but it can resume after their removal.

Radioembolic therapy with ^{90}Y-microspheres does not require breastfeeding interruption as ^{90}Y does not enter systemic circulation, breast tissue, or breast milk.

5.5. Administration of prescribed dosage

5.5.1. Safe handling and administration

Radiopharmaceutical administration for diagnosis or therapy requires a specific area or room that is separated from other operations. The area or room should be near the laboratory where the radiopharmaceuticals are stored. Transport of radiopharmaceuticals to a patient's room necessitates good radiation safety practice, often necessitating radiation safety staff or nuclear technologist staff monitoring and assistance. Physicians, radiation safety, and other allied staff should observe principles of ALARA to reduce exposure. These principles include holding radioactive sources with tongs or tweezers, informing staff about patient excretion of radioactive materials to avoid contamination, avoiding contamination of surfaces, securing radioactive materials when staff are not present, not risking oral contamination through any worker activities or eating/drinking near radiopharmaceuticals, and conducting training for workers. Individuals involved in administering volatile ^{131}I radiopharmaceuticals may be sampled for bioassay if > 10 mCi.

Syringe shields should be used for radiopharmaceutical administration. For positron emitters, either lead or tungsten may be employed in a syringe shield. Tungsten is the preferred material as it provides better radiation attenuation at a smaller thickness, allowing for a lighter and more manageable shield. It is also less toxic than lead. Lead is still used in some applications as it can be a more cost-effective option. Disposable gloves, as well as finger and body dosimeters should be worn when administering radiopharmaceuticals. Finger (ring) dosimeters should be worn under a glove on the hand most likely to be exposed to radiation, on a finger exposed to radiation, with the detector (badge) facing the palm.

Beta emitters can be stopped by lead shielding, but the bremsstrahlung (breaking radiation) that will result makes lead an ineffective shielding source as more energy would be created from lead interaction. Using lower atomic number material such as acrylic or aluminum shielding would be more effective choices for shielding beta emitters.

Criteria for the release of any patient or research subject who received unsealed byproduct material or implants with byproduct material is discussed in section 6.5.1.3 of this document. After treatment, all articles such as bedding, clothing, towels, food, and food trays should be surveyed for contamination before they are removed or held in storage for “Decay-in-Storage." The individual should be surveyed before release and instructed on ways to minimize contamination and exposure.

5.5.2. Shielding for ionizing radiation

Shielding is an important principle of ALARA. Shielding requires an understanding of radionuclides/radiopharmaceuticals and their radiation. Radionuclide generators should be placed in a remote, well-shielded enclosure. Dose calibrators should be shielded to protect workers. Lead shielding should be used to shield employees and others from procedures with ^{99m}Tc and other gamma-emitting radiopharmaceuticals. Fume hoods should be used for potential airborne radioactive materials.

For ^{133}Xe studies, additional lead shielding around the charcoal absorber canister, oxygen bag, and waste receptacle will prevent exposure. Leakage or contamination from the radioactive material should be prevented. Individualized ^{133}Xe room evacuation time calculations are required in rooms where ventilation scans are performed.

Shielded containers or waste cans should be used for syringes and other radioactive waste. These containers should be kept at as great a distance as possible from the workers.

6. Administrative/practice regulations, responsibilities and training

6.1. NRC authority/Agreement States

Role of NRC and Other Agencies in Regulating the Medical Use of Nuclear Materials

Radioactive byproduct material is used in calibration sources, radioactive drugs, bone mineral analyzers, brachytherapy sources and devices, gamma surgery devices, and teletherapy units used in medicine. With limited exceptions, all internal or external administrations of byproduct material to human patients or human research subjects must be done in accordance with a medical use license. Regulatory authority over the medical use of ionizing radiation is shared among several federal, state, and local government agencies.

The NRC or the responsible Agreement State (AS) has regulatory authority over the possession and use of byproduct materials or other nuclear material in medicine. The NRC oversees medical uses of nuclear material through licensing, inspection, and enforcement programs. The NRC issues medical use licenses to medical facilities and authorized physician users, develops guidance and regulations for use by licensees, and maintains a committee of medical experts to obtain advice about the use of byproduct materials in medicine.

The FDA oversees the good practices in the manufacturing of radiopharmaceuticals, medical devices, and radiation-producing x-ray machines and accelerators.

Agreement State Program

The Atomic Energy Act of 1954 allows the NRC to relinquish to an AS portions of its regulatory authority to license and regulate byproduct materials. The mechanism for the transfer of NRC's authority to a state is an agreement signed by the governor and the chair of the commission. The NRC also coordinates with an AS the reporting of event information and responses to allegations reported to NRC involving the AS. To date, 39 states have entered into agreements with the NRC.

The Integrated Materials Performance Evaluation Program (IMPEP) toolbox requires the NRC to periodically review Agreement States to ensure their radiation control programs are adequate to protect public health and safety and compatible with the NRC's regulatory program.

6.2. Personnel

6.2.1. Radiation safety officer

A licensee is required to have a radiation safety officer (RSO) with "authority and responsibilities for the radiation protection program." The RSO agrees in writing to be responsible for implementing the radiation protection program. The licensee, through the RSO, verifies that radiation safety activities are being performed in accordance with licensee-approved procedures and regulatory requirements. An associate RSO (ARSO) may be appointed, in writing, to support the RSO. The RSO, with written agreement of the licensee's management, must assign the specific duties and tasks to each ARSO. The RSO shall not delegate the authority or responsibilities for implementing the radiation protection program.

If an RSO or ARSO leaves or ceases to perform their duties, the licensee needs to notify the NRC or AS. The RSO or ARSO is certified by a specialty board that is recognized by the NRC or AS and each candidate must: hold at least a bachelor's degree from an accredited college or university in physical or biological science, have 5 or more years of professional experience in health physics, including at least 3 years in applied health physics, and pass an exam administered by diplomates of the specialty board.

The full-time radiation safety experience must involve, among other items: shipping, receiving, and performing related radiation surveys; performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and instruments used to measure radionuclides; securing and controlling byproduct material; using proper decontamination procedures; and disposing of byproduct material.

A licensee shall provide the RSO sufficient authority, organizational freedom, time, resources, and management prerogative, to:

- Identify radiation safety problems.
- Initiate, recommend, or provide corrective actions.

- Stop unsafe operations.
- Verify implementation of corrective actions.

An authorized user (AU) can be appointed as the RSO for a license if the AU is identified as an AU in the license; has experience with the radiation safety aspects of byproduct material for which the individual will have RSO responsibilities; has training in the radiation safety, regulatory issues, and emergency procedures for which a licensee seeks approval; and has obtained written attestation, signed by a preceptor RSO, that the AU has achieved a level of radiation safety knowledge sufficient to function independently as an RSO for a medical use licensee. Additionally, the AU must agree, in writing, to be responsible for implementing the radiation protection program.

6.2.2. Authorized user

An AU is a physician, dentist, or podiatrist who meets criteria and who is specified on the license to authorize the medical use of byproduct material. AU applicants must submit training and experience information for the purpose(s) for which licensed material will be used. The NRC and AS evaluate this information on a case-by-case basis to determine whether the training and experience of the identified individuals is appropriate for the proposed use(s). A preceptor statement concerning the individuals' completion of appropriate training and experience and ability to function independently is a necessary component for evaluating the individual's qualifications. Individuals seeking AU recognition for new (not previously authorized) medical uses should submit a written attestation from person(s) knowledgeable about the radiation safety aspects of the new medical use and the associated equipment. A license amendment is not needed to permit the physician to begin work as an AU under the NRC license. However, for licensees other than those possessing a Type A specific license of broad scope for medical use, a copy of the AS license would have to be submitted to the NRC within 30 days.

Delegation of Supervisory Responsibilities

Only AUs and authorized nuclear pharmacists (ANPs) are allowed to use or prepare, respectively, byproduct material in the practice of medicine. However, an AU or ANP may delegate specific tasks associated with the use or preparation of byproduct material in the practice of medicine to other individuals who are properly supervised and instructed. The AUs and ANPs are best suited for determining tasks that supervised individuals can perform and the degree of supervision that each individual needs.

Approval for Authorized Nuclear Pharmacist, Authorized Medical Physicist, or Authorized User

6.2.3. Authorized nuclear pharmacist

An individual can begin duties as an authorized nuclear pharmacist (ANP) as long as one of the following three conditions applies: (1) they meet the board certification criteria and recentness of training requirements; (2) they are identified as an ANP on an NRC or AS

medical use license or nuclear pharmacy license; or (3) they are identified as an ANP by a commercial nuclear pharmacy authorized to identify ANPs.

The ANP, like the AU, can be selected as an RSO or ARSO if they have experience with the radiation safety aspects of similar types of byproduct material for which the individual would have RSO responsibilities, similar to the requirements of an AU identified as an RSO. The ANP must agree, in writing, to be responsible for implementing the radiation protection program. Additionally, the licensee must apply to the NRC for an amendment and submit the ANP's training and experience qualifications to serve as RSO.

6.2.4. Authorized medical physicist

An authorized medical physicist (AMP) must be named on licenses authorizing the medical uses of ^{90}Sr ophthalmic applicators, teletherapy units, photon-emitting remote after-loader units, and gamma stereotactic radiosurgery units. Similar to an AU and ANP, an AMP may be identified as an RSO following a similar pattern of requirements as an ANP.

6.2.5. Radiation safety committee

Licensees who are authorized for two or more different types of uses of byproduct material must have a radiation safety committee (RSC) to oversee all uses of byproduct material permitted by the license. The RSC must include an AU of each type of use permitted by the license, the RSO, a representative of the nursing service, and a representative of management who is neither an AU nor an RSO. The committee may include other members the licensee considers appropriate.

The RSC has the authority and responsibilities for the radiation protection program including but not limited to evaluating requests for a license application, renewal, or amendment before submission to the NRC and allowing an individual to work as an AU, ANP, or AMP.

6.3 Radioactive Materials (RAM) License

The NRC issues specific licenses for possession and use of byproduct, source, and special nuclear material. After the initial license is granted, it may be modified during an amendment or renewal to reflect changes in circumstances affecting the operations after the license was issued. A company/facility that wishes to obtain a license to use nuclear materials must submit an application to the NRC. This application must demonstrate how the use of these materials will meet NRC safety requirements. Applicants must provide information on the type, form, and intended quantity of available facilities, qualifications of users, and radiation protection programs. The license may contain certain NRC conditions agreed to by the licensee.

6.3.1. Broad scope license

Type A: Type A licenses of broad scope are typically the largest licensed programs and encompass a broad range of uses. Type A broad scope licensees use an RSC, RSO, and criteria developed and submitted by the licensee. These licenses typically exist at a large academic center.

Type B: Type B broad scope licensed programs are normally smaller and less diverse than Type A broad scope programs. Type B broad scope licensees use an RSO and criteria developed and submitted by the licensee

Type C: Type C broad scope licensed programs are typically issued to institutions that do not require significant quantities of radioactive material but need the flexibility to possess a variety of different radioactive materials. Users of licensed material under these programs are approved by the licensee based on training and experience criteria. These licenses usually exist for nuclear cardiology clinics or small research labs requiring small quantities of radioactive material.

6.3.2. NRC Master Materials License

A Master Materials License (MML) is a license issued by the NRC to federal organizations authorizing use of byproduct material at multiple sites that fall under the jurisdiction of the federal agency for industrial and medical purposes. The MML allows the federal agency to conduct some activities as a regulator, such as issuing permits for radioactive materials use at the sites that use byproduct materials, conducting inspections, handling allegations, following up on incidents and events, and taking enforcement actions. The NRC, in turn, provides oversight of MML licensees and inspects MMLs at least every two years to evaluate how well the licensee is implementing their program.

6.4. Written directive

“Written directive” refers to an AU's written order for the administration of byproduct material or radiation from byproduct material to a specific patient or human research subject.

6.4.1. Uptake, dilution, and excretion studies

Use of unsealed byproduct material for uptake, dilution, and excretion studies do not require a written directive. A licensee may use any unsealed byproduct material prepared for medical use for uptake, dilution, or excretion studies that is obtained from a licensed manufacturer, a PET radioactive drug producer, or prepared by an ANP or AU with specific training approved by the NRC. Approved Radioactive Drug Research Committee (RDRC) or Investigational New Drug (IND) byproduct material also does not require a written directive when used for uptake, dilution, and excretion studies.

The licensee shall require an AU of unsealed byproduct material for uptake, dilution, and excretion studies to be a physician and have the following training: 60 hours of training and experience in basic radionuclide handling techniques and radiation safety applicable to the medical use of unsealed byproduct material for uptake, dilution, and excretion studies (including a minimum of 8 hours of classroom and laboratory training). Candidates must pass an exam, administered by diplomates of the specialty board, that assesses knowledge and competence in radiation safety, radionuclide handling, and quality control.

Classroom and laboratory training must be inclusive of the following areas: radiation physics and instrumentation, radiation protection, mathematics pertaining to the use and measurement of radioactivity, chemistry of byproduct material for medical use, and radiation biology. AU candidates must also demonstrate work experience, under the supervision of an AU who meets the NRC or AS requirements, including ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys; performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters; calculating, measuring, and safely preparing patient or human research subject dosages; using administrative controls to prevent a medical event involving the use of unsealed byproduct material; using procedures to contain spilled byproduct material safely and using proper decontamination procedures; and administering dosages of radioactive drugs to patients or human research subjects. AU candidates must also have a written attestation that they have satisfactorily completed the training and work requirements from either a preceptor AU or a residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an AU.

6.4.2. Imaging and localization studies

Use of unsealed byproduct material for imaging and localization studies for which a written directive is not required

Except for quantities that require a written directive, a licensee may use any unsealed byproduct material prepared for medical use for imaging and localization studies that is obtained from a licensed manufacturer, a PET radioactive drug producer, or prepared by an ANP or AU with specific training approved by the NRC. Alternatively, medical use for imaging and localization studies for use in research in accordance with a Radioactive Drug Research Committee (RDRC) approved protocol or an Investigational New Drug (IND) protocol accepted by the FDA do not require a written directive.

Training for imaging and localization studies

The licensee shall require an AU of unsealed byproduct material for imaging and localization studies to be a physician who (1) is certified by a medical specialty board whose certification process is recognized by the NRC or AS; (2) has completed 700 hours of training and experience in basic radionuclide handling techniques (including a minimum of 80 hours of classroom and laboratory training) and radiation safety applicable to the medical use of unsealed byproduct material for imaging and localization studies; and (3) passes an exam, administered by diplomates of the specialty board, that assesses knowledge and competence

in radiation safety, radionuclide handling, and quality control similar to the listed requirements for uptake, dilution, and excretion studies. Classroom and laboratory training is inclusive of the same areas for uptake, dilution, and excretion studies.

6.4.3. Unsealed byproduct material requiring written directive

Use of unsealed byproduct material for which a written directive is required

A licensee may use any unsealed byproduct material prepared for medical use and for which a written directive is required that is obtained from a licensed manufacturer following NRC or equivalent AS requirements, excluding production of PET radionuclides, prepared by an ANP or AU or an individual under supervision of an ANP or AU.

Required training for use of unsealed byproduct material for which a written directive is required includes certification by a medical specialty board whose certification process has been recognized by the NRC or AS, and that person is a physician who successfully completed residency training in a radiation therapy or nuclear medicine training program or a program in a related medical specialty. These residency training programs must include 700 hours (including 200 classroom hours) of training and experience, and graduates must pass an exam, administered by diplomates of the specialty board, that tests knowledge and competence in radiation safety, radionuclide handling, quality assurance, and clinical use of unsealed byproduct material for which a written directive is required.

In addition to the areas discussed under imaging and localization studies, training for use of unsealed byproduct material for which a written directive is required includes safely preparing patient or human research subject dosages; administrative controls to prevent a medical event involving the use of unsealed byproduct material; procedures to contain spilled byproduct material safely and using proper decontamination procedures; and administering dosages of radioactive drugs to patients or human research subjects.

Work experience must involve a minimum of **three** cases in each of the following categories for which the individual is requesting AU status:

(1) Oral administration of less than or equal to 1.22 GBq (33 mCi) of sodium iodide ^{131}I, for which a written directive is required;
(2) Oral administration of greater than 1.22 GBq (33 mCi) of sodium iodide ^{131}I;
(3) Parenteral administration of any radioactive drug that contains a radionuclide that is primarily used for its electron emission, beta radiation characteristics, alpha radiation characteristics, or photon energy of less than 150 keV, for which a written directive is required.

The AU candidate must have written attestation that the individual has satisfactorily completed the training and is able to independently fulfill the radiation safety-related duties as an AU for the medical uses for which the individual is requesting AU status from either a preceptor AU who meets the requirements from the NRC or equivalent AS requirements, or a residency program director who affirms in writing that the attestation represents the

consensus of the residency program faculty where at least one faculty member is an AU who meets the requirements.

6.5. Radiopharmaceutical therapy

A negative serum beta-hCG pregnancy test must be documented in the patient's chart for all potentially childbearing individuals who are under 50 years old when receiving therapeutic radiopharmaceuticals. The pregnancy test must be within one week of the sodium iodide ^{131}I therapy. A pregnancy test is not necessary if the patient has had a remote bilateral tubal ligation or hysterectomy.

6.5.1. Oral ^{131}I NaI

Training for the oral administration of sodium iodide ^{131}I requiring a written directive in quantities less than or equal to 1.22 GBq (33 mCi)

The licensee shall require a written directive dated and signed by an AU for the oral administration of all ^{131}I quantities greater than 1.11 MBq (30 μC). Additionally, ^{131}I quantities less than or equal to 1.22 GBq (33 mCi) must have a written directive by a physician who is certified by a medical specialty board whose certification process has been recognized by the NRC or an AS, or has successfully completed 80 hours of classroom and laboratory training, applicable to the medical use of sodium iodide ^{131}I for procedures requiring a written directive.

Training for the oral administration of sodium iodide ^{131}I requiring a written directive in quantities greater than 1.22 GBq (33 mCi)

The licensee shall require an authorized user for the oral administration of sodium iodide ^{131}I requiring a written directive in quantities greater than 1.22 GBq (33 mCi) to be a physician who fulfils the same requirements as that for less than 1.22 GBq (33 mCi).

6.5.1.1 Inpatient

A patient treated with therapeutic ionizing radiation as an inpatient should be treated in a room with appropriate shielding, such as lead or concrete. Where shielding is not available, a corner, private hospital room not next to a stairwell or open area is optimal. The head of the bed should be positioned against the outside wall. Additional protection can be achieved by placing a shield between the door and the patient.

Before a patient is dosed, the room should be prepared. Signage indicating a radiation hazard and “no housekeeping services” should be placed on the door. Linen and trash hampers are placed inside the room. All surfaces the patient may frequently touch, such as the toilet, faucet handles, phone, and bedrails, should be wrapped in plastic. Materials used in the care of the patient are left in the room for the entire hospital stay.

As much as possible, healthcare workers and visitors should minimize their contact with the patient’s body fluids. To minimize fluid exposure, managing nausea and preventing emesis, which are common side effects of sodium iodide ^{131}I therapy, are important. Hospitals may

ask patients receiving sodium iodide ^{131}I to handle their own urine collection and measurement, so that staff members need not have close contact with the fluid. Male patients should be instructed to sit while voiding, and all patients should be instructed to flush the toilet twice, with the lid closed, to reduce the risk of aerosolization. Vigorous hydration is highly encouraged because it hastens biologic elimination. Because sweat is a source of contamination, patients can be encouraged to take frequent showers as tolerated for the first two weeks after treatment.

In the event of cardiac arrest or other medical emergencies, staff should follow the facility's specific protocols. When a patient receiving sodium iodide ^{131}I is at immediate risk of death or severe harm, many facilities relax their radiation restrictions and allow the patient to be moved away from the shielded room. When administering cardiopulmonary resuscitation to a radioactive patient, staff members should be cautious and use appropriate barriers.

Visitor safety is promoted by prohibiting pregnant visitors and visitors younger than 18 years. State regulations and hospital policies vary, but visits typically are limited to 30 minutes and require that visitors maintain a distance of at least 6 feet from the patient.

The patient and room should be surveyed with dosimeters at prescribed points at least daily. Surveys include points where care is provided, such as 1 meter from the patient's chest, each side of the bed, the foot of the bed, and the doorway. In addition, the visitor chair, the inside and outside of the door, and the adjacent patient wall should be surveyed. When survey readings at 1 meter from the patient's chest are 7 mrem per hour or less, the patient is considered generally safe for discharge. However, the discharge criteria may vary from state to state and from facility to facility.

6.5.1.2. Outpatient

NRC regulations allow sodium iodide ^{131}I patients to be released following treatment when the radiation dose to third parties is not likely to exceed 500 mrem (5 mSv). (An average person receives about 300 mrem [3 mSv] each year from natural and background radiation.) The regulations assume the dose would apply principally to the patient's family or other caregivers during the first few days the patient spends at home following treatment. Accordingly, treating physicians are required to consider the patient's living conditions and provide instructions for avoiding unnecessary exposure to others.

The NRC strongly discourages medical licensees who conduct outpatient treatment of thyroid patients with sodium iodide ^{131}I from recommending patients stay at hotels immediately after treatment.

The NRC also reminds treating physicians to inquire about the patient's intended destination following treatment so that appropriate instructions may be given on how to manage exposure to others. If a patient is adamant about not being hospitalized or not going to a private residence and plans to go to an alternative location such as a hotel, treating physicians must still provide adequate instructions on how the patient can keep radiation doses to others as low as possible.

6.5.1.3. Release criteria

Licensees are allowed to authorize the release from their control of any individual who has been administered radiopharmaceuticals or permanent implants containing radioactive material if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 5 mSv (0.5 rem) or if the activity administered is no greater than the activity in column 1 of Table 7 below. The licensee must provide the released individual with instructions, including written instructions, on actions recommended to maintain doses to other individuals as low as reasonably achievable if the total effective dose equivalent to any other individual is likely to exceed 1 millisievert (0.1 rem).

Table 7. Activities and dose rates for authorizing patient release[a] (Adapted from: U.S. Nuclear Regulatory Commission, April 1997 Revision 0, Regulatory Guide, Office of Nuclear Regulatory Research, Regulatory Guide 8.39 Release of Patients Administered Radioactive Materials)

	Column 1 Activity at or below which patients may be released		Column 2 Dose rate at 1 meter, at or below which patients may be released[b]	
Radionuclide	(GBq)	(mCi)	(mSv/hr)	(mrem/hr)
^{64}Cu	8.4	230	0.27	27
^{123}I	6.0	160	0.26	26
^{125}I implant	0.33	9	0.01	1
^{131}I	1.2	33	0.07	7
^{111}In	2.4	64	0.2	20
^{99m}Tc	28	760	0.58	58
^{201}Tl	16	430	0.19	19
^{90}Y	N/A[c]	N/A	N/A	N/A

[a]The activity values were computed based on 5 mSv (0.5 rem) total effective dose equivalent.
[b]If the release is based on the dose rate at 1 meter in column 2, the licensee must maintain a record as required by 10 CFR 35.75(c) because measurement includes shielding by tissue. See Regulatory Position 3.1, "Records of Release," for information on records.
[c]Activity and dose rate limits are not applicable in this case because of the minimal exposures to members of the public resulting from activities normally administered for diagnostic or therapeutic purposes.

If the dose to a breastfeeding infant or child could exceed 1 mSv (0.1 rem), assuming there was no interruption of breastfeeding, the instructions shall also include: (1) guidance on the interruption or discontinuation of breastfeeding and (2) information on the potential consequences of failure to follow the guidance. The licensee must maintain a record of the basis for authorizing the release of an individual for 3 years after the date of release, if the total effective dose equivalent is calculated by: (1) using the retained activity rather than the activity administered, (2) using an occupancy factor less than 0.25 at 1 meter, (3) using the biological or effective half-life, or (4) considering the self-shielding by tissue.

6.5.2. Parenteral therapy (alpha, beta)

Training for the parenteral administration of unsealed byproduct material requiring a written directive

The licensee shall require an AU for the parenteral administration requiring a written directive to be a physician who is an AU or maintains equivalent AS requirements, or, alternatively, a physician certified by a medical specialty board whose certification process has been recognized by the NRC or AS and who has successfully completed training applicable to parenteral and work experience under the supervision of an AU who meets the requirements for parenteral administrations.

The work experience must involve ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys; performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters; calculating, measuring, and safely preparing patient or human research subject dosages; using administrative controls to prevent a medical event involving the use of unsealed byproduct material; using procedures to contain spilled byproduct material safely and using proper decontamination procedures; and administering dosages to patients or human research subjects that include at least three cases of the parenteral administrations.

Also required is written attestation that the individual is able to independently fulfill the radiation safety-related duties as an AU for the parenteral administration of unsealed byproduct material requiring a written directive. The attestation must be obtained from either a preceptor AU or a residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an AU.

6.6. Radiopharmacy ("hot lab")

Licensed materials must be secured, either by storage in a locked room (such as the nuclear pharmacy or “hot lab”) or by constant surveillance (such as in imaging rooms in which patient dosages may be located). The hot lab is used to receive, store, and/or prepare radiopharmaceuticals that are administered to patients for nuclear radiology studies.

An important component of the hot lab is the dose calibrator, which measures radioactivity in vials, syringes, capsules, etc. The calibrator is often placed behind a lead or leaded-glass shield to minimize radiation exposure to the individual while they are working with radioactivity. Patient dosages and shielded vials are also generally placed and/or stored behind this shield.

6.6.1. Safe procedures

Safety instruction

A licensee shall provide radiation safety instruction, initially and at least annually, to personnel caring for patients or human research subjects who cannot be released. To satisfy this requirement, the instruction must include patient or human research subject control; visitor control, including routine visitation to hospitalized individuals; contamination and waste control; notification of the RSO or their designee; and an AU if the patient or the human research subject has a medical emergency or dies. A licensee shall retain a record of individuals receiving instruction.

Safety precautions

For each patient or human research subject who cannot be released, a licensee shall quarter the patient or the human research subject either in a private room with a private sanitary facility or with another individual who also has received therapy with unsealed byproduct material and who also cannot be released. Also, the licensee must visibly post the patient's or the human research subject's room with a "Radioactive Materials" sign, note on the door or in the patient's or human research subject's chart specifying where and how long visitors may stay in the patient's or the human research subject's room. The licensee must either monitor material and items removed from the patient's or the human research subject's room to determine that their radioactivity cannot be distinguished from the natural background radiation level or handle the material and items as radioactive waste. The licensee shall notify the RSO, or their designee, and the AU as soon as possible if the patient or human research subject has a medical emergency or dies.

6.6.2. Generator systems

6.6.2.1. Elution

Eluting the generator

The procedures for elution are designed to provide a sterile, pyrogen-free product suitable for human injection or for compounding into other radiopharmaceutical preparations. Because the design of individual commercial generators varies, the precise methods used for their elution will also vary.

6.6.2.2. Quality control

Permissible molybdenum-99, strontium-82, and strontium-85 concentrations

A licensee may not administer to humans a radiopharmaceutical that contains:

- More than 0.15 kBq of ^{99}Mo per MBq of ^{99m}Tc (0.15 uCi of ^{99}Mo per mCi of ^{99m}Tc); or

- More than 0.02 kBq of ^{82}Sr per MBq of ^{82}Rb chloride injection (0.02 uCi of ^{82}Sr per mCi of ^{82}Rb chloride); or
- More than 0.2 kBq of ^{85}Sr per MBq of ^{82}Rb chloride injection (0.2 uCi of ^{85}Sr per mCi of ^{82}Rb).

The eluates from each generator should be measured to demonstrate compliance. For ^{82}Sr/^{82}Rb generators, the concentration of radionuclides ^{82}Sr and ^{85}Sr should be measured before the first patient of the day. The licensee shall report by telephone any measurement within 7 calendar days after discovery that an eluate exceeded the permissible concentration listed.

The licensee shall submit a written report to the NRC within 30 calendar days after discovery of an eluate exceeding the permissible concentration at the time of generator elution. The written report must include the action taken by the licensee, the patient dose assessment, the methodology used to make this dose assessment if the eluate was administered to a person, and the probable cause and an assessment of failure in the licensee's equipment, procedures or training that contributed to the excessive readings if an error occurred in the licensee's breakthrough determination.

^{68}Ga can be produced in a cyclotron or by the elution of a ^{68}Ge/^{68}Ga generator. ^{68}Ge/^{68}Ga generators are similar to conventional ^{99}Mo/^{99m}Tc and ^{82}Sr/^{82}Rb generators. Like ^{99}Mo/^{99m}Tc and ^{82}Sr/^{82}Rb generators, breakthrough of the parent radionuclide is possible when eluting the generator. This could lead to ^{68}Ge contaminating the ^{68}Ga radiopharmaceutical and potentially causing an unnecessarily high radiation exposure to patients. However, no similar limit of breakthrough is specified for ^{68}Ge/^{68}Ga generators and applicants must commit individually to safety protocols to the NRC.

6.6.3. Recordkeeping

Each record required must be legible throughout the specified retention period. The record may be the original or a reproduced copy. The record may be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records, such as letters, drawings, and specifications, must include all pertinent information, such as stamps, initials, and signatures. The licensee shall maintain adequate safeguards against tampering with and loss of records.

Each licensee shall report by telephone to the NRC any lost, stolen, or missing licensed material that becomes known to the licensee if it appears to the licensee that an exposure could result to persons in unrestricted areas. Each licensee is required to make a written report within 30 days after making the telephone report setting forth the following information:

- A description of the licensed material involved, including kind, quantity, and chemical and physical form.
- A description of the circumstances under which the loss or theft occurred.
- A statement of disposition, or probable disposition, of the licensed material involved.

- Exposures of individuals to radiation, circumstances under which the exposures occurred, and the possible total effective dose equivalent to persons in unrestricted areas.
- Actions that have been taken, or will be taken, to recover the material.
- Procedures or measures that have been, or will be, adopted to ensure against a recurrence of the loss or theft of licensed material.

Each licensee shall submit a written report within 30 days after learning of any of the following occurrences: doses in excess of any of the occupational dose limits for adults or minors, the limits for an embryo/fetus of a declared pregnant individual, or the limits for an individual member of the public.

Each licensee shall submit a written report within 30 days after learning of excesses of radiation air emissions, or excessive radiation in a restricted space, or 10 times the limits of an unrestricted area.

Reports should include individual dose estimates; levels of radiation involved; the cause of the elevated exposures, dose rates, or concentrations; and corrective steps taken or planned to ensure against a recurrence. For occupationally overexposed individuals, their name, Social Security account number, and date of birth should be included and clearly labeled with "Privacy Act Information: Not for Public Disclosure."

Records of authority and responsibilities for radiation protection programs

A licensee shall retain a record of actions for 5 years for the RSO and radiation program changes. The record must include a summary of the actions taken and a signature of licensee management. The licensee shall retain a copy of the duties and responsibilities of the RSO and must include a copy of the previous and current radiation safety procedures.

Records of written directives

A licensee shall retain a copy of each written directive for 3 years.

Records of calibrations of instruments used to measure the activity of unsealed byproduct material

A licensee shall maintain a record of instrument and radiation survey calibrations for 3 years. The records must include the model and serial number of the instrument, the date of the calibration, the results of the calibration, and the name of the person who performed the calibration.

Records of dosages of unsealed byproduct material for medical use

A licensee shall maintain a record of dosage determinations for 3 years. The record must contain the radiopharmaceutical; the patient's name or identification number; the prescribed dosage; the determined dosage including date and time or a notation that the total activity is less than 1.1 MBq (30 μCi); and the name of the person who determined the dosage.

Records of leaks tests and inventory of sealed sources and brachytherapy sources

A licensee shall retain records of leak tests for 3 years. The records must include the model number and serial number if one has been assigned; the identity of each source by radionuclide and its estimated activity; the results of the test; and the name of the person who performed the test. A licensee shall retain records of the semi-annual physical inventory of sealed sources and brachytherapy sources for 3 years.

Records of surveys for ambient radiation exposure rate

A licensee shall retain a record of each survey required for 3 years. The record must include the date of the survey; the results of the survey; the instrument used to make the survey; and the name of the person who performed the survey.

Records of the release of individuals containing unsealed byproduct material or implants containing byproduct material

A licensee shall retain a record for 3 years of the basis for authorizing the release of an individual if the total effective dose equivalent is calculated by using the retained activity, rather than the activity administered, using an occupancy factor less than 0.25 at 1 meter, or using the biological or effective half-life.

A licensee shall retain a record for 3 years that the instructions were provided to a breastfeeding individual if the radiation dose to the infant or child from continued breastfeeding could result in a total effective dose equivalent exceeding 5 mSv (0.5 rem).

7. Emergency procedures, accidents/incidents, special circumstances

This section covers medical/reportable events as defined by the NRC. It also addresses spills of radioactive materials and radiation accidents/incidents/disasters including “dirty bombs.”

7.1 Medical events/reportable events

The term “medical event” may sound alarming when used in nuclear radiology and radiation therapy. But it may not mean a patient has been harmed. It means there may have been a problem in a medical facility’s use of radioactive materials. These materials can help to diagnose and treat illnesses or be used in medical research. Small amounts can allow physicians to see certain organs. Images created using radioactive materials can help to find, identify, and measure tumors, or view problems in an organ’s structure or function. Radioactive materials can also kill cancerous tissue, shrink a tumor, or reduce pain.

NRC regulations aim to ensure that radioactive materials are used properly. This is also true when they are used in medical diagnosis, treatment, or research. The rules protect the safety of patients, medical workers, the public, and the environment. They define "medical event" in very specific terms.

A "medical event" involving radioactive materials occurs if **BOTH**:

1. The dosage given differs from the prescribed dose or dose that would have resulted from the prescribed dosage by more than 5 rem (0.05 Sv) effective dose equivalent, 50 rem (0.5 Sv) to an organ or tissue, or 50 rem (0.5 Sv) shallow dose equivalent to the skin. **AND**
2. One or more of the following incidents occur:
    - The dosage given is off by at least 20% from the prescribed dosage, either too high or too low.
    - The wrong drug is used.
    - The drug is given by the wrong route.
    - The wrong individual receives the dosage.
    - A dosage is administered to the wrong part of the body and exceeds by 50% or more the dosage that area should have received.
    - A sealed source used in the treatment leaks.

The NRC requires reporting because a medical event shows the licensee had a problem in administering the physician's (AU's) prescription. The problem may have been technical or a quality assurance issue. Dosage errors may be a sign of problems in the medical facility's operations. But there is no scientific basis to conclude that such an error results in harm to a patient.

To know if a patient has been harmed, the physician (AU) must do more analysis. Harm may come from too high a dosage. But it could also result from inadequate treatment when a dosage is too low.

The NRC also analyzes each event to see if further action is needed. If there is a violation of the regulations, the NRC might take enforcement action. The agency will also look for trends to see if something in NRC regulations or guidance may need to be clarified.

Severe events are rare. An example would be a dosage error that is well over 20% too high or too low. In severe events, an independent medical consultant will assess the patient's risk of harm.

In all cases, a "medical event" indicates potential problems in a facility's use of radioactive materials. It does not necessarily result in harm to a patient. But the NRC's rules are designed so events are reported to the NRC and the public. Even when there is no harm to a patient, the NRC protects the public health and safety.

7.2 Radiation spills

The decision to implement a **major spill** procedure instead of a **minor spill** procedure depends on many incident-specific variables, such as the number of individuals affected, other hazards present, likelihood of contamination spread, and types of surfaces contaminated as well as the radiotoxicity of the spilled material. For some spills of short-lived radionuclides, the best spill procedure may be restricted access pending complete decay.

To determine whether a major or minor spill procedure should be implemented, take the following steps, using Table 8 for guidance:

- Estimate the amount of radioactivity spilled.
- Initiate a major or minor spill procedure based on the listed dividing line.
- Spills above these millicurie amounts are considered major, below are considered minor.
- Note that some spills require evacuation of the area.

Table 8. Spill levels of common radioisotopes

Unsealed Radionuclides in Clinical Nuclear Radiology	**Minor Spill (< mCi)**	**Major Spill (>= mCi)**	**Evacuate Level (mCi)**
Actinium-225 (^{225}Ac)	n/a	Any	n/a
Lead-212 (^{212}Pb)	n/a	Any	n/a
Radium-223 (^{223}Ra)	n/a	Any	n/a
Xenon-133 (^{133}Xe) [gas]	n/a	n/a	Any
Iodine-131 (^{131}I)	1	1	n/a
Yttrium-90 (^{90}Y)	1	1	n/a
Lutetium-177 (^{177}Lu)	2	2	n/a
Copper-64 (^{64}Cu)	10	10	50
Gallium-67 (^{67}Ga)	10	10	n/a
Indium-111 (^{111}In)	10	10	n/a
Iodine-123 (^{123}I)	10	10	15
Rubidium-82 (^{82}Ru)	10	10	50
Gallium-68 (^{68}Ga)	20	20	100
Fluorine-18 (^{18}F)	100	100	250
Technetium-99m (^{99m}Tc)	100	100	400
Thallium-201 (^{201}Tl)	100	100	n/a

7.2.1 Major spill – response and handling

A. CLEAR THE AREA: Notify all persons not involved in the spill to vacate the room.

B. PREVENT THE SPREAD: Cover the spill with absorbent paper, but do not attempt to clean it up. To prevent the spread of contamination, limit the movement of all personnel who may be contaminated.

C. SHIELD THE SOURCE: If possible, shield the spill. This should be done only if it can be done without further contamination or a significant increase in radiation exposure.

D. CLOSE THE ROOM: Lock or otherwise secure the area to prevent entry.

E. CALL FOR HELP: Notify the RSO immediately.

F. PERSONNEL DECONTAMINATION: Remove contaminated clothing and flush contaminated skin with lukewarm water and then wash with mild soap. If contamination remains, induce perspiration by covering the area with plastic. Then wash the affected area again to remove any contamination that was released by the perspiration.

G. CLEANUP: The RSO will supervise the cleanup of the spill and will complete the Radioactive Spill Report and the Radioactive Spill Contamination Survey report forms.

7.2.2 Minor spill – response and handling

A. NOTIFY: Notify persons in the area that a spill has occurred.

B. PREVENT THE SPREAD: Cover the spill with absorbent paper.

C. CLEAN UP: Use disposable gloves and absorbent paper. Carefully fold the absorbent paper with the clean side out and place in a labeled plastic bag for transfer to a radioactive waste container. Also put contaminated gloves and any other contaminated disposable material in the bag.

D. SURVEY: Check the area around the spill with a low-range radiation detection survey meter. Also check your hands, clothing, and shoes for contamination.

E. REPORT: Report the incident to the RSO.

F. DOCUMENT: Complete the Radioactive Spill Report and the Radioactive Contamination Survey forms.

7.2.3 Surface contamination limits

The amount of removable radioactive material per 100 cm^2 of surface area should be determined by wiping that area with a filter or soft absorbent paper, applying moderate pressure, and assessing the amount of radioactive material on the wipe with an appropriate instrument of known efficiency. When removable contamination on objects of less surface area is determined, the pertinent levels should be reduced proportionally, and the entire surface should be wiped. Table 9 lists the maximum allowable surface contamination for different radionuclides in a restricted area.

Table 9. Surface contamination levels in restricted areas

Unsealed Radionuclide	**Level (dpm/100 cm^2)**
All alpha emitters	200
^{111}In, ^{123}I, ^{131}I, ^{177}Lu, ^{90}Y	2,000
^{67}Ga, ^{99m}Tc, ^{201}Tl	20,000

7.2.4 Medical/Nonmedical emergencies (e.g., “dirty bomb”)

Primary Response:

Always address life- or limb-threatening medical situations first and foremost.

Background

A "dirty bomb" is a type of "radiological dispersal device" (RDD) that combines a conventional explosive, such as dynamite, with radioactive material. The terms dirty bomb and RDD are often used interchangeably. Most RDDs would not release enough radiation to kill people or cause severe illness – the conventional explosive itself would be more harmful to people than the radioactive material. However, an RDD explosion could create fear and panic, contaminate property, and require potentially costly cleanup.

A dirty bomb is not a nuclear bomb. A nuclear bomb creates an explosion that is millions of times more powerful than a dirty bomb. The cloud of radiation from a nuclear bomb could spread thousands of square miles, whereas a dirty bomb’s radiation could be dispersed within a few blocks or miles of the explosion. A dirty bomb is not a "weapon of mass destruction" but a "weapon of mass disruption," where contamination and anxiety are the major objectives.

Impact of a Dirty Bomb

The extent of local contamination would depend on a number of factors, including the size of the explosive, the amount and type of radioactive material used, the means of dispersal, and weather conditions. Those closest to the RDD would be most likely to be injured by the explosion. As radioactive material spreads, it becomes less concentrated and less harmful. Prompt detection of the type of radioactive material used will greatly assist local authorities in advising the community on protective measures, such as sheltering in place or quickly leaving the immediate area. Radiation can be readily detected with equipment already carried by many emergency responders. Subsequent decontamination of the affected area may involve considerable time and expense.

Immediate health effects from exposure to the low radiation levels expected from an RDD would likely be minimal. The effects of radiation exposure would be determined by:

- The amount of radiation absorbed by the body.
- The type of radiation (gamma, beta, or alpha).
- The distance from the source of radiation to an individual.
- The means of exposure – external or internal (absorbed by the skin, inhaled, or ingested).
- The length of time exposed.

The health effects of radiation tend to be directly proportional to radiation dose. The higher the radiation dose, the higher the risk and severity of injury.

Protective Actions

In general, protection from radiation is afforded by:

- Minimizing the time exposed to radioactive materials.
- Maximizing the distance from the source of radiation.
- Shielding from external exposure and inhaling radioactive material.

Control of Radioactive Material

Radioactive materials are routinely used at hospitals, research facilities, and industrial and construction sites. These radioactive materials are used for such purposes as diagnosing and treating illnesses, sterilizing equipment, and inspecting welding seams. The NRC and its Agreement States, which also regulate radioactive material, administer more than 22,000 licenses of such materials. The majority of these materials would not be useful in an RDD.

The NRC and its Agreement States have in place a multi-layered, comprehensive security program to protect these sources. This program has been effective, keeping incidents to a minimum and their consequences low. Most lost or stolen sources are quickly found, with little or no radiation exposure or contamination. The NRC continues to work at home and abroad to make risk-significant radiation sources even more secure. The United States was the first country to require enhanced security measures for radioactive sources, and the NRC continues to lead the world in source security.

Other Contact Information

A number of federal agencies have responsibilities for dealing with RDDs, including the Department of Homeland Security, Environmental Protection Agency, and Federal Emergency Management Agency. Their public affairs offices can answer questions on the subject or provide access to experts in and out of government.

Accidents Involving Personal Injury

For any accident involving personal injury, medical treatment or assistance will always be the first priority. This may involve administering first aid and/or calling 911 for emergency medical assistance. For accidents involving radioactive materials, contamination control and exposure control are important but should never delay or impede medical assistance. If radioactive materials are involved, emergency personnel should be notified before treatment takes place, so they can take appropriate action to protect themselves as well as prevent the spread of contamination. After the injured person is treated and removed from the accident site, the previously described procedures should be followed as appropriate.

Personal Contamination

In the event of any personal contamination, laboratory personnel should follow these steps:

1. Remove all contaminated laboratory personal protective clothing (lab coat, gloves, etc.).
2. Wash the contaminated area with mild soap and water if possible.
3. Monitor the contaminated area; repeat washing as necessary.

Decontamination Procedures

If surfaces or equipment within the laboratory are suspected or determined to be contaminated with radioactive material, the radionuclide user must initiate and complete appropriate decontamination procedures. For most relatively minor contamination incidents, the following general steps should be taken upon discovery of the contamination:

1. Mark the perimeter of the contaminated area.
2. Notify the RSO of the contamination so that their staff can more accurately assess the extent of the contamination and advise and assist in the decontamination effort.
3. Assemble cleaning supplies (paper towels, detergent in water, plastic bags, and plastic gloves); proceed with scrubbing the area from the borders to the center, cleaning small areas at a time.
4. Periodically monitor the effectiveness of the decontamination effort with surface wipes and portable instrument surveys; place all contaminated cleaning materials, including paper towels, rags, and gloves, in a plastic bag and label as "radioactive waste."
5. Notify Environmental Health and Safety upon completion of the decontamination effort so that a follow-up contamination survey can be made.

Acute Radiation Syndrome

Acute Radiation Syndrome (ARS) is defined as radiation exposures that involve the following:

- Acute high dose (>0.7 Gy) radiation exposure.
- High dose rate in a short time interval.
- External dose of penetrating radiation.
- Greater than 70% of the body is exposed to the radiation (whole body exposure).

Patients with ARS develop classic signs and symptoms that run a typical time course, regardless of the exposure dose. Patients undergo four phases during that time course: prodromal phase, latent phase, manifest illness, and recovery or death. With increasing doses, the time interval for each phase is shortened and the symptoms worsen. The signs, symptoms, and considerations for each phase are found in Figure 5.

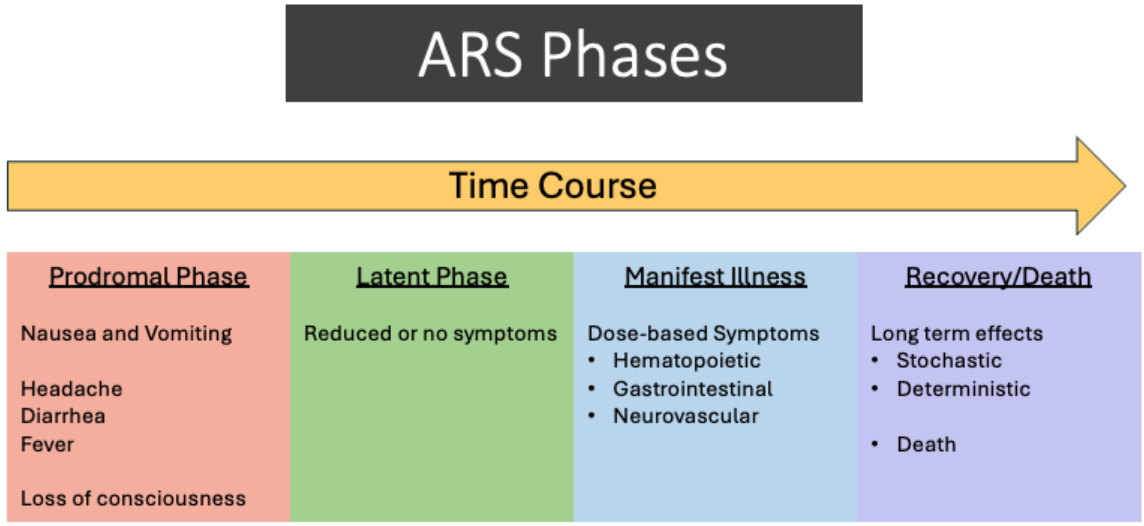


Figure 5. The phases of acute radiation syndrome

In the manifest illness phase of ARS, patients will experience symptoms consistent with the dose of radiation they were exposed to. These symptoms can be grouped into subsyndromes of ARS that correspond with the organ system or cell type that has been critically injured. They are hematopoietic subsyndrome (bone marrow toxicity), gastrointestinal subsyndrome (gastrointestinal stem cell toxicity), and neurovascular subsyndrome (neurovascular endothelial cell toxicity). Figure 6 describes these subsyndromes in more detail, including the doses at which they manifest and patient symptoms.

Subsyndromes	Dose	Characteristic Findings
Hematopoietic	0.7 - 5 Gy	Bone Marrow Failure, Pancytopenia
Gastrointestinal	6 – 9 Gy	Severe GI symptoms, GI Bleeding, Electrolyte Abnormalities, Sepsis
Neurovascular	> 10 Gy	Hemorrhagic stroke, Loss of Conciousness, Decreased BP

Figure 6. Acute radiation subsyndromes

The estimated $LD_{50/60}$ of acute, whole-body, low-LET irradiation is 3.5 to 4.0 Gy without medical intervention. However, swift medical intervention can increase the likelihood of survival. Administering antibiotics and supportive treatment can increase the $LD_{50/60}$ to 4.5 to 7 Gy, and intensive care, reverse isolation, and hematopoietic cell transplantation can potentially increase it to 7 to 9 Gy.

FDA-approved treatments generally target hematopoietic subsyndrome effects; however, new treatments are looking at gastrointestinal subsyndrome as well. The following colony stimulating factors (CSF) have been approved for ARS treatment:

- Filgramostim (Neupogen®)
- PEGylated filgramostim (Neulasta®)
- Sargramostim (Leukine®)

These agents predominantly promote neutrophil recovery, while sargramostim also promotes additional bone marrow cell lineages. The FDA has also approved a thrombopoietin (TPO) receptor activator that promotes megakaryocytes and platelets for ARS treatment: romiplostim (Nplate®).

A logical thought is that stem cell transplant would be an appropriate treatment for hematopoietic subsyndrome. Unfortunately, historical data on the use of stem cell transplants is limited and mixed with a very low and questionable success rate.

In addition to these targeted therapies, treatment of ARS depends on careful management of patients susceptible to infection, bleeding, nutritional deficiencies, and electrolyte abnormalities. Consequently, treatment often involves IV fluids/electrolytes, blood products (irradiated and leukocyte-reduced to prevent infection and graft versus host disease), and antimicrobial prophylaxis.

Appendix 1. Radiation-Measuring Instrumentation and Quality Control Tests

A **Geiger-Mueller Counter** has two main parts — a sealed tube, or chamber, filled with gas and an information display. Radiation enters the tube and when it collides with the gas, it pushes an electron away from the gas atom and creates an ion pair. A wire in the middle of the tube attracts electrons, creating other ion pairs and sending a current through the wire. The current goes to the information display and moves a needle across a scale or makes a number display on a screen. These devices usually provide "counts per minute," or the number of ion pairs created every 60 seconds. A Geiger counter indicates when an ion pair is created, but nothing about the type of radiation or its energy.

Well Counters are used for high-sensitivity counting of radioactive specimens such as blood or urine samples or “wipes” from surveys of removable contamination (i.e., wipe testing). A well counter includes a cylindric scintillation crystal (most commonly thallium-doped sodium iodide) with a circular bore (well) for the sample, backed by a photomultiplier tube (PMT) and its associated electronics. Modern scintillation well counters are often equipped with a multichannel analyzer (MCA) for energy (i.e., isotope)-selective counting and an automatic sample changer for unattended counting of multiple samples. Because of their high intrinsic and geometric efficiencies (resulting from the use of a thick crystal and a well-type counting geometry, respectively), well counters are extremely sensitive and, in fact, can reliably be used only for counting activities up to approximately 37 kBq (0.001 mCi); at higher activities, dead-time counting losses become prohibitive and the measured counts, inaccurate.

Scintillation Detection Systems use a substance that creates a flash of light when ionizing radiation interacts with it. **Liquid scintillation** counting is an analytical technique used to identify and quantify low levels of radioactivity, such as for contamination or for particulate emitting (b and a) radioactive samples. **Solid scintillators** are sensitive to gamma radiation and can measure dose rates in the µrem/hr range.

An **Ionization Chamber** is an instrument used to measure the number of ions within a medium. It usually consists of a gas-filled enclosure between two conducting electrodes (the anode and cathode). When gas between the electrodes is ionized by any means, such as by gamma rays or other radioactive emission, the ions and dissociated electrons move to the electrodes of the opposite polarity, thus creating an ionization current that may be measured. Each ion essentially deposits or removes a small electric charge to or from an electrode, such that the accumulated charge is proportional to the number of like-charged ions. Ionization chambers can be open or sealed depending on their function. Open ionization chambers are typically used as personal dosimeters. Radioisotope dose calibrators are sealed ionization chambers widely used in the nuclear industry as they provide an output that is proportional to radiation dose and are calibrated to specific isotopes.

Radio-thin-layer Chromatography (radio-TLC) is commonly used to analyze purity of radiopharmaceuticals or to determine the reaction conversion when optimizing radiosynthesis processes. In applications where there are few radioactive species, radio-TLC is preferred over radio-high-performance liquid chromatography due to its simplicity and relatively quick analysis time. Most approaches to radio-TLC were merely extensions or modifications of techniques that had been used in paper chromatography (PC).

Appendix 2. ABR Currently-in-Use Radiopharmaceuticals (Through 12/31/2025)

Candidates should be familiar with the normal distribution and indications for these radiopharmaceuticals.

Gamma Camera/SPECT & SPECT/CT

^{67}Ga citrate*
^{111}In DTPA *OR* ^{111}In pentetate*
^{111}In pentetreotide (OctreoScan)
^{111}In WBCs
^{123}I iobenguane *OR* ^{123}I MIBG (AdreView)
^{123}I ioflupane (DaTscan)
^{123}I NaI
^{131}I NaI
^{99m}Tc bicisate *OR* ^{99m}Tc ECD (Neurolite)
^{99m}Tc DMSA *OR* ^{99m}Tc succimer
^{99m}Tc DTPA *OR* ^{99m}Tc pentetate
^{99m}Tc DTPA aerosol *OR* ^{99m}Tc pentetate aerosol
^{99m}Tc exametazime *OR* ^{99m}Tc HMPAO (Ceretec)
^{99m}Tc HDP (or other diphosphonate)
^{99m}Tc mebrofenin (Choletec)
^{99m}Tc MAA
^{99m}Tc mertiatide *OR* ^{99m}Tc MAG3
^{99m}Tc MDP (or other diphosphonate)
^{99m}Tc pertechnetate
^{99m}Tc pyrophosphate (TechneScan PYP)
^{99m}Tc RBCs
^{99m}Tc RBCs (denatured)*
^{99m}Tc sestamibi (Cardiolite)
^{99m}Tc sulfur colloid (filtered)
^{99m}Tc sulfur colloid (unfiltered)
^{99m}Tc sulfur colloid (e.g., scrambled eggs)
^{99m}Tc carbon aerosol (Technegas)
^{99m}Tc tetrofosmin (Myoview)
^{99m}Tc tilmanocept (Lymphoseek)
^{99m}Tc WBCs
^{201}Tl Cl
^{133}Xe gas

THERAPY

^{131}I iobenguane *OR* ^{131}I MIBG (Azedra)
^{131}I NaI
^{177}Lu dotatate (Lutathera)*
^{177}Lu vipivotide tetraxetan *OR* ^{177}Lu PSMA (PLUVICTO)*
^{223}Ra dichloride (Xofigo)*
^{90}Y dotatate
^{90}Y microspheres (SIR-Spheres, TheraSpheres)*

PET/CT

^{11}C acetate
^{11}C choline
^{11}C methionine
^{64}Cu dotatate (Detectnet)
^{18}F florbetaben (NeuraCeq)
^{18}F florbetapir (Amyvid)
^{18}F flortaucipir (TAUVID)
^{18}F flotufolastat *OR* ^{18}F PSMA (POSLUMA)
^{18}F FLT
^{18}F fluciclovine (Axumin)
^{18}F fludeoxyglucose *OR* ^{18}F FDG
^{18}F fluorodopa (FDOPA)
^{18}F fluoroestradiol (Cerianna)
^{18}F flurpiridaz
^{18}F flutemetamol (Vizamyl)
^{18}F NaF
^{18}F piflufolastat *OR* ^{18}F PSMA (PYLARIFY)
^{68}Ga dotatate (NETSPOT)
^{68}Ga gozetotide *OR* ^{68}Ga PSMA-11 (Illuccix)
^{68}Ga gozetotide *OR* ^{68}Ga PSMA-11 (LOCAMETZ)
$^{13}NH_3$ (ammonia)*
^{15}O water
^{82}Rb Cl

NON-IMAGING

^{14}C urea
^{99}Mo
^{99}Tc

QUALITY CONTROL

^{133}Ba
^{137}Cs
^{57}Co
^{153}Gd
^{68}Ge
^{99m}Tc

*Certifying and Subspecialty exams only

Appendix 3. Physical Properties of Important Radionuclides

		Physical Properties of Important Radionuclides		
Radionuclide	Decay mode	Half-life	Charged Particles (MeV)	Photopeak(s) (MeV)
^{133}Ba	EC	10.5 y		g 0.081 (32.9%) g 0.303 (18.3%) g 0.356 (62.1%)
^{11}C	EC, b^+	20.3 min		g 0.511 (99.8%)
^{57}Co	EC	270 d		g 0.122 (85.6%) g 0.136 (11%)
^{137}Cs	b^-	30 y	b^- 0.514 (94.4%)	g 0.660 (85%)
^{64}Cu	EC, b^+, b^-	12.7 hr	b^- 0.573 (38.5%)-max	g 1.346 (0.5%) g 0.511 (17.5%)
^{67}Cu	b^-	61.8 hr	b^- 0.562 (100%)-max b^- 0.141 (100%)-mean	g 0.091 (7%) g 0.094 (16.1%) g 0.185 (48.7%) g 0.209 (0.12%) g 0.300 (0.8%) g 0.393 (0.22%)
^{18}F	EC, b^+	110 min		g 0.511 (96.9%)
^{67}Ga	EC	3.26 d		g 0.093 (39.2%) g 0.184 (21.2%) g 0.300 (16.8%) g 0.394 (4.7%)
^{68}Ga	EC, b^+	67.8 min		g 0.511 (89%) g 1.077 (3.2%)
^{68}Ge	EC	271 d		g 0.511 (from ^{68}Ga daughter)
^{123}I	EC	13.0 hr		g 0.159 (94%)
^{131}I	b^-	8.06 d	b^- 0.807 (0.4%) b^- 0.606 (89%)-max b^- 0.192 (89%)-mean b^- 0.334 (7.3%)	g 0.164 (0.02%) g 0.284 (6.1%) g 0.364 (81.5%) g 0.637 (7.2%)
^{111}In	EC, b^+	2.81 d		g 0.171 (90%) g 0.245 (94%)
^{177}Lu	b^-	6.65 d	b^- 0.497 (78.6%)-max b^- 0.1 (78.6%)-mean b^- 0.384 (9%) b^- 0.179 (12%)	g 0.321 (0.2%) g 0.208 (11.1%) g 0.113 (6.6%)
^{13}N	EC, b^+	10.0 min		g 0.511 (99.8%)

^{15}O	EC, b^+	124 s		g 0.511 (99.9%)
^{223}Ra	a	11.4 d	a 5.77 Daughter a's a 6.8 a 7.5 a 6.6	g 0.062 (24%) g 0.286 (20%) g 0.330 (13%)
^{82}Rb	EC, b^+	1.27 min		g 0.511 (94.9%) g 0.777 (13%)
^{99m}Tc	IT	6.03 hr		g 0.140 (89%)
^{201}Tl	EC	3.05 d		g 0.135 (2.7%) g 0.167 (10%)
^{133}Xe	b^-	5.3 d	b^- 0.346 (99%)	g 0.081 (36.9%)
^{90}Y	b^-, IPP	64.6 hr	b^- 2.278 (99.9%)-max b^- 0.940 (99.9%)-mean	g 0.511 (0.003%) X-ray spectrum
^{89}Zr	EC, b^+	78.4 min		g 0.511 (22.7%) g 0.909 (1.1%)

The values in parenthesis represent % abundance
Isomeric Transition (IT)
Internal pair production (IPP)
Electron Capture (EC)
*Alpha Decay (*a*)*
Beta Minus Decay (b^-)
Beta Minus Decay (b^+)

Sources:

www.nrc.gov
https://www.nrc.gov/docs/ML0222/ML022250828.pdf

National Research Council (US) Board on Radiation Effects Research. Health Risks from Exposure to Low Levels of Ionizing Radiation: BEIR VII, Phase I, Letter Report (1998). Washington (DC): National Academies Press (US); 1998. PMID: 25077203.

https://www.jointcommission.org/standards/standard-faqs/home-care/national-patient-safety-goals-npsg/000001545/

www.osha.gov

Essentials of Nuclear Medicine and Molecular Imaging: Expert Consult - Online and Print 7th Edition. Fred A. Mettler, Jr. and Milton J. Guiberteau, Elsevier, 2019 ISBM-10 0323483194

Military Medical Operations Department, Armed Forces Radiobiology Research Institute, et al. *Medical Management of Radiological Casualties Handbook.* 5th Edition. 2022.

López M, Martín M. Medical management of the acute radiation syndrome. Rep Pract Oncol Radiother. 2011 Jul 13;16(4):138-46.