

Radiation Safety in Nuclear Medicine

A Practical, Concise Guide

Gopal B. Saha

Second Edition

 Springer

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*To all selfless and benevolent souls
Who help make the world a better place
to live in!*

Preface

The book, *Radiation Safety in Nuclear Medicine*, was written as a guide to radiation safety practice for nuclear medicine professionals. It helps the nuclear medicine technologists prepare their board certifying examination. The NRC requires the appointment of a radiation safety officer (RSO) or an associate radiation safety officer (ARSO) for different uses of radioactive material. Board-certified nuclear medicine technologists are eligible to be RSO and ARSO in specific uses of radioactive material (RAM) after successfully completing a 40-h or 200-h course on radiation safety depending on the type of RAM use. These courses are offered online or in-person by many professional organizations in the USA. My book covers all subject materials in these courses on radiation safety.

The major change in the new edition of the book is the addition of a set of questions at the end of each chapter, to ensure the comprehension of the material by the examinees taking their certifying board examinations. In all my three other textbooks, probing questions had been added and were appreciated by residents and technologists in radiology and nuclear medicine. These questions help them prepare for their board certification examination. Nuclear Medicine Technology Certification Board (NMTCB) administers a certification examination in radiation safety (NMTCB-RS) to qualify technologists as RSO or ARSO. The Society of Nuclear Medicine and Molecular Imaging administers frequent webinars on radiation safety in the format of questions for the technologists. This is the incentive for adding relevant questions at the end of each chapter in the book.

As mentioned in the first edition, the NRC 10CFR20 for Standards for Radiation Protection and the NRC 10CFR35 for Medical Uses of Radioactive Materials are the primary sources of practical information on radiation safety in nuclear medicine. Much of the information is still valid, though many changes and additions have been made since, which are included in the new edition. Some sections have been upgraded with elaboration with appropriate new information. Some relevant materials that were omitted in the first edition are included along with relevant tables and figures.

I am very grateful to Ms Margaret Moore, Senior Editor, Clinical Medicine of Springer Nature, for offering the publishing contract for the second edition of the book and her sincere advice and encouragement in my publishing effort. I am also thankful to Ms Swathiga Karthikeyan, Project Coordinator of Springer Nature, for

her coordinated help in the successful production of the book. I am extremely appreciative of project managers, Caroline Rejina, Sangamithirai Arulprakasam, and Geetha Dhandapani for their meticulous effort in bringing the book to a very pleasant shape. Thanks are due to Springer Nature for their trust in me for more than four decades supporting the publications of four textbooks and their many editions.

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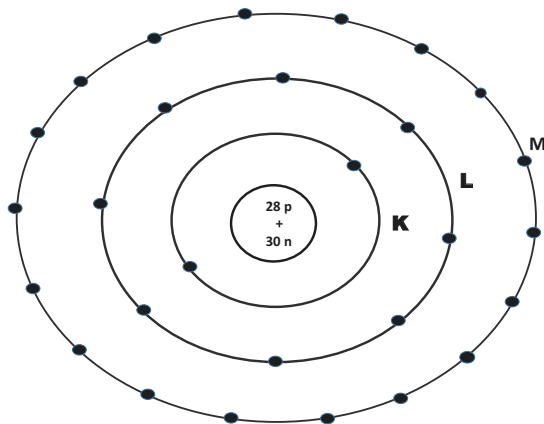
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1.1 Atomic and Nuclear Structure

Atoms are basic components of matter. According to Bohr's atomic theory, they are composed of a positively charged nucleus at the center and negatively charged electrons circulating in orbits around the nucleus to neutralize the charge of the nucleus. The dimension of an atom is of the order of 10^{-8} cm (1 Angstrom, Å) and that of a nucleus is of the order of 10^{-13} cm (1 Fermi, F). The nucleus consists of neutrons (no charge) and protons (positively charged), collectively called nucleons. The weight of the atom is mainly due to neutrons (1.6744×10^{-27} g) and protons (1.6721×10^{-27} g), which in turn accounts for the weight of matter. Nucleons are strongly bound together with nuclear energy which is discussed later. The electrons rotate around the nucleus given in different energy shells in increasing order, designated as *K*, *L*, *M*, *N*, etc. (Fig. 1.1). These shells have a definite capacity to hold electrons given by $2n^2$, where *n* is numerical values of 1, 2, 3, 4, etc. for *K*, *L*, *M*, *N* shells, etc. respectively. Thus, the *K* shell accommodates 2 electrons, the *L* shell 8 electrons, the *M* shell 18 electrons, the *N* shell 32, etc.

Fig. 1.1 The electronic configuration of ${}_{28}\text{Ni}$ atom. The *K* shell has 2 electrons, the *L* shell has 8 electrons, and *M* shell has 18 electrons



The total number of protons and neutrons in an atom is called the mass number A , and the number of protons is called the atomic number Z . The neutron number is denoted by N . An atom characterized by a specific number of protons, neutrons, and mass number is termed a *nuclide*. There exist about 3700 known nuclides of which nearly 288 nuclides are stable and the remainder (~3400) are unstable meaning they break down (decay) emitting radiations. These are called *radionuclides*, and the majority of them are artificially produced in a cyclotron or a reactor and decay to stable nuclides by emitting α particles, β particles, and/or γ radiations. β particles are basically electrons with a negative charge (negatron denoted by β^-) or with a positive charge (positron denoted by β^+). Common radionuclides used in nuclear medicine are given in Appendix A.

The nuclides having the same number of protons are called the *isotopes*, e.g. $^{11}_6\text{C}$ and $^{14}_6\text{C}$ with 6 protons; those with the same number of neutrons the *isotones*, e.g. $^{131}_{53}\text{I}$ and $^{132}_{54}\text{Xe}$, each having 78 neutrons; those with same mass number are called the *isobars*, e.g. $^{90}_{39}\text{Y}$ and $^{90}_{40}\text{Zr}$ each having A equal to 90; *Isomers* are the nuclides with the same mass number i.e. the same number of protons and neutrons, but with different energy states, e.g. $^{99m}_{43}\text{Tc}$ and $^{99}_{43}\text{Tc}$.

1.2 Radioactive Decay

As mentioned above, radionuclides are unstable and decay by emission of particulate radiations (α , β particles), electromagnetic radiations (γ , X-ray radiations), or spontaneous fission depending on the composition of the nucleus. A radionuclide can decay in one step or several successive steps until it reaches the stability. The ratio N/Z of a nuclide predicts the stability of a nuclide, and radioactive decay occurs to achieve stability of the nucleus by altering the proton or neutron number, i.e., the N/Z ratio of the nucleus. Radionuclides decay by several specific modes, which are discussed below.

1.2.1 Spontaneous Fission

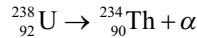
This occurs in only very heavy radionuclides such as ^{235}U , ^{239}Pu , etc., with extremely low probability. These heavy nuclei are dumbbell shaped with a narrow neck in the middle. During vibrational oscillation of the nucleus, spontaneous fission occurs, and the nuclide breaks up in the neck into two new nuclides of similar or dissimilar mass along with the emission of two or three neutrons. For example, the fission of ^{235}U may lead to ^{99}Mo and ^{134}Sn plus two neutrons, two ^{116}Pd nuclides plus three neutrons, etc.



Each fission is accompanied by release of about 200 MeV energy, which appears as heat. Nuclear reactors operate using this heat to run the turbine in electricity generator.

1.2.2 Alpha (α) Decay

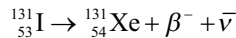
This mode of decay also occurs in heavy nuclides such as ^{235}U , ^{232}Th , ^{222}Rn , etc. with emission of an α particle, which is basically a helium atom stripped of two electrons from the outer shell (He^{2+}) of the atom. For example,



The α particles are monoenergetic carrying unique energy in the order of several MeV. The product ^{234}Th may again decay depending on its residual energy. Because of the heavy mass, the range of α particles in matter is very short, usually 0.03 mm in human tissue, and they cause relatively more radiation damage in human tissues. So α particles are useful for radiation treatment of various cancers.

1.2.3 Beta (β^-) Decay

Radionuclides having the N/Z ratio more than that of nearby stable nuclides (that is, more neutrons) decay by β^- emission. In this decay, a neutron in the nucleus is transformed into a proton decreasing the N/Z ratio. In the process, a particle called antineutrino $\bar{\nu}$ with negligible mass and no charge is emitted to balance the energy in the decay. For example,



Note that the β^- particle is an electron which arises from the conversion of a neutron to a proton in the nucleus. The difference between the rest mass of the parent radionuclide and the rest masses of the daughter nuclide plus β^- particle is called the *transition* or decay energy, E_{max} , which is shared between the β^- particle and antineutrino. From a cohort of radionuclides, β^- particles are emitted with a spectrum of energy, carrying a fraction of E_{max} to maximum E_{max} . The average energy of β^- particles in the spectrum is about one-third of E_{max} .

If the product nucleus still has enough energy after β^- particle emission, further emission of particles and/or γ rays can follow. So the decay of radionuclides is illustrated by decay schemes to illustrate these transitions. The decay scheme of ^{99}Mo is shown in Fig. 1.2.

1.2.4 Positron (β^+) Decay

When the N/Z of a radionuclide is relatively lower than that of the close stable nuclide, i.e., the radionuclide is proton-rich, it decays by emitting a β^+ particle to reach a stable nucleus, accompanied by a neutrino ν emission for energy conservation. In the process, a proton is converted to a neutron reducing the atomic number of the residual nuclide by 1. Since a neutron is heavier than a proton by an electron rest mass (0.511 MeV), this rest mass plus that of emitted β^+ particle equals to

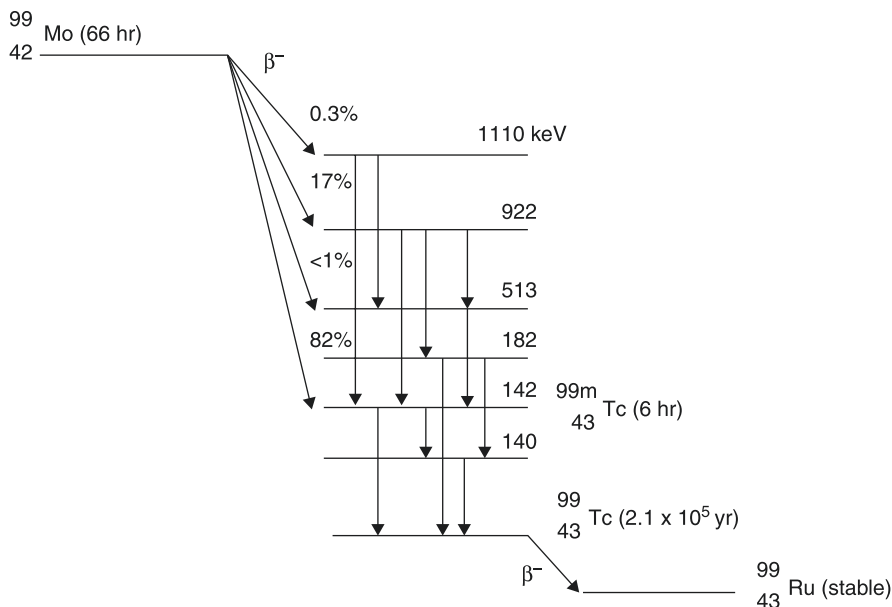
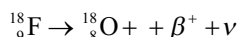


Fig. 1.2 Decay scheme of ^{99}Mo . Approximately 87% of the total ^{99}Mo decays to isomer $^{99\text{m}}\text{Tc}$ and 13% to the ground state ^{99}Tc . (Reprinted by permission from Springer Nature, *Physics and Radiobiology of Nuclear Medicine* by Saha GB, 2013)

1.022 MeV, which the parent radionuclide must have, as a minimum, as transition energy to decay by β^+ emission. The transition energy in excess of 1.022 MeV is shared by the β^+ and neutrino ν as kinetic energy, and like β^- particle, the β^+ particles also exhibit a spectrum of energy. An example is



When positrons travel through matter, they interact with atomic electrons and annihilate each other to produce two annihilation radiations of 0.511 MeV, which are emitted in opposite direction. Positron emission tomography is based on the detection of these two annihilation radiations in coincidence to form images of tissues or organs. The decay scheme of ^{68}Ga is illustrated in Fig. 1.3.

1.2.5 Electron Capture

When a radionuclide has relatively lower N/Z compared to nearby stable nuclides and also less than 1.022 MeV in transition energy, meaning that it is proton-rich, then it decays by electron capture (EC) by capturing an electron from the outer shell, normally K shell, along with emission of a neutrino. In the process, a proton is transformed into a neutron, thus reducing the atomic number Z by 1 in the

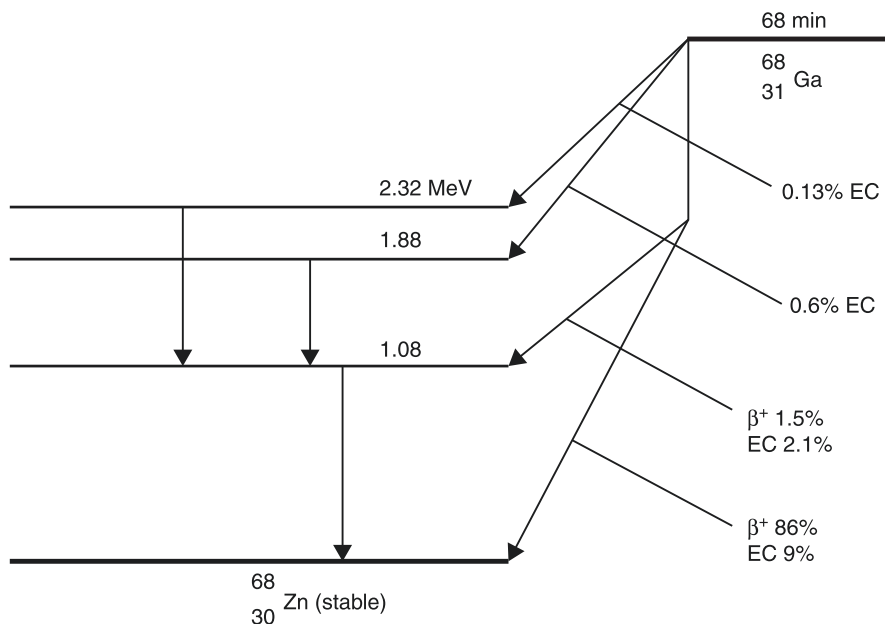


Fig. 1.3 Decay scheme of ^{68}Ga . Positrons interact with medium and are annihilated to produce two 511 keV photons. Electron capture is an alternative process to positron emission determined by the characteristics of the radionuclide. (Reprinted by permission from Springer Nature, *Physics and Radiobiology of Nuclear Medicine* by Saha GB, 2013)

residual nucleus. Note that electron capture can also occur in the nuclides having greater than 1.022 MeV transition energy, but the probability decreases with increasing energy. An example is

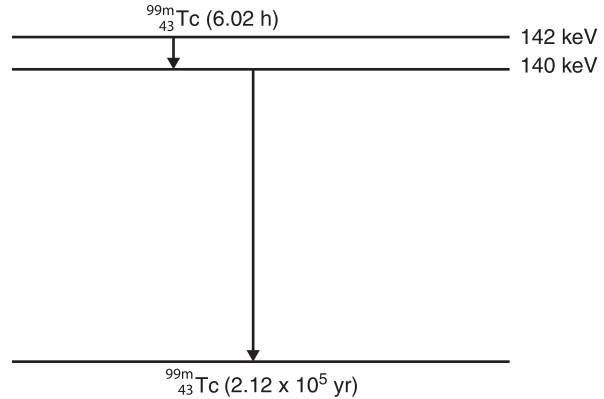


The vacancy created in the shell is filled in by the transition of an electron from the upper shell, and the difference in energy between the two shells appears as a characteristic K X-ray, in a situation similar to internal conversion of γ rays discussed below. ^{68}Ga decays 13% by electron capture, as shown in Fig. 1.3.

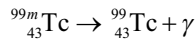
1.2.6 Isomeric Transition

Radionuclides can exist in different states of excitation energy, the majority of which are very short-lived (nanoseconds to femtoseconds) and some are long-lived (seconds to million years). These nuclides are called isomers. An isomer disposes of excitation energy by decaying from an upper excited state to a lower energy state of a nucleus with emission of a γ ray (electromagnetic radiation), and the process is called the isomeric transition. The mass number A, atomic number Z, and neutron

Fig. 1.4 Isomeric transition of ^{99m}Tc
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number N do not change in isomeric transition. When the half-life of an isomer is relatively long, it is called the metastable state and denoted by m . The decay of metastable ^{99m}Tc is given below and illustrated in Fig. 1.4.



As an alternative to γ ray emission, the γ ray energy can be transferred to an electron in the nearest K- or L- shell and eject it. The electron is called the conversion electron and carries the energy equal to $E_\gamma - E_b$, where E_γ and E_b are the energy of the γ ray and the binding energy of the electron in the shell, respectively. The vacancy in the K shell is filled by the transition of an electron from an upper shell (L-, M- shells, etc.), and the difference in energy between the two shells appears as the so-called characteristic K X-ray, L X-ray, etc. The process is called the internal conversion and is illustrated in Fig. 1.5. Probability of internal conversion increases with increasing atomic number of the medium and decreasing photon energy. Note that for a given number of isomeric transitions, some transitions will be by γ ray emission, and the remaining transitions will be by internal conversion. The ratio of internal conversions to γ ray emissions is called the conversion coefficient. For example, if 315 transitions of the total 838 isomeric transitions occur by internal conversion and the remaining 523 transitions by γ ray emission, then the conversion coefficient is $315/523 = 0.6$.

The characteristic X-rays from the internal conversion process behave like γ rays, and a K X-ray can transfer its energy to an electron in an upper shell and eject it, similar to internal conversion, if energetically possible. This process is called the Auger process, and the ejected electron is called the Auger electron. The fraction of characteristic X-rays that are not used in the Auger process is called the fluorescence yield, and the fraction that undergoes the Auger process is called the Auger yield. The Auger process increases with increasing atomic number of the medium.

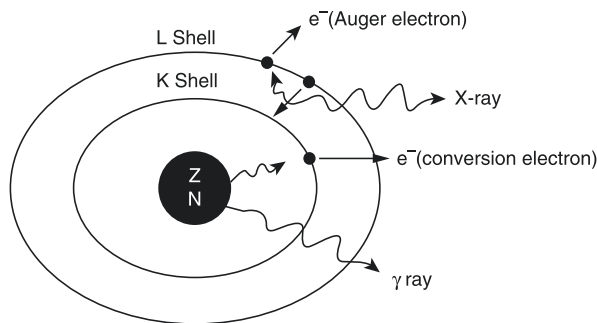


Fig. 1.5 Illustration of internal conversion process. The excitation energy E_γ of the nucleus is transferred to a K-shell electron, which is ejected with kinetic energy equal to $E_\gamma - E_B$, where E_B is the binding energy of the electron, and the K-shell vacancy is filled by an electron from the L shell. The energy difference between the L shell and K shell appears as the characteristic K X-ray. Alternatively, the characteristic K X-ray may transfer its energy to an L-shell electron, called the Auger electron, which is then ejected. (Reprinted by permission from Springer Nature, *Physics and Radiobiology of Nuclear Medicine* by Saha GB, 2013)

1.3 Radioactive Decay Equation

Radioactive decay is random in nature and is not affected by environmental conditions such as pressure, chemical composition, temperature, etc. So the time of decay of an individual radionuclide cannot be ascertained and we can only assess the average decay of a cohort of radionuclides. The rate of decay of a radionuclide in a sample is called *activity* A and is proportional to the number of atoms present in the sample

$$A = -\frac{dN}{dt} = \lambda N \quad (1.1)$$

where N is the number of radionuclides present in the sample and λ is the decay constant. On integration, Eq. (1.1) becomes for decay for time t ,

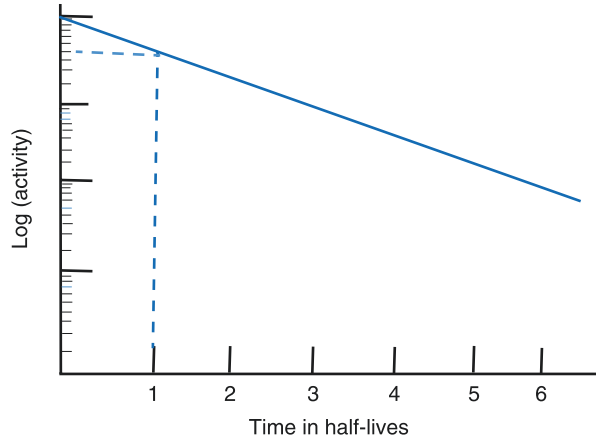
$$N_t = N_0 e^{-\lambda t} \quad (1.2)$$

where N_0 is the number of atoms at time $t = 0$ and N_t is the number of atoms at time t . Equation (1.2) is expressed in activity by multiplying the equation by λ on both sides

$$A_t = A_0 e^{-\lambda t} \quad (1.3)$$

Equation (1.2) shows that radionuclides decay exponentially. The semilogarithmic plot of radioactivity against time of decay is shown as a straight line in Fig. 1.6. The radioactive decay is characterized by a half-life, $t_{1/2}$, which is defined by the time a radionuclide decays to one half of the initial activity. It is related to the decay constant λ by

Fig. 1.6 Semilogarithmic plot of radioactivity versus time of decay



$$\lambda = \frac{0.693}{t_{1/2}} \quad (1.4)$$

The half-life of a radionuclide can be determined by plotting the measured activity on a log scale and the decay time on a linear scale. From the straight line plot, one chooses an activity at a time point and then half the chosen activity at its corresponding time. The difference between the two time values is the half-life of the radionuclide.

If the decay constant λ is known from Eq. (1.4) and the number of atoms in a sample is known, then the activity of the sample can be calculated by Eq. (1.1). The latter is calculated from the knowledge that one-gram atom of a nuclide contains 6.02×10^{23} nuclides (Avogadro number). Examples are: 99 g of ^{99m}Tc or 131 g of ^{131}I contains 6.02×10^{23} nuclides.

Problem 1.1

Calculate the disintegration rate in 2 g of ^{18}F whose half-life is 110 min.

Answer:

$$\text{Number } N \text{ of nuclides in 2 g of } ^{18}\text{F} = \frac{2}{18} \times 6.02 \times 10^{23} = 6.69 \times 10^{22}.$$

$$\text{Decay constant } \lambda = \frac{0.693}{110} \text{ min}^{-1} = 0.0063 \text{ min}^{-1}.$$

$$\begin{aligned} \text{Disintegration rate} &= \lambda N = 0.0063 \times 6.69 \times 10^{22} \\ &= 4.2 \times 10^{20} \text{ disintegrations per min (dpm)}. \end{aligned}$$

Another important parameter is the mean life τ , which represents the average life of a cohort of radionuclides. It is given by the reciprocal of decay constant λ ,

$$\tau = \frac{1}{\lambda} = \frac{t_{1/2}}{0.693} \quad (1.5)$$

In one mean life, the activity of a radionuclide is reduced to 37% of its initial value.

1.3.1 Successive Decay Equation

Equation (1.2) describes the decay of a radionuclide to a nuclide, which may be stable or radioactive. If the decay product nuclide is radioactive, it grows by the decay of the parent nuclide and also decays by itself, and hence the decay equations are different.

When a parent radionuclide p decays to a radioactive daughter nuclide d, which decays to another nuclide, i.e., $p \rightarrow d \rightarrow$, the equation for the growth of d is given by

$$-\frac{dN_d}{dt} = \lambda_p N_p - \lambda_d N_d \quad (1.6)$$

where $\lambda_p N_p$ is the growth rate and $\lambda_d N_d$ is the decay rate of the daughter nuclide d. On integration of Eq. (1.6), the net activity of the daughter at time t is

$$(A_d)_t = \lambda_d N_d = \frac{\lambda_d (Ap)^0}{\lambda_d - \lambda_p} (e^{-\lambda_p t} - e^{-\lambda_d t}) \quad (1.7)$$

1.3.1.1 Transient Equilibrium

When $(t_{1/2})_p$ is sufficiently longer than $(t_{1/2})_d$, that is, $\lambda_d > \lambda_p$, $e^{-\lambda_d t}$ is negligible relative to $e^{-\lambda_p t}$, and Eq. (1.7) becomes

$$(A_d)_t = \frac{\lambda_d (Ap)^0}{\lambda_d - \lambda_p} e^{-\lambda_p t} \\ = \frac{\lambda_d (Ap)^t}{\lambda_d - \lambda_p} \quad (1.8)$$

$$= \frac{(t_{1/2})_p (Ap)t}{(t_{1/2})_p - (t_{1/2})_d} \quad (1.9)$$

Equations (1.8) and (1.9) describe a relationship called the *transient equilibrium*. The activity of the daughter grows initially by the decay of the parent, and later as the daughter nuclide accumulates, it reaches a maximum. After that, the transient equilibrium is achieved, when the rates of growth and decay of the daughter become equal, and it appears to decay with the apparent half-life of the parent. As evident from Eq. (1.9), at

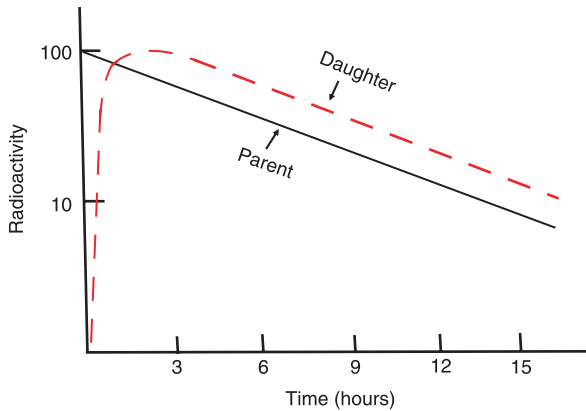


Fig. 1.7. Semilogarithmic plot of radioactivity of the parent and the daughter versus time of decay demonstrating the transient equilibrium. The activity of the daughter initially increases, reaches maximum, and then transient equilibrium sets in to decay with an apparent half-life of the parent. In equilibrium, the daughter grows and decays at the same rate, and the daughter activity is higher than that of the parent by a constant ratio

equilibrium, the activity of the daughter is always greater than that of the parent. A typical schematic illustration of transient equilibrium is shown in Fig. 1.7.

^{99}Mo - $^{99\text{m}}\text{Tc}$ generators are good examples of transient equilibrium (13%), in which 87% of ^{99}Mo ($t_{1/2} = 66$ h) decays to $^{99\text{m}}\text{Tc}$ ($t_{1/2} = 6$ h) and the rest to the ground state, ^{99}Tc . Equations (1.8) and (1.9) must be multiplied by 0.87 to calculate the amount of $^{99\text{m}}\text{Tc}$. So, the time activity curve for $^{99\text{m}}\text{Tc}$ will be lower than that of ^{99}Mo after equilibrium, and the maximum activity reaches in about 4 half-lives of $^{99\text{m}}\text{Tc}$.

1.3.1.2 Secular Equilibrium

When $\lambda_d \gg \lambda_p$, i.e., when the parent half-life is far greater than that of the daughter, the *secular equilibrium* is achieved. In Eq. (1.8), λ_p can be neglected relative to λ_d , and Eq. (1.7) can be written as

$$(A_d)_t = (A_p)_t \quad (1.10)$$

A good example of secular equilibrium is the ^{82}Sr - ^{82}Rb generator, in which ^{82}Sr ($t_{1/2} = 25$ days) decays to ^{82}Rb ($t_{1/2} = 75$ s).

1.4 Units of Radioactivity

The conventional unit of radioactivity is a curie defined as

$$\begin{aligned} 1 \text{ curie (Ci)} &= 3.7 \times 10^{10} \text{ disintegrations per second (dps)} \\ &= 2.22 \times 10^{12} \text{ disintegrations per minute (dpm)}. \end{aligned}$$

$$1 \text{ millicurie (mCi)} = 3.7 \times 10^7 \text{ dps} = 2.22 \times 10^9 \text{ dpm}$$

$$1 \text{ microcurie (\mu Ci)} = 3.7 \times 10^4 \text{ dps} = 2.22 \times 10^6 \text{ dpm}$$

In System International (SI), the unit of activity is a becquerel (Bq), which is given by 1 dps

$$1 \text{ becquerel (Bq)} = 1 \text{ dps} = 2.7 \times 10^{-11} \text{ Ci}$$

$$1 \text{ kilobecquerel (kBq)} = 1 \times 10^3 \text{ dps} = 2.7 \times 10^{-8} \text{ Ci}$$

$$1 \text{ megabecquerel (MBq)} = 1 \times 10^6 \text{ dps} = 2.7 \times 10^{-5} \text{ Ci}$$

$$1 \text{ gigabecquerel (GBq)} = 1 \times 10^9 \text{ dps} = 2.7 \times 10^{-2} \text{ Ci}$$

$$1 \text{ terabecquerel (TBq)} = 1 \times 10^{12} \text{ dps} = 2.7 \times 10 \text{ Ci}$$

Problem 1.2

A radionuclide has a half-life of 5 h. A sample of this radionuclide has 15 mCi at 10:00 am. What are the activities at 9:00 am and at 4 pm on the same day?

Answer:

Decay constant λ of the radionuclide = $0.693/5 = 0.1386 \text{ h}^{-1}$.

Time from 9:00 am to 10:00 am = 1 h

So activity at 9:00 am = $15 \times e^{1 \times 0.1386} = 17.23 \text{ mCi}$

Time from 10:00 am to 4:00 pm = 6 h

So activity at 4:00 pm = $15 \times e^{-6 \times 0.1386} = 6.53 \text{ mCi}$

Problem 1.3

A radioactive sample gives a total count of 53,000 for 10 min and an hour later, a total count of 23,000 for 5 min. What is the half-life of the radionuclide?

Answer:

The first count rate is $53,000/10 = 5300 \text{ cpm}$.

The second count rate is $23,000/5 = 4600 \text{ cpm}$.

$$\text{So, } 4600 = 5300 \times e^{-\frac{0.693 \times 1}{t_{1/2}}}$$

$$0.86792 = e^{-\frac{0.693 \times 1}{t_{1/2}}}$$

Taking logarithm,

$$0.14166 = 0.693 / t_{1/2}$$

$$t_{1/2} = 4.89 \text{ h}$$

1.5 Interaction of Radiations with Matter

As understood from above, radiations are either particulate type with mass (n) and/or charge (β^-) or electromagnetic radiations (γ) without mass, and so their modes of interaction with matter are different. Here the mechanisms of interaction of these radiations with medium are separately described below.

1.5.1 Interaction of Particulate Radiations

1.5.1.1 Ranges

Energetic charged particles, while passing through matter, interact with orbital electrons in the medium transferring their energy causing either excitation or ionization of the atoms. In excitation, the charged particle transfers all its energy to the electron and raises it to a higher excited state, whereas in ionization, the electron is ejected from the shell leaving an ionized atom. Charged particles may encounter several such interactions before it loses all its kinetic energy and come to a stop. The shortest distance between the origin and the end of the trajectory of the particle is called the *range* (Fig. 1.8). As seen in the figure, for a cohort of charged particles, there is a spread of ranges (3–4%) near the end of their path, which is termed the *straggling* of ranges. The energy lost by the incident particle appears as heat in the matter causing damage. The range of charged particles varies with their mass and charge. The heavier the mass, the shorter the range. Thus, β particles have longer range than protons (protons are almost 1800 times heavier than β particles) and α particles with two protons and two neutrons have the shortest range.

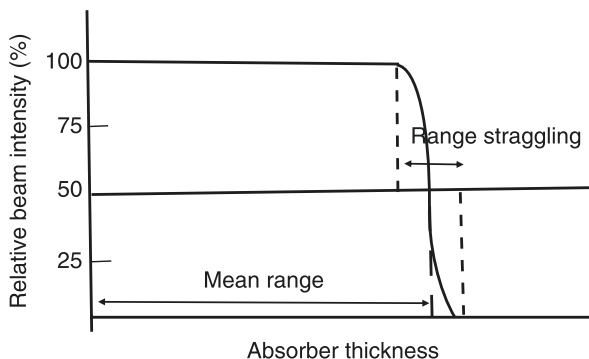
In air, the range R_a of an α particle with energy E is empirically given by.

$$R_a (\text{cm}) = 0.325 E^{3/2} \quad (1.11)$$

and in any other medium, it is given by the Bragg-Kleeman rule:

$$R_M = 3.2 \times 10^{-4} \frac{\sqrt{M}}{\rho} R_a \quad (1.12)$$

Fig. 1.8 Mean range and straggling of charged particles in a medium



where R_M is the range of the α particle in a medium of atomic mass M and density ρ . The α particles are most damaging to the matter due to their heavy mass and two positive charges.

An important parameter called *linear energy transfer* (LET) is defined by the loss of energy by the incident particle per unit length and usually expressed in keV/ μm . The heavier particles such as α particles have higher LET than the lighter particles like β particles. This parameter is useful in radiation protection and radiation biology.

The β^- particles also, like α particles, have range in medium, which is, however, much longer than that of α particles. It is empirically expressed for β^- energies $0.01 \leq E \leq 2.5$ MeV as

$$R = 412 E^{1.265 - 0.094 \ln E} \quad (1.13)$$

and for β energies >0.6 MeV (Feather's rule),

$$R = 542 E - 133 \quad (1.14)$$

1.5.1.2 Specific Ionization

Specific ionization (SI) is the number of ion pairs produced per unit length of the path traversed by an incident particulate radiation. The average energy required to produce an ion pair in an absorber is denoted by a work function, W , which somewhat varies with the type of absorber (about 34 keV for air). SI depends on the mass and energy of the radiation. So α particles have higher SI than β particles. A characteristic phenomenon of SI is *Braggs ionization* in which SI increases sharply toward the end of the travel of the particle. This phenomenon is more prominent with heavy charged particles and almost absent with electrons.

1.5.1.3 Annihilation Radiation

When positrons pass through matter, they interact with atomic electrons losing energy and ultimately come to almost rest. At that moment, the positron combines with an atomic electron and the pair annihilates to produce two 0.511 MeV photons equivalent to the masses of an electron and a positron. These photons are called the *annihilation radiations*, which are emitted in opposite direction (at 180°). Positron emission tomography (PET) imaging is based on the detection of these coincident annihilation radiations emitted from the organ in humans.

1.5.1.4 Bremsstrahlung

During the passage through matter, charged particles such as α and β^- particles are decelerated near the nuclei by Coulomb interaction with the nucleus and the loss in energy appears as electromagnetic radiation called the *bremsstrahlung*, which in German means "braking down radiation." The energy of bremsstrahlung radiation can vary from nearly zero (minimal interaction with nucleus) to the full energy of the incident particle (when the incident particle is completely stopped by the interaction). These radiations are useful in radiographic scanning.

Bremsstrahlung radiation increases with increasing energy of the particle and the atomic number of the medium (proportional to Z^2), but is inversely proportional to

the mass of the radiation because of the low penetrating probability of the heavy charged particles like α particles near the nucleus. The X-rays used in radiography and CT scanning mostly consist of bremsstrahlung produced by high energy electrons impinging on tungsten targets in the X-ray tube. Because of the bremsstrahlung production in high Z material, high energy β emitters are normally stored in containers of low Z material such as plastic. Bremsstrahlung radiations have been used in organ imaging in procedures in nuclear medicine.

1.5.2 Interaction of γ Radiations with Matter

γ rays and X-rays interact with matter by three mechanisms described below:

Photoelectric interaction: During the passage through matter, a γ ray may interact with an atomic electron transferring all its energy and the electron is ejected from the orbital, provided the photon energy exceeds the binding energy of the electron. The process is called the photoelectric process and the ejected electron is called the photoelectron. It generally occurs by interaction of the γ radiation with K-shell electrons. The photoelectron carries kinetic energy of $E_\gamma - E_B$ where E_γ is the γ ray energy and E_B is the binding energy of the electron in the shell (Fig. 1.9), and spends this energy in ionization and excitation of atoms of the medium through which it passes.

The probability of photoelectric effect increases with the atomic number Z of the medium and decreases with the energy of the γ ray, as roughly given by the formula Z^4/E_γ^3 . Thus it mostly occurs in high Z medium like lead and with low energy photons (less than 200 keV).

Compton scattering: In the Compton scattering, a γ ray, while passing through a medium, interacts with an electron of an outer orbital of an atom of the medium, and only a part of the photon energy is transferred to the electron, which is ejected

Fig. 1.9 The photoelectric effect in which a γ ray, while passing through an absorber, transfers all its energy to a K-shell electron, and the electron is ejected with energy $E_\gamma - E_B$, where E_γ and E_B are the γ ray energy and binding energy of the electron in the K shell, respectively. (Reprinted by permission from Springer Nature, *Physics and Radiobiology of Nuclear Medicine* by Saha GB, 2013)

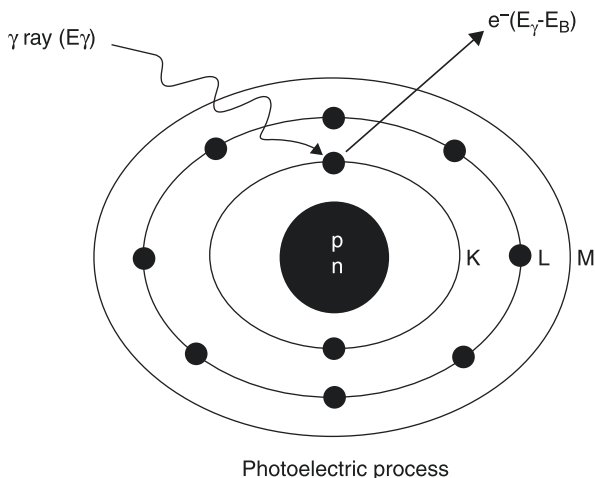
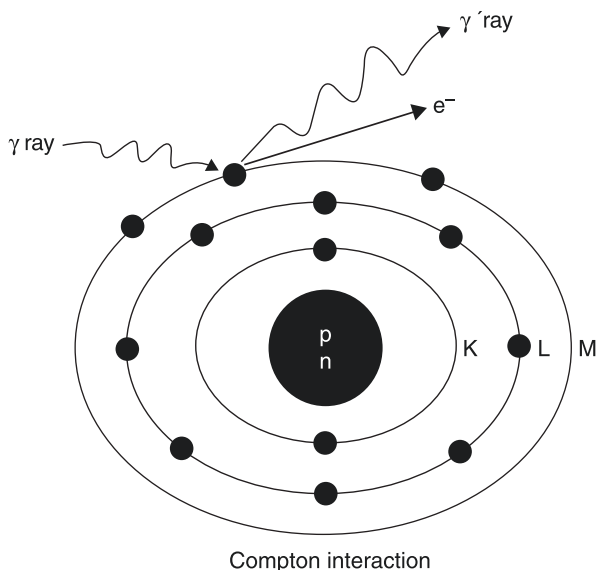


Fig. 1.10 The Compton scattering, in which a γ -ray, while passing through an absorber, interacts with an outer orbital electron of an absorber atom. Only a part of the photon energy is transferred to the electron which is ejected, and the photon itself is scattered at an angle. Depending on the energy, the scattered photon may undergo subsequent photoelectric effect, or Compton scattering in the absorber, or may escape the absorber. (Reprinted by permission from Springer Nature, *Physics and Radiobiology of Nuclear Medicine* by Saha GB, 2013)



(Fig. 1.10). The scattered photon with reduced energy may undergo another photoelectric or Compton interaction or may exit out of the medium without further interaction. At low energies, if the scattered photon and the Compton electron are scattered at an angle θ , it can be shown from conservation of momentum and energy that

$$E_{sc} = E_{\gamma} / \left[1 + \left(E_{\gamma} / 0.511 \right) (1 - \cos \theta) \right] \quad (1.15)$$

where E_{γ} and E_{sc} are the energies of the initial and scattered photons. The photon will transfer minimum energy to the electron at $\theta = 0$, whereas the maximum transfer will occur at $\theta = 180^{\circ}$. The latter situation is called the backscattering of photons. This process decreases slowly with energy of the radiation and increases with the atomic number Z of the medium and predominantly occurs in the energy range of 0.1–10 MeV. However, these changes are so miniscule that practically the probability of Compton scattering is considered independent of Z and E .

Pair production: When the photon energy is greater than 1.022 MeV, it can interact with the nucleus producing a positron and an electron utilizing 1.022 MeV and sharing the remaining energy as kinetic energy between them. Note that even if the remaining energy is more than 1.022 MeV after pair production, another pair production cannot occur, because the remaining energy is carried by the two particles as kinetic energy, which is not photon energy. This means that pair production occurs only once for a photon regardless of the energy of the photon. The probability increases with photon energy E_{γ} and the atomic number Z^2 of the atom. As discussed above, the positron may again annihilate in the medium producing two 0.511 MeV photons (Fig. 1.11).

Photodisintegration: This process occurs between a very high energy photon and an atomic nucleus, in which the protons, neutrons, and even α particles are

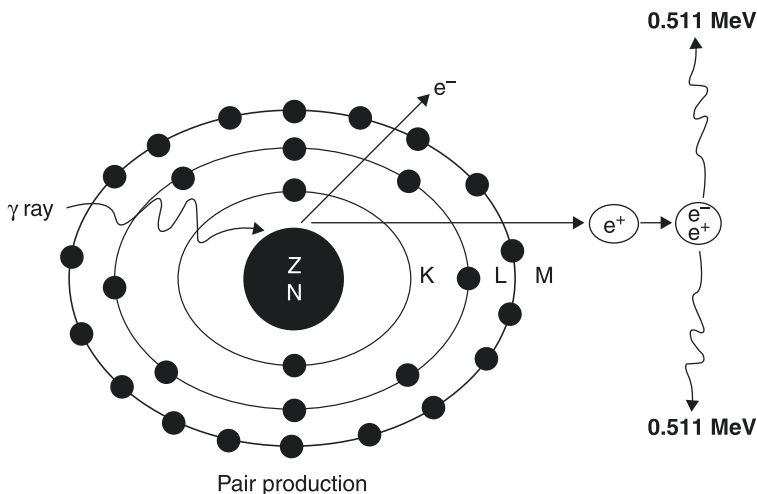


Fig. 1.11 Illustration of the pair production process. An energetic γ -ray with energy greater than 1.02 MeV interacts with the nucleus, and one positive electron (e^+) and one negative electron (e^-) are produced at the expense of the photon. The photon energy in excess of 1.02 MeV appears as the kinetic energy of the two particles. The positive electron eventually undergoes annihilation to produce two 511-keV photons emitted in opposite directions (Reprinted by permission from Springer Nature, *Physics and Radiobiology of Nuclear Medicine* by Saha GB, 2013)

emitted. This interaction is utilized to produce new radionuclides, but is of little importance in nuclear medicine.

1.5.3 Attenuation of γ Radiation

When an X-ray or γ ray photon passes through an absorber, it may pass through without any interaction with the absorber or undergoes one or more of the processes—photoelectric interaction, Compton interaction, and at high energy, pair production (Fig. 1.12). When we consider a beam of γ rays, some will pass through without any interaction with the absorber, while others will interact with the absorber. Photons undergoing photoelectric interaction and those undergoing Compton scattering are not counted in attenuation, because the energy of the former is completely absorbed and that of the latter is partially absorbed. The attenuation of a photon beam is defined by the fraction of the beam that passes through the absorber without interaction. As a result, the attenuated photon beam possesses the same energy as the incident beam, but contains a reduced number of photons. The attenuated beam intensity I_x is then given by

$$I_x = I_0 e^{-\mu x} \quad (1.16)$$

where I_0 is the incident beam intensity, x is the thickness of the absorber in centimeter (cm), and μ is the linear attenuation coefficient given in cm^{-1} . This coefficient is the sum of the coefficients of photoelectric interaction (τ), Compton scattering (σ), and pair production (κ) (Fig. 1.13) and is given by

Fig. 1.12 Illustration of attenuation of a photon beam (I_0) while passing through an absorber of thickness x . Photons passing through without any interaction in the absorber is the attenuated beam, I_x . I_x is given by $I_x = I_0 e^{-\mu x}$, where μ is the linear attenuation coefficient

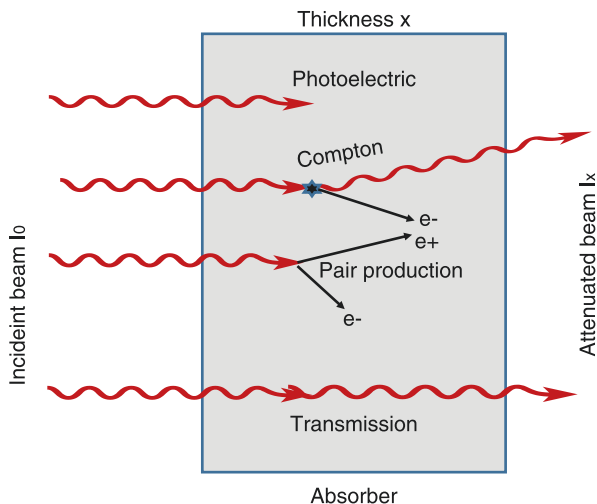
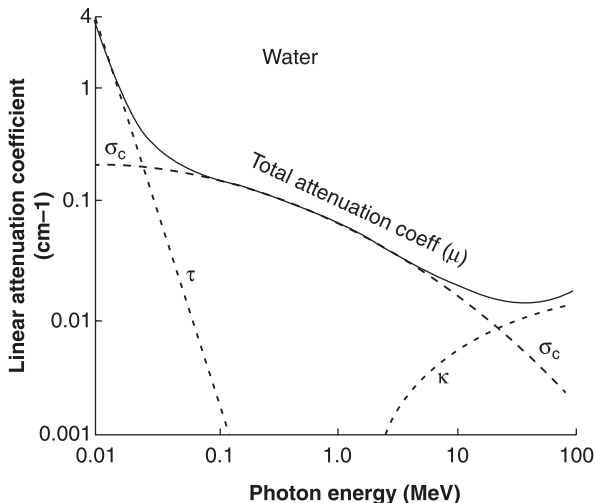


Fig. 1.13 Plot of linear attenuation coefficient of γ -ray interaction in water (equivalent to body tissue) as a function of photon energy. The relative contributions of photoelectric, Compton, and pair production processes are illustrated (Reprinted by permission from Springer Nature, *Physics and Radiobiology of Nuclear Medicine* by Saha GB, 2013)



$$\mu = \tau + \sigma + \kappa \tag{1.17}$$

μ is related to the energy of the photon beam and the density of the absorber. It is an important parameter in radiation protection and normally decreases with energy of the γ radiation and increases with atomic number and density of the absorber. Since linear attenuation coefficient depends on the absorber density, it is customary to use the mass attenuation coefficient μ_m in many situations, which removes density dependence. For example, it is the same for water whether present in liquid or vapor form. The mass attenuation coefficient is given by

$$\mu_m = \frac{\mu}{\rho} \tag{1.18}$$

where ρ is the density of the absorber. Its unit comes out to be

$$\frac{\text{cm}^{-1}}{\text{g/cm}^3} = \frac{\text{cm}^2}{\text{g}}$$

The values of μ_m are available in literature. Linear attenuation coefficients are obtained by multiplying μ_m with the density ρ of the absorber, which are then used in Eq. (1.16).

Half-value layer: It is defined by the thickness of the absorber which reduces the intensity of an incident photon beam to half following its passage through the absorber. The half-value layer (HVL) is related to the linear attenuation coefficient by

$$\text{HVL} = \frac{0.693}{\mu} \quad (1.19)$$

The HVL depends on the energy of a photon beam and the density of the medium. It increases with γ ray energy and decreases with increasing density of the medium. The knowledge of HVL is useful in the calculation of shielding in the design of radiation areas (see Chap. 4).

Another quantity, *tenth value layer (TVL)*, is defined as the thickness of an absorber that reduces the beam intensity to one-tenth of the initial value and is given by

$$\begin{aligned} \text{TVL} &= -\frac{\ln(0.1)}{\mu} \\ &= \frac{2.3}{\mu} \\ &= 3.32 \text{ HVL} \end{aligned} \quad (1.20)$$

The values of HVLs and TVLs of some useful radionuclides are listed in Table 1.1.

Table 1.1 Half-value layers HVLs and tenth value layers TVLs of lead, concrete, and water or tissue for commonly used radionuclides in nuclear medicine

Radionuclides	HVL, lead (cm) ^a	HVL, concrete (cm)	HVL, water or tissue (cm)	TVL, lead (cm) ^a
¹³⁷ Cs	0.72	4.8		2.18
¹⁸ F	0.50			1.51
¹³¹ I	0.27	2.93	6.3	0.99
¹²³ I	0.007			0.11
^{99m} Tc	0.023		4.6	0.091
¹¹¹ In	0.026			0.20
⁶⁷ Ga	0.086			0.48
⁵⁷ Co	0.03	6.6		0.085
⁶⁰ Co	1.56			4.53
²⁰¹ Tl	0.026		3.7	0.089
⁹⁹ Mo	0.058			2.34
¹⁷⁷ Lu	0.054			0.211

^aAdapted with permission from DS Smith and MG Stabin. Exposure rate constants and lead shielding values for over 1100 radionuclides. Health Physics. 102(3): 271–291; 2012.

Problem 1.4

What is the thickness of lead that would reduce the exposure from an ^{18}F -FDG sample by 70%, given the half-value layer value (HVL) as 0.5 cm^{-1} ?

Answer:

The linear attenuation coefficient $\mu = 0.693/0.5 = 1.386\text{ cm}^{-1}$

Reduction by 70% means the exit exposure is 30%, i.e., 0.3

Thus, $0.3 = 1 \times e^{-1.386 \times X}$

$$1.204 = 1.386 \times X$$

$$X = 0.87\text{ cm.}$$

1.5.4 Linear Energy Transfer

The linear energy transfer (LET) is the energy deposited per unit length traversed by a radiation. It is given for a given radiation by

$$\text{LET} = \text{SI} \times W$$

where SI is the specific ionization and W is the average energy required for creating an ion pair. LET is low for β particles and γ radiations because of their relatively low mass, whereas α particles, neutrons, etc. have high LET, producing many ionizations and hence depositing more energy in a short distance. The LET is expressed in $\text{keV}/\mu\text{m}$ and is an important factor in radiation biology. Typical LET values of some radiations are given in Table 1.2.

Table 1.2 LET values of several radiations in human tissues

Radiation	LET (keV/ μm)
1 MeV electron	0.25
250 KV X-ray	3.0
14 MeV neutron	20.0
5 MeV α particle	100.0

1.6 Counting Statistics

Radioactive decay is a random process and one cannot ascertain when a radionuclide will decay. When a radioactive sample is counted, what we observe as counts from the decay is an aggregate of the decay events for a certain period of time such as counts per second (cps) or counts per minute (cpm). In 1 s or in 1 min, all counts did not arrive at the counter in equal spaces of time. An indication of randomness of radioactive decay can be realized by the fact that two counts of the sample taken for the same period are likely to be different. This decay is typified by the number of radioactive atoms present and a probability factor that is characterized by their physical properties. In general, binomial distribution describes these types of random events. Two special cases of binomial distributions are Poisson distribution and Gaussian distribution, which are briefly described below.

1.6.1 Poisson Distribution

For the measurement of a small number of events, the probability distribution for detecting a specific number of events is given by a Poisson distribution and mathematically, it is expressed as

$$P(x) = \frac{n^x}{x!} e^{-n} \quad (1.21)$$

where $P(x)$ is the probability that x events will be detected in a time interval and n is the average number of events observed from many measurements. Equation (1.21) is a distribution function characterizing events with very low probabilities of occurrence within some definite time or space. Also n is equal to $P \times x$. The Poisson distribution applies to distinct and independent events only occurring at a constant rate. It is not symmetrical and skewed in shape. In nuclear medicine, a variety of processes are defined by Poisson distribution, namely radioactive decay, production of scintillation photons, production of pulses in the photomultiplier tube, etc.

Problem 1.5

Amazon sells an average of 3 computers per day. What is the probability of selling exactly 4 computers the next day?

Answer:

$$n = 3$$

$$x = 4$$

$$e = 2.718$$

$$P(4) = \frac{(2.718)^{-3} \times 3^4}{4!}$$

$$= 0.168$$

Thus, the probability of selling 4 computers next day is 0.168.

1.6.2 Mean and Standard Deviation

The mean or average value \bar{n} of a number of measurements of an item, in our case radioactive decay rates, is obtained by adding the values of all measurements and dividing the sum by the number of measurements. Thus,

$$\bar{n} = \sum n_i / N$$

where n_i is the value of individual measurements and N is the total number of measurements. Since radioactive decay rates are random, some measurements will be lower than \bar{n} and some will be higher than \bar{n} . This deviation from the mean value is called the *standard deviation*, denoted by σ . The standard deviation σ is given by

$$\sigma = \sqrt{\frac{\sum_i (n_i - \bar{n})^2}{N - 1}} \quad (1.22)$$

We can express the mean value of a series of measurements as

$$\bar{n} \pm \sigma$$

1.6.3 Error, Precision, and Accuracy

Errors are likely to occur in the measurement of a quantity and are two types: *random error* and *systematic error*. Random errors are variable errors and arise from experimental conditions such as fluctuations in high voltage supply or statistical fluctuations of radioactive decay. On the other hand, systematic errors are constant errors caused by malfunction of the equipment, wrong setting of the instrument, etc. While the random errors are difficult to eliminate, the systematic errors can be corrected by appropriate repair of the equipment or adopting appropriate experimental conditions.

The *accuracy* of a measurement of a quantity indicates how closely it agrees with the true value of the quantity. The *precision* of a series of measurements defines the reproducibility of the measurements showing closeness of the values to the mean or average value. The closer a measurement is to the mean value, the more precise is the measurement. A measurement is more accurate, if it is closer to the true value. Note that a series of measurements may be quite precise, but they are far from the true value and so are inaccurate.

The standard deviation σ of a series of measurements of a quantity is actually a measure of precision and signifies the spread of deviation of measurements from the mean.

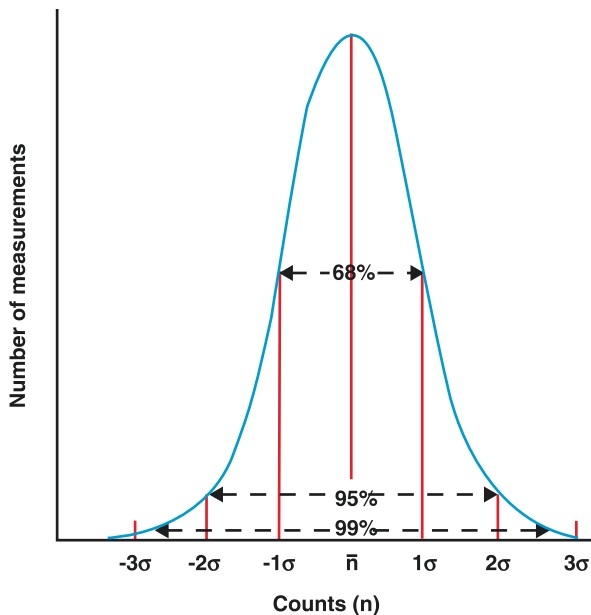
1.6.4 Gaussian Distribution

As mentioned above, the distribution of \bar{n} counts from series of measurements (n) of a radioactive sample with a mean value \bar{n} is normally governed by a skewed Poisson distribution. However, if the number of measurements is large, the distribution becomes symmetrical around the mean value and is termed the Gaussian distribution. It is graphically illustrated as a bell-shaped curve in Fig. 1.14. It shows that 50% of the measurements are below \bar{n} and the other 50% above \bar{n} . This curve is characterized by two parameters, mean and standard deviation. The general formula for Gaussian function is

$$P(x) = \frac{1}{\sigma\sqrt{2\pi}} \frac{e^{-(n-\bar{n})^2}}{2\sigma^2} \quad (1.23)$$

where $P(x)$ is the probability of having a value x in a distribution characterized by a mean value of \bar{n} and a standard deviation σ . From the Gaussian curve, it can be seen that 68% of all measurements fall within one standard deviation of the mean, that is, within the range $\bar{n} \pm \sigma$. This is called 68% confidence level. In other words, one is 68% confident that a count n lies within one standard deviation on either side of the mean. Similarly, at 95% confidence level, 95% of all measurements fall within the range $\bar{n} \pm 2\sigma$, and at 99% confidence level, 99% of all measurements fall within $\bar{n} \pm 3\sigma$.

Fig. 1.14 Gaussian distribution of radioactive measurements. Note the 68% confidence level at $\pm 1\sigma$, 95% confidence level at $\pm 2\sigma$, and 99% confidence level at $\pm 3\sigma$ (Reprinted by permission from Springer Nature, *Physics and Radiobiology of Nuclear Medicine* by Saha GB, 2013)



If a measured count n is large, it can be approximated to be close to the mean value \bar{n} ; that is, $n = \bar{n}$ and $\sigma = \sqrt{n}$. Although this assumption is simplified, it is realistic. A useful quantity is the percent standard deviation of a count given by

$$\% \sigma = \frac{\sigma}{n} \times 100 = 100 \frac{\sqrt{n}}{n} = \frac{100}{\sqrt{n}} \quad (1.24)$$

Equation (1.24) indicates that with increasing counts, the $\% \sigma$ decreases and hence precision increases. For example, for a count of 10,000 counts, $\% \sigma$ is 1%, whereas for 1,000,000, $\% \sigma$ is 0.1%.

Problem 1.6

A radioactive sample is counted in a well counter for 4 min and gives 120,000 counts. What is the standard deviation and $\%$ standard deviation of this count?

Answer:

$$\text{Standard deviation } \sigma = \sqrt{n} = \sqrt{120000} \sim 346$$

$$\% \sigma = \frac{100}{346} = 0.29\%$$

Problem 1.7

How many counts need to be collected for a radioactive sample to have a 3% error at 95% confidence level?

Answer:

95% confidence level is 2σ , that is, $2\sqrt{n}$.

$$3\% = \frac{2\sigma \times 100}{n} = \frac{2\sqrt{n}}{n} \times 100$$

$$3 = \frac{200}{\sqrt{n}}$$

$$n = \left(\frac{200}{3} \right)^2 \\ = 4444$$

1.6.5 Standard Deviation of Count Rate

The standard deviation of a count rate is given by

$$\sigma_c = \frac{\sigma}{t}$$

where σ is the standard deviation of the total count n obtained in time t . Since the total count n is the product of count rate and counting time,

$$n = ct$$

$$\text{Then, } \sigma_c = \frac{\sqrt{n}}{t} = \frac{\sqrt{ct}}{t} = \sqrt{\frac{c}{t}} \quad (1.25)$$

Problem 1.8

A radioactive sample was counted for 5 min and gave 21,000 total counts. What is the standard deviation of the count rate of the sample?

Answer:

Count rate of the sample = $21,000 / 5 = 4200$ counts per min

$$\text{Standard deviation of the count rate} = \sqrt{\frac{4200}{5}} = 14.5$$

1.6.6 Propagation of Errors

There are situations when two quantities, say x and y , having the standard deviations, σ_x and σ_y , are added, subtracted, multiplied, and divided. The standard deviations of the products of these arithmetic operations are given by the following expressions:

$$\text{Addition } \sigma_{x+y} = \sqrt{\sigma_x^2 + \sigma_y^2} \quad (1.26)$$

$$\text{Subtraction } \sigma_{x-y} = \sqrt{\sigma_x^2 + \sigma_y^2} \quad (1.27)$$

$$\text{Multiplication } \sigma_{x \times y} = (x \times y) \sqrt{\left(\frac{\sigma_x}{x}\right)^2 + \left(\frac{\sigma_y}{y}\right)^2} \quad (1.28)$$

$$\text{Division } \sigma_{x/y} = (x/y) \sqrt{\left(\frac{\sigma_x}{x}\right)^2 + \left(\frac{\sigma_y}{y}\right)^2} \quad (1.29)$$

Problem 1.9

A radioactive sample is counted for 8 min and 14,500 counts are obtained and the background for the same period is found to be 6500 counts. What is the net count rate and its standard deviation?

Answer:

Count rate of the sample = $14,500 / 8 = 1813$ cpm

$$\text{Background count rate} = 6500 / 8 = 813 \text{ cpm}$$

$$\text{Net count rate of the sample} = 1813 - 813 = 1000 \text{ cpm}$$

$$\begin{aligned} \text{Standard deviation of the count rate} &= \sqrt{(1813/8)^2 + (813/8)^2} \\ &= \sqrt{(51359 + 10328)} \sim 248 \text{ cpm} \end{aligned}$$

Problem 1.10

In determining the thyroid uptake measurement of a patient after administration of ^{131}I -NaI capsule, two-min counts for different parameters are obtained as follows:

$$\text{NaI capsule counts} = 98,500$$

$$\text{Thyroid counts} = 63,000$$

$$\text{Thigh counts} = 1200$$

$$\text{Room background counts} = 650$$

Calculate the thyroid uptake (%) and its percent standard deviation.

Answer:

$$\text{Corrected standard count } (C_s) = 98,500 - 650 = 97,850$$

$$\text{Standard deviation of } C_s (\sigma_s) = \sqrt{98500 + 650} = 314$$

$$\text{Net thyroid count } (C_t) = 63,000 - 1200 = 61,800$$

$$\text{Standard deviation of } C_t = \sqrt{63000 + 1200} = 253$$

$$\% \text{thyroid uptake } (U) = (61,800 / 97850) \times 100 \sim 63\%$$

$$\text{Standard deviation of thyroid uptake } (\sigma_u) = \frac{61800}{97850} \sqrt{\left(\frac{314}{97850}\right)^2 + \left(\frac{253}{61800}\right)^2}$$

$$= 0.6316 \times \sqrt{0.0000103 + 0.00001676}$$

$$= 0.6316 \times 0.005202$$

$$\sim 0.00329$$

$$\% \text{standard deviation of thyroid uptake} = \frac{0.00329}{0.63} \times 100 = 0.52\%$$

Thus thyroid uptake is given as $63 \pm 0.52\%$

1.6.7 Minimum Detectable Activity

Because of the inherent activity present in the environment, one can get a background count even without a sample present in the counter. Also, the background count is not a constant value and varies from count to count. If someone counts a high activity sample, the background count, even though variable, may not be significant to affect the high count of the sample. On the other hand, in practical life we often deal with low activity samples and the variable background count is a concern. This leads to the question as to what the minimum detectable activity (MDA) is that can be differentiated from the background. It is empirically given by three times the standard deviation of the background count rate. Mathematically,

$$\text{MDA} = 3\sigma_R = 3\sqrt{R_b / t} \quad (1.30)$$

where σ_R is the standard deviation of the background count rate R_b obtained over time t .

Questions

- Neutrons and protons weigh
 - as much as 10 neutrinos
 - approximately 1800 times the weight of an electron
 - more than an alpha particle
 - less than a positron
- Match the following symbols:
 - Z mass number
 - N atomic number
 - A isomer
 - m neutron number
- The difference between the mass of a nucleus and the combined mass A of all nucleons is called _____ and is utilized as _____.
- Helium ion nucleus is composed of
 - one proton and one neutron
 - one proton and two neutrinos
 - two protons and two neutrons
 - two protons and an electron
- The stability of a nucleus is roughly determined by the neutron/proton (N/Z) ratio. True _____; False _____.
- After 20 days decay of 100 MBq, which of the following can be disposed of, without special processing?
 - ^{57}Co
 - ^{201}Tl
 - $^{99\text{m}}\text{Tc}$
 - ^{67}Ga

7. In a β^- decay
 - (a) A neutrino and a γ -ray are emitted _____ True, or _____ False.
 - (b) A neutron is converted to a proton _____ True, or _____ False.
 - (c) An α -particle and a neutron are emitted _____ True, or _____ False.
 - (d) No radiation is emitted _____ True, or _____ False.
8. In a β^+ – decay, which of the following are true:
 - (a) A neutrino is emitted, _____ True, or False _____.
 - (b) The mass number of the nucleus remains the same, _____ True, or _____ False.
 - (c) The nucleus must have a minimum of 1.02 MeV for β^+ – decay, -----True, or ___ False.
 - (d) The atomic number of the nucleus remains the same, -----True, or _____ False.
9. The atomic number decreases in the following processes:
 - (a) β^- -decay
 - (b) β^+ – decay
 - (c) α –decay
 - (d) isomeric decay
 - (e) electron capture
10. In the process of internal conversion:
 - (a) the nuclear charge is changed
 - (b) a gamma ray is emitted
 - (c) an electron is captured by the nucleus
 - (d) an electron is ejected
11. Define Becquerel and Curie.
12. In β^- -decay, the average energy of the β^- particle is 1/3 of the maximum transition energy. What happens to the rest of the energy?
13. The weight of ^{99m}Tc ($t_{1/2} = 6$ h) in a sample is 10 μg . Calculate the disintegration rate of the sample.
14. A radioactive sample gives a count of 36,000 for 7 min and 19,000 for 10 min. Calculate the half-life of the sample.
15. A sample of a radionuclide with a half-life of 3 days has 50 mCi on a given day. What would be the activity 10 days later?
16. A sample contains 30 mCi of ^{123}I ($t_{1/2} = 13.2$ h) and 15 mCi of ^{67}Ga ($t_{1/2} = 78$ h). What time later, will their activities be the same?
17. After 1 month of decay of 100 MBq of a radioactive sample, which of the following can be disposed of without special processing?
 - (a) ^{57}Co
 - (b) ^{201}Tl
 - (c) ^{99m}Tc
 - (d) ^{67}Ga
18. Transient equilibrium occurs between two radionuclides when
 - (a) the half-lives of two radionuclides are equal
 - (b) one half-life is greater than the other
 - (c) one half-life is much greater than the other
 - (d) radionuclide A is red-colored and radionuclide B is blue-colored

19. If an atom has too many neutrons, how does it decay?
 - (a) α decay
 - (b) β^+ decay
 - (c) β^- decay
 - (d) electron capture
20. If N atoms decay in one half-life, how many atoms would decay in next half-life?
21. In a ^{99}Mo - $^{99\text{m}}\text{Tc}$ generator, 150 mCi of ^{99}Mo is loaded on the generator column. When do you expect the maximum $^{99\text{m}}\text{Tc}$ activity on the column?
 - (a) 6 h
 - (b) 1 day
 - (c) 2 days
 - (d) in few minutes
22. Standard deviation of a measurement indicates
 - (a) accuracy
 - (b) skewness of data
 - (c) precision
 - (d) mean
23. Linear energy transfer (LET) of a radiation in a medium is defined by
 - (a) energy transferred per mean free path
 - (b) loss of energy by radiation per unit length of medium traveled
 - (c) particle energy transferred to the nucleus
 - (d) particle energy transferred to the electron
24. In isomeric decay, which of the following are true:
 - (a) a γ -ray may be emitted
 - (b) a β^- particle is emitted
 - (c) a conversion electron may be emitted
 - (d) no radiation is emitted
25. In one mean life, the activity of a radionuclide is reduced to
 - (a) 50%
 - (b) 75%
 - (c) 10%
 - (d) 37%
26. In photoelectric interaction of a γ ray in medium, which of the following is true:
 - (a) a photoelectron is emitted
 - (b) a positron is emitted
 - (c) a neutrino is emitted
 - (d) a photon is emitted
27. In Compton interaction of a γ ray in a medium, which of the following is true:
 - (a) no radiation is emitted
 - (b) a photon with reduced energy is emitted
 - (c) a positron may be emitted
 - (d) an α particle is emitted

28. Attenuation of a 2.5 MeV γ ray in a medium may result from
 - (a) photoelectric interaction only
 - (b) Compton interaction only
 - (c) photodisintegration only
 - (d) combination of A, B, and C
29. Which of the following are true for the half-value layer of a medium for γ rays.
 - (a) 45% of the γ ray energy is reduced in one half-value layer
 - (b) HVL depends on the energy of the γ ray
 - (c) HVL depends on the density of the medium
 - (d) HVL is used in the calculation of shielding in radiation protection
30. The half-life of a radionuclide is:
 - (a) influenced by temperature and pressure
 - (b) related to the decay constant
 - (c) less than the mean life
 - (d) unique and unalterable for a particular radionuclide
31. If you obtain 100 counts in 1 min, what is 95% confidence interval?
 - (a) 90–110
 - (b) 70–130
 - (c) 80–120
 - (d) 95–105
32. Approximately how many HVLs are in 4 TVLs? (TVL—tenth value layer)

References and Suggested Reading

- Cherry SR, Sorensen, Phelps PME. Physics in nuclear medicine. 4th ed. Philadelphia: Elsevier; 2012.
- Saha GB. Physics and radiobiology of nuclear medicine. 4th ed. New York: Springer; 2013.
- Smith DS, Stabin MG. Exposure rate constants and lead shielding values for over 1100 radionuclides. Health Phys. 2012;102(3):271–91.



Various instruments are used in radiation safety for the purpose of detecting the presence of radiation sources and quantitative measurement of radiation exposure from the radioactive sources. These instruments are of three types: gas-filled detectors, liquid scintillation detectors, and solid scintillation detectors. Each type is described in detail below.

2.1 Gas-Filled Detector

Gas-filled detectors are based on the ionization caused by interaction of radiations with gas molecules contained in the detectors. When a radiation passes through the gas in a detector, the gas molecules are ionized by radiation producing a positive ion and an electron. If a voltage is applied to the detector, the positive ions move to the cathode and the electrons to the anode, and a current is registered on a meter, which depends on the magnitude of voltage applied (Fig. 2.1).

The dependence of the current on applied voltage is illustrated in Fig. 2.2. The figure is segmented in six regions. Region A is called the *region of recombination* indicating the too low energy of the ion pair to migrate to the electrodes, so they recombine to form the original molecule. In Region B, called the *region of saturation*, the ionization is independent of the applied voltage but depends on the type of radiations (α , β^- , γ radiations). Ionization chambers and dose calibrators are operated in this region at 50–300 V. When the applied voltage is further increased beyond 300 V, the current increases in proportion to the type of radiation as shown in Region C, which is called the *proportional region*. At this stage, the high energy positive ion and electrons produce secondary electrons upon striking the electrodes, which generate excessive ionization causing gas amplification by as much as 10^6 . Beyond Region C comes the region of limited proportionality (Region D) where the current tends to converge for all radiations with increasing voltage and this region has no practical utility in radiation safety.

Fig. 2.1 Principle of operation of a gas-filled counter (reprinted by permission from Springer Nature, physics, and radiobiology of nuclear medicine by Saha GB, 2013)

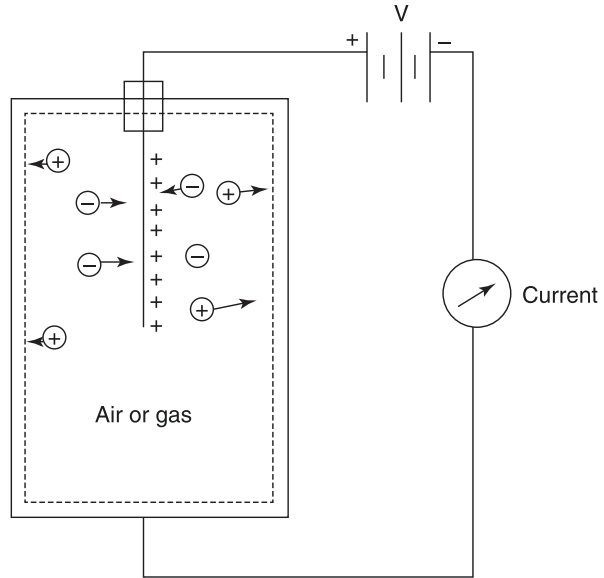
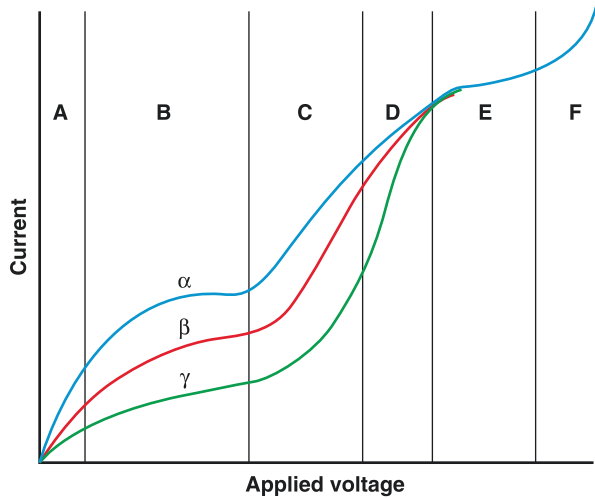


Fig. 2.2 Composite curve illustrating the output in a gas-filled counter as a function of applied voltage for different radiations. (A) Region of recombination, (B) region of saturation, (C) proportional region, (D) region of limited proportionality, (E) Geiger region, and (F) continuous discharge. (Reprinted by permission from Springer Nature, *Physics and Radiobiology of Nuclear Medicine* by Saha GB, 2013)



In Region E, as the applied voltage is increased further, the current does not change much with voltage and approaches a plateau. The initial radiation causes ionization of the fill gas either by direct ionization or by secondary electrons emitted from the wall as a result of the interaction of the radiation with the metallic wall causing very high gas amplification at higher voltage resulting in an avalanche. A pulse generated in this region is independent of the type and energy of the radiation. The Geiger-Muller (G-M) counter is operated in this region and discussed below in detail.

Further on, an increase in voltage results in repetitive discharges that cause the detector totally insensitive (Region F). This region is called the *region of continuous discharge*, and the counter should not be used in this region because of the possibility of the damage.

2.1.1 Ionization Chamber Survey Meter

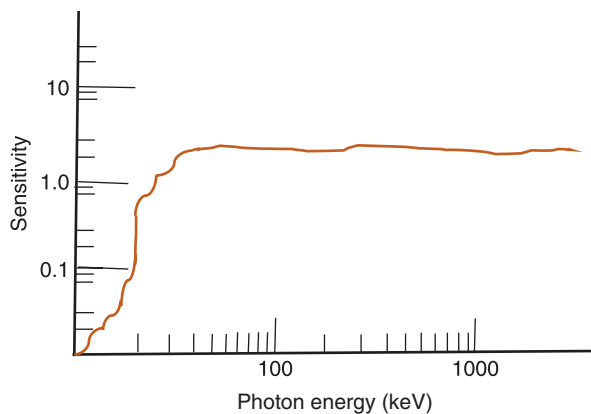
Ionization chamber survey meters are cylindrical or rectangular metallic chambers filled with inert gas or air and operate at 50–300 V in Region B of Fig. 2.2. Regular batteries provide the voltage by a step-up electronic circuit to ionize the gas, and the current is detected by a meter and converted to exposure values (mR/h) by a built-in electronic circuitry. Counts or exposure values are displayed on either analog or digital scale of over several decades. The window of the chamber is a thin metalized polyester film (7 mg/cm²) which permits the detection of α , β^- , and γ radiations. However, a retractable β^- shield made of phenolic slide is placed beside the window, which, when in position, prevents α and β^- radiations from entering the chamber and allows γ radiations only to enter. Sometimes, films made of mica with a density of about 1.5–2.0 mg/cm² are used for the window. While the pulse mode is employed in α particle detection, the current mode is used in β^- and γ ray detection. The pressure in the chamber is affected by the atmospheric pressure and temperature in different geographical regions causing dubious readings. A correction circuit is installed inside the chamber to correct for these changes. Moisture present in the chamber causes inaccuracy in readings. All cables and electronics are completely dried to minimize the effect of moisture. A typical ionization chamber survey meter is illustrated in Fig. 2.3.

The response of ionization chambers is uniformly constant over a wide range of photon energies except at very low energies (Fig. 2.4). Unlike in G-M counters (see

Fig. 2.3 A digital cutie pie survey meter (photo courtesy of Capintec)



Fig. 2.4 Energy-independent response of a typical ionization chamber



later), there is no amplification of the signal because of the low voltage applied in these counters, and also they have no dead time, so high activity can be measured without loss of counts. For low energies, some chambers are filled with pressurized gas to increase the detection efficiency. The overall efficiency of the counter is high. Ion chambers can be used both for activity measurements and for dose measurements. The latter can be obtained with knowledge about the energy needed to form a pair of ions in the gas.

These survey meters are usually employed to monitor high intensity radiation sources such as ^{99}Mo - $^{99\text{m}}\text{Tc}$ generators in nuclear medicine and X-ray sources from radiology equipment. These counters must be calibrated using a National Institute of Standards and Technology (NIST) certified ^{137}Cs ($t_{1/2} = 30$ years; 662 keV γ) source annually, and after adjustment or repair.

2.1.2 Dose Calibrator

A dose calibrator is an ionization chamber routinely used in nuclear medicine to measure radioactivity and administered dosages for patients. It is a double-walled cylindrical unit with the inner cylinder cavity to hold the radioactive sources. The space between the two cylinders is filled with ionizing gas of argon mixed with a trace of halogen at a pressure of 5–12 atmospheres and two cylinders are firmly sealed. It operates in Region B at a voltage of ~ 150 V (Fig. 2.2). The γ radiations from a radiation source in the calibrator cross the inner wall of the cylinder and ionize the gas producing ion pairs, which produce a measurable current proportional to the energy and amount of radioactivity. The current is displayed in curies or becquerels on a meter connected to the dose calibrator. A commercial dose calibrator is illustrated in Fig. 2.5.

Different radionuclides produce different ionization (current) due to varying type and energy of radiations (exposure constant), so equal quantity (e.g., mCi) of different radionuclides will read different values on the dose calibrator. To correct for this, resistors are provided to compensate for the difference, which are called isotope selectors for individual radionuclides. Push-button type isotope selectors are

Fig. 2.5 A commercial dose calibrator (Capintec CRC-55TR) (picture courtesy of Capintec)



used in some dose calibrators for common radionuclides (e.g., ^{99m}Tc , ^{67}Ga etc.) used in nuclear medicine, whereas in others a continuous rotating dial is used to set the value of a radionuclide established by the manufacturer.

Readings are displayed by selection in becquerel or millicurie. To ensure proper functioning of the dose calibrator, four parameters need to be checked, namely constancy, accuracy, linearity, and geometry. In the past, the NRC used to mandate these tests; however, nowadays the users are required to perform these tests according to manufacturers' recommendations. Constancy defines the precision or reproducibility of day-to-day measurements in the dose calibrator and is determined at the beginning of a workday by measuring the activity of a long-lived source such as ^{137}Cs . Also at the same time with the ^{137}Cs standard in the dose calibrator, readings are taken for each radionuclide (e.g., ^{99m}Tc , ^{131}I , ^{67}Ga , ^{123}I , ^{111}In , ^{18}F , etc.) routinely used in the institution to assess the proper functioning of the calibrator at their settings. The readings should be within $\pm 10\%$ of the previous day reading. If not, the dose calibrator needs to be repaired or replaced.

Accuracy is determined by verifying the activity of at least two long-lived standard radionuclides (e.g., ^{137}Cs and ^{57}Co) certified by the NIST. The agreement between the measured and standard activities should be within $\pm 10\%$. If there is a disagreement, the dose calibrator needs to be repaired or replaced. The test is performed at installation, annually, after repair or adjustment.

The linearity of the dose calibrator is determined by a decay method, in which the activity of a ^{99m}Tc source in the highest range of clinical use (multimillicuries) at a given institution is measured at subsequent time intervals until it decays down to less than $30 \mu\text{Ci}$ (1.11 MBq). The semilog plot of activity versus time should be linear showing a half-life of 6 h (Fig. 2.6), and deviation of a measurement from linearity by more than more than $\pm 10\%$ needs correction. The test is performed at installation, quarterly, after repair or adjustment.

Fig. 2.6 Time-activity curve for linearity test of a dose calibrator by the decay method

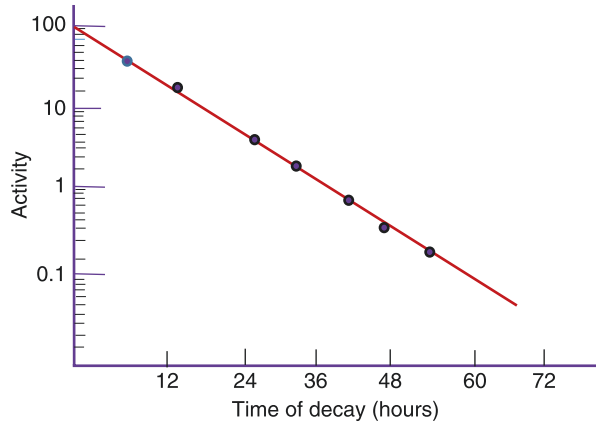


Fig. 2.7 Calicheck linearity test kit for shielding method (Courtesy of Calicheck- LLC)



The decay method may take a couple of days. For convenience and the brevity of time, a shielding method is employed as an alternative using a commercial kit called Calicheck linearity test kit (Fig. 2.7). It consists of seven concentric lead-lined tubes of different thicknesses (except the innermost one with no lead). The thickness of each tube is made to correspond to a decay factor at different times. Prior to routine use of the kit, correction factors are established for each tube. It is accomplished by measuring the activity of a ^{99m}Tc source in each of the seven tubes in a dose calibrator. A correction factor for a tube is then calculated by dividing the innermost tube reading (no shielding) by the reading of the tube. In subsequent linearity tests, the activity of a ^{99m}Tc source is measured using all tubes individually, and each reading is multiplied by the respective correction factor for the tube, which should give the same value for all tubes. Variation of more than $\pm 10\%$ in a tube reading requires correction of data, or repair or replacement of the calibrator. Note that for a new dose calibrator, the linearity test must first be performed by the decay method, and then for subsequent linearity tests, the shielding method can be used.

Geometry correction arises from the use of different shapes and sizes of syringes and vials made of different materials that give varying measurements for the same activity. This correction is made by comparing the measured activity in a container with a known calibrated activity obtained from a vendor. This test is performed at installation, after adjustment or repair.

2.1.3 Pocket Dosimeter

The pocket dosimeter works on the principle of ionization of air by radiation and consists of a hollow metallic chamber containing inside a quartz fiber electrode and a scale to read radiation exposure of 200 mR, 500 mR, or 1 R. Prior to use, the dosimeter is fully charged by a dosimeter charger, which applies a high DC voltage, usually around 150–200 V. The scale of a fully charged dosimeter reads zero. When it is exposed to radiation, ion pairs are produced in air inside the dosimeter and neutralize some of the charge on the electrode. The loss of charge on the electrode reduces the force on the fiber, causing it to move back toward the electrode, which indicates a reading seen through the window at the end of the dosimeter (Fig. 2.8). The reading on the scale is proportional to radiation exposure. The dosimeter is useful for an instant estimate of radiation exposure, if worn on the body, during handling of radioactivity.

2.1.4 Proportional Counter

Proportional counters are gas counters operated on the basis of the ionization of a fill gas inside the detector chamber by particulate radiations such as α and β^- particles. When a radiation travels through the fill gas, gas molecules are ionized, and a trail of positively charged ions and electrons are produced, the number of ion pairs being proportional to the energy of the radiation. As can be seen in Region C in Fig. 2.2, the operating voltage of the counter is in the proportional region of the applied voltage, and the voltage is strong enough to prevent recombination of the

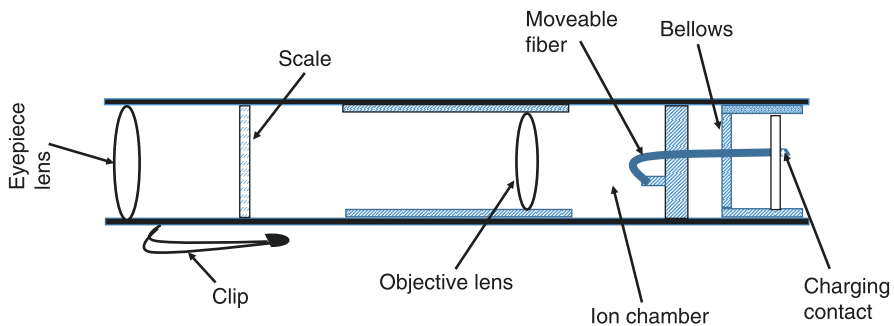
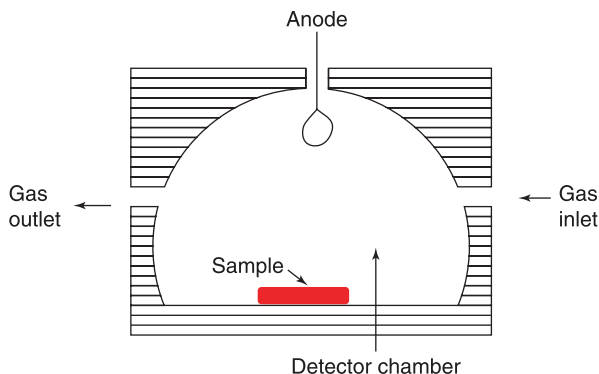


Fig. 2.8 A pocket dosimeter (exploded view)

Fig. 2.9 Schematic illustration of a proportional counter



ion pairs facilitating positive ions to drift toward the cathode and electrons toward the anode. Because of the higher voltage beyond the saturation region, electrons released by initial ionization become more energetic and cause further ionization of the gas. In the vicinity of the anode, the voltage is large enough to cause an avalanche. The proportional chamber is so designed that one original ionizing event produces only one avalanche, thus maintaining the proportionality between the number of original events and total output pulse.

Proportional counters are typically hemispherical in shape fitted with various configurations of the anode and the cathode (Fig. 2.9). Instead of air, a special gas, called P10, composed of 90% argon and 10% methane, is used as fill gas at slightly positive pressure above ambient atmospheric pressure. The chamber can be sealed with gas inside or the gas can flow continuously through the chamber although the former is commonly used in nuclear medicine. For easy particle entrance into the detector and efficient counting, the window of the detector is made of very thin Mylar foil. Extreme care is exercised in handling these films, and excessive gas pressure must be avoided in the detector because of their brittleness.

Proportional counters are used primarily for counting α and β^- particles. If samples are prepared for counting by evaporating liquid solution on planchets, the thickness of the dried samples may be thick enough to cause self-absorption of the particulate radiation. In such situations, correction factors need be assessed a priori using various sample thicknesses and applied to subsequent measurements.

2.1.5 Geiger–Muller Counter

The Geiger–Muller (G-M) counter operates in Region E (Fig. 2.2) and consists of a cylindrical probe attached to a metal box fitted with a control switch and a digital or analog meter to read radiation events in counts or radiation exposure in mR/h. The G-M probe has a central metallic wire (e.g., tungsten) to act as an anode, while the body of the probe acts as a cathode. It is filled with an inert gas such as argon, helium, or methane mixed with a trace amount of halogen at low pressure (~ 0.8 atmosphere). Argon is preferred because it is heavy (compared to neon or helium),

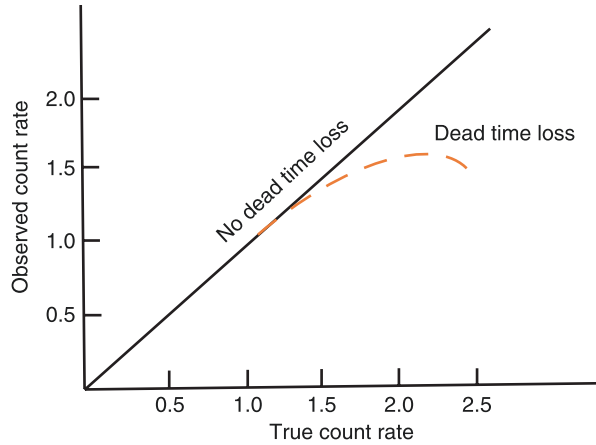
which allows for more deposition of energy within the gas and thus increases counting efficiency. An optional metal cover is provided to stop β^- particles and low energy γ radiations and thus allowing only high energy γ counting. The battery-operated bias voltage range is about 900–1200 V. As can be seen in Fig. 2.2, the current reaches a plateau with only slight variation with applied voltage. The current produced is independent of the type and energy of radiation. The G-M counter can be used for counting α , β^- , γ radiations and neutrons with manipulation of the construction of the probe.

As stated in Sect. 2.1 above, in G-M counters, initial radiation interacts with the fill gas molecule causing ionization producing electrons and positive ions. Upon application of the voltage, the electrons are accelerated to the anode and the positive ions to the cathode (wall). Some of the accelerated electrons can further ionize the gas and the primary electrons and secondary electrons continue to gain energy to move toward the anode. As they move, more and more ionizations are produced causing an avalanche of events. In addition to ionization, excitation of gas molecules also occurs raising them to higher energy states. The deexcitation of the excited molecules leads to UV radiations, which can further produce more ion pairs in gas by photoelectric process, thus adding to the avalanche events. Multiple avalanches result in amplification of gas ionization in the order of 10^{10} . The uncontrolled spread of avalanches throughout the entire detector is known as a Geiger discharge. The detector remains unresponsive during this single event and cannot count the next event until it recovers, i.e., the Geiger discharge is terminated. The Geiger discharge is terminated by the slow-moving positive ions which concentrate increasingly around the anode and reduce the strength of the electric field below the required value to continue the avalanche and eventually terminate the discharge.

Recovery from the Geiger discharge begins with the migration of the positive ions toward the cathode and takes about 200 μs at a gas pressure of 0.1 atmosphere to start processing the next event. This time lag between the two events is defined as the *dead time* of the counter. However, with positive ions near the cathode, secondary electrons may be emitted from the surface of the cathode, which then set another discharge just about 200 μs after the previous one. Such repetitive discharges by the secondary electrons make the counter partially or totally unresponsive for radiation counting depending on the amount of activity causing loss of counts (dead time loss). A typical illustration of dead time is given in Fig. 2.10. Note that such a dead time does not exist in ionization chambers, because multiple avalanches do not occur in them.

To prevent multiple discharges in G-M counters, a technique called *quenching* is employed, in which gaseous vapor of ethanol, isobutane, etc., or halogen gases (chlorine and bromine—5–10%) are added into the counter. The quenching molecules transfer electrons to the “positive” cloud, neutralizing it and themselves becoming “positive.” The positive quenching ions then dislodge electrons from the cathode, which neutralize them releasing energy but without any UV light emission. This essentially terminates the avalanche and stops repetitive discharges, stabilizing the operation of G-M counters for extended periods.

Fig. 2.10 Plot of observed counts versus true counts illustrating the dead time loss of counts with increasing activity in counting systems



G-M counters have a dead time of about 100–500 μs due to repetitive discharges in the gas during avalanche, depending on the design of the counters. The G-M counter operates in pulse mode and counts each event as a count. Counts are displayed as counts per minute (cpm) or are summed up and converted to exposure rates (mR/h) by a built-in electronic circuitry, which are displayed in several decades (1, 10, 100 and 1000) by means of a switch. Some counters are equipped with an audible alarm that is triggered by radiation counts above a certain set value and are useful for area monitoring.

G-M probes are either window type or windowless. The former has a window of thin mica (0.01 mm) and is used to detect α particles, low energy β^- particles, and γ radiations. The pancake probe is a variation of end window probe, having a circular shape with a mica window and is commonly used in monitoring the radioactivity or survey of exposure. A typical G-M counter is shown in Fig. 2.11 with a pancake probe.

Windowless probes of the G-M counter are generally two types: thick-walled or thin-walled. Thick-walled probes of chrome steel are used for high energy γ radiations, which pass through the fill gas without interaction and strike the tube wall producing high energy electrons. Some of the electrons from the wall surface may interact with the fill gas producing an avalanche. Thin-walled probes allow high energy β^- rays through the wall, which interact with the fill gas to produce avalanches.

G-M survey meters are almost an order of magnitude more sensitive than ion chambers because the former responds to individual ionization events. The counting efficiency of these counters is almost 100% for β^- radiations, whereas it is only 1–2% for γ rays and X-rays. Because of the long dead time (100–500 μs) of these counters, counting rates are limited to 15,000–20,000 cpm without count loss, which occurs at high activities due to saturation of the counter. The US NRC requires annual calibration of the G-M counters with a NIST-certified standard source such as ^{137}Cs and the procedure for calibration is given in Sect. 6.14 in Chap. 6.

Fig. 2.11 A Ludlum G-M survey meter with a pancake probe (courtesy of Ludlum/Pinestar technology)



Furthermore, a check source of nominal activity of a long-lived radionuclide such as ^{137}Cs is placed in a holder, which is affixed to the counter housing. The check source gives a reading of counts, which is posted on the counter. Prior to measurement of the exposure, the battery of the G-M counter is first checked by moving the dial knob to battery check position, which is indicated by movement of the counter needle to the battery display area. If the batteries are bad, they need to be replaced. Next a background reading is taken in a non-radioactive area to see if the counter is contaminated. Then the G-M counter is checked by placing the pancake probe against the check source and verifying the reading against the check source value to ensure the proper functioning of the meter. The G-M counter is now ready to use for survey.

To use the G-M counter to measure radiation exposure or ambient dose rate, a correction needs to be made, because the G-M pulses do not contain any energy information, which is needed to convert counts to exposure values. At low energies (so, low-dose rate), the response of the probe to low energy γ radiations is 2–3 times higher than the response to high energy γ radiations due to more interactions with fill gas (Fig. 2.12a). The G-M probes are calibrated with the high energy 662 keV γ rays of ^{137}Cs , so low energy response in these probes will be overestimated and hence exposure reading will be erroneous. To compensate for this energy response difference, filters made of metals like lead and tin are used to flatten the response by attenuation (Fig. 2.12b) These filters are made of materials in different designs. Attenuation of low

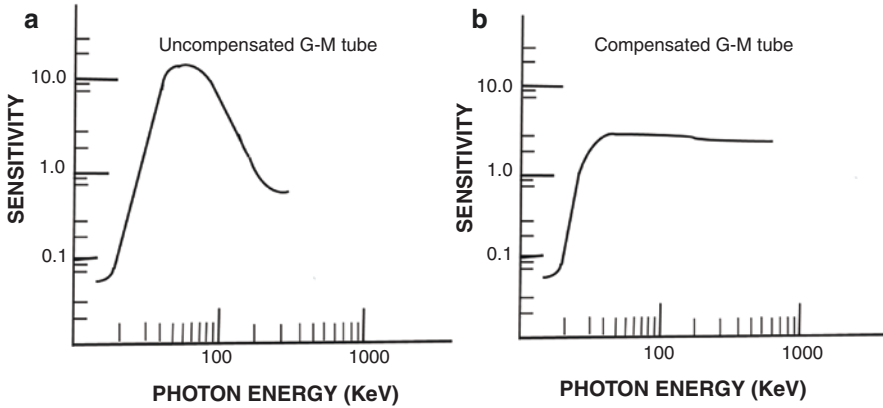


Fig. 2.12 Energy-dependent response of a Geiger–Muller counter. (a) G-M tube without energy compensation shows overestimation of sensitivity at low photon energy. (b) G-M tube with energy compensation correction flattens the response curve

Fig. 2.13 An area monitor (courtesy of Ludlum/Pinestar technology)



energy γ radiations in some of these filters is too severe, so holes or gaps are cut in the filter to allow some of them. These probes are called *energy compensated* probes.

A helpful use of G-M counters is to measure 24/7 continuously the ambient radiation exposure in an area or a room to indicate the level of radiation. These are called *area monitors* that operate with G-M counters or scintillation counters and provide audio alarm and digital counts. The data can be printed out from a printer attached to it. These are useful for detecting radiations from a source left unattended unintentionally. A typical area monitor is shown in Fig. 2.13.

2.2 Scintillation Counter

When γ or X-rays interact with solid scintillation detectors via photoelectric interaction, Compton scattering, or pair production, detector molecules are raised to higher energy states through ionization or excitation. The high energy states return to lower energy states by emitting light photons (scintillation) in a time called *scintillation decay time*. The scintillation photons are processed in a series of steps to convert photon energy to a pulse for detection. They are first processed by a photomultiplier tube (PM) to produce a pulse or signal, followed by its amplification in a linear amplifier and then sorting of the pulses by a pulse-height analyzer (PHA) to finally generate a suitable count for recording (Fig. 2.14). Whereas many scintillation detector materials are in use for various purposes, sodium iodide doped with traces of thallium metal (NaI(Tl)) is the common detector used in radiation safety and nuclear medicine, so we will discuss this material in some detail and its use in radiation safety.

When interacted with γ radiations, NaI alone does not emit sufficient light photons, but it does so if it contains a trace of thallium metal as in NaI(Tl). The NaI(Tl) crystal (probe) is fabricated in a cylindrical form of 5 cm diameter \times 5 cm thickness to 23 cm diameter \times 23 cm thickness. While smaller crystals are used in contamination survey

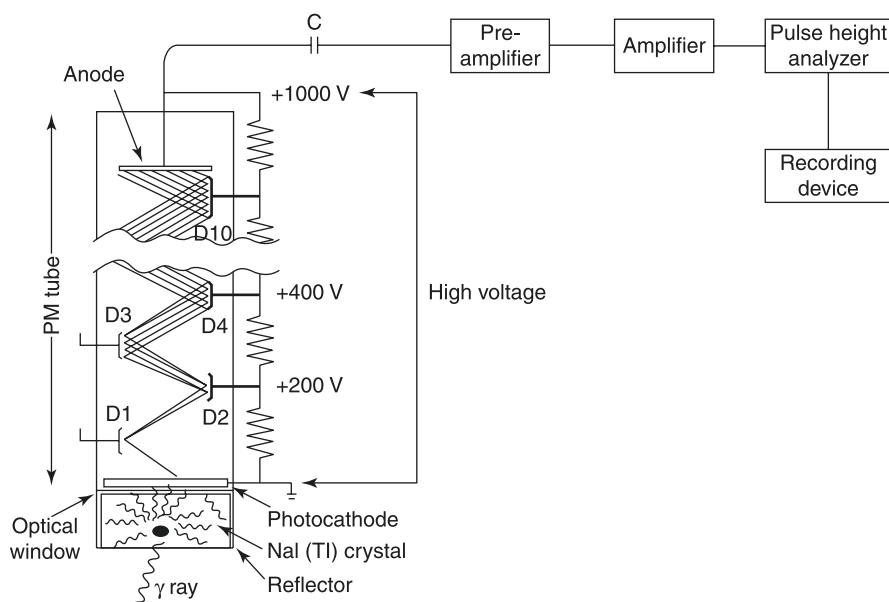
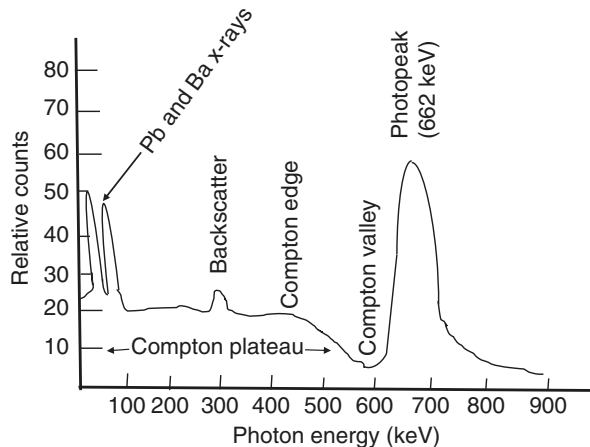


Fig. 2.14 Scintillation counting system consisting of a NaI(Tl) detector connected to a PM tube, an amplifier, a PHA, and a recording device. (reprinted by permission from Springer Nature, *physics and radiobiology of nuclear medicine* by Saha GB, 2013)

meters, larger crystals are used in well counters and thyroid probes. In these counters, the crystal is attached to a PM tube, which is a metallic cylindrical tube with a photocathode (sensitive to light) at the light entrance end. It contains as many as 10 dynodes (cathodes) in the middle, and an anode at the exit end (Fig. 2.14). The voltage is applied to the PM tube such that there is a potential difference of 100 V between successive dynodes. Light photons produced by interaction of γ radiations with the NaI(Tl) crystal strike the photocathode and produce photoelectrons, which are accelerated and strike the first dynode due to potential difference. This produces more electrons, which are further accelerated to the next dynode producing additional electrons. Production and acceleration of electrons at successive dynodes generate a pulse at the anode at the end of the PM tube. The pulse is then fed into a linear amplifier for amplification to make it detectable by electronic circuitry. γ radiations interact with the detector material in several ways (photoelectric, Compton scattering, and pair production) producing pulses of different amplitudes, which are displayed as a spectrum of photopeaks on a spectrometer (Fig. 2.15). Similar spectrum is also obtained when radionuclides with different γ radiations are counted together.

Only γ radiations with complete absorption (photoelectric) in the crystal are of interest and need to be counted. However, even in photoelectric absorption, the photopeak appears as a spread instead of a vertical line, because of the statistical variation in light photons produced in the photocathode by γ ray interaction and in subsequent electron multiplication in the dynodes of the PM tube. To measure the counts under a photopeak, the PHA is utilized to sort out the appropriate pulses by using an energy window, which are then registered as counts. The energy window is commonly set at 20% below and above the photopeak. The counts are displayed in cpm in a digital mode or on a meter scale in analog mode. Like G-M counters, scintillation counters too have a dead time arising from processing of pulses in different parts of the electronics (PM tube, amplifier, PHA, etc.). During this time of processing, the counter remains unresponsive for the next count to process and record. It is about 0.5–10 μ s for NaI(Tl) detectors and semiconductors.

Fig. 2.15 A typical energy spectrum of a radionuclide on a spectrometer



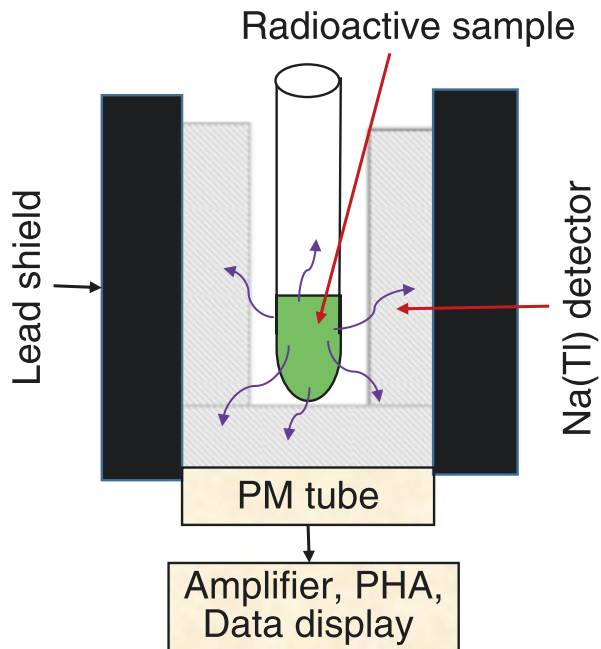
The sensitivity (overall efficiency) of a scintillation counter has two components: intrinsic efficiency and geometric efficiency. The intrinsic efficiency varies with photon energy, PHA setting, and composition of the detector material. The geometric efficiency depends on the shape and size of the detector and its position relative to the source. These counters are useful for counting low activity of γ radiations.

Detectors of other materials such as bismuth germanate (BGO), lutetium oxyorthosilicate (LSO), etc. are used in imaging equipment such as single photon emission computed tomography (SPECT) and positron emission tomography (PET). Semiconductor materials such as lithium-drifted germanium (Ge-Li) and lithium-drifted silicon (Si-Li) detectors are also used for various counting purposes in radiation protection and nuclear medicine.

2.2.1 Well Counter

In radiation safety practice, NaI(Tl) scintillation well counters are used commonly for the wipe test to detect low radioactive contamination. The detector material is fabricated in the form of a 5 cm diameter \times 5 cm thick cylinder with a hole at the center for holding plastic or glass vials or tubes containing radioactive sample for counting γ radiations (Fig. 2.16). Larger size detectors (23 cm diameter \times 23 cm thick) are used for higher energy γ radiations. The detector is shielded with 8.5 cm thick circular lead rings to reduce the background counts from cosmic rays and

Fig. 2.16 Schematic diagram of a well counter



surrounding work areas. Multiple samples in several hundreds can be counted sequentially and automatically, and data printed out. A sample containing no radioactivity is counted along with all other radioactive samples to correct for background activity. Modern well counters are energy-calibrated by the manufacturer sparing the user the time for calibration. High voltage may drift due to fluctuations in ambient temperature, line-voltage, and equipment usage over time, and daily check of calibration is warranted prior to counting of samples.

The detection efficiency of the well counter is determined by counting a NIST-certified ^{137}Cs standard source (accuracy $\pm 5\%$) by placing it in the well (X) and a background count without the sample in the well (B). The efficiency (Eff) is calculated as

$$\text{Eff} = \frac{X - B}{A_0 e^{-\lambda t}}$$

where A_0 is the calibrated activity of ^{137}Cs source from the NIST, λ is the decay constant of ^{137}Cs , and t is the time difference between calibration of the ^{137}Cs source and the current measurement. The efficiency is almost 100% when the sample is deep inside the well; however, as the sample volume increases reaching the opening of the well, photons are lost through the opening without interaction with the crystal, thus compromising the counts. The detection efficiency of a well counter decreases with increasing γ ray energy and increases with detector size. Typical detection efficiency for $^{99\text{m}}\text{Tc}$ (140 keV) is almost 100%, and for ^{131}I (364 keV), it varies between 30% and 90% depending on the detector size.

The well counter is provided with a display, which depicts the energy spectrum of the radionuclide when placed inside the well (Fig. 2.15) The photopeak of the spectrum corresponds to the photon energy of the radionuclide due to complete absorption (photoelectric effect) in the detector material, which only needs to be counted. Low energy peaks result from Compton interactions in the detector and housing material and appear as Compton edge, backscatter, etc. and are to be discarded. The advantage of the well counter is that one simply puts the sample in the well counter and selects the photopeak energy $\pm 20\%$, followed by pushing the start button for counting. After counting for a certain time, the total counts and count rates are displayed to record and save.

2.2.2 Thyroid Uptake Probe

The thyroid uptake probe contains a $5'' \times 5''$ NaI(Tl) crystal, a PM tube and associated electronics and operates on the same principle as in a well counter. A typical thyroid probe is shown in Fig. 2.17. It is primarily used to measure the thyroid uptake of ^{123}I or ^{131}I administered to patients in NaI form to diagnose thyroid diseases. Since extraneous scatter radiation from outside the thyroid and room background may strike crystal during measurements, the crystal and PM tube is enclosed in a 20–25 cm long barrel-shape lead collimator to minimize these radiations.



Fig. 2.17 A typical thyroid counter (courtesy of Mirion technologies (Capintec) Inc.)

The thyroid probe is calibrated by the manufacturer at 662 keV with a ^{137}Cs source (NIST certified accuracy $\pm 5\%$) in the same way as a well counter, and daily check is performed with the same source each day of use. A monitor is used to display the data. The settings for ^{123}I (159 keV) or ^{131}I (364 keV) are set on the counter for uptake measurement on a patient. The detection efficiency of the thyroid probe varies inversely with the distance between the thyroid glands and the probe.

In thyroid uptake measurement, a capsule containing 10–15 μCi (0.37–0.55 MBq) of $^{131}\text{I-NaI}$ is initially placed in a lucite phantom (called a thyroid phantom), the thickness and composition of which are chosen to be equivalent to those of average human thyroid glands. The phantom is then placed at a distance where the patient would be positioned, and a count is taken for a certain period, which gives the standard count (A). The iodine capsule is then orally administered to the patient and 24 h later, a thyroid count (C) is obtained of the front of the neck (thyroid) of the patient positioned at the same distance as the phantom. A room background count

(B) is taken to subtract from the standard count, and a thigh count (D) is taken as background to subtract from the thyroid count. All counts A, B, C, and D are converted to counts per minute (cpm), and the thyroid uptake is calculated as

$$24 \text{ h uptake}(\%) = \frac{(A - B)}{(C - D)} \times 100$$

where A = Thyroid counts in cpm

B = Thigh counts in cpm

C = Standard counts in cpm

D = Room background counts in cpm

An identical procedure is used with 300 μCi (11.1 MBq) of ^{123}I -NaI for 24 h thyroid uptake measurement. Sometimes a 6 h uptake is obtained at physician's discretion. The thyroid uptake value for normal individuals (euthyroid) is 8–25%. Patients with uptake value below the normal range are considered hypothyroid and those with values above the range are considered hyperthyroid. Thyroid cancer tissue does not accumulate I^- ion and the uptake is less than 1%.

2.2.3 Liquid Scintillation Counter

Often in radiation safety and research facilities, liquid scintillation counting is employed to measure low energy β^- radiations (for example, ^{14}C and ^3H). In this technique, the radioactive sample is mixed with a “cocktail” containing a solvent and a fluorescent scintillator called fluor or phosphor. Solvents are typically organic liquids such as toluene, xylene, etc. and phosphors are two fluorescent scintillators –primary (e.g., PPO, (2,5-diphenyloxazole)) and secondary (e.g., POPOP, (1,4-bis [5-phenyloxazol-2-yl]benzene)). Organic solvents are required to dissolve the solute (phosphor), but they are immiscible with water and so their disposal in sewerage is restricted. Currently, biodegradable solvents like alkylbenzene and phenyl-xylyl-ethane are available and preferably used.

The β^- radiations initially interact with the solvent molecules, which absorb the radiation energy and get excited. The excited solvent molecules interact with and transfer the excitation energy to the primary phosphor producing light photons, which are too weak (shorter wavelength) to result in enough response of the PM tube. These photons are then absorbed by the secondary phosphor (POPOP), which emits photons of longer wavelength for detection and processing by PM tubes.

There are two PM tubes connected in coincidence on opposite sides of the NaI(Tl) detector in the liquid scintillation counter. Pulses from PM tubes are processed by an amplifier followed by a pulse-height analyzer (PHA), and only pulses in coincidence are counted. Coincidence circuitry is employed to prevent the spurious counts due to background noises. Samples for counting are prepared in plastic, polyethylene, or glass vials containing solvent and phosphor and are placed in trays inside the liquid scintillation counters. Multiple samples can be counted automatically and sequentially. Processing of the light photons by PM tubes and subsequent

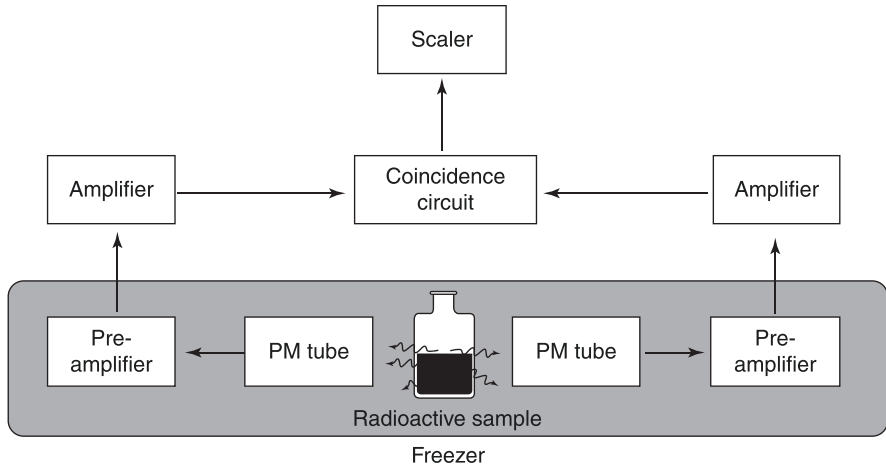


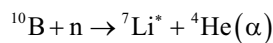
Fig. 2.18 Schematic illustration of a liquid scintillation counter in which two PM tubes and associated electronics are connected in coincidence. Light photons produced by interaction of β^- particles with phosphor are processed by two sets of PM tubes, amplifier, and PHA to produce pulses. Only the coincident pulses are detected. (reprinted by permission from Springer Nature, *physics and radiobiology of nuclear medicine* by Saha GB, 2013)

electronics is identical to that in solid scintillation counting. A schematic diagram of a liquid scintillation counter is illustrated in Fig. 2.18. Pulses generated are recorded as counts. The counting efficiency of liquid scintillation counters varies with the energy of the β^- particle, so while the efficiency for ^3H (18 keV β^- energy) counting is only $\sim 30\%$, it is nearly 100% for ^{32}P (1.71 MeV β^- energy).

2.3 Neutron Detector

Because neutrons are neutral particles, their interaction with the absorber is quite different and G-M counters as such cannot be used to detect them. They commonly interact with nuclei of the absorber, producing energetic particles such as α particles and protons. The principle of neutron detectors is primarily based on the detection of these emitted particles, and normally gas-filled proportional counters are used for this purpose.

One of the common nuclear reactions used is the $^{10}\text{B}(n, \alpha)^7\text{Li}$ neutron capture reaction, in which a neutron is captured by a ^{10}B nucleus and an α particle is emitted, which is detected by the detector. Enriched ^{10}B in the form of BF_3 is used in the gas-filled counter. The reaction has high cross section to produce α particles and is given by

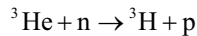


The energy released by the reaction in the fill gas ionizes the gas releasing energetic charged particles. The counters are operated in the proportional mode, and the

ionization produced by these particles initiates the multiplication process that leads to detection. Excited ${}^7\text{Li}^*$ recoil atoms also produce ion pairs in the gas that can be detected, but their contribution in the α detector is negligible.

For high energy neutrons, the detector is enclosed in spherical paraffin foils of different thickness and diameters, whereby the flux of neutrons is attenuated by the paraffin to the thermal level for detection. One can estimate the initial neutron flux at different energies from the thickness and diameter of the spherical paraffin enclosures. However, too thick paraffin tends to absorb thermal neutrons compromising its quantitative measurement, thus limiting the thickness of paraffin foil in these counters to about 6 cm. These detectors are operated at 1500–2000 V.

Another nuclear reaction used for neutron detection is the (n, p) reaction on a stable atom, where the protons are detected by the counter. While the (n, p) reactions can occur on many stable atoms, ${}^3\text{He}$ atoms are commonly used for this purpose.



The recoil proton produced in the reaction causes ionization of the gas and the ion pairs further ionize the gas, total number being proportional to the energy deposited in the gas. The total charge collected (due to multiplication in the gas) increases rapidly with the applied voltage and is collected as a pulse at the cathode. The operating voltage of these counters is 1200–1800 V. The detection efficiency of these detectors can often be calculated rather reliably because of the simple detection process and the well-known cross sections.

The ${}^3\text{He}$ gas has high neutron detection efficiency and is non-toxic. These good characteristics make ${}^3\text{He}$ proportional counters the obvious choice for neutron detection, particularly in portable radiation monitors used to control the illicit transport of nuclear material. However, the availability of ${}^3\text{He}$ is now very limited for this purpose, which makes it very expensive.

In the absence of an easily available and better detector, ${}^{10}\text{BF}_3$ detectors are still the counters of choice for neutron detection, even though they are toxic. For the latter reason, they are not suitable for use outside the laboratory.

2.4 Personnel Monitoring

Radiation workers are exposed to radiation in their work and it is essential to assess their exposure to comply with the NRC limits. Several methods are used to estimate the exposure, which are described below.

2.4.1 Film Badge

Film badge is a personnel monitoring badge worn by radiation workers to estimate the radiation exposure they receive during the working period. The badge contains a radiation-sensitive X-ray film contained in a firm plastic frame of different shapes.

α , β^- , and γ radiations interact with the film, which change the optical density proportional to the radiation exposure. Filters of different metals such as aluminum, copper, and cadmium are placed on top of the film to discriminate different types and energies of radiations. The badge is usually worn on the chest or waist of a radiation worker to obtain an integrated exposure during work for a month. The film is developed like the X-ray film that shows the optical density variation with the type and energy of the radiation in different sections of the film corresponding to filter positions. The optical density is measured by a densitometer and compared with that of a calibrated film exposed to a known radiation. Since the badge is exposed to environmental background radiation, a background correction needs to be made to the measured density. This is accomplished by placing a separate film badge in the working area, which works as a control for background radiation. The background badge is processed along with other radiation workers' badges, and its reading is subtracted from the badge reading of each individual worker.

The exposure readings are integral values for a month for each worker, and a new badge is issued for the next month. Fogging may result from mechanical pressure, high temperatures, or exposure to light before development, and film images may fade depending on the interval between exposure and processing. So exposure values are not as accurate. Nowadays thermoluminescence dosimeters and optically stimulated luminescence dosimeters are preferred for personnel monitoring, of which the latter is more commonly used. These are described briefly below.

2.4.2 Thermoluminescent Dosimeter

A thermoluminescent dosimeter (TLD) utilizes radiation-sensitive inorganic crystals such as lithium fluoride (LiF) and manganese-activated calcium fluoride ($\text{CaF}_2:\text{Mn}$), which are activated by radiation exposure raising the electrons from valence band to forbidden band. When the exposed crystals are heated at 300 °C to 400 °C, the electrons are further raised to conduction band, which next make a transition to valence band emitting visible light. The amount of light is proportional to the radiation exposure to TLD and is determined by a PM tube (called TLD reader). TLDs are sensitive to all radiations and are enclosed in plastic holders of different configurations for wearing on body and fingers. Like film badges, TLDs are normally worn for a month and then sent to commercial firms for a report of exposure readings. Unlike film badges, TLDs are less affected by environmental conditions such as heat, light, and humidity and are reusable.

2.4.3 Optically Stimulated Luminescence Dosimeter

The optically stimulated luminescence (OSL) method is used for optical dating of ancient material and in radiation dosimetry, and the later application is of our primary interest. These dosimeters are now widely used in the USA. OSL dosimeters work on the similar principle as the TLDs described above, except that light is used

instead of heat for stimulation during processing of radiation-exposed crystals. These dosimeters use certain types of materials such as quartz and aluminum oxide as the detector, which are purposely made imperfect in lattice structure by adding some impurities. Aluminum oxide is doped with traces of carbon (C) as impurity and has the structure of $\text{Al}_2\text{O}_3:\text{C}$. When radiation interacts with these materials, ionization occurs in the valence band creating electron-hole pairs. These electrons and holes are held in “traps” in the impurity lattice located in the forbidden band between the valence band and the conduction band. When the crystal is processed by applying pulsed laser light or LED, the trapped electrons are stimulated and move to the conduction band. The freed electrons subsequently recombine with positive holes, emitting visible light (luminescence) which is fed into the PM tube to produce a signal. The signal is proportional to absorbed radiation energy and recorded.

Several commercial vendors provide these OSL dosimeters of which Landauer Inc. and Mirion Technologies (Capintec) Inc. are the leaders. In the Landauer model, the OSL chips for β^- and γ radiations are encased in a 0.5 mm thick PVC holder of hexagonal shape. The dosimeter has an open window sealed with a thin layer of clear plastic, positioned at the lower half of the front face. The Luxel +Pa dosimeter packets contain filter packs of different materials of various thickness shown in Fig. 2.19 to differentiate between β^- and γ radiations. For neutron detection, a CR-39 element is placed in the lower half of the enclosure, which are termed Luxel+Ta and Luxel+Ja dosimeters.

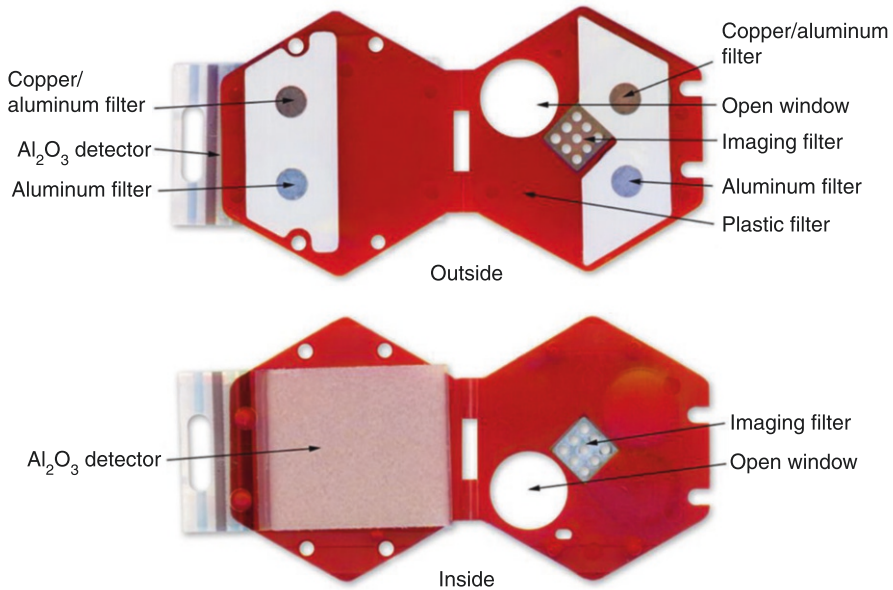


Fig. 2.19 Open view of Luxel OSLD showing different filters used for differentiating radiation exposures (image courtesy of Landauer, Inc)



Fig. 2.20 Illustrations of OSLD badges for body and finger monitoring (image courtesy of Landauer, Inc)

OSL dosimeters are relatively unaffected by heat, light, and humidity. These are more sensitive than TLDs to a wider range of γ ray and β^- particle energies providing more information about the energy of the incident radiation. They provide estimates of deep dose, dose to the lens of the eye, and shallow dose. The readout process of OSL dosimeters is faster and more accurate than that of TLDs and they can be read multiple times without erasing the data.

Hexagonal badges are worn on the chest or waist and ring-shaped badges on fingers (Fig. 2.20) by radiation workers normally for a month. While OSL dosimeters are commonly used in personal monitoring of radiation exposure, they can also be used in vivo dosimetry in radiation therapy. The dosimeters can be used multiple times and read in the range of 1–1000 mR for γ rays and 10–1000 mR for β^- radiations.

The personnel monitoring dosimeters (film badge, TLD, and OSL) of all workers in an institution are sent to a commercial firm accredited by the National Voluntary Laboratory Accreditation Program (NVLAP) of the National Institute of Standards and Technology (NIST), which processes them and sends back the reports of exposure readings to the institution. Landauer Inc. and Mirion Technologies (Capintec) Inc. are two NVLAP accredited commercial firms. Radiation workers are informed of their monthly exposures, and the permanent records of exposure are kept by the radiation safety officer under the authority of the licensee. If the dosimeter is damaged, lost or accidentally overexposed, the radiation safety officer should be notified immediately for proper action to take. When a badged worker terminates employment, the licensee will provide a termination radiation exposure report to the individual.

2.4.4 Electronic Personal Dosimeter

Electronic personal dosimeters (EPDs) or personal radiation monitors are very useful radiation monitoring units that give an instantaneous exposure reading for

radiation workers. They are encased in light-weight waterproof plastic cases. These dosimeters use different detectors such as NaI(Tl), gas-filled G-M counters, and solid-state detectors like silicon diodes. Most of them are operated by batteries which last for 5000–6000 h. They detect low energy γ rays and X-rays, high energy γ rays, and β^- radiations depending on the manufacturer's design. They provide both the dose exposure rate and accumulated dose displayed on a backlit LCD display. Most of them have an alarm that can be manually set to go off above certain limits of exposure. This feature warns the worker of potential high radiation areas so that the worker can take precautions. Also they have a low battery indicator.

Ludlum Instruments Inc. markets two personal radiation monitoring dosimeters M25 and M25–1, and Fig. 2.21 illustrates M25–1. The only difference between the two dosimeters is that M25 reads doses in mR, while M25–1 gives data in mSv. The monitor has the dimension of $7.6 \times 5.4 \times 1.7$ cm (H \times W \times thickness) and weighs 144 g (5.1 oz), including two AAA lithium batteries. The model 25–1 digital dosimeter has an internal energy compensated G-M tube containing a counting and a quenching gas. It has a sensitivity of ~ 1800 cpm per mSv/h. and displays an energy range of 60 keV to 2 MeV gamma rays. The backlit LCD readout displays dose rate, accumulated dose, and time remaining to the dose limit. This dosimeter gives the dose rate in the range of 0.001 mSv/h. to 9.99 Sv/h., while Model 25 displays the exposure rates in the range of 0.01 mR/h. to 999 R/h. Maximum accumulated dose is displayed as 9.99 Sv on Model 25–1 and as 999 R on Model 25. The units can be worn on a belt, a lanyard, or an armband.

Thermo Fisher Scientific markets an Electronic Pocket Dosimeter (EPD) called EPD TruDose dosimeter that is quite versatile in monitoring personnel dosimetry. A typical dosimeter is shown in Fig. 2.22 labeled with all operational features it offers. It utilizes two or three solid state silicon diode detectors depending on the model, housed in a sturdy plastic case with a digital LCD display. A two PIN diode detector is used in EPD TruDose G for γ ray detection, and three PIN diode detector in EPD

Fig. 2.21 Electronic personal radiation monitor M25-1 (courtesy of Ludlum instruments Inc.)



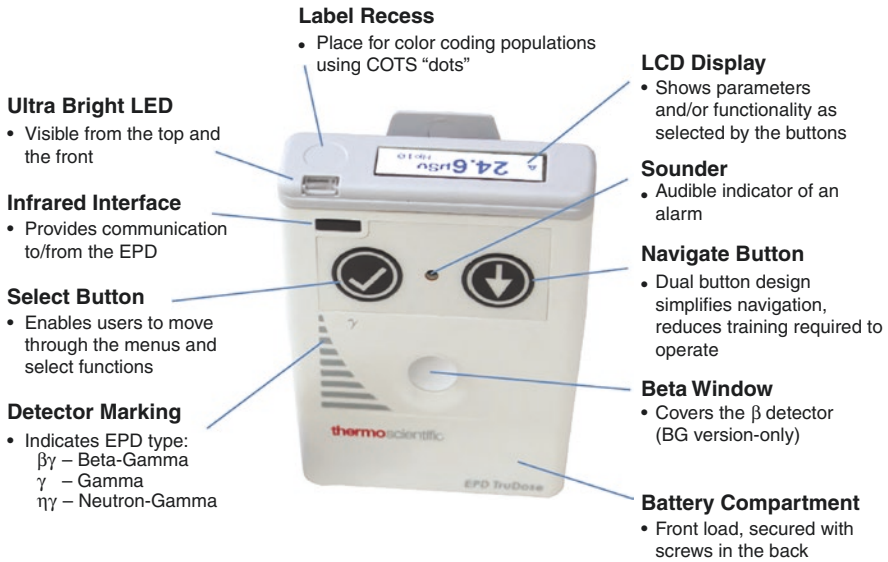


Fig. 2.22 An EPD TruDose dosimeter marketed by Thermo Fisher Scientific showing all operational features (image supplied by Thermo Fisher Scientific)

TruDose BG for β^- and γ radiation detection and also in EPD TruDose NG for neutron and γ ray detection.

The EPD TruDose operates with an alkaline or lithium battery which lasts for many months. It weighs about 114 g and is fitted with an audible alarm, which goes off at doses and dose rates above a set value. The dosimeter can be worn over the belt or on the chest. It provides an instantaneous reading of both the cumulative dose and the dose rate displayed on the LCD in any radiation environment. The dose reading ranges from 0 μSv to >10 Sv, and the dose rate ranges from 0 $\mu\text{Sv/h}$ to >10 $\mu\text{Sv/h}$ for G and BG models, and 0 $\mu\text{Sv/h}$ to >2 $\mu\text{Sv/h}$ for NG model. The dosimeter operates accurately in the energy range of 10 keV to 10 MeV.

Depending on the model, the dosimeter has a nice feature of calculating the deep dose $H_p(10)$ and skin dose $H_p(0.07)$ from the exposure values of the radiation workers. All data are stored in an internal memory chip inside the EPD, which can be retrieved and displayed on the LCD by pressing a button. With the use of an EPD TruDose reader and software, the data can be retrieved and archived electronically. The dosimeter can be reset for reuse.

The dosimeter has a unique provision of Bluetooth telemetry that communicates with computers and other storage units for storage of acquired data in the dosimeter. Because of the high accuracy and instantaneous processing of the data, it has the potential of replacing the film badge monitors, thus eliminating the time-consuming hassle of collecting, returning, and redistributing dosimeters for processing. These dosimeters are very useful for radiation workers in high radiation areas and also very appropriate for those who carry out planned special exposure experiments.

Questions

1. Ionization chambers are more efficient than G-M counters in the detection of γ rays.
True _____, or False _____.
2. Match the following operating voltages with the corresponding counting regions.

(a) 500–900 V	1. Ionization chamber
(b) 50–100 V	2. Proportional counter
(c) 10–50 V	3. Geiger–Muller counter
(d) above 1500 V	4. Pocket dosimeter
3. A dose calibrator is operationally
 - (a) a Geiger–Muller counter
 - (b) a proportional counter
 - (c) a scintillation counter
 - (d) an ionization counter
4. Describe the four quality control methods needed for the dose calibrator. Are these methods mandated by the NRC?
5. What are the common radionuclides used for assessing constancy and accuracy of a dose calibrator?
6. What maximum percentage error is allowed for constancy, accuracy, and linearity of a dose calibrator?
 - (a) $\pm 5\%$
 - (b) $\pm 20\%$
 - (c) $\pm 15\%$
 - (d) $\pm 10\%$.
7. The dead time of a counter is
 - (a) time taken by the counter to count 100 counts of a radioactive sample
 - (b) time the counter remains sensitive to radiation
 - (c) duration of time when the counter remains insensitive between two successive counts
 - (d) time to warm up the counter
8. Typical dead time of a G-M counter is
 - (a) less than 0.1 μsec
 - (b) B. 10–20 μsec
 - (c) C. 40–50 μsec
 - (d) D. 100–500 μsec
9. What is quenching in a G-M counter and how is it employed?
10. Different filters are used in film badge personnel dosimeters because of
 - (a) ability to estimate energy
 - (b) shielding effects
 - (c) ability to differentiate absorbed doses from different types of radiation
 - (d) convenience to measure entrance exposure

11. For area survey and contamination detection, which of the following counters is commonly used?
 - (a) ion chamber
 - (b) proportional counter
 - (c) G-M counter
 - (d) multichannel analyzer
12. To measure a 12.5 mCi (463 MBq) ^{99m}Tc sample, which equipment would you normally use?
 - (a) dose calibrator
 - (b) G-M counter
 - (c) pulse-height analyzer
 - (d) thyroid probe
13. The purpose of a photocathode in a photomultiplier tube is to convert
 - (a) β^- energy to light photons
 - (b) β^- energy to electrons
 - (c) β^- particle to kinetic energy
 - (d) γ -ray energy to light photons
14. A pulse-height analyzer is used to
 - (a) increase the count rate of a radioactive sample
 - (b) reduce the dead time loss
 - (c) sort out photons of selected energy in a radioactive sample
 - (d) prevent the scattering of photons
15. Match the following
 - (a) Well counter
 - (b) Liquid scintillation counter
 - (c) Neutron counter
 - (d) Dose calibrator
 - (a) ^{32}P
 - (b) 10 mCi of γ emitting radionuclide
 - (c) ^{235}U
 - (d) 2 μCi of ^{99m}Tc in a blood sample
16. Nowadays which of the following is commonly used for personnel monitoring?
 - (a) film badge
 - (b) thermoluminescent dosimeter
 - (c) optically stimulated luminescence dosimeter
 - (d) G-M counter
17. To identify a photon-emitting radionuclide, which of the following equipment is appropriate?
 - (a) ionization chamber
 - (b) scintillation spectrometer
 - (c) G-M counter
 - (d) proportional counter
18. Why does the measured count rate differ from the actual disintegration rate of a radioactive sample?
19. Describe the operational principle of an OSL dosimeter.

20. Film badges are used by radiation workers as personnel monitors because they
- (a) are the only reliable means of low-dose measurement
 - (b) absorb part of the radiation and thus protect the worker
 - (c) can measure dose very accurately
 - (d) provide a permanent dose record
21. A thyroid counter gives the following 2 min counts on a patient at 24 h following the $^{131}\text{I-NaI}$ administration. Calculate the % thyroid uptake.

Thyroid count	4500 counts
Thigh count	200 counts
Standard count	10,000 counts
Room background	150 counts

Is the patient hypothyroid, euthyroid, or hyperthyroid?

22. The dead time of a scintillation counter is
- (a) 200–500 μs
 - (b) 10–100 μs
 - (c) 900–1000 μs
 - (d) 0.5–10 μs
23. What is the advantage of an electronic personal dosimeter?

Suggested Reading

Knoll G. Radiation Detection and Measurement. 4th ed. New York: Wiley; 2010.
Saha GB. Physics and Radiobiology in Nuclear Medicine. 4th ed. New York: Springer; 2013.



Radiation Units, Exposure, and Absorbed Dose

3

3.1 Units of Radiation Exposure and Absorbed Dose

Radiation causes harm to human tissues and organs by exposure and absorption in proportion to the quantity of radiation. For this reason, quantitation of radiation exposure and absorption is essential. There are three essential units for radiation exposure and absorbed dose used in radiation safety practice, namely roentgen, rad, and rem. These are defined and discussed below.

Roentgen (R) is the measure of radiation exposure and is defined by the amount of X-ray and γ radiation that produces one electrostatic unit (esu) of positive or negative ions by ionization of one cubic centimeter (cc) of air at standard temperature and pressure STP, i.e., at 0 °C and 750 mmHg pressure. Since one esu is equal to 1.6×10^{-10} coulomb (C) and the air density is 1.293 kg/m^3 , it can be shown that

$$1 \text{ R} = 2.58 \times 10^{-4} \text{ C / kg} \quad (3.1)$$

Rad is the amount of energy absorbed by 1 g of any material from a radiation. With energy unit in ergs, it is defined by

$$1 \text{ rad} = 100 \text{ ergs / g absorber} \quad (3.2)$$

Rad is a universal unit for radiation absorbed dose for any type of radiation. Since 1 joule (J) = 10^7 ergs,

$$1 \text{ rad} = 10^{-2} \text{ J / kg} \quad (3.3)$$

In System International (SI) unit, the absorbed dose is expressed in gray (Gy) and defined as

$$\begin{aligned} 1 \text{ gray} &= 100 \text{ rad} \\ &= 1 \text{ J / kg} \end{aligned} \quad (3.4)$$

From Eq. (3.4),

$$1 \text{ rad} = 1 \text{ centigray (cGy)}$$

Another unit closely related to absorbed dose is *kerma* (acronym for kinetic energy released in matter) and is defined as the sum of kinetic energies of all charged particles liberated by an uncharged ionizing radiation passing through a unit mass of material. It is identical to rad for all practical purposes, but measures only energy liberated rather than energy absorbed.

The extent of radiation damage to organs and tissues varies with the mass of radiations. Therefore, α radiations will cause more damage than β radiations, which in turn will cause more damage than the massless γ radiations. To correct for the difference in radiation damage, the dose equivalent H_r (rem) has been introduced and is defined as

$$H_r (\text{rem}) = \text{rad} \times W_r \quad (3.5)$$

where W_r is the radiation weighting factor related to each radiation. In 2007, the International Commission on Radiation Protection (ICRP 103, 2007) has recommended these factors, which are presented in Table 3.1. In the past and now, the US NRC uses somewhat different values and terms them as quality factors (Q), which are also included in Table 3.1 for comparison.

In SI unit, the dose equivalent is expressed in sievert (Sv) and given by

$$1 \text{ sievert} = 100 \text{ rem} \quad (3.6)$$

The units of R, Rad, Gy, and Sv can be conveniently expressed in one-thousandth fraction such as mR, mrad, mGy, and mSv or one-millionth fraction such as μR , μrad , μGy , and μSv . Additionally, as mentioned above, one rad is also expressed as one centigray (cGy).

An important analysis shows that one R of radiation exposure deposits 86.9×10^{-4} J/kg of dry air, which means one R is equal to 0.869 rad or 0.00869 Gy in air. In comparison, one R deposits 0.96 rad or 0.0096 Gy in soft tissue.

Table 3.1 Radiation weighting factor W_r (ICRP 103) and quality factor Q (NRC 10CFR20)

Radiation	Radiation weighting factors W_r (ICRP 103) ^a	Quality factors Q (10CFR20)
Photons, all energies	1	1
Electrons and muons, all energies	1	1
Neutrons, all (unknown) energies	Continuous function	10
< 10 keV	2.5	2 to 2.5
10–100 keV	2.5 to 10	2.5 to 7.5
100–2 MeV	10 to 20	7.5 to 11
2 to 20 MeV	7 to 17.5	8 to 9
> 20 MeV	5 to 7	3.5 to 8
Protons, energy >2 MeV	2	10
Alpha particles, fission fragments heavy nuclei	20	20

^aReproduced with permission from ICRP 103, (2007)

3.2 Radiation Exposure

3.2.1 Sources of Radiation

Radiations can be natural or artificially produced. Natural radiations originate from the sun and the earth, whereas artificial radiations are produced in cyclotrons, reactors, and X-ray and CT machines. The population at large receives radiation exposure from five sources, namely (1) natural background radioactivity, (2) medical procedures, (3) consumer products, (4) industrial, security, education and research, and (5) occupational sources. Annual total exposure to individuals in the US population from all sources have significantly increased from ~360 mrem (3.6 mSv) in 1980–1982 to 625 mrem (6.25 mSv) in 2006 (NCRP 2009), largely due to prolific growth of medical procedures involving radiation. The number of CT scans and nuclear medicine procedures performed in the USA during 2006 was estimated to be 67 million and 18 million, respectively. These two imaging modalities alone contributed 36% of the total radiation exposure and 75% of the medical radiation exposure to the US population. Fig. 3.1 presents a chart showing effective doses in percent from different radiation sources to the US population in 2006, and these data are presented in a tabular form in Table 3.2.

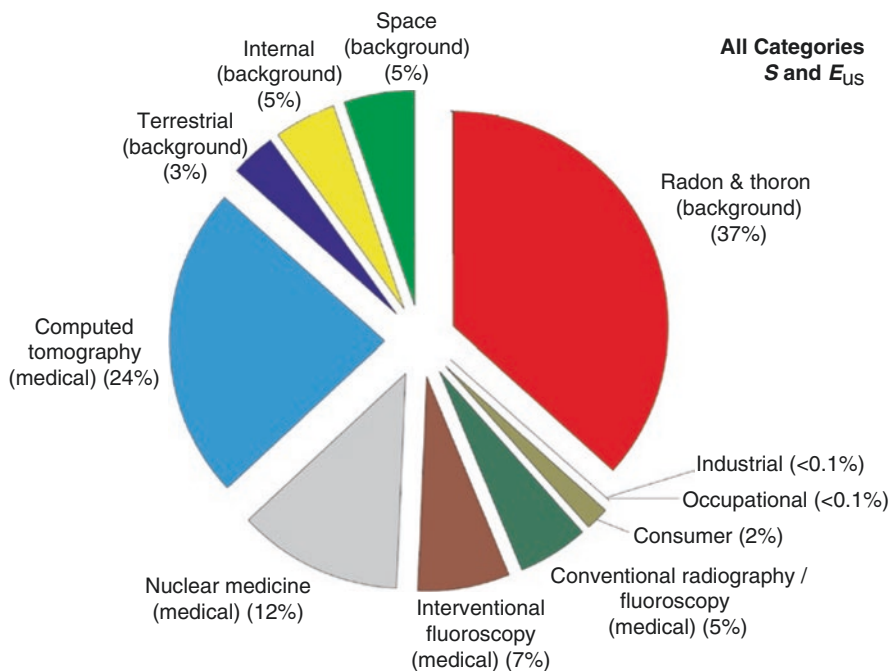


Fig. 3.1 Annual effective doses in percent to individuals of the US population in 2006 (Reprinted with permission of the National Council on Radiation Protection and Measurements, <http://NCRPonline.org>)

Table 3.2 Annual effective dose per individual in the US population from different sources in 2006¹

Sources	Average annual effective dose in mrem (mSv)
Natural sources	311 (3.11)
Radon & Thoron	228 (2.28)
External, space	33 (0.33)
External, terrestrial	21 (0.21)
Internal, ingestion	29 (0.29)
Medical procedures	300 (3.0)
CT	147 (1.47)
Nuclear medicine	77 (0.77)
Interventional radiology	43 (0.43)
Conventional radiography and fluoroscopy	33 (0.33)
Consumer products	13 (0.13)
Industrial, security, medical, education, and research	0.3 (0.003)
Occupational	0.5 (0.005)
Total	~625 (6.25)

^aAdapted with permission of the National Council on Radiation Protection and Measurements, <http://NCRPonline.org>

3.2.1.1 Natural Background Radiation

Natural background radiation exposure largely comes from radon (^{222}Rn , $t_{1/2} = 3.8$ days) and thoron (^{220}Rn , $t_{1/2} = <1$ min) (~75%), which are inert gases that originate from the natural decay of uranium and radium, and thorium, respectively. They are present in the soil, rock, and water and are trapped as gas in building materials, particularly in the basement walls. Over time, these gases are released from the crevices of the walls and rocks and float around in the enclosed basement. Radon and its decay products ^{218}Po and ^{214}Pb can attach to dust and other particles, which can be inhaled and settle in the lungs in living species. The inhaled particle radioactivity breaks down giving off α radiations that can damage the DNA of lung cells causing cancer, which is second in incidences of lung cancer due to smoking. The Environmental Protection Agency (EPA) estimates that nearly 1 out of every 15 homes in the USA has elevated radon levels. It is estimated that the average exposure to homeowners in the USA is about 228 mrem (2.28 mSv). Because of the radiotoxicity of radon, the EPA has set an action limit at 148 Bq/m³ (4 pCi/l) of radon, above which a corrective action is needed. The action limit is in reality about 4 times the average radon concentration in the US homes (~37 Bq/m³ or ~ 1.2 pCi/L). During 1989 and 1990, the National Residential Radon Survey found that about 6.0% of US homes (5.8 million) had radon levels greater than the EPA limit (Marcinowski et al., 1994) Corrective actions include to open the basement windows, increase airflow, and paint the wall with nonporous paint.

Other external exposure includes cosmic rays, terrestrial radiation (primarily from potassium, uranium, and thorium in surface soil and rocks), and internal exposure from radionuclides in the body (particularly ^{40}K).

Cosmic rays arise from the solar system, and exposure varies with altitude ranging from 28 mrem (0.28 mSv) in Honolulu to 82 mrem (0.82 mSv) in Colorado Springs. The average exposure from this source to the US population amounts to about 33 mrem (0.33 mSv). Note that air travelers are exposed to cosmic rays and receive about 0.5 mrem/h (5 μ Sv/h) resulting in an annual dose of 1 mrem (0.01 mSv).

Terrestrial radiation exposure comes from ^{40}K and decay products of thorium and uranium in soil and accounts for \sim 21 mrem (0.21 mSv).

Internal exposure arises from ingestion and inhalation of radioactivity such as ^{40}K and other radioactivity present in the food and water. Annually this adds up to \sim 29 mrem (0.29 mSv).

3.2.1.2 Medical Radiation Exposure

Medical procedures account for the highest exposure to the US population amounting to \sim 300 mrem (3.0 mSv), of which CT contributes \sim 147 mrem (1.47 mSv), nuclear medicine \sim 77 mrem (0.77 mSv), interventional radiology \sim 43 mrem (0.43 mSv), and conventional radiography and fluoroscopy 33mrem (0.33 mSv). Radiation treatment of cancer patients includes about 50% of all cancer patients (only 3% of the US population), and this exposure is insignificant and is not included in the total population exposure.

A current report NCRP 184 (2019) containing 2016 data shows that the radiation exposure from medical procedures to the US population has dropped 15–20% since the last report in NCRP 160 (2009) containing data in 2006.

- CT dose dropped about 6% in 2016, despite a 20 percent increase in CT scans since 2006.
- Drop of more than 50% in doses from nuclear imaging studies during the period 2006–2016.
- 15–40% decrease in doses across all x-ray imaging modalities during the period 2006–2016.

This reduction in dose is the result of adopting “as low as reasonably achievable” (ALARA) principles, following new dose procedure guidelines approved by medical societies, using improved imaging equipment, and applying sophisticated dose management software.

3.2.1.3 Industrial, Security, Education, and Research Exposure

Industrial security, education, and research involve the use of radioactivity in nuclear fuel cycle, by the Departments of Energy and Homeland Security, by research investigators and waste disposal in nuclear facilities. The exposure to the US population from these activities amounts to 0.3 mrem (0.003 mSv).

3.2.1.4 Occupational Exposure

Coal miners, workers in nuclear reactors, and other industries using radioactivity receive occupational exposure of about 0.5 mrem (0.005 mSv) annually.

Interestingly, the following anecdotal doses one can receive from different common living modes are provided for comparison.

- $5 \mu\text{rem}$ ($0.05 \mu\text{Sv}$)—Sleeping next to someone.
- $9 \mu\text{rem}$ ($0.09 \mu\text{Sv}$)—Living within 30 miles of a nuclear power plant for a year.
- $30 \mu\text{rem}$ ($0.3 \mu\text{Sv}$)—Living within 50 miles of a coal power plant for a year.
- 2 mrem ($20 \mu\text{Sv}$)—Chest X-ray.
- 70 mrem ($70 \mu\text{Sv}$)—FDG PET scan.
- 60 mrem ($600 \mu\text{Sv}$)—Mammogram.
- 580 mrem ($5800 \mu\text{Sv}$)—Chest CT scan.
- 17.5 rem ($175,000 \mu\text{Sv}$)—Annual dose from natural radiation on a monazite beach near Guarapari, Brazil.

3.3 Absorbed Dose

Absorbed dose to human tissues and organs results from external exposure, internal ingestion, and/or absorption. External exposure arises from handling radioactive sources, exposure to X-ray beam, treatment of patients by external electron or proton beam, accidental radioactive spill, etc. On the other hand, internal absorption of radiation energy comes from the administered dosage, inhalation, absorption of radiation through skin, or accidental ingestion of radioactivity. Before we go into detailed calculation of external exposure and internal absorbed doses, we will first define and describe relevant terms applicable in dosimetry.

Annual limit on intake (ALI): ALI is the derived limit on the amount of radioactive material allowed to be taken into the body of an adult worker by inhalation or ingestion in a year. ALIs are given in Table 1 of Appendix B to 10CFR20. ALIs of several radionuclides commonly used in nuclear medicine are given in Table 3.3.

Committed dose equivalent (CDE): CDE is the dose equivalent to organs or tissues of interest T, which is received from an intake of radioactive material by an individual for a period of 50 years following the intake and is denoted by $H_{T,50}$.

Committed effective dose equivalent (CEDE): It is the sum of the products of CDE ($H_{T,50}$) values for each organ and tissue that is irradiated by internal radiation and the corresponding tissue weighting factors W_T (see below).

Deep-dose equivalent (DDE): This is the dose equivalent at tissue depth of 1 cm (1000 mg/cm^2) from external radiation exposure.

Derived air concentration (DAC) is the concentration of a radionuclide in air that inhaled by the reference man for a working year of 2000 h under conditions of light work (with an inhalation rate of 1.2 cubic meters of air per h), results in an intake of ALI. DAC values are given in Table 1 of Appendix B to 10CFR20. DACs of several commonly used radionuclides in nuclear medicine are given in Table 3.3.

Shallow-dose equivalent (SDE): SDE is the dose equivalent received from external radiation exposure to the skin or extremities at a depth of 0.007 cm (0.007 mg/cm^2) averaged over an area of 1 square centimeter. It is denoted as H_s .

Table 3.3 Values of ALIs and DACs of several radionuclides used in nuclear medicine obtained from Appendix B to 10CFR20^a

Radionuclide	Class ^b	Occupational values		
		Col. 1	Col. 2	Col. 3
		Oral ingestion	Inhalation	
		ALI (μCi)	ALI (μCi)	DAC (μCi/ml)
³ ₁ H	Water, DAC Includes skin Absorption	8E+4	8E+4	2E-5
¹⁴ ₆ C	monoxide	–	2E+6	7E-4
	dioxide	–	2E+5	9E-5
	compounds	2E+3	1E-6	3E-9
^{99m} ₄₃ Tc	D, all compounds except those given for W	8E+4	2E+5	6E-5
	W, oxides, hydroxides, halides, and nitrates	–	2E+5	2E-4
¹¹¹ ₄₉ In	D, all compounds except those given for W	4E+3	6E+3	3E-6
	W, oxides, hydroxides, halides, and nitrates	–	6E+3	3E-6
¹²³ ₅₃ I	D, all compounds	3E+3	6E+3	3E-6
		Thyroid (1E+4)	Thyroid (2E+4)	–
¹³¹ ₅₃ I	D, all compounds	3E+1	5E+1	2E-8
		Thyroid (9E+1)	Thyroid 2E+2	–
⁶⁷ ₃₁ Ga	D, all compounds except those given for W	7E+3	1E+4	6E-6
	W, oxides, hydroxides, carbides, halides, and nitrates	–	1E+4	4E-6
²⁰¹ ₈₁ Tl	D, all compounds	2E+4	2E+4	9E-6
¹³³ ₅₄ Xe	Submersion	–	–	1E-4
¹⁸ ₉ F	D, fluorides of H, Li, Na, K, Rb, Cs, and Fr	5E+4	7E+4	3E-5
	W, fluorides of Be, Mg, Ca, Sr, Ba, Ra, Al, Ga, In, Tl, As, Sb, Bi, Fe, Ru, Os, Co, Ni, Pd, Pt, Cu, Ag, Au, Zn, Cd, Hg, Sc, Y, Ti, Zr, V, Nb, Ta, Nm, Tc, and Re	–	9E+4	4E-5
	Y, Lanthanum fluoride	–	8E+4	3E-5

^a The ALIs in this appendix are the annual intakes of a given radionuclide by “Reference Man” which would result in either (1) a committed effective dose equivalent of 5 rems (stochastic ALI) or (2) a committed dose equivalent of 50 rems to an organ or tissue (non-stochastic ALI).

The DAC values are derived from the relationship between the DAC and the ALI given by: $DAC = ALI(\text{in } \mu\text{Ci}) / (2000 \text{ h per working year} \times 60 \text{ min/h} \times 2 \times 10^4 \text{ mL per min}) = [ALI / 2.4 \times 10^9] \mu\text{Ci/mL}$, where $2 \times 10^4 \text{ mL}$ is the volume of air breathed per minute at work by “Reference Man” under working conditions of “light work.” ALIs and DACs are given for specific chemical forms

^b ALIs and DACs for inhalation in Columns 2 and 3 are given for aerosol for three types of radioactive material according to retention time in the lungs: D for less than 10 days, W for 10 to 100 days, and Y for more than 100 days

Refer to Appendix B to 10CFR20 for explanation of how different values in Tables 1, 2, 3 are calculated

3.3.1 External Dosimetry

This category of exposure includes all types of radiations such as α , β , γ radiations and neutrons. While external γ rays can cross the skin surface to give absorbed dose to internal tissues, only β radiations (electrons) have the probability of penetrating the external layer (dead layer) of the skin, which is on average 0.007 g/cm^2 thick (ranging from 0.005 g/cm^2 for the trunk and head to 0.04 g/cm^2 for hands and bottom of the feet). However, high energy β particles can penetrate up to 1 cm deep in the skin. α particles are generally stopped in the medium prior to arrival at the body, and even if they arrive, they cannot penetrate the skin. External exposure primarily affects the skin, the lens of the eye, and the surface of the whole body.

In estimating the doses from external exposure, dosimeters such as film badge, pocket dosimeter, thermoluminescent dosimeter, optically stimulated luminescence dosimeter, and electronic personal dosimeter are employed. In one technique, dosimeters are placed at seven locations of the body which are designated as compartments (C) (NRC Regulatory Guide 8.40). Each compartment is assigned a weighting factor called W_c , which is determined for each compartment by summing the stochastic tissue weighting factors (W_T) for all the organs located within that compartment. The readings of deep-dose equivalents (DDE_c) are then weighted by these compartment factors W_c . The sum of the weighted dose equivalent in each compartment gives the whole-body dose EDEX from external exposure. The dose in each compartment is measured at the highest exposed position. Thus,

$$\text{EDEX} = \sum W_c \cdot \text{DDE}_c \quad (3.7)$$

The values of W_c from NRC Regulatory Guide 8.40 are given in Table 3.4.

3.3.1.1 Calculation of External Dose

Calculation of absorbed dose from external radiation exposure to an object depends on several factors, namely exposure rate constant and strength of the radioactive source, its distance from the object, and geometrical shape of the source. The shape of the source may be a point, a line, a plane, or a volume. The following is a brief description of the calculation of doses from each of these sources. A common constant factor in these calculations is the exposure rate constant Γ , which is discussed below.

Table 3.4 Compartment factors

Area of the body/compartment	Compartment factor (W_c)
Head and neck	0.10
Thorax, above the diaphragm	0.38
Abdomen, including the pelvis	0.50
Upper right arm	0.005
Upper left arm	0.005
Right thigh	0.005
Left thigh	0.005

3.3.1.2 Exposure Rate Constant

Radiation exposure arises from the emission of radiations from radionuclides and depends on their energy and decay characteristics. Radiations are emitted isotropically around 360° from a point source. The exposure X on a sphere of radius r from a point source of activity A mCi (MBq) is given by

$$X = (A \sum N_i \cdot E_i \cdot \mu_i) / 4\pi r^2 \quad (3.8)$$

where N_i is the fractional abundance of photons of energy E_i in MeV per disintegration and μ_i is the mass absorption coefficient (cm^2/g) of the photon in air. The quantity $(\sum N_i \cdot E_i \cdot \mu_i) / 4\pi$ in Eq. (3.8) is called *exposure rate constant* denoted by Γ , and is defined as the exposure from γ rays and X-rays from 1 mCi (37 MBq) of a radionuclide at a distance of 1 cm. Thus replacing 1 mCi for A and 1 cm for r in Eq. (3.8),

$$\Gamma = (\sum N_i \cdot E_i \cdot \mu_i) / 4\pi \quad (3.9)$$

Introducing units of the parameters,

$$\Gamma = \frac{\sum \left(N_i \left(\frac{\gamma}{dis} \right) \times E_i \left(\frac{\text{MeV}}{\gamma} \right) \times \mu_i \left(\frac{\text{cm}^2}{g} \right) \times 3.7 \times 10^7 (mCi \cdot s) \right)}{4\pi} \quad (3.10)$$

Using $1 \text{ MeV} = 1.6 \times 10^{-6} \text{ erg}$, $1 \text{ erg} = 0.01 \text{ g} \cdot \text{rad}$, $1 \text{ hr} = 3600 \text{ s}$, $1 \text{ R} = 0.869 \text{ rad}$ in air and $\pi = 3.14$,

$$\begin{aligned} \Gamma &= \sum \left(N_i \left(\frac{\gamma}{dis} \right) \times E_i \left(\frac{\text{MeV}}{\gamma} \right) \times \mu_i \left(\frac{\text{cm}^2}{g} \right) \times 3.7 \times 10^7 (mCi \cdot s) \right) \\ &\quad \times 1.6 \times 10^{-6} \text{ erg} / \text{MeV} \\ &\quad \times 0.01 \text{ g} \cdot \text{rad} / \text{erg} \\ &\quad \times \frac{1 \text{ R}}{0.869 \text{ rad}} \text{ in air} \\ &\quad \times 3600 \text{ s} / \text{hr} \\ &\quad \times \frac{1}{4 \times 3.14} \\ \Gamma &= 195.5 \sum N_i E_i \mu_i \left(\text{R} \cdot \text{cm}^2 / \text{mCi} \cdot \text{h} \right) \end{aligned} \quad (3.11)$$

The conventional unit of Γ is $\text{R} \cdot \text{cm}^2 / \text{mCi} \cdot \text{h}$ at 1 cm, and in System International (SI) unit, $\mu\text{Gy} \cdot \text{m}^2 / \text{GBq} \cdot \text{h}$ at 1 m. The Γ values for some representative radionuclides are presented in Table 3.5.

Table 3.5 Exposure rate constants in lead for commonly used in nuclear medicine^a

Radionuclides	Γ (C.m ² /kg.MBq.s at 1 cm)	Γ (μ Gy · m ² /GBq · h at 1 m) ^b	Γ (R-cm ² /mCi-h at 1 cm)
³⁷ Cs	6.64×10^{-13}	92.70	3.43
¹⁸ F	1.10×10^{-12}	153.51	5.68
¹³¹ I	4.26×10^{-13}	59.46	2.20
^{99m} Tc	1.54×10^{-13}	21.08	0.78
¹¹¹ In	6.70×10^{-13}	93.51	3.46
⁶⁷ Ga	1.55×10^{-13}	2.16	0.08
⁶⁸ Ga	1.05×10^{-12}	146.76	5.43
⁵⁷ Co	1.09×10^{-13}	25.95	0.96
⁶⁰ Co	2.50×10^{-12}	348.65	12.9
²⁰¹ Tl	8.72×10^{-14}	12.16	0.45
⁹⁹ Mo	1.78×10^{-13}	24.86	0.92

^aAdapted with permission from Smith DS and Stabin MG. Exposure rate constants and lead shielding values for over 1100 radionuclides. Health Physics. 102(3): 271; 2012

^b These values are obtained by multiplying values in column 3 by 27.027, since the R-cm²/mCi-h at 1 cm = 27.027 μ Gy · m²/GBq-h at 1 m

3.3.2 External Exposure from a Point Source

Exposure X at a distance d from a point source of radioactivity A is given by

$$X = \frac{A \cdot \Gamma}{d^2} \quad (3.12)$$

If the distance from a source is 10 times larger than the size of a source, the source can be considered as a point source. This item is discussed in detail in Sect. 4.1.2 in Chap. 4.

3.3.2.1 External Dose from a Line Source

A line source can be exemplified by rod sources of radioactivity of certain length, which are used for various purposes. A typical geometry for exposure from a line source is illustrated in Fig. 3.2. For the rod source to be considered as a line source, the diameter of the source must be much smaller than the distance between the rod and the point of exposure. Suppose an individual stands off-center at a distance d from the line source of length L and activity A (mCi/cm or MBq/m). Because of the off-center standing, exposure comes from two unequal sublengths L_1 and L_2 as seen in the figure. So, the exposure rate X to the individual (Stabin 2008) is

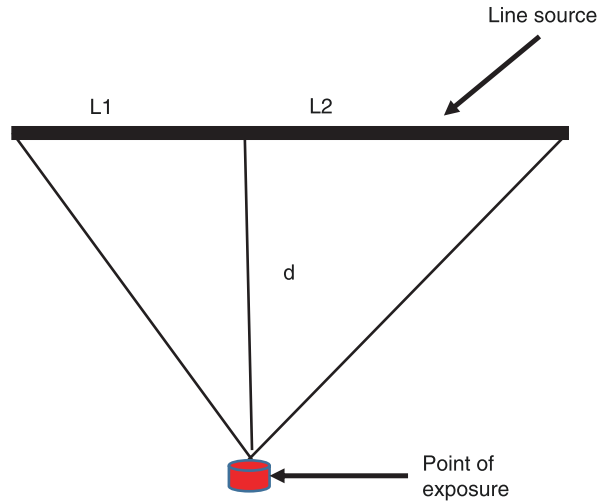
$$X = (\Gamma A / d)[(\tan^{-1}(L_1 / d)) + (\tan^{-1}(L_2 / d))] \quad (3.13)$$

Note that if the individual stands far away (10 times the length of the source) from the line source, then the source may be considered a point source.

3.3.2.2 External Exposure from a Plane Source

Plane sources can be conceived of as thin circular or rectangular flood sources used for calibration of scintillation cameras, or spilled radioactivity spread over an area.

Fig. 3.2 Illustration of exposure from a typical line source of radioactivity



Using a circular source of radius r and having a concentration of C (mCi/cm² or MBq/m²), the exposure rate X at a distance d above the center of the source (Stabin, 2008) is given by

$$X = \pi \times \Gamma \times A \times \ln \left(\frac{r^2 + d^2}{d^2} \right) \quad (3.14)$$

3.3.2.3 External Exposure from a Volume Source

Calculation of exposure rate from three-dimensional volume sources of radioactivity is difficult and challenging because of the complexity of the geometry of the source. A theoretical simplistic example of exposure rate X from a sphere of radius r containing concentration C of a radionuclide is

$$X = \frac{C \Gamma}{2} \frac{4\pi}{\mu} (1 - e^{-\mu r}) \quad (3.15)$$

where μ is the linear absorption coefficient and Γ is the exposure rate constant.

3.3.3 Internal Dosimetry

Internal absorbed dose to different organs and the whole-body results from radiations administered to the body or from inhalation of radioactivity that deposits in the lungs, or ingestion of food or drink contaminated with radioactivity. Calculation of absorbed dose is based on several factors, namely

1. Physical decay and biological elimination of radioactivity over time
2. Amount and biodistribution of radioactivity

3. Fractional abundance of a radiation from the radionuclide
4. Fraction of energy of the radiation deposited in the target (organ or tissue) from a source (organ or tissue) activity.

The physical parameters of radionuclides are established and known, and their biodistributions are obtained by experiments in humans and animals. The internal dose is given in CEDE and calculated by using (1) concentrations of radioactive materials in air in work areas of the individual; (2) quantities of radionuclides in the body determined by bioassay or biodistribution; (3) quantities of radionuclides excreted from the body; or (4) combination of these measurements.

Based on the above factors, the equation for absorbed dose (D_t) is given by

$$D_t = (f \cdot A_0 / m) \cdot \frac{1}{\lambda_e} (1 - e^{-\lambda_e t}) \cdot \sum_{i=1}^n Ni \cdot Ei \cdot \phi_i(v \leftarrow r) \quad (3.16)$$

where A_0 = administered activity in μCi (3.7×10^4 dis/s)

m = mass of the target tissue in g

f = fraction of administered radioactivity localized in the source organ obtained from biodistribution.

Ni = the abundance of i th radiation

Ei = energy in MeV of i th radiation (1 Mev = 1.6×10^{-6} ergs and 1 erg = 0.01 g.rad)

λ_e = effective decay constant ($= \frac{0.693}{T_e}$), where T_e is the effective half-life,

which is given by $\frac{T_p \times T_b}{T_p + T_b}$, where T_p is the physical decay half-life and T_b is the biological elimination half-life of the radionuclide. All half-lives are given in h.

t = time of decay in h (3600 s).

$\phi_i(v \leftarrow r)$ = absorbed fraction defined as the fraction of energy of the i th radiation emitted from the source volume r deposited in the target volume v .

Assuming complete decay of the radionuclide in the body, i.e., the cumulated activity over time $t = \infty$, and substituting all conversion factors mentioned above, Eq. (3.16) becomes

$$D_\infty = 1.44 \cdot (f \cdot A_0 / m) \cdot T_e \cdot \sum_{i=1}^n 2.13 Ni \cdot Ei \cdot \phi_i(v \leftarrow r) \quad (3.17)$$

The quantity $2.13NiEi$ is called the *equilibrium dose constant* and denoted by Δi , which has the unit of g.rad/ $\mu\text{Ci}\cdot\text{h}$. Eq. (3.17) becomes

$$D_\infty = 1.44 \cdot (f \cdot A_0 / m) \cdot T_e \cdot \sum_{i=1}^n \Delta i \cdot \phi_i(v \leftarrow r) \quad (3.18)$$

Although Eq. (3.18) is derived for administered activity, it is equally valid for inhaled and ingested radioactivity with appropriate attention to its biodistribution.

In dosimetry, Eq. (3.18) is expressed in abbreviation (omitting subscript ∞) as

$$D(v \leftarrow r) = \tilde{A} \cdot S \quad (3.19)$$

$$\text{where } \tilde{A} = 1.44 \cdot f \cdot A_0 \cdot T_e \quad (3.20)$$

$$S = \sum_{i=1}^n \Delta i \cdot \phi_i (v \leftarrow r) / m \quad (3.21)$$

The quantity \tilde{A} is called the *cumulated activity* and has the unit of $\mu\text{Ci}\cdot\text{h}$ or $\text{MBq}\cdot\text{h}$. The quantity S is termed *mean absorbed dose per cumulated activity* and has the unit of $\text{rad}/\mu\text{Ci}\cdot\text{h}$ or $\mu\text{Sv}/\text{MBq}\cdot\text{h}$.

The effective half-life in Eq. (3.18) is valid for the assumption that the radiopharmaceutical localizes in the organ instantaneously and is cleared by both physical decay and biological decay at equal rate. But in reality, the tracer uptake may be slower or faster, and T_b may be different, because of the elimination of the tracer by different routes.

When $T_p \gg T_b$, then

$$\tilde{A} = 1.44 \cdot f \cdot A_0 \cdot T_b \quad (3.22)$$

When $T_b \gg T_p$, then

$$\tilde{A} = 1.44 \cdot f \cdot A_0 \cdot T_p \quad (3.23)$$

When the uptake of the tracer is gradual and the clearance is slow,

$$\tilde{A} = 1.44 \cdot f \cdot A_0 \cdot T_e \cdot (T_q / T_u) \quad (3.24)$$

where T_u is the biological uptake half-time, T_q is the effective uptake half-time, and T_e is the net effective half-time for physical decay and biological elimination. T_q is calculated as

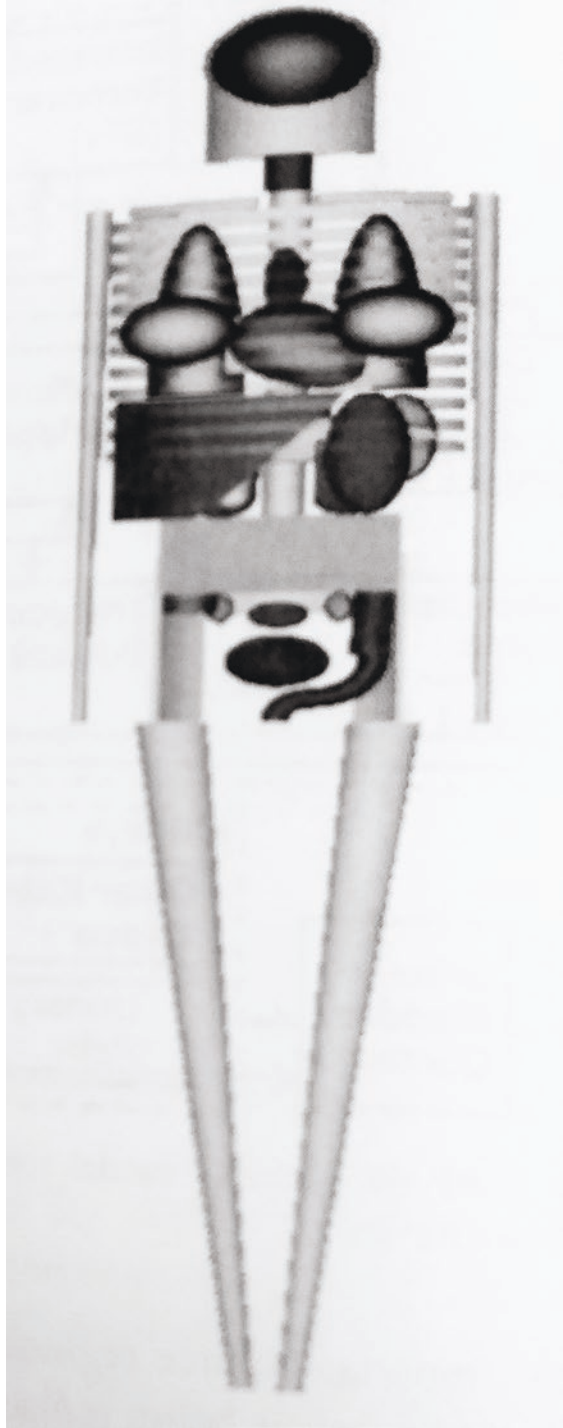
$$T_q = (T_p \times T_u) / (T_p + T_u) \quad (3.25)$$

The biodistribution and fractional energy deposition are variable from patient to patient and are, therefore, approximated for a “Standard” or “Reference” 70-kg man. The target is an organ or tissue of interest that receives the radiation emitted from multiple organs (sources) in the body containing radioactivity.

The calculation of S values is quite laborious, because ϕ_i varies from subject to subject (variation in shape, size, and location of different organs resulting in variation in absorption of radiation). Particulate radiations such as α particles, β^- particles, conversion electrons, and low energy X-rays and γ rays with energy less than 11 keV are absorbed in the source volume r , i.e., the source and target volume are the same, and ϕ_i will be equal to 1.

The Society of Nuclear Medicine and Molecular Imaging (SNMMI) has established the Medical Internal Radiation Dose (MIRD) committee to calculate the S values for different radionuclides for a reference man (Fig. 3.3). For this purpose, different organs are assigned appropriate locations in the reference man. One organ is considered a target, while all other organs are considered the sources of radiation. The Monte Carlo method is employed to estimate ϕ_i in different organs from all

Fig. 3.3 The first adult phantom designed by the MIRD committee in pamphlet 5 (Reprinted by permission from Stabin MG. Radiation Protection and Dosimetry. Springer, New York; 2008: p 224)



radiations of a radionuclide and then to calculate S by Eq. (3.21) from the knowledge of the characteristics of the radionuclide and mass of the target organ in the reference man. A MIRDOSE software program was used to perform the Monte Carlo simulation of the radiation interaction in the body. The S values have been given in MIRD pamphlet no 11 for many clinical radiopharmaceuticals used in nuclear medicine. The S values for commonly used ^{99m}Tc obtained from MIRD Pamphlet No 11 are given in Table 3.6.

Problem 3.1

Calculate the absorbed dose to the kidneys from administration of 10 mCi of ^{99m}Tc -MAG3. Assume that 10% of it accumulates in the kidneys without further biological elimination, 5% remains in the body indefinitely, and 85% is excreted in the urine (bladder) with an uptake half-time of 2 h. The net biological half-time is 4 h.

Answer

Absorbed dose arises from three sources of radioactivity, namely kidneys (10%), total body (5%), and urinary bladder (85%).

Administered activity = 10 mCi = $10 \times 1000 \mu\text{Ci} = 10,000 \mu\text{Ci}$.

Effective half-life $T_e = \frac{6 \times 4}{6 + 4} = 2.4 \text{ h}$.

Cumulated activity in kidneys using Eq. (3.23),

$$\tilde{A} = 1.44 \times 0.1 \times 10,000 \times 6 = 8640 \mu\text{Ci} \cdot \text{h}$$

Cumulated activity in the total body using Eq. (3.23),

$$\tilde{A} = 1.44 \times 0.05 \times 10,000 = 4320 \mu\text{Ci} \cdot \text{h}$$

Cumulated activity in the bladder using Eqs. (3.24) and (3.25),

$$\tilde{A} = 1.44 \times 0.85 \times 10,000 \times 2.4 \times \left(\frac{(6 \times 2)}{(6 + 2)} \right) / 2 = 214,200 \mu\text{Ci} \cdot \text{h}$$

From Table 3.4, the following S values for ^{99m}Tc are obtained:

- S (kidneys ← kidneys) = $1.9 \times 10^{-4} \text{ rad} / \mu\text{Ci} \cdot \text{h}$.
- S (kidneys ← total body) = $2.2 \times 10^{-6} \text{ rad} / \mu\text{Ci} \cdot \text{h}$.
- S (kidneys ← bladder) = $2.6 \times 10^{-7} \text{ rad} / \mu\text{Ci} \cdot \text{h}$.

Now using Eq. (3.19), the doses from each source:

- D (kidneys ← kidneys) = $8740 \times 1.9 \times 10^{-4} = 1.66 \text{ rad}$
- D (kidneys ← total body) = $4320 \times 2.2 \times 10^{-6} = 0.01 \text{ rad}$
- D (kidneys ← bladder) = $214,200 \times 2.6 \times 10^{-7} = 0.056 \text{ rad}$

Total dose to the kidneys = $1.66 + 0.01 + 0.056 \sim 1.73 \text{ rad}$ or 17 mSv .

Table 3.6 S^i , mean absorbed dose per unit cumulated activity ($\text{rad}/\mu\text{Ci} \cdot \text{h}$)^b for ^{99m}Tc

Source organs	Bladder content	Stomach content	Kidneys	Liver	Lungs	Ovaries	Red marrow	Spleen	Testes	Thyroid	Total body
Adrenal	1.5E-07	2.7E-06	1.1E-05	4.5E-06	2.7E-06	3.3E-07	2.3E-06	6.3E-06	3.2E-08	1.3E-07	2.3E-06
Bladder wall	1.6E-04	2.7E-07	2.8E-07	1.6E-07	3.6E-08	7.2E-06	9.9E-07	1.2E-07	4.8E-06	2.1E-09	2.3E-06
Bone (total)	9.2E-07	9.0E-07	1.4E-06	1.1E-06	1.5E-06	1.5E-06	4.0E-06	1.1E-06	9.2E-07	1.0E-06	2.5E-06
Stomach	2.7E-07	1.3E-04	3.6E-06	1.9E-06	1.8E-06	8.1E-07	9.5E-07	1.0E-05	3.2E-08	4.5E-08	2.2E-06
Kidneys	2.6E-07	3.5E-06	1.9E-04	3.9E-06	8.4E-07	9.2E-07	2.2E-06	9.1E-06	4.0E-08	3.4E-08	2.2E-06
Liver	1.7E-07	2.0E-06	3.9E-06	4.6E-05	2.5E-06	5.4E-07	9.2E-07	9.8E-07	3.1E-08	9.3E-08	2.2E-06
Lungs	2.4E-08	1.7E-06	8.5E-07	2.5E-06	5.2E-05	6.0E-08	1.2E-06	2.3E-06	6.6E-09	9.4E-07	2.0E-06
Marrow (red)	2.2E-06	1.6E-06	3.8E-06	1.6E-06	1.9E-06	5.5E-06	3.1E-05	1.7E-06	7.3E-07	1.1E-06	2.9E-06
Ovaries	7.3E-06	5.0E-07	1.1E-06	4.5E-07	9.4E-08	4.2E-03	3.2E-06	4.0E-07	0.0	4.9E-09	2.4E-06
Skin	5.5E-07	4.4E-07	5.3E-07	4.9E-07	5.3E-07	4.1E-07	5.9E-07	4.7E-07	1.4E-06	7.3E-07	1.3E-06
Spleen	6.6E-07	1.0E-05	8.6E-06	9.2E-07	2.3E-06	4.9E-07	9.2E-07	3.3E-04	1.7E-08	1.1E-07	2.2E-06
Testes	4.7E-06	5.1E-08	8.8E-08	6.2E-08	7.9E-09	0.0	4.5E-07	4.8E-08	1.4E-03	5.0E-10	1.7E-06
Thyroid	2.1E-09	8.7E-08	4.8E-08	1.5E-07	9.2E-07	4.9E-09	6.8E-07	8.7E-08	5.0E-10	2.3E-03	1.5E-06
Total body	1.9E-06	1.9E-06	2.2E-06	2.2E-06	2.0E-06	2.6E-06	2.2E-06	2.2E-06	1.9E-06	1.8E-06	2.0E-06

^a Adapted with permission of the Society of Nuclear Medicine from Snyder, et al. "Sⁱ absorbed dose per unit cumulated activity for selected radionuclides and organs. MIRD pamphlet no. 11. New York: Society of Nuclear Medicine; 1975

^b Divide by 3.7 to convert to SI unit (Gy/MBq · h)

The absorbed doses to different organs from different nuclear medicine procedures are mostly available from the package inserts of the radiopharmaceuticals and are given in Table 3.7. The MIRD anatomical model was too simplistic to provide

Table 3.7 Radiation absorbed doses in adults from different radiopharmaceuticals in nuclear medicine

Radiopharmaceutical	Organ	Dose	
		rad/ mCi	mGy/GBq
^{99m} Tc-pertechnetate	Thyroid	0.130	35.1
	Upper large intestine	0.120	32.4
	Lower large intestine	0.110	30.0
	Stomach	0.051	13.8
	Ovaries	0.030	8.1
	Testes	0.009	2.4
^{99m} Tc-sulfur colloid	Liver	0.335	91.2
	Spleen	0.213	57.4
	Marrow	0.028	7.4
	Ovaries	0.056	15.2
^{99m} Tc-diethylenetriaminopentacetic acid (DTPA)	Bladder (2-h void)	0.115	31.1
	Kidneys	0.090	24.3
	Gonads	0.011	3.0
^{99m} Tc-tetrofosmin (Myoview) at rest	Gallbladder	0.180	48.7
	Upper large intestine	0.113	30.5
	Lower large intestine	0.082	22.2
	Heart (wall)	0.015	4.1
	Kidneys	0.046	12.4
	Ovaries	0.035	9.5
	Bladder (wall)	0.071	19.2
^{99m} Tc-macroaggregated albumin (MAA)	Lungs	0.22	59.5
	Kidneys	0.011	3.0
	Liver	0.018	4.9
	Ovaries	0.008	2.2
	Testes	0.006	1.6
^{99m} Tc-stannous pyrophosphate (blood pool imaging)	Bladder	0.034	9.2
	Red marrow	0.019	5.1
	Ovaries	0.023	6.2
	Testes	0.013	3.5
	Blood	0.051	13.8
^{99m} Tc-methylenediphosphonate (MDP)	Bone	0.035	9.5
	Bladder wall (2-h void)	0.130	35.1
	Kidneys	0.040	10.8
	Marrow	0.026	7.0
	Ovaries	0.012	3.2
	Testes	0.008	2.1
^{99m} Tc-mebrofenin (Choletec)	Liver	0.047	12.7
	Lower large intestine	0.474	128.1
	Upper large intestine	0.364	98.4
	Gallbladder	0.137	37.0
	Bladder	0.029	7.8
	Red marrow	0.034	9.1
	Ovaries	0.101	27.3

(continued)

Table 3.7 (continued)

Radiopharmaceutical	Organ	Dose	
		rad/ mCi	mGy/GBq
^{99m} Tc-mercaptoacety glycyl glycyl glycine (MAG3)	Bladder wall	0.480	129.7
	Gallbladder	0.016	4.3
	Kidneys	0.014	3.8
	Lower large intestine	0.033	8.9
	Ovaries	0.026	7.0
^{99m} Tc-hexamethylpropylene amine oxime (Ceretek)	Brain	0.026	7.0
	Thyroid	0.100	27.0
	Kidneys	0.130	35.1
	Ovaries	0.023	6.2
	Gallbladder	0.190	51.4
	Lacrimal gland	0.258	69.7
^{99m} Tc-dimercaptosuccinic acid (DMSA)	Bladder wall	0.070	18.9
	Kidneys	0.630	170.3
	Liver	0.031	8.6
	Bone marrow	0.022	5.9
	Ovaries	0.013	3.6
	Testes	0.007	1.8
^{99m} Tc-ethyl cysteinat dimer (Neurolite)	Brain	0.020	5.4
	Gallbladder wall	0.092	24.9
	Upper large intestine	0.063	17.0
	Kidneys	0.027	7.3
	Liver	0.020	5.4
	Ovaries	0.030	8.1
^{99m} Tc-sestamibi (Cardiolite) at rest	Bladder wall	0.270	72.9
	Gallbladder	0.067	18.1
	Upper large intestine	0.180	48.6
	Lower large intestine	0.13	35.1
	Heart wall	0.017	4.6
	Kidneys	0.067	18.1
	Ovaries	0.050	13.5
	Bladder wall	0.067	18.1
¹³¹ I-sodium iodide (25% uptake)	Thyroid	1300.00	3.50×10^5
	Ovaries	0.14	37.8
	Liver	0.48	129.7
¹²³ I-ioflupane (DaTscan) ^c	Brain	0.066	17.8
	Striata	0.85	230.0
	Liver	0.10	27.9
	Lungs	0.15	41.2
	Bladder wall	0.20	53.1
	Lower large intestinal wall	0.16	42.0
¹²³ I-sodium iodide (25% uptake)	Thyroid	12.75	3445.9
	Bladder	0.30	81.1
	Ovaries	0.05	13.5
¹²³ I-metaiodobenzylguanidine (MIBG)	Adrenals	0.059	16.0
	Brain	0.018	4.8
	Gallbladder	0.080	22.0
	Heart	0.067	18.0
	Kidneys	0.039	11.0
	Liver	0.270	73.0
	Red marrow	0.026	7.1
	Testes	0.260	7.1

Table 3.7 (continued)

Radiopharmaceutical	Organ	Dose	
		rad/ mCi	mGy/GBq
¹³¹ I-metaiodobenzylguanidine (MIBG)	Bladder (wall)	2.96	800.0
	Liver	2.92	789.2
	Spleen	2.18	589.2
	Heart (wall)	1.41	381.1
	Adrenal medulla	0.78	210.8
	Kidneys	0.33	89.2
	Ovaries	0.27	73.0
¹¹¹ In-white blood cell (WBC)	Spleen	26.0	7027.0
	Liver	38.0	10,270.0
	Red marrow	26.0	7027.0
	Skeleton	7.28	1967.6
	Ovaries	3.80	1027.0
¹¹¹ In-pentetreotide (OctreoScan)	Kidneys	1.81	488.4
	Liver	0.41	110.0
	Spleen	2.46	664.9
	Bladder wall	1.007	272.2
	Ovaries	0.16	44.1
¹¹¹ In-capromab pendetide (ProstaScint)	Liver	3.70	1000.0
	Spleen	3.26	881.1
	Kidneys	2.48	670.3
	Marrow	0.86	232.4
	Testes	1.12	339.0
	Prostate	1.64	443.2
¹⁸ F-fluciclovine (Axumin)	Heart wall	0.19	52
	Liver	0.12	33
	Lungs	0.13	34
	Pancreas	0.38	102
	Marrow	0.09	25
	Bladder wall	0.09	25
	Uterus	0.17	45
¹⁸ F-sodium fluoride	Bone surface	0.15	40.0
	Bladder wall	0.81	220.0
	Red marrow	0.15	40.0
¹⁸ F-florbetapir (Amyvid)	Upper large intestine wall	0.27	74.0
	Small intestine	0.24	66.0
	Osteogenic cells	0.104	28.0
	Brain	0.037	10.0
	Gallbladder wall	0.53	143.0
	Liver	0.24	64.0
	Bladder wall	0.10	27.0
¹⁸ F-florbetaben (Neuraceq)	Brain	0.05	13.0
	Kidneys	0.09	24.0
	Liver	0.14	39.0.0
	Lower large intestine wall	0.13	35.0
	Small intestine	0.11	31.0
	Upper large intestine wall	0.14	38.0
	Urinary bladder wall	0.26	70.0

(continued)

Table 3.7 (continued)

Radiopharmaceutical	Organ	Dose	
		rad/ mCi	mGy/GBq
¹⁷⁷ Lu -DOTATATE Lutathera	Kidneys	2.42	654.0
	Liver	1.11	299.0
	Spleen	3.12	846.0
	Bladder wall	1.62	437.0
	Osteogenic cell	0.56	151.0
	Heart wall	0.12	32.0
	Lungs	0.11	31.0
¹⁸ F-flutemetamol (Vizamy1)	Gallbladder wall	1.06	287.0
	Brain	0.041	11.0
	Upper large intestinal wall	0.433	117.0
	Bladder wall	0.537	145.0
	Liver	0.211	57.0
	Small intestinal wall	0.377	102.0
¹⁸ F-fluorodeoxyglucose (FDG)	Brain	0.07	18.9
	Heart	0.22	59.5
	Bladder	0.32	86.6
	Spleen	0.14	37.9
	Ovaries	0.053	14.3
	Uterus	0.062	16.8
	Kidneys	0.032	8.6
⁸² Rb-rubidium chloride	Heart (wall)	0.007	1.9
	Kidneys	0.032	8.6
²⁰¹ Tl-thallous chloride	Heart	0.50	135.1
	Kidneys	1.20	324.3
	Liver	0.55	148.6
	Thyroid	0.65	175.7
	Testes	0.50	135.1
	Adrenals	0.31	86.0
⁶⁸ Ga-DOTATATE	Kidneys	0.34	93.0
	Liver	0.19	50.0
	Spleen	0.40	109.0
	Bladder wall	0.36	98.0
	Liver	0.46	124.3
⁶⁷ Ga-gallium citrate	Marrow	0.58	156.7
	Kidneys	0.41	110.8
	Spleen	0.53	143.2
	Upper large intestine	0.56	151.4
	Lower large intestine	0.90	243.2
	Gonads	0.26	70.0
	Bone surfaces	25.000	6756.8
	Red marrow	5.700	1540.0
¹⁵³ Sm-lexidronam (Quadramet)	Bladder wall	3.600	973.0
	Kidneys	0.065	17.6
	Ovaries	0.032	8.6
	Liver	0.019	5.1

Table 3.7 (continued)

Radiopharmaceutical	Organ	Dose		
		rad/ mCi	mGy/GBq	
⁸⁹ Sr-strontium chloride (Metastron)	Bone surfaces	63.0	17,000.0	
	Red bone marrow	40.7	11,000.0	
	Lower bowel	17.4	4700.0	
	Bladder wall	4.8	1300.0	
	Ovaries	2.9	800.0	
	Kidneys	2.9	800.0	
⁹⁰ Y-ibritumomab tiuxetan (Zevalin) ^a	Spleen	27.2	7350.0	
	Liver	16.0	4320.0	
	Lungs	7.6	2050.0	
	Bladder wall	3.3	890.0	
	Red marrow	2.2	590.0	
	Kidneys	0.8	220.0	
	Other organs	1.5	400.0	
	Lungs	0.008	2.2	
¹³³ Xe-xenon	Lungs	0.008	2.2	
	²²³ Ra-radium chloride (Xofigo)	Osteogenic cells	4262.6	1.15 × 10 ⁶
		Red marrow	513.5	1.4 × 10 ⁵
		Bladder wall	14.9	4030.0
		Lower intestine wall	171.9	4.6 × 10 ⁴
		Liver	11.0	2980.0
Kidneys		11.9	3200.0	

^aFrom Wiseman GA, Kornmehl E, Leigh B, et al. Radiation dosimetry results and safety correlations from ⁹⁰Y-Ibritumomab tiuxetan radioimmunotherapy for relapsed or refractory non-Hodgkin's lymphoma: combined data from 4 clinical trials. *J Nucl Med.* 44:465; 2003

realistic and accurate S values and the cumulated activities from biokinetic data of radiopharmaceuticals in the model. Over time, the ICRP and the Radiation Dose Assessment Resources (RADAR) group associated with the Society of Nuclear Medicine and Molecular Imaging have improvised these anatomical models to account for accuracy of relative positions of different organs in the body, and for difference in gender, age, and body weight of individuals. Essentially, differences between male and female (including pregnancy) and between adults and children of different ages (including newborn) have been appropriately accounted for using these models. An example of the latest model devised by Stabin et al. (2018) is illustrated in Fig. 3.4. Several computer software have been developed by the ICRP and RADAR group to calculate the S values. The OLINDA/EXM 2.0 developed by the RADAR group is the most sophisticated program that provides more accurate and realistic dosimetry of different radiopharmaceuticals.

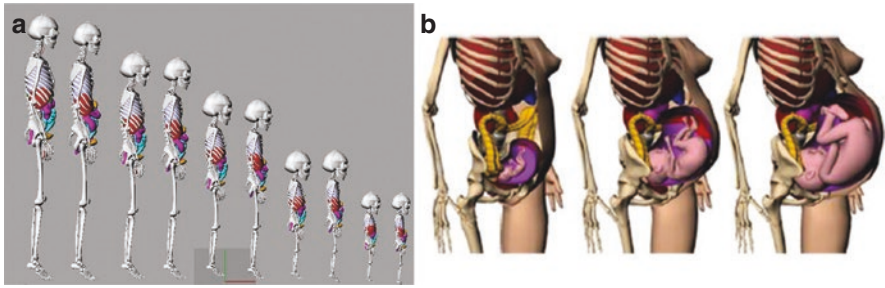


Fig. 3.4 (a) Male (left in the pairs) and female (right in pairs) adult-to-pediatric dosimetry phantoms. (b) Pregnant female dosimetry phantoms (Reprinted with permission from Stabin MG, Siegel JA, Xu. G. RADAR develops new generation of dosimetry phantoms. *J Nucl Med.* 2018; 59 (5): 11 N)

3.3.4 Dose Limits to Radiation Workers and Others

1. The annual maximum permissible dose (MPD) to an adult occupational radiation worker is the more limiting of (a) TEDE of 5 rem (0.05 Sv) or (b) the sum of the deep-dose equivalent and the committed dose equivalent to any individual organ or tissue other than the lens of the eye being equal to 50 rem (0.5 Sv). Note that there is no lifetime cumulative dose limit in the current 10CFR20 although the NCRP recommends a lifetime cumulative dose of 1 rem (0.01 Sv) \times age in years.
2. The annual limit on the occupational dose to the lens of the eye is 15 rem (0.15 Sv).
3. The annual limit on the occupational dose to the skin and other extremities is the shallow-dose equivalent of 50 rem (0.5 Sv).
4. The annual occupational dose limit for minors (age < 18 years) is 10% of the annual dose limit for adults.
5. The dose limit for a *declared pregnant woman* during the entire pregnancy (gestation period of 10 months) from occupational radiation exposure is 0.5 rem (0.005 Sv). A declared woman is one who declare her pregnancy to the immediate supervisor for consideration of occupational exposure, if she wants to be monitored. To that effect, a declaration form is signed by the employee and the supervisor. By mutual agreement based on judgment of the RSO and depending on the condition of pregnancy, the employee may be assigned an alternate position involving no radiation, take a leave of absence for pregnancy period, or resign. The RSO shall provide the employee information regarding potential radiation injury associated with in utero radiation exposure and the NRC regulatory limits.
6. The dose to the fetus/embryo is the sum of the deep-dose equivalent to the pregnant woman and the dose equivalent from the radionuclides localized in the embryo/fetus, not to exceed 0.5 rem (5 mSv) per gestation period.

7. The total effective dose equivalent (TEDE) limit to individual members of the public is 0.1 rem (0.001 Sv) per year. However, this limit can be increased to 0.5 rem (0.005 Sv) annually, provided the need for such a higher limit is demonstrated and approved by the NRC on the condition that the ALARA principle is followed. Despite the dose limit of 0.1 rem (0.001 Sv) for the public, a visitor to a patient administered radiopharmaceutical may receive up to 0.5 rem (0.005 Sv) if the visit is deemed appropriate.
8. The dose in an unrestricted area from an external source is 2 mrem (0.02 mSv) in an h.

3.3.5 Planned Special Exposure

Under a planned special exposure, a licensee may authorize an adult worker to receive extra doses in addition to the limit permitted by the NRC on the following conditions:

- (a) When an alternative procedure resulting in less exposure than the planned special exposure is unavailable or impractical.
- (b) Authorization for the planned exposure must be in writing by the licensee prior to the procedure.
- (c) Before a planned special exposure is adopted, the licensee ensures that the individuals involved are knowledgeable in the purpose of planned operation, estimated doses, potential risk, and in the ALARA principle.
- (d) Planned special exposure is not permissible if the dose from all planned special exposures and all doses in excess of the limits received by an individual worker exceed the NRC annual dose limit in a year and 5 times the annual dose limit during the individual's lifetime.
- (e) Prior to permitting an individual to participate in a planned special exposure, the licensee ascertains prior doses as required by § 20.2104(b) during the lifetime of the individual for each individual involved.
- (f) The licensee makes a record of the planned special procedure and submits a written report to the NRC.
- (g) The licensee is required to estimate the dose from the planned procedure, records it in individual's dose record, and informs him of the estimate in writing within 30 days from the date of planned special exposure.
- (h) The dose from the planned special exposure is not to be included in the future occupational dose of the individual.

Depending on license conditions, both internal and external doses have to be summed up to comply with the dose limits. The total dose from all planned procedures plus all doses in excess of the limits must not exceed the dose limit (5 rem or 0.05 Sv) in a given year, nor must it exceed 5 times the annual dose limits in the individual's lifetime.

Table 3.8 NRC annual dose limits for radiation workers and the public

Exposed personnel	Dose limit
Adult radiation worker	More limiting of TEDE of 5 rem (50 mSv) or 50 rem (500 mSv) to other organs except the eye lens
Lens of the eye (adult)	15 rem (150 mSv)
Minor, age < 18 yrs	10% of adult dose
Declared pregnant woman	0.5 rem (5 mSv) for gestation period (i.e., 50 mrem (0.5 mSv)/mo)
Members of public	0.1 rem (1 mSv); 0.5 rem (5 mSv) with justification
Planned special procedure	Dose from all planned special exposures plus all doses in excess of the limits not to exceed the annual limit given above and 5 times the dose limit during lifetime

The licensee shall reduce the dose that an individual may receive in the current year by the amount of occupational dose already received while employed by another person.

The NRC dose limits for occupational radiation workers and the public are listed in Table 3.8.

3.4 Effective Dose Equivalent and Effective Dose

In 1977, the ICRP introduced the concept of effective dose equivalent to take into account of the variation in sensitivity of different tissues to radiations (ICRP 26). Parallel to radiation weighting factors, W_r , the tissue weighting factors, W_T , have been chosen for different tissues based on relative radiosensitivities that were assessed from the expression of cancer and genetic defects caused by radiation in population. This weighting factor is the proportion of the risk of stochastic effects resulting from irradiation of the organ or tissue, T, to the total risk of stochastic effects when the whole body is irradiated uniformly. The W_T values are assigned as a fraction of 1 for individual organs, which add up to 1 for the whole body. The ICRP has revised these values several times over the years. In 1991, the ICRP revised these values (ICRP 60) and further upgraded them in 1999 (ICRP 80) and again in 2007 (ICRP 103) by adding several addendums. The latest ICRP 103 values of W_T are given in Table 3.9 along with the NRC values for comparison. Note that the effective dose equivalent gives a better overall risk estimate than the whole-body dose used earlier, because the former takes into account the radiosensitivity of individual organs.

Table 3.9 Tissue weighting factors W_T from ICRP 103 and NRC 10CFR20

Organ/Tissue	W_T (ICRP 103) ^a	W_T (NRC 10CFR20)
Gonads	0.08	0.25
Breast	0.12	0.15
Red bone marrow	0.12	0.12
Lung	0.12	0.12
Thyroid	0.04	0.03
Bone surfaces	0.01	0.03
Colon	0.12	–
Stomach	0.12	–
Bladder	0.04	–
Esophagus	0.04	–
Liver	0.04	–
Brain	0.01	–
Salivary glands	0.01	–
Skin	0.01	–
Remainder	0.12 ^b	0.30 ^c

^aReprinted with permission from ICRP 103 (2007)

^bThe remainder is composed of the following additional tissues and organs: adipose tissue, adrenals, connective tissue, extrathoracic airways, gallbladder, heart wall, kidneys, lymphatic nodes, muscle, pancreas, prostate, small intestine wall, spleen, thymus, and uterus/cervix

^c0.30 results from 0.06 for each of the 5 “remainder” organs (excluding the skin and lens of the eye) that receive the highest dose

Effective dose equivalent (EDE): EDE is defined as the sum of the products of the dose equivalent to an organ or tissue (H_r) and the corresponding weighting factor W_T for the organ or tissue that is irradiated. Thus,

$$\text{EDE} = \sum W_T \cdot H_r \quad (3.26)$$

$$= \sum_{T,r} W_T \cdot W_r \cdot \text{rad} \quad (3.27)$$

EDE is a general term and is applicable to both external exposure dose and internal absorbed dose. For internal dose, it is CEDE discussed earlier, and for external exposure dose, it is EDEX calculated by Eq. (3.7). In internal dosimetry, however, the ICRP has termed EDE, simply the effective dose (ED), which are normally given in literature for different radiopharmaceuticals. Effective doses for pertinent radiopharmaceuticals used in nuclear medicine are listed in Table 3.10.

Total effective dose equivalent (TEDE): TEDE is the sum of effective dose equivalent from external exposure and committed effective dose equivalent, i.e.,

$$\text{TEDE} = \text{EDEX} + \text{CEDE} \quad (3.28)$$

Table 3.10 Effective doses from various radiopharmaceuticals in nuclear medicine (ICRP 80, ICRP 106, and package inserts)

Radiopharmaceutical	Effective dose	
	rem/mCi	mSv/MBq
^{99m} Tc-pertechnetate	0.048	0.013
^{99m} Tc-sestamibi (Cardiolite) (exercise)	0.030	0.008
^{99m} Tc-macroaggregated albumin (MAA)	0.040	0.011
^{99m} Tc-tetrofosmin (Myoview)	0.026	0.007
^{99m} Tc-ECD ^a	0.030	0.008
^{99m} Tc-DTPA aerosol	0.022	0.006
^{99m} Tc-methylene diphosphonate (MDP)	0.022	0.006
^{99m} Tc-red blood cell	0.026	0.007
^{99m} Tc-iminodiacetic acid (IDA) derivatives	0.063	0.017
^{99m} Tc-diethylenetriaminepentaacetic acid (DTPA)	0.019	0.005
^{99m} Tc-dimercaptosuccinic acid (DMSA)	0.033	0.009
^{99m} Tc-sulfur colloid	0.033	0.009
^{99m} Tc-white blood	0.041	0.011
^{99m} Tc-hexamethylpropylene amine oxime (Ceretek)	0.033	0.009
^{99m} Tc-mercaptoacetylglycylglycylglycine (MAG3)	0.026	0.007
¹¹¹ In-white blood cell (WBC)	1.33	0.360
¹¹¹ In-diethylenetriaminepentaacetic acid (DTPA)	0.078	0.021
¹¹¹ In-pentetreotide (Octreoscan)	0.200	0.054
¹²³ I-NaI (35% uptake)	0.814	0.220
¹³¹ I-NaI (35% uptake)	88.80	24.00
¹²³ I-ioflupane (DaTscan) ^b	0.078	0.021
²⁰¹ Tl-thallium chloride ^a	0.520	0.140
¹⁸ F-fluciclovine (Axumin) ^b	0.814	0.220
¹⁸ F-florbetaben (NeuraCeQ) ^b	0.070	0.019
¹⁸ F-florbetapir (Amyvid) ^b	0.070	0.019
¹⁸ F-sodium fluoride ^b	0.078	0.021
¹⁸ F-flutemetamol (Vizamyl) ^b	0.118	0.032
¹⁸ F-fluorodeoxyglucose ^a	0.070	0.019
⁶⁸ Ga-DOTATATE (Netspot) ^b	0.078	0.021
¹⁷⁷ Lu- DOTATATE (Lutathera) ^c		
⁶⁷ Ga-citrate	0.370	0.100
¹²³ I-metaiodobenzylguanidine (MIBG)	0.048	0.013
¹³¹ I- metaiodobenzylguanidine (MIBG)	0.520	0.140
⁸² Rb-rubidium chloride	0.011	0.003

The remaining doses have been obtained with permission from ICRP 80 (1999)

^a Reprinted with permission from ICRP publication 106

^b From package insert

^c From Nicolas GP, Mansi R, McDougall L. Biodistribution, pharmacokinetics, and dosimetry of ¹⁷⁷Lu-, ⁹⁰Y-, and ¹¹¹In-labeled somatostatin receptor antagonist OPS201 in comparison to the agonist ¹⁷⁷Lu-DOTATATE: The mass effect. J Nucl Med. 2017, 58 (9) 1435

3.5 Reportable Events

The licensee must report to the NRC or Agreement State if the dose in any situation (adult individual, minor, pregnant woman, planned special exposure, public, any restricted or unrestricted area) exceeds the permitted limit. The following events are required to be reported to the NRC or Agreement States within 30 days after learning of the event.

1. Doses in excess of the limit set in Sect. 3.3.3 of this chapter to occupational workers, minors, the embryo/fetus of a declared woman worker, and a member of the public.
2. Doses exceeding the ALARA constraints or limit for air emissions.
3. Levels of radiation or concentrations of radioactive material in a restricted area in excess of the applicable limit on the license.
4. Levels of radiation or concentrations of radioactive material in an unrestricted area in excess of 10 times the applicable limit set forth in the license.

The report must contain the estimated dose to each individual, level of radiation, or concentration of radioactivity, cause of exposure, and corrective action taken. In addition, for occupational workers, the name, social security number, and birth date are required to be included in the report.

3.6 Notification of Incidents

It is mandatory that a licensee notifies the NRC or the Agreement State of any incident that involves undue radiation exposure to any individual exceeding the approved limit. Immediate notification is required if the exposure results in more than 5 times any of the occupational dose limits given in Sect. 3.3.3 of this chapter and also if an individual receives an intake of 5 times the annual limit on intake (ALI) over 24 h from the release of radioactive material. A 24 h. notice is required if the exposure only exceeds the dose limits in Sect. 3.3.3 and receives an intake equal to the occupational ALI from release of radioactive material. The notification including all pertinent information such as names of all exposed individuals must be sent to the NRC Operations Center.

The report must include the exposure estimate of each individual, level of activity involved, cause of exposure, and corrective action taken. Furthermore, the names, birthdates, and social security number of each individual involved must be included in the report.

Questions

1. Match the following:

- | | |
|--------------|--------------------|
| A. Gray | A. Exposure |
| B. Roentgen | B. Absorbed dose |
| C. Becquerel | C. Dose equivalent |
| D. Sievert | D. Activity |

2. A γ ray source gives an absorbed dose of 15 rad to an organ. What is the dose in gray, rem, and sievert?

3. Match the following radiation exposures with their sources:

- | | |
|-------------|---|
| (a) 625 rem | (a) Nuclear medicine procedure |
| (b) 228 rem | (b) Total exposure to the US population |
| (c) 77 rem | (c) CT studies |
| (d) 147 rem | (d) Radon and thoron |

4. An air traveler receives nearly _____ mrem/h radiation exposure while flying.

5. Internal dose calculations:

- (a) assume complete absorption of γ radiations in the body
- (b) are based on average data from different age groups
- (c) are based on standardized reference models developed by expert groups
- (d) are valid only for α -emitters

6. A person residing in North America receives about _____ mrem from natural background radiation (excluding radon) in a year.

- (a) 10
- (b) 50
- (c) 100
- (d) 500

7. One sievert (Sv) is equal to:

- (a) 100 rad
- (b) 1 rem
- (c) 1 rad
- (d) 100 rem

8. The cumulated activity in dosimetry equation is

- (a) the area under the time-activity curve for an organ or region
- (b) the maximum activity in an organ after administration of radioactivity
- (c) is not affected by the effective half-life
- (d) depends on the energy of the radiation

9. The effective half-life T_e is

- (a) the time required for half of the remaining activity in an organ or the body to be eliminated by physical processes only
- (b) the time required for half of the remaining activity in an organ or the body to be removed, by both physical and biological processes
- (c) the time required for half of the activity in an organ or the body to be eliminated by biological processes only
- (d) the time required for half of the activity in an organ or the body to be eliminated by exhalation

10. Typical dose estimates for a radiopharmaceutical are given in units of
 - (a) mGy/mSv of equivalent dose expected to a population
 - (b) mGy/MeV of emitted radiation energy
 - (c) mGy/mR to a standardized individual
 - (d) mGy/MBq of administered radiopharmaceutical
11. For a radioactive material in the liver, the lowest dose to the liver will be likely to be delivered by a _____ emitter.
 - (a) beta plus
 - (b) beta minus
 - (c) metastable gamma with internal conversion
 - (d) metastable gamma without internal conversion
12. The effective dose ED is
 - (a) the sum of the organ dose equivalents from individual organs in the body, which gives a total dose equivalent to that individual
 - (b) the sum of absorbed doses to a population, weighted according to age group and cancer risk statistics
 - (c) the sum of weighted dose equivalents from individual organs in the body, in theory equal to a uniform whole-body dose equivalent that would result in the same overall risk
 - (d) the sum of absorbed doses to individual organs multiplied by a tissue weighting factor
13. An absorbed fraction of unity (1.0) is usually assigned:
 - (a) for alpha and beta emissions when the source of radiation is different from the target
 - (b) for alpha and beta emissions when the source of radiation is also the target
 - (c) for photon emissions when the source of radiation is also the target
 - (d) for photon emissions when the source of radiation is different from the target
14. The absorbed fraction ϕ_i is
 - (a) the fraction of radiation energy converted to heat in the absorber
 - (b) the fraction of radiation energy lost in the source organ of interest
 - (c) the fraction of radiation energy absorbed in the target organ
 - (d) is an unnecessary factor in dosimetry
15. The absorbed fraction ϕ_i for particulate radiations is
 - (a) 1.0 when the source and the target are different
 - (b) 0.5 when the source and the target are the same
 - (c) 1.0 when the source and the target are the same
 - (d) is not considered in calculation
16. The International Commission on Radiological Protection (ICRP) considers it necessary to provide a factor that denotes the modification of the effectiveness of a given absorbed dose by the linear energy transfer (LET) of the radiation. This factor is called the
 - (a) dose equivalent (H)
 - (b) relative distribution function
 - (c) radiation weighting factor (W_r)
 - (d) the roentgen to rad conversion factor (f)

17. The dose delivered by a uniformly distributed low energy beta emitter to an organ is proportional to all of the following except the:
 - (a) effective half-life
 - (b) exposure rate constant
 - (c) average beta ray energy
 - (d) initial activity concentration
18. The absorbed fraction for a gamma emitting nuclide depends on:
 - (a) the energy of the gamma rays
 - (b) the amount of the radionuclide present
 - (c) the mass of the volume in which the radionuclide is distributed
 - (d) the shape of the volume in which the radionuclide is distributed
19. The maximum permissible dose (MPD):
 - (a) is the same for all organs
 - (b) includes contributions from both internal and external sources of radiation
 - (c) includes contributions from background radiation
 - (d) includes exposure from medical procedures
20. Calculate the exposure from a 15 mCi (555 MBq) ^{18}F -FDG sample at a distance of 1 ft. (For ^{18}F , $\Gamma = 5.68 \text{ R}\cdot\text{cm}^2/\text{mCi}\cdot\text{h}$. at cm, or $153.5 \mu\text{m}^2/\text{GBq}\cdot\text{h}$. at 1 m).
21. A teletherapy beam deposits 500 ergs of energy in a tumor weighing 4 gm. Calculate the dose in rad and cGy.
22. The absorbed doses in three organs A, B, and C from a 10 mCi (370 MBq) radioactive source are 5 rad (cGy), 8 rad (cGy), and 3 rad (cGy). The radionuclide has two radiations with radiation weighting factor of 1 and 10. Assuming tissue weighting factors of the three organs are 0.12(A), 0.04(B), and 0.01(C), calculate the effective dose equivalent for each organ.
23. Calculate the absorbed dose to the thyroid glands of a patient who is given orally 33 mCi (1.22 GBq) ^{131}I -NaI, assuming 55% uptake, a biological half-life of 5 days for thyroid clearance and S equal to $2.3 \times 10^{-3} \text{ rad}/\mu\text{Ci}\cdot\text{h}$.
24. A target organ of 30 g contains 2 mCi of a radionuclide that emits a β^- particle and a γ radiation. For β^- particle, $\Delta i = 0.3 \text{ g}\cdot\text{rad}/\mu\text{Ci}$, $\phi_1 = 0.2$; for γ radiation, $\Delta i = 0.2 \text{ g}\cdot\text{rad}/\mu\text{Ci}$, $\phi_2 = 0.10$. Calculate the mean absorbed dose per cumulated activity.

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4.1 Principles of Radiation Protection

Radiation causes cellular damage in humans resulting in cancers and genetic defects and therefore, all people, particularly radiation workers, should make every effort to avoid radiation exposure. Radiation protection includes a set of common-sense and technical principles of dealing with radiation to minimize the external exposure or internal absorption of radiation and hence to reduce the odds of cancers. Three basic strategies of radiation protection are *time, distance, and shielding*, which is represented by the acronym TDS.

4.1.1 Time

Time spent near a radioactive source is an important factor in radiation protection. The more time one spends near the radioactive source, the more exposure or absorption of radiation is likely to occur. One should not stay near the radioactive sources longer than necessary. Since the radioactivity decays with time, the actual exposure from a source for a period of time comes from the cumulated activity, which is the time integral of the initial activity A_0 , given by Eq. (4.1) below. The integrated activity over time t is

$$A_t = \int A_0 e^{-\lambda t} dt = A_0 \frac{1 - e^{-\lambda t}}{\lambda} \quad (4.1)$$

where A_t is the cumulative activity over time t , A_0 is the initial activity, and λ is the decay constant of the radionuclide. Thus the corresponding exposure X would be (assuming one unit of distance away from the source):

$$X = A_t \cdot \Gamma \quad (4.2)$$

where Γ is the exposure rate constant of the radionuclide. The factor of distance is discussed next. The longer one stands near a radiation source, A_t increases, and the

exposure gets higher. One should implement a “stay time” that is calculated from the exposure rate of a source and the expected dose, to complete the intended job.

4.1.2 Distance

The exposure X from a radioactive point source is inversely proportional to the square of the point-to-source distance d . Thus if X is an exposure at distance d from a radioactive source, it will be $X/4$ at distance $2d$. However, the decrease in exposure is more linear for extended sources. It is imperative to design radiation procedures and workplaces to minimize radiation exposure to workers.

The equation for exposure X at a distance d from a radioactive point source of strength A is given as

$$X = \frac{A \cdot \Gamma}{d^2} \quad (4.3)$$

Combining Eqs. (4.3) and (4.1), the cumulative exposure X_t from a point source will be

$$X_t = A_0 \left(\frac{1 - e^{-\lambda t}}{\lambda} \right) \frac{\Gamma}{d^2} \quad (4.4)$$

Equation (4.4) is commonly used to calculate the exposure at a distance from a point source of radiation using Γ values from Table 3.4 in Chap. 3.

Problem 4.1

A radiation worker stands 35 cm away from a radioactive source of 30 mCi (11.1 GBq) ^{99m}Tc (Γ for ^{99m}Tc is 0.80 R·cm²/mCi·h at 1 cm or 18.0 $\mu\text{Gy}\cdot\text{m}^2/\text{GBq}\cdot\text{h}$ at 1 m). Calculate the exposure value received by the worker, while standing for 1 h near the source.

Answer

$$t_{1/2} \text{ of } ^{99m}\text{Tc} = 6 \text{ h}$$

$$\lambda = \frac{0.693}{6} \text{ h}^{-1} = 0.1050 \text{ h}^{-1}$$

$$t = 1 \text{ h}$$

$$e^{-\lambda t} = e^{-0.1050 \times 1} = 0.9003$$

$$\text{Cumulative activity} = A_0 \frac{1 - e^{-\lambda t}}{\lambda} = 30 \times \frac{1 - 0.9003}{0.1050} = 28.49 \text{ mCi}$$

$$\text{Or,} = 11.1 \times \frac{1 - 0.9003}{0.1050} = 10.54 \text{ GBq}$$

$$\text{Cumulative exposure} = \frac{28.49 \times 0.80}{35 \times 35} = 0.0186 \text{ R} = 18.6 \text{ mR}$$

$$\text{Or,} = \frac{10.54 \times 18.0}{0.35 \times 0.35} = 1.55 \text{ mGy}$$

4.1.3 Shielding

While passing through matter, radiations lose energy in the medium via attenuation (absorption, scattering) and so the medium serves as shielding for radiations. While particulate radiations (α particle, β^- particle, etc.) are stopped by small thickness of shielding material, X-rays and γ rays are attenuated exponentially as given by Eq. (1.15) (Chap. 1). Thus exposure X from a radioactive source shielded by a material of thickness x is given by

$$X = X_0 e^{-\mu x} \quad (4.5)$$

where X_0 is the initial exposure and μ is the linear attenuation coefficient of radiation in the shielding material. As discussed in Chap. 1, linear attenuation coefficients are obtained by multiplying mass attenuation coefficients μ_m with the density of the absorber, which are available in literature.

A relevant quantity in this discussion is the mean free path, mfp, defined by the average distance traveled by a photon before the next interaction and is given by the reciprocal of the linear attenuation coefficient of the radiation in the absorber,

$$\text{mfp} = \frac{1}{\mu}$$

The term μx in Eq. (4.5) is termed the relaxation length R_t , which is defined by the thickness of the shielding in number of mean free paths that reduces the beam intensity to 37% of the initial value.

As discussed in Chap. 1, the half-value layer (HVL) of the medium for a radiation is defined by the thickness of the medium that attenuates the radiation intensity by half and is given by

$$\text{HVL} = \frac{0.693}{\mu}$$

where μ is the linear attenuation coefficient of the radiation in the medium. A similar entity, tenth-value layer TVL, is defined by the amount of medium that attenuates radiation intensity to 10% of the initial intensity. The values of HVLs and TVLs are given in Table 1.1 in Chap. 1.

Note that Eq. (4.5) is valid for a “good” (*narrow beam*) geometry where radiations passing through an absorber scatter minimally and reach straight to the

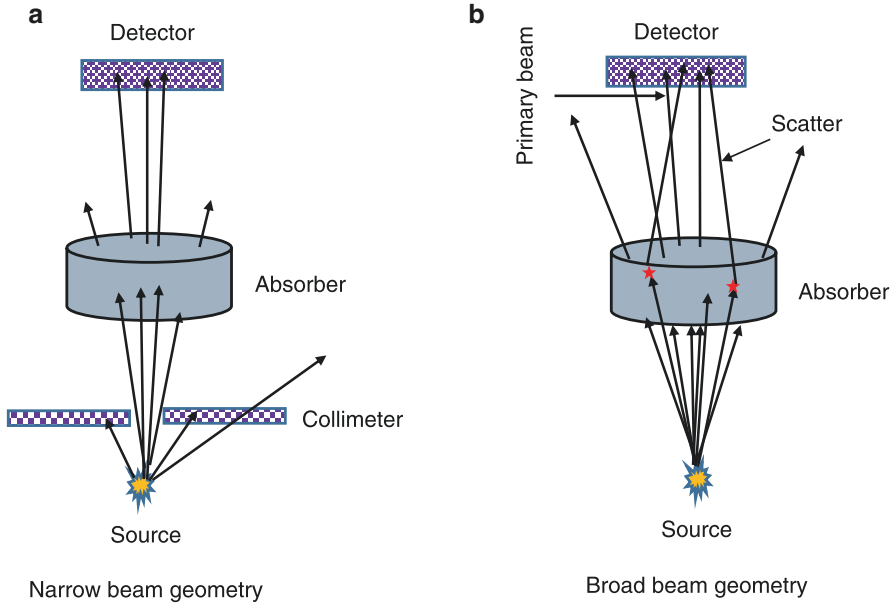


Fig. 4.1 Illustrations of (a) narrow beam geometry and (b) broad-beam geometry of radiation beam affecting the shielding

detector. The only effect on the detected beam is the attenuation of the primary beam in the absorber. This is true for a point source, a thin absorber, and a collimated beam (Fig. 4.1a). However, in real situations, photons which are heading away from the detector can be scattered in the absorber (shielding material) back toward the detector as secondary radiation thus adding to the exposure (Fig. 4.1b). This results in a *broad-beam* geometry and gives rise to what is called a *build-up factor*, B , defined by

$$B = \frac{\text{Intensity of primary plus secondary radiations}}{\text{Intensity of primary radiations only}} \quad (4.6)$$

Mathematically, for broad-beam geometry, Eq. (4.5) thus becomes

$$X = B \cdot X_0 e^{-\mu x} \quad (4.7)$$

Obviously, B is greater than 1 and depends on the type and thickness of the absorber and energy of the photon. For low energy photons, photoelectric effect is predominant (proportional to Z^4/E_p^3), whereas at medium energies, Compton scattering is the primary mechanism of interaction. In high Z materials of a given thickness, photons are primarily absorbed by photoelectric effect compared to low Z material, and also secondary photons produced by Compton scattering are likely to be absorbed. So only attenuated high energy photons will exit from the absorber (beam hardening) and reach the detector. However, if a low Z material is used as an absorber of the same thickness, incident primary photons are more likely to be

scattered and exit the absorber and reach the detector. This will increase the B factor. Thus B is greater in low Z medium (e.g., gypsum) than in high Z medium (e.g., lead).

The values of build-up factors Bs are difficult to measure, and various techniques have been employed, namely the iteration method, Monte Carlo method, and transmission method. The calculated values for different materials and photon energies are presented in look-up tables and published in literature. Dose build-up factors for point sources of several energies in lead and different values of μx (relaxation length) are given in Table 4.1. The build-up factors for energies other than those given in the table are estimated by interpolation. An example is given below.

Problem 4.2

Calculate the build-up factor for photon energy of 1.3 MeV in lead, given that the linear attenuation coefficient of the photon μ is 1.4 cm^{-1} and the thickness of the shielding material is 4 cm.

Answer

The relaxation length μx is $1.4 \times 4 = 5.6$

Using Table 4.2, for 1.0 MeV,

$$B_{1.0} = 2.26 + \frac{5.6 - 4}{7 - 4} \times (3.02 - 2.26) = 2.67$$

for 2.0 MeV,

$$B_{2.0} = 2.51 + \frac{5.6 - 4}{7 - 4} \times (3.66 - 2.51) = 3.12$$

$$\text{Thus, } B_{1.3} = 2.67 + \frac{1.3 - 1}{2 - 1} \times (3.12 - 2.67) = 2.81$$

Table 4.1 Dose build-up factors for lead shielding dose build-up factors for an isotropic point source in lead for different μx

MeV	1	2	4	7	10	15	20
0.5	1.24	1.42	1.69	2.00	2.27	2.65	2.73
1.0	1.37	1.69	2.26	3.02	3.74	4.81	5.86
2.0	1.39	1.76	2.51	3.66	4.84	6.87	9.00
3.0	1.34	1.68	2.43	2.75	5.30	8.44	12.30

^aReprinted by permission from Springer Nature, *Radiation protection and dosimetry. An introduction to health physics* by Stabin MG: 2008. (<http://cted.inel.gov/cted/radpro/rp16.pdf>)

Problem 4.3

Using the build-up factor in Problem 4.2, calculate the thickness of lead required to reduce the exposure of the above source to 25%.

Answer

Reduction to 25% means X/X_0 is 0.25

$$\mu = 1.4 \text{ cm}^{-1}$$

From Eq. (4.7),

$$0.25 = 2.81 \times e^{-1.4 \times x}$$

$$-1.386 = 1.033 - 1.4 \times x$$

$$-2.419 = -1.4 \times x$$

$$x = 1.73 \text{ cm of lead}$$

Shielding is a principal criteria of radiation protection. Particulate radiations (α and β particles) are mostly stopped by containers, while X-ray and γ radiations are highly penetrating and hence these sources need to be shielded. High Z materials such as lead, tungsten, etc. are good absorbers of γ radiations and for cost effectiveness, lead is commonly used for this purpose. Physicians and technologists put on lead apron during X-ray and radiation therapy procedures to minimize radiation exposure. Radioactive sources are stored in a shielded container or area and handled behind the lead shield, called L-Block (Fig. 4.2). Patients' dosages are carried in lead shielded syringe carriers (Fig. 4.3). Radioactive waste is collected in lead-lined baskets (Fig. 4.4).

Since β^- particles produce bremsstrahlung radiations in high Z material such as lead, radionuclides emitting β^- particles (e.g., ^{32}P) are normally stored in containers of low Z materials such as plastic. Concrete is another low-cost material that is commonly used for shielding large-size and high activity sources such as cyclotrons and nuclear reactors, in which neutrons and γ radiations are produced by activation by radionuclides produced in these units.

4.1.4 Do's and Don'ts in Radiation Protection Practice

- Do post-radiation signs in radiation areas.
- Do wear laboratory coats and disposable gloves when working with radioactive materials.
- Do handle radioactivity behind the lead barrier shield.
- Do work in a ventilated fume hood when working with radioactive gases.
- Do cover the trays and workbench with absorbent paper.
- Do store and transport radioactive material in lead containers.
- Do wear a radiation monitoring badge and/or extremity badge while working in the radiation laboratory.

- Do identify all radionuclides and dates of assay on the containers.
- Do use a syringe shield for injection unless it is contraindicated.
- Do survey work areas for any contamination as frequently as possible.
- Do wipe test the radioactive work areas weekly.
- Do clean up spills promptly and survey the area after cleaning.
- Do dispose of radioactive waste in designated labeled receptacles.
- Do not eat, store food, drink, or smoke in the radiation laboratory.
- Do not pipette any radioactive material by mouth.
- Do monitor hands and feet before leaving the radiation work area.
- Do notify the RSO in case of any major spill or other emergencies related to radiation.

Fig. 4.2 Tabletop L-Block shield (for beta and gamma radiation) (photo courtesy of Capintec)



Fig. 4.3 Shielded syringe carrier (photo courtesy of Capintec)



Fig. 4.4 Lead-lined waste container (courtesy of Capintec)



4.2 NRC Regulations of Radiation Protection

NRC regulations of radiation protection are covered in detail in NRC 10 CFR Part 20: Standards for Protection Against Radiation; 2018 and include issues of exposure and absorbed dose to the occupational worker, members of the public, pregnant women, and minors. It also sets rule for the methods of receiving and transferring byproduct materials and guidance to the radioactive waste disposal. While 10CFR20 is quite detailed in its content, only pertinent information is provided here.

4.2.1 Definition of Specific Terms

- *Controlled area* means an area, beyond a restricted area but inside the site boundary, access to which can be limited by the licensee for any reason.
- *Radiation area* is an area in which an individual could receive from a radiation source a dose equivalent in excess of 5 mrem (0.05 mSv) in 1 h at 1 foot (30 cm) from the source.

- *High radiation area* is an area in which an individual could receive from a radiation source a dose equivalent in excess of 100 mrem (1 mSv) in 1 h at 1 ft (30 cm) from the source.
- *Very high radiation area* is an area in which an individual could receive from radiation sources an absorbed dose in excess of 500 rad (5 Gy) in 1 h at 3 ft (1 m) from the source.
- *Restricted area* is an area of limited access that the licensee establishes for the purpose of protecting individuals against undue risks from exposure to radiation and radioactive materials.
- *Unrestricted area* is an area in which an individual could receive from an external source a maximum dose of 2 mrem (20 μ Sv)/h, and access to the area is neither limited nor controlled by the licensee.

4.2.2 Caution Signs

The NRC requires that specific signs, symbols, and labels be used to warn people of possible danger from the presence of radiation. These signs use magenta, purple, and black colors on a yellow background, and some typical signs are shown in Fig. 4.5.

Caution: Radiation Area: This sign must be posted in radiation areas.

Caution: High Radiation Area, or danger: high radiation area: This sign must be posted in high radiation areas.

Caution: "GRAVE DANGER, VERY HIGH RADIATION AREA." This sign must be posted in very high radiation areas.

Caution: "CAUTION, AIRBORNE RADIOACTIVITY AREA" or "DANGER, AIRBORNE RADIOACTIVITY AREA." This sign must be posted in areas with airborne radioactivity.

Caution: "RADIOACTIVE MATERIAL or DANGER: RADIOACTIVE MATERIAL": This sign is posted in areas or rooms in which 10 times the quantity or more of any licensed material specified in Appendix C of 10CFR20 are used or stored.

4.2.3 Posting Requirement

According to 10CFR19.11, a licensee is required to post the following information on NRC Form 3 "Notice to Employees"

- (a) The location where the license, license conditions, amendments, and the operating procedures applicable to licensed activities as approved by the NRC could be examined.
- (b) Any NRC or Agreement State notice of violation involving radiological working conditions, proposed imposition of civil penalty, or order issued for correction, and any response from the licensee. Posting shall be made within 2 working days after receipt of the notice from or response to the NRC. These documents shall remain posted for a minimum of 5 working days or until corrective action for the violation is completed.

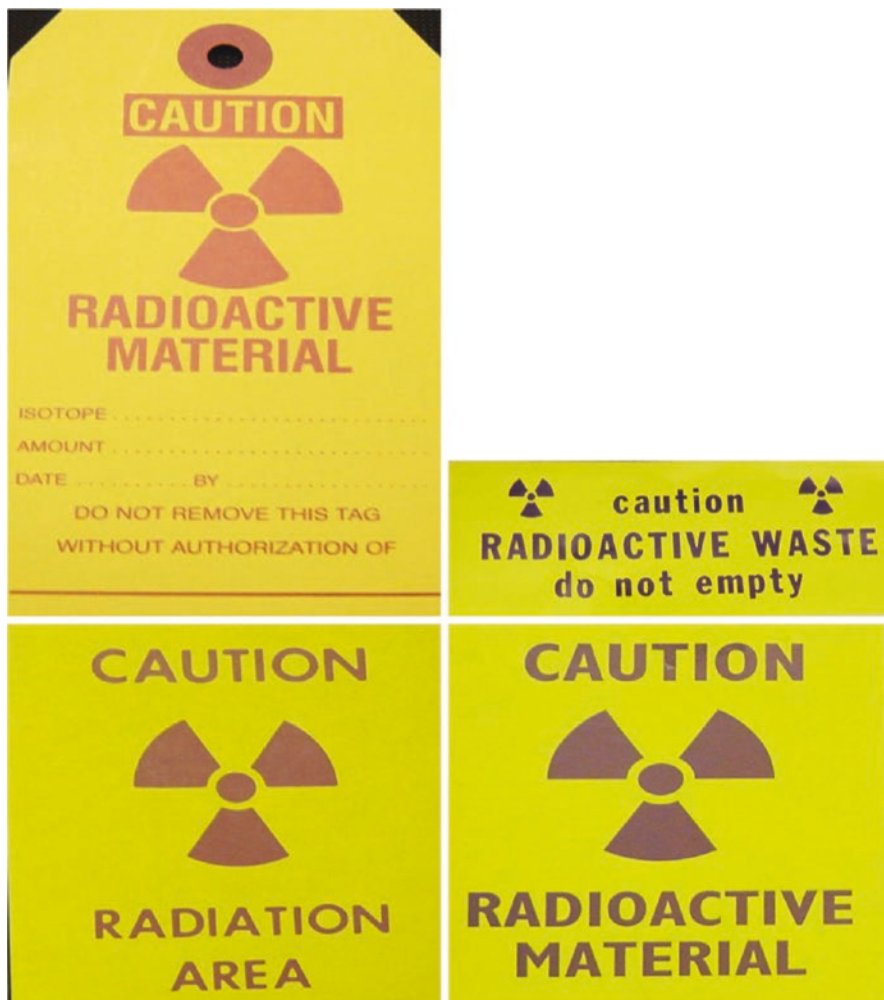


Fig. 4.5 Radiation caution signs

Posting of caution sign is not required in an area or room if the radioactivity container is stored in the area for less than 8 h under constant attention by an individual. Areas or rooms containing sealed sources need not have caution sign posted, provided the exposure from the source does not exceed 0.005 rem (0.05 mSv) per h at 1 ft (30 cm) from the source.

4.2.4 Labeling Requirement

Each container of licensed material must be labeled with a conspicuous label “CAUTION, RADIOACTIVE MATERIAL” or “DANGER, RADIOACTIVE

MATERIAL.” The label must include information such as the radionuclide(s) present, the quantity of radioactivity, and the date.

Labeling is not required for (a) containers holding licensed material in quantities less than the quantities listed in Appendix C to 10CFR20, (b) containers holding licensed material in concentrations less than those specified in Table 4.3 of Appendix B to 10CFR 20, or (c) containers attended by an individual who takes the precautions necessary to prevent the exposure to individuals in excess of the limits established by this part.

4.2.5 ALARA Program

ALARA is an acronym for *As Low As Reasonably Achievable*, which emphasizes the implementation of methods and procedures involving radiations to minimize radiation exposure as low as possible below the permissible limit. The licensee shall use procedures and engineering controls to achieve occupational doses and doses to members of the public that are ALARA, taking into account the feasibility of technology, the economics of improvements in technology, benefits to the public health and safety, and other societal and socioeconomic considerations. For the ALARA requirement, a constraint on air emissions of radioactive material to the environment, excluding Radon-222 and its daughters, is required to be established by licensees, such that the individual member of the public will not receive a TEDE in excess of 10 mrem (0.1 mSv) per yr. from these emissions. ALARA is a part of the NRC regulations (10CFR20.1003) and must be adhered to strictly. Practice of ALARA involves adoption of cardinal principles of TDS (time, distance, and shielding) discussed above. Also following the instructions in Sect. 4.1.4 above will help maintain the exposure dose ALARA.

According to Regulatory Guide NUREG-1556, volume 9, Appendix L, two action levels have been recommended. Action Level I occurs when radiation exposure to a worker exceeds 10% of the permissible limit of occupational exposure in a quarter. The RSO investigates the situation and makes a report to the RSC for review, and a definite action is taken. When the occupational exposure exceeds 30% of the limit, it becomes Action Level II and corrective actions are taken or the licensee must justify a higher dose level for ALARA in the situation.

4.3 Security Control of High Radiation Areas

Security control of entrances to high radiation areas such as the gamma knife room must be maintained 24/7 with locks except for authorized entrances, which are monitored and recorded. Entrances may be controlled by electronic surveillance that is capable of preventing unauthorized entry. Provision may be made to trigger an alarm for unauthorized entrances, which is connected to the security department of the facility. Prompt response of the security personnel is tested by triggering the alarm by mimicking an unauthorized entry.

Control is not required for entrance to a high radiation area containing radioactive materials prepared and labeled for transport in accordance with the regulations of the Department of Transportation, provided that (1) the packages do not remain in the area longer than 3 days and (2) the dose rate at 1 m from the surface of the package does not exceed 0.01 rem (0.1 mSv) per h.

Control of access to rooms housing patients containing radioactive material in hospitals is not required provided there are personnel in attendance who will take the necessary precautions to prevent the exposure of individuals to radiation.

Additional measures are to be taken for very high radiation areas to prevent the exposure in excess of 500 rad (5 Gy) in 1 h at 1 m.

4.4 Use of Individual Respiratory Protection Equipment

To prevent intake of airborne radioactivity, respiratory protective equipment may be necessary for radiation workers to wear. These equipment must be tested and certified by the National Institute for Occupational Safety and Health (NIOSH) or must be approved by the NRC. The integrity of the unit needs to be tested periodically for proper operation. The air samples are checked for compliance with ALI and DAC values. The respirator and the user must be checked by a physician for medical fitness of the person and proper fitting of the equipment initially and every 12 months thereafter, or as required by the physician. The licensee must have in place written procedures for the use of respiratory equipment and also frequently estimate the dose to the user from measured airborne activity.

4.5 Receiving and Monitoring of Radioactive Packages

The NRC or Agreement States authorize individual users or institutions for the use of byproduct materials by issuing specific licenses. Vendors require these licenses on hand as proof of authorization prior to shipping radioactive packages to the authorized user or institution.

The vendors deliver the radioactive packages at a designated area of the licensee. Upon receiving the package, the licensee or his designee checks the integrity of the package as to whether it is damaged (bent, torn) or there are signs of leakage. If any of these occurs, the vendors are contacted for advice as to return the package to them or store until decay and disposal. Also the Radiation Safety Officer should be contacted for advice. If the package appears intact, monitoring must be performed with a survey meter for exposure rate at the surface and at 1 m from the surface, and a wipe test for any removable surface contamination. Monitoring must be done as soon as possible, but no later than 3 h after the receipt of the package, if received within working hours; or within 3 h of the beginning of the next day, if received after working hours. Authorized users are required to have a written protocol of how to open a radioactive packages.

The surveyor must wear gloves and a lab coat prior to survey. Survey of the package is performed with a GM counter at the surface and at 1 m from the surface of the package. The NRC limits of survey are shown in Table 4.2.

The wipe test for removable contamination is performed by wiping an area of 300 cm² on and around the package with a swab or absorbent material and counting

Table 4.2 Limits of survey data for radioactive packages

Type of package	Reading at surface	Reading at 1 m
Limited quantity package	0.5 rem (5 mSv)/h	Background
White-1 label	0.5 rem (5 mSv)/h	Background
Yellow-II label	50 rem (0.5 Sv)/h	1 rem (10 mSv)/h
Yellow III label	200 rem (2.0 Sv)/h	10 rem (0.1 Sv)/h

it in a calibrated well counter for certain time. The counts per minute (C) from the well counter is converted to disintegrations per minute (dpm) using the counting efficiency (c_{eff}) of the counter. The total dpm is divided by the area wiped (300 cm^2) and by the wipe efficiency (w_{eff}) of removing the contamination (fraction of contamination activity removed by the absorbent material) to get the dpm/cm². Thus

$$\text{Wipe dpm / cm}^2 = \frac{C}{(c_{eff}) \cdot 300 \cdot (w_{eff})} \quad (4.8)$$

Actual wipe efficiency (w_{eff}) may be practically determined, or in its absence, a conservative value of 10% wipe efficiency may be assumed. The NRC limit (essentially DOT limit per 49CFR173.443) is 240 dpm per cm² for β^- and γ ray emitting radionuclides and low-toxicity α emitters, and 24 dpm per cm² for all other α particle emitters.

If the survey and wipe test meet the limits, then the package is carefully opened and the radioactive sample is removed and the integrity of the inner container is checked. The quantity and entity of radioactivity are verified and recorded. If the shipping box is reusable, any packaging material is discarded after surveying for contamination and the box is kept for reuse. Otherwise, the box is discarded after the survey.

If any of the monitoring criteria above is not met, i.e., the survey reading and/or the wipe test value exceed the limit, the vendor, Radiation Safety Officer, and the NRC should be notified by telephone, and telegram, mailgram, or facsimile for appropriate action.

Records of receipt of the package must be kept with information on date of receipt, radionuclide, manufacturer, lot number, amount of activity, total volume, number of vials, survey readings at surface and at 1 m from the surface, the wipe test results, and the name of the individual processing the receipt of the package.

4.6 Requirement of Monitoring of Occupational Doses to Radiation Workers

Monitoring is mandatory for individuals who are likely to receive external and internal doses from their occupation above the limit set by the NRC.

- (a) For external exposure, monitoring by badges is required if
- Adult individuals are likely to receive in 1 year more than 10% of the NRC occupational dose limit
 - Minors are likely to receive in 1 year a deep dose equivalent in excess of 0.1 rem (1 mSv), a lens dose in excess of 0.15 rem (1.5 mSv), or a shallow-dose equivalent to the skin or to the extremities in excess of 0.5 rem (5 mSv)
 - Declared pregnant women likely to receive during the entire pregnancy a deep dose equivalent in excess of 0.1 rem (1 mSv)

- Individuals entering a high or very high radiation area
 - Caregivers who perform procedures using fluoroscopic radiations such as in interventional radiology, cardiac catheterization, electrophysiology etc., who are likely to receive 5 mSv /yr
- (b) For internal uptake, committed effective dose equivalent (CEDE) is assessed if
- Adults are likely to receive in 1 year an intake in excess of 10 percent of the applicable ALI(s) in Table 4.1, Columns 1 and 2, of Appendix B to 10CFR20.1001–20.2402
 - (2) Minors are likely to receive, in 1 year a CEDE in excess of 0.1 rem (1 mSv)
 - Declared pregnant women are likely to receive during the entire pregnancy a deep dose equivalent (DDE) in excess of 0.1 rem (1 mSv)

4.7 Wearing Badges

Film badges, optically stimulated luminescence dosimeters, electronic personal dosimeters are normally worn by the radiation workers on the neck, chest level, or waist in the front of the body. They should be worn all the time while at work. If a lead apron is used during a radioactive procedure, then the badges are placed at the collar level beyond the lead apron. For pregnant women (fetal dose), the badge needs to be placed at the waist level under the lead garments. For extremities (fingers), the ring badges are worn under the gloves to prevent contamination of the badge, if exposed. It should never be worn by the radiation worker as a patient during a medical procedure using radiation and should be left behind in the workplace in a background area away from any radiation source.

4.8 Bioassay

Radiation absorbed dose arises from ingestion, inhalation, or absorption of radioactivity through skin. To estimate these contributions, bioassay is employed. The need for bioassay for most radionuclides is rare in nuclear medicine except for iodine radionuclides (e.g., ^{125}I , ^{131}I , and ^{123}I). NRC Regulatory Guide 8.20 details the requirements for bioassay of individuals handling radioactive iodine. Frequency of bioassay depends on the type of iodine isotope and their ALI and DAC values. However, maximum bioassay duration from the beginning of the operation is given by the NRC as 1 day for ^{123}I , 1 week for ^{124}I , and 2 weeks each for ^{125}I and ^{131}I .

Routine bioassays are required if one handles an unsealed radioiodine source exceeding the limits given in Table 4.3. The quantities shown in the table apply to either the quantity handled at any one time or the total amount of activity by an employee over a period of 90 days. Routine bioassay means that individuals in this category are asked to submit specimens for indirect bioassay such as urinalysis or direct thyroid uptake measurement at a specified frequency. Most of the time in nuclear medicine, the thyroid uptake test is commonly employed. A bioassay is required within the maximum bioassay duration when an operation is discontinued or when a worker is terminating.

Table 4.3 NRC limits of radioactive iodine activity above which bioassay is required

Type of handling	Volatile	Non-volatile or bound
In open room or bench	1 mCi (37 MBq)	10 mCi (370 MBq)
In ventilated areas (i.e., fume hood)	10 mCi (370 MBq)	100 mCi (3.7 GBq)
In closed system (e.g., glovebox)	100 mCi (3.7 GBq)	1 ci (37 GBq)

If an individual wearing respiratory devices or protective clothing is exposed to radioiodine such that his or her intake with no protection would have resulted in a dose exceeding the permissible limit, bioassays are necessary to verify the effectiveness of protective respiratory devices and clothing. These special bioassays should be performed within 24 h of notification.

Bioassays for iodine radionuclides are performed by thyroid uptake tests within 72 h to 14 days after handling, depending on the frequency of handling the radioactivity. In the case of ^{123}I ($t_{1/2} = 13$ h), the thyroid count is obtained at 24 h and each workday after. The count obtained from the thyroid is converted to activity in μCi (kBq) by using the counting efficiency factor of the thyroid probe. If the thyroid content exceeds 1 μCi (37 kBq), a repeat uptake test is performed to further confirm the uptake. Corrective action is taken following investigation. If the uptake is more than 5 μCi (185 MBq), the worker is referred for medical consultation for possible blocking of the thyroid glands with cold iodine (e.g., potassium iodide). Also uptake tests should be repeated on the individual every week to confirm the decrease in radioiodine concentration.

It is essential to establish a baseline uptake value for an individual prior to handling of the radioactive iodine. Sometimes urinalysis may be warranted for confirmation. When a worker routinely handles and works close to unsealed radioiodine sources with quantities greater than 10% but less than 100 percent of the limit, a routine bioassay is recommended, but can be skipped with proper justification, for which a report of justification will be prepared and saved for NRC inspection.

Capsules (such as gelatin capsules given to patients for diagnostic tests) may be considered to contain iodine in the sealed form, and bioassay would not be necessary unless a capsule is inadvertently broken (e.g., dropped and crushed). Bioassay for other radionuclides may be necessary depending on the amount and the type.

If overexposure is determined by bioassay, then an immediate 24 h report must be made to the NRC and to the exposed individual with all pertinent information, and the individual may be refrained from further handling iodine radioactivity, if the exposure remains high.

4.9 Decommissioning of Radiation Laboratory

If a facility utilizing radioactive material needs to be closed for any reason, a decommissioning protocol must be followed by the licensee, so that the facility is reusable and does not cause any undue radiation exposure to the workers occupying the adjacent facility and to the public. Whereas the NRC has broad challenging criteria for decommissioning nuclear facilities such as nuclear reactor, nuclear power plant, etc., the requirements for decommissioning small facilities like nuclear medicine and research laboratories are not as stringent. The basic criteria for decommissioning are that all equipment, surface area, walls, benches, etc. must be cleaned of

radioactivity such that TEDE due to the residual activity at the site does not exceed 25 mrem (0.25 mSv) per yr., if the site is still under licensee's control, or 100 mrem (1 mSv) per yr. if the site is under third party control. If the latter criteria is impractical, too expensive, or not achievable, a TEDE of 500 mrem (5 mSv) per yr. may be approved with justification. The NRC also requires financial assurance from the licensee by establishing a trust fund beyond the control of the licensee to enable an independent third party, including a governmental custodian of a site, to carry out responsibilities for any necessary control and maintenance of the site.

For decommissioning a nuclear medicine or a research laboratory, the licensee or the laboratory manager should follow the steps below.

At least 4 weeks ahead

- Notify the Radiation Safety (RS) and/or the Environmental Health and Safety (EHS) office about the decommissioning proposal for a designated facility. Make an inventory of all chemicals, byproduct materials, biological agents, etc.
- If necessary, seek advice from the RS or the EHS for transporting hazardous material.

2 weeks ahead

- Remove all hazardous chemicals/waste, all biologicals/waste, all sharp boxes.
- Empty and clean all refrigerators, freezers, or other lab equipment that will be left behind.
- Remove all hazard labels from lab area/equipment.
- Dispose of unwanted chemicals, biohazard, and radioactive materials appropriately with the help of the RS and the EHS. If these materials are to be transported to an off-site, the EHS and the RS should help.
- Check with the RS for the transfer or disposal of any radioactive materials or equipment used with radioactivity, which need to be surveyed and approved by them.
- Dispose of all empty containers and ancillary items properly.

Closure

- Finally the licensee or his designee shall conduct a radiation exposure survey using a GM survey meter and wipe test using a well counter to ensure the appropriate decontamination of the laboratory space. If there is any contamination detected, further decontamination is carried out until acceptable contamination is achieved.
- A report is generated with all information obtained from the steps above, and the RS and the EHS will audit it and will sign it off as a document for completion of decommission of the facility.
- If the licensee is closing the facility permanently and would not use any byproduct material in it, then a complete report of decommissioning must be submitted to the NRC or Agreement State for final approval.

4.10 Verification Card for Radioactive Patient

Following the 9/11 disaster in 2001, various security measures have been adopted by the US federal government in an effort to prevent the repeat of such incidents. Congress has passed laws to establish the Department of Homeland Security (DHS)

to monitor and take action in these security measures. Accordingly, the DHS has introduced checkpoints at various strategic locations such as airports, tunnels, bridges, border crossing, historical monuments, landmarks, and the like, where radiation detectors have been installed to detect the presence of any radioactive dispersal device (RDD) (see Sect. 8.4 in Chap 8). Security check of passengers at the airport, background scrutiny of the visitors, and suspected terrorist groups are some of the responsibilities of the DHS.

A downside of this measure is that patients administered with radioactivity in nuclear medicine for diagnosis or treatment may trigger these detectors while crossing the checkpoint and often have to go through undue hassle with the authority to prove that they recently had medical tests with radioactivity. To address this issue, in 2003, the NRC issued a guidance “NRC Information Notice 1003-2022: Heightened Awareness for Patients Containing Detectable Amounts of Radiation from Medical Administration.” According to the guidance, if a patient has a medical procedure involving the administration of radioactive material, the licensee is then required to inform the patient that the internal radioactivity may trigger the detector while crossing the checkpoints and the patient may be questioned for verification of the medical tests. For implementation of the ruling, the guidance further recommends that a verification card with the following information be issued to the patient to carry:

- Address of the licensee.
- Name of the patient.
- Type of radionuclide.
- Amount of activity administered.
- Date of examination.
- Contact phone number.
- Expiration date (see below).

Additionally, a statement that the level of activity is allowed by the NRC for medical use and does not pose any danger to the public, should be included in the card. The patient is asked to carry the card as a proof of medical procedure with radioactive material for a period of time till the radioactivity decays to a level that does not trigger the detector.

A logical question arose as to how long the patient has to carry the card. It depends on the half-life of the radionuclide, the quantity administered, types of radiations of the radionuclide, and biological elimination of the radionuclide. Zucker et al.(2004) suggested the following periods of time for different radionuclides for the patients to carry the card:

^{18}F	1 day
$^{99\text{m}}\text{Tc}$ and ^{123}I	3 days
^{111}In	14–17 days
^{67}Ga and ^{201}Tl	30 days
^{131}I	95 days

4.11 Radiation Phobia

The public in general are fearful of radiation because of the perception that radiation causes harm to humans inducing cancer and genetic defects. Extremely scary and graphic images of explosion of atomic bombs in Japan and reactor meltdown at Chernobyl are also sources of fear of radiation. These images demonstrate the devastating effects on the population including burn, cancer, and death. However, such incidents are rare, and yet people are very concerned about the ill effects of radiation at low exposure.

There are other factors too that creates radiation phobia. The linear-no-threshold (LNT) theory advocated by some radiation experts assumes that any level of radiation, however small, has adverse effects on humans. Psychological warfare expressing anecdotal rhetoric between countries possessing nuclear weapons can further fuel fear of radiation. The media aggravates these situations by displaying the dreadful effects of radiation. So radiation phobia justifiably exists among the public, and it is the responsibility of scientists and radiation experts to allay the radiation phobia by convincing them through education.

A case in point is that even though there was massive destruction of property and human lives after nuclear detonation in Japan and reactor meltdown at Chernobyl immediately after the event, the long-term effects of low doses, even from the fallout of these incidents, have shown to be relatively minimal. The average individual lifetime dose from Chernobyl fallout is estimated to be 0.6–6 rem (6–60 mSv) (Jaworowski 1999). By comparison, the worldwide average annual dose to an individual from natural background is 220 mrem (2.2 mSv) and the lifetime dose of about 15 rem (150 mSv). In the USA, the annual individual dose from natural background including radon is nearly 311 mrem (3.11 mSv) and the lifetime dose is 21 rem (210 mSv). In some regions of India and Brazil, these values are 10 times higher, yet there is no evidence of excess cancer in these places, illustrating the fact that radiation in low doses is not as harmful as perceived. Another argument against radiation phobia is that people on earth face the risk of cancer, and even death, from day-to-day living activities, such as driving, smoking, drinking alcohol, eating food, breathing air, etc., which are no less detrimental than radiation. Thirty seven percent of the population contract cancer just from these activities without any radiation exposure and 22% will die from natural causes (American Cancer Society, 2003). If the population is exposed to 1 rem (0.01 Sv) of radiation exposure, the risk of cancer increases only by 0.1% and half of them die (BEIR VII, 2005), which is quite low. From these examples, it appears that exposure to low dose radiation should not be of major concern, but extreme caution should be exercised in case of incidents involving high radiation exposure.

To allay the fear of radiation, a concerted effort by radiation experts, educators, and different scientific societies is essential. Efforts are made to explain the small risk associated with the use of low level of radiation compared to day-to-day living activities. The media can play an important role in communicating this information to the public. Radiation experts should take the initiative to convince the public of minimal risk of low-level radiation exposure. Similarly different professional

societies such as the American Cancer Society, the Society of Nuclear Medicine and Molecular Imaging, the American College of Radiology, the Health Physics Society, and the American Association of Physicists in Medicine can make a great difference in allaying the fear of radiation in the public's mind.

Questions

- Match the following organs with corresponding dose limits:

(a) 0.5 rem (5 mSv)/yr	(a) Radiation worker
(b) 5 rem (50 mSv)/yr	(b) Pregnant woman
(c) 0.1 rem (1 mSv)/yr.	(c) Unrestricted area
(d) 2 mrem (0.02 mSv)/h	(d) Members of public
- Radiation exposure varies with distance d _____.
 - linearly
 - squarely
 - as $1/d^2$
 - as $1/d$
- A controlled area is defined as an area:
 - with less than 2 mR in any 1 h
 - limited to primary beams
 - access to which is limited by the licensee
 - monitored by an alarm that is activated by radiation levels above a predetermined amount
- A person stands 10 ft away from a source of 10 mCi (370 MBq) ^{131}I . What is the exposure rate to the person? (Γ for ^{131}I is $2.21 \text{ R}\cdot\text{cm}^2/\text{mCi}\cdot\text{h}$ at 1 cm, or $59.5 \mu\text{Gy} \cdot \text{m}^2/\text{GBq} \cdot \text{h}$ at 1 m)
- If 1% of the primary beam exits a patient body with uniform attenuation, calculate the exposure at the midline of the patient.
- How much of lead thickness in cm needed to reduce a radiation exposure from a 15 mCi (550 MBq) ^{18}F -FDG source by 30%, given the half-value layer value of lead for ^{18}F as 0.5 cm^{-1} ?
- Explain broad-beam geometry in radiation exposure.
- When does the NRC require an occupational radiation worker to wear a personnel monitoring badge?
- A radiation source shielded with 5 cm thick lead sheet gives an exposure of 12 mR/h. How many cm of lead sheet is needed to reduce the exposure to 2 mR/h? (HVL of lead for the radiation = 2 cm^{-1}).
- An 0.5 mm protective lead apron will afford approximately _____ times as much protection as a 0.25 mm apron.
 - 0.5
 - 2
 - 4
 - Depends on the energy of the radiation

11. Match the following designations of areas with their corresponding limit of radiation exposure allowed for an occupational radiation worker:
- | | |
|------------------------------|------------------------|
| (a) High radiation area | (a) 500 rad/h at 3 ft |
| (b) Unrestricted area | (b) 100 mrem/h at 1 ft |
| (c) Very high radiation area | (c) 5 mrem/h at 1 ft |
| (d) Radiation area | (d) 2 mrem/h |
12. Discuss the principle of ALARA.
13. All procedures involving ionizing radiation should be designed to limit the yearly dose equivalent to ____ rem.
- (a) 0.5
(b) 5
(c) 12
(d) as low as reasonably achievable
14. Yellow II label is required for a radioactive shipment if the surface reading is _____ and the reading at 1 meter is _____.
15. Describe the procedure for receiving and monitoring a radioactive package, particularly surveying and wipe testing.
16. If 1 Ci of a radionuclide is adequately protected by 5 HVLs, _____ HVLs are needed to offer equal protection from 4 Ci.
- (a) 8
(b) 6
(c) 7
(d) 9
17. What is the survey and wipe test limits of β^- and γ radiations for radioactive packages?
18. What is the lowest limit of volatile iodine one can handle that does not require a bioassay?
19. Describe timely procedures for decommissioning a nuclear medicine facility.

References and Suggested Reading

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Regulatory Framework for Radiation Protection

5

5.1 Introduction

Since radiation causes damage in human tissues, use of radiation for treatment and diagnosis of human diseases is regulated by several national and international authorities. The International Commission on Radiation Protection (ICRP) under the International Atomic Energy Agency (IAEA) and the National Commission on Radiation Protection and Measurements (NCRP) recommend the guidelines and principles of safe use and handling of radiation based on published scientific data. The US Nuclear Regulatory Commission (NRC) adopts these principles and guidelines to establish rules and regulations in the radiation protection programs in the USA and publishes them in the Federal Registrar in the form of Codes of Federal Regulations (CFR). Many countries around the world adopt the recommendations of the ICRP to implement the radiation protection program in their own countries. Besides the NRC, other federal agencies in the USA such as the Food and Drug Administration (FDA), the Environmental Protection Agency (EPA), the Department of Energy (DOE), the Department of Transportation (DOT), etc. also have regulations for the use of radiations under specific circumstances, which are primarily in line with those of the NRC.

In the USA, the NRC regulates the use of byproduct material in any form and in any species by issuing licenses to individuals or institutions. The license conditions are set by the NRC based on the scope and need of the licensee. While the smaller facilities are allowed only limited use of byproducts, the larger institutions are permitted to utilize much larger quantities. However, the basic principles of radiation protection, monitoring of exposure, waste disposal, etc. are the same for all groups. Below is a description of requirements for different licenses essential for safe use of byproduct material.

5.2 Licensing

An entity, a person, or an institution must have a license from an appropriate authority to use radioactive material (RAM) for any purpose. Until 2005, only byproduct RAMs produced in reactors were regulated by the NRC, whereas naturally occurring and accelerator-produced radioactive materials (NARM) including Ra-226 were regulated by the States. In 2005, US Congress authorized the NRC to regulate all radioactive materials including NARM as byproduct materials. The individual or the institution must apply to the regulatory authority to get the license for the use of radioactive material. In the USA, licenses for all byproduct materials are issued by one of the two authorities, the NRC, or the Agreement State.

5.2.1 Agreement State

An Agreement State is a state that, for convenience of operation, has entered into agreement with the NRC to implement and manage certain uses of RAMs according to the NRC rules and regulations. One exception is that the NRC retains the regulatory control of nuclear power plants. The rules and regulations of the Agreement States may be stricter, but not less, than those of the NRC. Out of 50 states and three territories, there are now 39 Agreement States, and the States of Indiana and Connecticut have submitted letters of intent to become Agreement States, which are now under consideration by the NRC. The remaining states are called the NRC states meaning that the NRC controls all aspects of byproduct usage within the state. The Agreement States run these programs via the Health department, Environmental Protection division, or some other appropriate department.

The NRC or the Agreement States are the primary authority in the USA for issuing various licenses for specific uses. There are various types of domestic licenses for different uses, but for the use of byproduct materials in nuclear medicine and biomedical research, only three categories of licenses are applicable: general domestic license for in vitro testing, specific license of limited scope, and specific license of broad scope, which are described below:

5.2.2 General Domestic License for In Vitro Testing

Per [10 CFR 31.11](#), this license is issued to a physician, a veterinarian, a clinical laboratory, or a hospital to acquire, possess, transfer, or use of the listed byproduct materials in prepackaged units containing limited quantities (given in parenthesis) for a specific use: ^{125}I , ^{131}I , ^{75}Se , ^{57}Co , and ^{14}C each (10 μCi or 370 kBq), ^3H (50 μCi or 1.85 MBq), and ^{59}Fe (20 μCi or 740 kBq). The maximum possession limit is 200 μCi (7.4 MBq) for any of the above radionuclides at a time and at a location. The radioactivity in this category is not used in humans and animals. Specific provisions of 10CFR20 applicable to general licenses are established by this part. Although an application with the NRC is not required for the general license, the

applicant is required to obtain a registration number from the NRC or Agreement State by submitting Form 483 with all information related to intended use. Other general licenses include the use of ^{241}Am and ^{226}Ra (limit 5 μCi or 185 kBq) for solid sources for calibration of equipment in the pertinent field. The general licensee is exempt from parts 19, 20, and 21 for byproduct materials covered by the license. Any change in information provided in the original application must be reported to the NRC within 30 days after the change takes effect.

5.2.3 Specific Domestic License of Limited Scope

Specific license of limited scope is issued to a private or group practice and certain medical institutions (hospitals) for human use. The authorized users are listed on the license, and the limits of radioactivity to be used are given. In the case of group practice under a medical institution, the hospital is the licensee and remains responsible for activities with byproduct material. If the latter has provision for holding patients administered with radioactivity, it is permitted to treat patients with radio-nuclide. Private or group practice without an inpatient facility cannot treat patients with radioactivity who require hospitalization.

Specific licenses of limited scope may also be issued to mobile services (10 CFR 35.80, 10CFR35.647). A medical institution or a private or group practice may apply for authorization to use byproduct material in a mobile medical service.

5.2.4 Specific Domestic License of Broad Scope

There are three categories of specific domestic license of broad scope, briefly termed as “broad license” (10CFR33.11), Type A, Type B, and type C, based on maximum activity allowed for receipt, possession, use, and transfer of byproduct material in any physical or chemical form. The allowed maximum limit of receipt, possession, and use of byproduct materials in sealed sources under a broad scope license is 100,000 curies (370 TBq).

A Type A broad license is primarily issued to large medical institutions with past experience that are engaged in medical research, and in diagnostic and therapeutic uses of byproduct materials. It allows specified quantities of radioactivities, usually in multicuries. It requires the management of the institution to appoint a radiation safety officer (RSO defined later) and establish a radiation safety committee (RSC defined later) to monitor the activities related to the use of byproduct materials. While the RSC and the RSO are responsible for day-to-day operation of the radioactive programs, the management of the institution is overall responsible and accountable to the licensing authority (NRC or Agreement States) for any deletion, addition, or change in the radiation protection programs. Individual users in the institution are approved by the RSC for the use of radioactive materials in their specific projects, provided that they fulfill the criteria of training and experience required by the NRC or Agreement State.


A Type B broad license allows maximum activities of byproduct material specified in 10CFR33.100, Schedule A, Column I and is usually issued to physicians in private practice or group practice and smaller medical institutions where the use of byproduct material is limited. If two or more radionuclides are possessed thereunder, the possession limit for each radionuclide is determined by calculating the ratio of the quantity possessed of each radionuclide to the applicable quantity specified in 10CFR 33.100, Schedule A, Column I, for that radionuclide and the sum of the ratios of all radionuclides shall not exceed unity. An RSO is required to implement and monitor the use of byproduct materials, but the RSC is not required. The names of all authorized users are included on the license, who are approved by the RSO based on their training and experience.

A Type C licenses are issued to individuals, who have a bachelor degree in physical or biological science or engineering with 40 h of training and experience in handling radioactivity. The maximum activities of byproduct materials specified in 10CFR33.100, Schedule A, Column II are allowed, which are two orders of magnitude less than those in the Type B license. For possession of two or more radionuclides, the limit is determined by calculating the ratio of the quantity of each radionuclide to the applicable quantity specified in 10CFR 33.100, Schedule A, Column II, for that radionuclide and the sum of the ratios for all radionuclides shall not exceed unity. This license does not require an RSO or RSC, but the licensee is required to make a commitment that the byproduct material will be used by him, or persons under his supervision who satisfy the training requirement in 10CFR33.15.

5.2.5 Application for Specific License

Applications for all types of specific licenses must be made on the NRC Form 313 (Fig. 5.1) or similar form from the Agreement State following guidance in 10CFR30.32. All requested information such as receipt, possession, use, and disposal of byproduct materials must be provided in the form. Information from previous applications, statements, or reports filed with the NRC may be incorporated for reference. Each application is signed by the applicant or an authorized person on his behalf. In the case of Type A broad license, the management (e.g. CEO) is the applicant who signs the application. Each application must be accompanied by a fee set by the NRC or the Agreement State for a specific license. Normally, a fee is not charged for renewal or amendment to a license. Any violation of, or any conspiracy to violate the terms and conditions of, the license, is punishable by simple citation or by financial penalty, based on the severity of the mishap.

An application for possession and use of byproduct material for activities that the NRC considers may adversely affect the environment must be filed 9 months before construction of the facility along with an Environmental impact report. Application for a sealed source of byproduct material must contain the manufacturer's name and model number as registered with the NRC or the Agreement State. For sealed sources and devices without registration or safety information, the applicant may

<p>NRC FORM 313 (MM-YYYY) 10 CFR 30, 32, 33, 34 35, 36, 37, 39, and 40</p> 	<p>U.S. NUCLEAR REGULATORY COMMISSION</p> <p>APPLICATION FOR MATERIALS LICENSE</p>	<p>APPROVED BY OMB: NO. 3150-0120</p> <p><small>Estimated burden per response to comply with this mandatory collection request: 4.3 hours. Submittal of the application is necessary to determine that the applicant is qualified and that adequate procedures exist to protect the public health and safety. Send comments regarding burden estimate to the FOIA, Privacy, and Information Collections Branch (T-5 F33), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by e-mail to Infocollections.Resource@nrc.gov, and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202, (3150-0120), Office of Management and Budget, Washington, DC 20503. If a means used to impose an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.</small></p>	<p>EXPIRES: (MM/DD/YYYY)</p>		
<p>INSTRUCTIONS: SEE THE CURRENT VOLUMES OF THE NUREG-1556 TECHNICAL REPORT SERIES ("CONSOLIDATED GUIDANCE ABOUT MATERIALS LICENSES") FOR DETAILED INSTRUCTIONS FOR COMPLETING THIS FORM: http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/rs1556/. SEND TWO COPIES OF THE COMPLETED APPLICATION TO THE NRC OFFICE SPECIFIED BELOW.</p>					
<p>APPLICATION FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH:</p> <p>MATERIALS SAFETY LICENSING BRANCH DIVISION OF MATERIAL SAFETY, STATE, TRIBAL AND RULEMAKING PROGRAMS OFFICE OF NUCLEAR MATERIALS SAFETY AND SAFEGUARDS U.S. NUCLEAR REGULATORY COMMISSION WASHINGTON, DC 20555-0001</p> <p>ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS:</p> <p>IF YOU ARE LOCATED IN:</p> <p>ALABAMA, CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, FLORIDA, GEORGIA, KENTUCKY, MAINE, MARYLAND, MASSACHUSETTS, NEW HAMPSHIRE, NEW JERSEY, NEW YORK, NORTH CAROLINA, PENNSYLVANIA, PUERTO RICO, RHODE ISLAND, SOUTH CAROLINA, TENNESSEE, VERMONT, VIRGINIA, VIRGIN ISLANDS, OR WEST VIRGINIA.</p> <p>SEND APPLICATIONS TO:</p> <p>LICENSING ASSISTANCE TEAM DIVISION OF NUCLEAR MATERIALS SAFETY U.S. NUCLEAR REGULATORY COMMISSION, REGION I 2100 RENAISSANCE BOULEVARD, SUITE 100 KING OF PRUSSIA, PA 19406-2713</p>		<p>IF YOU ARE LOCATED IN:</p> <p>ILLINOIS, INDIANA, IOWA, MICHIGAN, MINNESOTA, MISSOURI, OHIO, OR WISCONSIN, SEND APPLICATIONS TO:</p> <p>MATERIALS LICENSING BRANCH U.S. NUCLEAR REGULATORY COMMISSION, REGION III 2443 WARRENVILLE ROAD, SUITE 210 LISLE, IL 60532-4332</p> <p>ALASKA, ARIZONA, ARKANSAS, CALIFORNIA, COLORADO, HAWAII, IDAHO, KANSAS, LOUISIANA, MISSISSIPPI, MONTANA, NEBRASKA, NEVADA, NEW MEXICO, NORTH DAKOTA, OKLAHOMA, OREGON, PACIFIC TRUST TERRITORIES, SOUTH DAKOTA, TEXAS, UTAH, WASHINGTON, OR WYOMING.</p> <p>SEND APPLICATIONS TO:</p> <p>NUCLEAR MATERIALS LICENSING BRANCH U.S. NUCLEAR REGULATORY COMMISSION, REGION IV 1600 E. LAMAR BOULEVARD ARLINGTON, TX 76011-4511</p>			
<p>PERSONS LOCATED IN AGREEMENT STATES SEND APPLICATIONS TO THE U.S. NUCLEAR REGULATORY COMMISSION ONLY IF THEY WISH TO POSSESS AND USE LICENSED MATERIAL IN STATES SUBJECT TO U.S. NUCLEAR REGULATORY COMMISSION JURISDICTIONS.</p>					
<p>1. THIS IS AN APPLICATION FOR (Check appropriate item)</p> <p><input type="checkbox"/> A. NEW LICENSE</p> <p><input type="checkbox"/> B. AMENDMENT TO LICENSE NUMBER _____</p> <p><input type="checkbox"/> C. RENEWAL OF LICENSE NUMBER _____</p>		<p>2. NAME AND MAILING ADDRESS OF APPLICANT (Include ZIP code)</p>			
<p>3. ADDRESS WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED</p>		<p>4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION</p> <p>BUSINESS TELEPHONE NUMBER _____ BUSINESS CELLULAR TELEPHONE NUMBER _____</p> <p>BUSINESS EMAIL ADDRESS _____</p>			
<p>SUBMIT ITEMS 5 THROUGH 11 ON 8-1/2 X 11" PAPER. THE TYPE AND SCOPE OF INFORMATION TO BE PROVIDED IS DESCRIBED IN THE LICENSE APPLICATION GUIDE.</p>					
<p>5. RADIOACTIVE MATERIAL</p> <p>a. Element and mass number; b. chemical and/or physical form; and c. maximum amount which will be possessed at any one time.</p>		<p>6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED</p>			
<p>8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS.</p>		<p>7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING AND EXPERIENCE.</p>			
<p>10. RADIATION SAFETY PROGRAM.</p>		<p>9. FACILITIES AND EQUIPMENT.</p>			
<p>12. LICENSE FEES (Fees required only for new applications, with few exceptions*) (See 10 CFR 170 and Section 170.31) *Amendments/Renewals that increase the scope of the existing license to a new or higher fee category will require a fee.</p>		<p>FEE CATEGORY <input type="text"/> AMOUNT ENCLOSED \$ <input type="text"/></p>			
<p>13. CERTIFICATION. (Must be completed by applicant) THE APPLICANT UNDERSTANDS THAT ALL STATEMENTS AND REPRESENTATIONS MADE IN THIS APPLICATION ARE BINDING UPON THE APPLICANT.</p> <p>THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATION ON BEHALF OF THE APPLICANT, NAMED IN ITEM 2, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PARTS 30, 32, 33, 34, 35, 36, 37, 39, AND 40, AND THAT ALL INFORMATION CONTAINED HEREIN IS TRUE AND CORRECT TO THE BEST OF THEIR KNOWLEDGE AND BELIEF.</p> <p>WARNING: 18 U.S.C. SECTION 1001 ACT OF JUNE 25, 1948 62 STAT. 749 MAKES IT A CRIMINAL OFFENSE TO MAKE A WILLFULLY FALSE STATEMENT OR REPRESENTATION TO ANY DEPARTMENT OR AGENCY OF THE UNITED STATES AS TO ANY MATTER WITHIN ITS JURISDICTION.</p>		<p>SIGNATURE _____ DATE _____</p>			
<p>CERTIFYING OFFICER - TYPED/PRINTED NAME AND TITLE</p>		<p>SIGNATURE _____ DATE _____</p>			
<p>FOR NRC USE ONLY</p>					
TYPE OF FEE	FEE LOG	FEE CATEGORY	AMOUNT RECEIVED \$	CHECK NUMBER	COMMENTS
APPROVED BY				DATE	

NRC FORM 313 (MM-YYYY)

Fig. 5.1 NRC Form 313 for application for license for byproduct materials

supply only the manufacturer, model number, and the radionuclide and quantity. Certain applications for specific licenses must contain a proposed decommissioning funding plan or a certificate of financial assurance for decommissioning. Each application to possess radioactive materials in unsealed form, on foils or plated

sources, or sealed in glass in excess of the quantities in 10CFR30.72, “Schedule C—Quantities of Radioactive Materials Requiring Consideration of the Need for an Emergency Plan for Responding to a Release” must contain either (a) an evaluation showing that the maximum dose to a person offsite due to release of radioactive materials would not exceed 1 rem (10 mSv) effective dose or 5 rem (50 mSv) to the thyroid or (b) an emergency plan for responding to and containing release of radioactive material.

An emergency plan for responding to accidental release of radioactive material must include the following information: facility description, types of accidents, classification of accidents, mitigation of consequences, assessment of releases of radioactive materials, formation of a team of personnel responsible for coordination of communication, and medical triage in case of injury, with appropriate individuals and authorities. The NRC operation center or the Agreement State must be notified of the emergency accident within an hour of emergency declaration. The licensee must make a commitment to the authority that training will be provided to workers on how to respond to a radiation emergency, and also guidance will be provided to fire, police, and medical personnel for their roles in emergency. More details on emergency procedures involving radiation accidents are available in Chap. 8 “Emergency Procedures.”

5.3 Food and Drug Administration Regulations for Radiopharmaceuticals

The US Food and Drug Administration (FDA) regulates drugs, food, cosmetics, and many devices for their production, efficacy, and use in humans and animals. The agency approves the manufacturing, quality control, and safety of the products and requires the manufacturers to follow the Current Good Manufacturing Practice (CGMP) in the production of drugs. For marketing a drug, the manufacturer must follow the two steps of the FDA regulations: Investigational New Drug (IND) application (21CFR312) and New Drug Application (NDA) (21CFR314). The details of these steps are available in the Federal Register specified in parenthesis. An individual or a manufacturer submits an IND to the FDA for a particular drug used for a particular disease. The IND involves three phases of studies: Phase I, Phase II, and Phase III. In Phase I, the pharmacology, biodistribution, metabolism, excretion, toxicity, optimum dosage, and adverse reactions of the radiopharmaceutical are assessed in a limited number of human subjects. In Phase II, the drug is evaluated in some more patients for a specific disease, and in Phase III, the efficacy and safety of the drug are determined in a large number (thousands) of patients for the given disease. Once all three phases are successfully completed, the individual or the manufacturer submits an application to the FDA asking for an NDA approval of the drug for marketing.

5.3.1 PET Radiopharmaceuticals

Since PET radiopharmaceuticals are prepared daily at a cyclotron facility, their production is considered manufacturing and so, like conventional drugs, falls under the purview of the FDA. However, the methods of production of PET radiopharmaceuticals vary among facilities, and the FDA requires each PET facility to have an IND or NDA. For an IND, three phases of IND are carried out as mentioned above, and after completion, an NDA approval for marketing or distribution is obtained from the FDA. Once approved, the NDA becomes a master file, and a prospective user can apply to the FDA for manufacturing the product by submitting what is called an *abbreviated* NDA (ANDA). An ANDA essentially refers to an already approved NDA, provided the method of synthesis, ingredients, route of administration, dosage, and strength are identical as specified in the master file. The FDA has approved more than a dozen PET radiopharmaceuticals for clinical use in humans, which are listed in Table 5.1. One can apply for an ANDA for any of these PET radiopharmaceuticals by referring to an NDA that is already filed with the FDA by other users. Remember that all rules and principles of radiation protection must be followed and applied in the operation of a cyclotron for manufacture of PET radiopharmaceuticals.

In addition to the FDA requirement, a medical use licensee, using PET radionuclide production facility in the preparation of PET radiopharmaceuticals for its own use, needs two licenses—one for production (10CFR30) and the other for medical use (10CFR35). If the PET facility distributes the PET radiopharmaceuticals to other licensees, then a distribution license also is required of the facility.

Table 5.1 FDA-approved current PET radiopharmaceuticals for different disease indications in nuclear medicine

Radiopharmaceutical	Indication
¹¹ C-choline	Prostate cancer recurrence
⁶⁴ Cu-dotatate (Detectnet™)	Neuroendocrine tumors (NETs)
¹⁸ F-florbetaben (Neuraceq™)	Amyloid plaque imaging in AD
¹⁸ F-florbetapir (Amyvid™)	Amyloid plaque imaging in AD
¹⁸ F-flortaucipir (Tauvid™)	Tau protein imaging in AD
¹⁸ F-fluciclovine (Axumin™)	Prostate cancer
¹⁸ F-fludeoxyglucose (FDG)	Various cancers, myocardial viability, epilepsy
¹⁸ F-fluorodopa	Parkinson disease
¹⁸ F-fluoroestradiol (Cerianna™)	Estrogen receptor-positive breast cancer
¹⁸ F-flutemetamol (Vizamyl™)	Amyloid plaque imaging in AD
¹⁸ F-piiflutolastat (PYLARIFY®)	PSMA positive lesions in men
¹⁸ F-sodium fluoride	Bone imaging
⁶⁸ Ga-DOTATATE (Netspot™)	Neuroendocrine tumors (NETs)
⁶⁸ Ga-DOTATOC	Neuroendocrine tumors (NETs)
⁶⁸ Ga-gozetotide (Illuccix®, Locamet®)	PSMA positive lesions in men
¹³ N-ammonia	Myocardial perfusion in CAD
⁸² Rb-chloride (Cardiogen-82®)	Myocardial perfusion in CAD

AD: Alzheimer Disease; NET: Neuroendocrine Tumor; CAD: Cardiovascular Arterial Disease

5.3.2 Radioactive Drug Research Committee

For convenience and to expedite investigation of new radiopharmaceuticals in humans, the FDA allows institutions and research facilities to form the so-called Radioactive Drug Research Committee (RDRC). The details of the composition and responsibility of the committee are given in 21CFR361.1(c). An RDRC membership includes the following expertise: (1) a physician recognized as a specialist in nuclear medicine, (2) a person qualified to formulate radioactive drugs, and (3) a person with special competence in radiation safety and radiation dosimetry. Additional members may be included, if necessary. Changes in the membership of an RDRC must be approved by the FDA in a timely manner prior to assuming responsibility in the committee.

The committee can be formed by one institution or a consortium of multiple institutions and must be approved by the FDA. Individual investigators submit to the committee an application detailing all required information related to the investigation of the new radioactive drug in humans, and the committee after satisfactory review approves the application.

The RDRC acts as a mini-FDA and imposes some restrictions on each protocol. The radiation dose to the critical organs in subjects under RDRC protocols cannot exceed 3 rem (0.03 Sv) for a single dosage of the drug and the sum of the doses from all dosages not to exceed 5 rem (0.05 Sv) per year. Only 30 patients are allowed per protocol. Pregnant women are excluded with assurance in writing from the woman patient that she is not pregnant. Pediatric patients may be included in the research study with due consideration to potential risk of radiation dose. Annual summary reports of all studies must be submitted to the FDA for review. The RDRC works in consultation with the Institutional Review Board (IRB), which monitors the ethical aspects of projects involving human subjects.

5.4 Accreditation of Nuclear Medicine Facility

The Joint Commission (formerly known as the Joint Commission on Accreditation of Healthcare Organizations (JCAHO)) is a non-profit organization in the USA that accredits nearly 21,000 health organizations for the quality assurance, patient safety, and outcome of their operation. While the Joint Commission is responsible for the accreditation of the entire hospital, the nuclear medicine and PET facilities are accredited by two organizations: The American College of Radiology (ACR) and The Intersocietal Accreditation Commission (IAC). Such accreditation is essential for the reimbursement for nuclear and PET studies by the Center for Medicare and Medicaid Services (CMS). A nuclear medicine or PET facility needs accreditation only by one of them and needs to apply for it by paying a fee. Although the goals of the two organizations are the same for perpetual quality improvement of the facilities through peer reviews and continuing education and training, there are subtle differences in their review process and requirements. The entire nuclear medicine facility or if desired, only a section of the facility such as the nuclear cardiology

section or a PET center can apply for accreditation, which is approved by the ACR or the IAC based on the fulfillment of requirements. The entire process of accreditation is conducted primarily electronically or by mail. It is beyond the scope of the book to describe all the requirements of either organization in detail, so only salient points and the differences in requirements between the two organizations will be alluded to. It is emphasized to note that the following discussion is not a substitute for actual accreditation requirements of the two organizations and one needs to consult the website of these organizations to apply for accreditation.

5.4.1 Accreditation by the IAC

The IAC emphasizes on the specifics of an organ study, critically reviewing the quality of the procedure, technique, and interpretation of patient examination. Specific requirements are as follows:

- A board-certified Medical Director is responsible for the overall operation of the facility including the quality of the procedure, radiation safety, appropriate interpretation of the tests results, etc. He must maintain continuing medical education (CME) of 15 h of credit every 3 years., of which 5 h may be in MR and/or CT or Certification Board of Cardiovascular Computed Tomography (CBCCT).
- A Technical Director, typically a certified chief technologist, who is responsible for the day-to-day operation of the facility. He also needs to have continuing education of 15 h credit every 3 years in his particular discipline, of which 5 h may be MR or CT credits. Must be able to delegate authorities in writing to others.
- All other medical staff and technical staff need to be certified according to the requirements of the IAC. They must obtain at least 15 h of AMA CME credits, relevant to nuclear medicine, every 3 years, of which 5 h may be MR or CT credits. Medical staff must be competent to interpret the imaging studies.
- Organizational chart of the physicians and all other personnel.
- Radiation safety and radioactive material handling protocols.
- All imaging protocols.
- QC protocols for all imaging and non-imaging equipment.
- For nuclear cardiology, 4 cases of myocardial perfusion studies (1 normal and 3 abnormal) and 4 normal and/or abnormal cases of equilibrium radionuclide angiography.
- For PET accreditation, 4 abnormal cases of PET studies in cardiac, neurologic, and oncologic patients.
- For general nuclear medicine, a minimum of 2 cases (maximum 12) per body system (musculoskeletal, endocrine, etc.) for which accreditation is sought.
- Number and type of imaging equipment.
- All personnel need certification in basic life support training.
- Quality control of procedures and equipment performed daily, weekly, and annually as required by the guidance of the IAC.
- Radiation safety program.

- NRC/Agreement State license.
- Board certificates of physicians and technologists.
- Record of all studies and any deviations therein.

Initially, the IAC checks online the pre-submission application for any errors and missing information, which the applicant, upon notification, corrects and submits the final application along with all images by uploading. A fee set by the IAC must be paid for accreditation and is paid by check within 5 days of application. On satisfactory review, IAC accreditation is granted for 3 years, which is renewable with submission of a new application. The IAC can make site a visit prior to approval of application for accreditation or during the accreditation period to monitor the compliance.

5.4.2 Accreditation by the ACR

The ACR requirements for accreditation are similar to those of the IAC and they are:

- Physicians licensed by the state and certified by their respective professional specialty boards or qualified by having definite hours of training and experience approved by the ACR. The ACR requires Maintenance of Certificate (MOC) with 150 h CME pertinent to the physician's practice patterns and 15 h of CME in 3 years specific to the imaging modality. Must read a minimum of 200 cases in PET/nuclear medicine in 3 years, and a minimum of 60 organ system-specific PET exams in 3 years.
- The physician is responsible for all protocols and must approve all aspects of the application and testing materials prior to submission.
- A board-certified medical physicist or a graduate physicist with experience and training in quality control of imaging equipment. MOC, or 15 h of continuing education (CE) as required by the ACR. He/she is responsible for the QC of the equipment, images of the nuclear medicine studies, and the phantom images.
- Lead Technologist certified by the professional board and licensed by the state.
- Must have a MOC or 24 h of CE every 2 years. Normally he/she is the primary contact person for all technical information.
- An administrative contact person to make sure the resources are available.
- Submission of the NRC or the Agreement State license. Submission of semiannual or quarterly quality assurance tests of all equipment using ACR-designated phantom reviewed by the medical physicist. Three modules of imaging: planar, SPECT, and nuclear cardiology. Submission of two different examination types for each module as specified by the ACR. One can choose one, two, or all three modules for accreditation.
- Clinical protocols for all studies submitted.
- A specific number of images for PET application.
- All submitted images properly labeled and oriented and the physician's interpretation.

- Reports of recent audit by the NRC or the Agreement State.
- Certificates of basic life support training for personnel supervising the nuclear stress studies.
- Fee for accreditation.

The ACR application involves two steps: The first step includes the submission of all information without the phantom images and case studies. Once the initial application seems satisfactory, the facility is then asked to submit the phantom data and case studies. If the final application is acceptable, accreditation is granted for 3 years upon payment of a fee. Accreditation is renewable with a new application and a fee. The ACR visits the facility during the accreditation period to monitor the compliance.

For detailed information, consult www.acr.org and www.intersocietal.org/nuclear-PET

Questions

1. Which of the following agencies regulates the use of radioactive materials in nuclear medicine?
 - (a) Food and Drug Administration
 - (b) Environmental Protection Agency
 - (c) Nuclear Regulatory Commission
 - (d) Occupational Safety and Health Administration
2. Match the following facilities with the corresponding license:

(a) Large hospital	(a) Type B broad scope license
(b) Private practice	(b) Type A broad scope license
(c) In vitro study	(c) General domestic license
3. In Type A license, who signs the application for the license?
 - (a) the Radiation Safety Officer
 - (b) the Radiation Safety Committee
 - (c) the Management of the Facility
 - (d) the Chairman of Nuclear Medicine Department
4. Discuss the difference between the Agreement States and the NRC States.
5. What are the two basic steps required by the FDA in an application for a PET drug to be produced and marketed?
6. Radioactive Drug Research Committee has the following limitations:
 - (a) Number of patients enrolled in the research _____.
 - (b) Dose limit to critical organs of a research subject from a single dosage of the drug is _____.
7. What are the two organizations that accredit nuclear medicine facilities for operation?

References and Suggested Reading

- FDA 21CFR312. Investigational New Drug Application. 2018.
- FDA 21CFR361.1(c). Radioactive Drug Research Committee. 2018.
- FDA 21CFR 314. New Drug Application 2018.
- NRC 10CFR 30. Rules and General Applicability to Domestic Licensing of Byproduct Material. 2018a.
- NRC 10CFR 31. General Domestic Licenses For Byproduct Material. 2018b.
- NRC NUREG 1556 Consolidated Guidance About Materials Licenses: Program—Specific Guidance About Medical Use Licenses. vol 9, rev 3. 2019.
- NRC 10CFR33.11. Types of specific licenses of broad scope. 2014.
- www.acr.org.
- www.intersocietal.org/nuclear-PET.



6.1 Introduction

The Nuclear Regulatory Commission (NRC) or the Agreement State regulates the use of radioactive byproduct materials in humans for diagnosis and therapy of different diseases. These regulations are covered in detail in NRC 10CFR35 for medical uses of radioactive materials and are grouped in six categories:

1. Uptake, dilution, and excretion (10CFR35.100).
2. Imaging and localization including generators and kits (10CFR35.200).
3. Radionuclide therapy (10CFR35.300).
4. Sealed sources for brachytherapy (10CFR35.400).
5. Sealed sources for diagnosis such as sources of ^{125}I and ^{153}Gd for bone mineral analysis (10CFR35.500).
6. Sealed sources such as those of ^{60}Co and ^{137}Cs in remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit (10CFR35.600).

Categories 1, 2, and 3 are relevant in nuclear medicine, categories 4 and 6 in radiation therapy, and category 5 in any specialty including endocrinology. As mentioned in Chap. 5, the byproduct materials must be approved for human use by the FDA under an IND or an NDA. The radionuclide generators and kits used in preparing radiopharmaceuticals also must be approved by the FDA.

In 2002, the NRC published the final rule in 10CFR35 for medical use of byproduct materials in humans. Since then, several revisions and updates have been made in 10CFR35 for improvement in medical use of byproduct materials. The latest revision has been made recently and is effective as of January 14, 2019. While the major part of the original 10CFR35 has been retained, some distinct changes and additions have been made as late as April, 2022, based on input from stakeholders in nuclear medicine and radiation therapy.

Specific changes applicable in nuclear medicine include:

1. Addition of an Associate Radiation Safety Officer (ARSO) in addition to the RSO in an institution.
2. Addition of an ophthalmic physicist.
3. Determination of ^{99}Mo breakthrough after each elution of the ^{99}Mo - $^{99\text{m}}\text{Tc}$ generator.
4. Removal of requirement for preceptor's attestation from approval criteria of authorized user, authorized medical physicist, authorized nuclear pharmacist, provided they are specialty board certified.

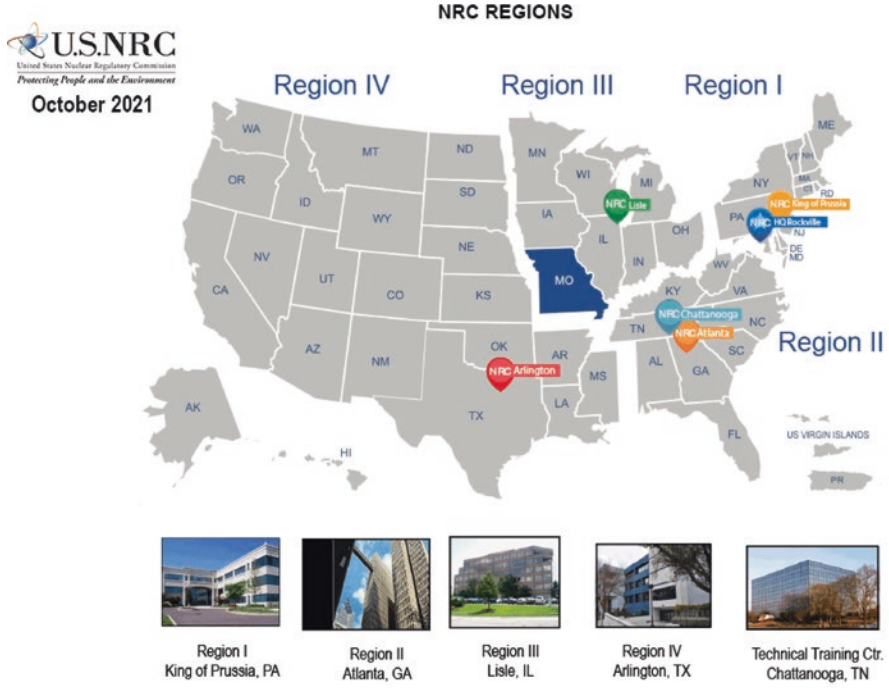
Pertinent rules and regulations in 10CFR35 including the current changes and additions applicable in nuclear medicine are elucidated below.

6.2 Application for License or Renewal

According to 10CFR35.12, an applicant or the applicant's management must apply for a license on NRC Form 313, "Application for Material License," (Fig. 5.1 in Chap. 5), providing all information pertinent to the medical use of byproduct materials. The application must include the detailed information on the facility layout, equipment, and training and experience of the RSO, ARSO, authorized user(s), authorized medical physicist(s), and authorized nuclear pharmacist(s). Information on radiation safety precautions, methods of measuring dosage and dose to the patient, and calibration and repair of equipment are required in the application. The application may be made by mail or electronically by visiting the NRC's Web site at <http://www.nrc.gov/site-help/e-submittals.html>. Application fees are variable depending on the category of byproduct use, and all applicable fees must be paid along with the application. Renewal can be made using the same NRC Form 313 or simply submitting a letter to the NRC or the Agreement State along with all procedures and requirements in detail.

6.3 Where to File

The NRC has four regional offices with headquarters in Rockville, Maryland, which are shown in Fig. 6.1 below. Agreement State applicants apply to the respective agency department, and the NRC applicants submit the application to the respective Regional office, except applicants in the Region II geographical area should send their applications to Region I.



Nuclear Power Plants

- Each regional office oversees the plants in its region—except for the Callaway plant in Missouri, which Region IV oversees.

Materials Licensees

- Region I oversees licensees and Federal facilities located in Region I and Region II.
- Region III oversees licensees and Federal facilities located in Region III.
- Region IV oversees licensees and Federal facilities located in Region IV.

Nuclear Fuel Processing Facilities

- Region II oversees all the fuel processing facilities in all regions.
- Region II also handles all construction inspection activities for new nuclear power plants and fuel cycle facilities in all regions.

Fig. 6.1 Four NRC regions and their locations in the USA. (Reproduced from NUREG 1556, vol 9, 2021)

6.4 License Amendment and Notification

Amendments to the license are made on NRC Form 313 for the following:

1. Appointment or discontinuation of an authorized user, a RSO or ARSO, an authorized medical physicist, an ophthalmic physicist, or an authorized nuclear pharmacist. However, individuals who are on a current NRC or Agreement State license for their respective practice are exempt from amendment requirement.

2. Change of name or address of the licensee.
3. Change or addition of the use area (areas used for uptake, dilution, and excretion (10CFR35.100) and for imaging and localization (10CFR35.200) are exempt except those where PET activities are involved).
4. Use of a new byproduct material, or excess byproduct material currently permitted in the license.
5. Any revision or new procedures that impact radiation safety.
6. Appointment of a temporary RSO.

Notification of these changes must be made to the NRC or an Agreement State no later than 30 days of occurrence along with pertinent documents such as license, board certificates, training and experience, case experience of authorized users, etc. The Type A specific license of broad scope is exempt from these requirements, which are scrutinized by the RSC of the facility.

6.5 Authorities and Responsibilities for Radiation Protection Program

According to 10CFR35.24, the licensee's management is responsible for the implementation of a radiation safety program in the facility for medical use of byproduct material, following 10CFR20.1101. Responsibilities of the management include approval of application, renewal and amendment prior to submission to the NRC or the Agreement State, approval in writing of an authorized user, an RSO, a nuclear pharmacist, a medical physicist, or an ophthalmic physicist. An RSO may delegate duties and tasks to the Associate Radiation Safety Officer, but not to run the entire safety program. At times, if necessary, the management can appoint one or more temporary RSOs for up to 60 days in a year. Ministerial changes can be made by management, provided the overall radiation safety program is not affected, and a record of each change made is kept.

6.5.1 Radiation Safety Officer

A Radiation Safety Officer (RSO) is an individual who is qualified with training and experience to manage a radiation protection program at a facility that utilizes byproduct material for various purposes. The management of a facility delegates the various responsibilities for radiation safety program to the RSO, which include, among others,

- Acting as a liaison between the facility and the NRC or the Agreement State.
- Implementation of the ALARA principle and all license conditions.
- Taking corrective actions or even stoppage of unsafe activities involving licensed materials and follow-up of implementation of corrective actions.
- Monitoring and quarterly review of personnel exposure records and advising personnel to reduce exposure.

- Training of personnel in proper handling and transportation of byproduct materials at regular intervals.
- Keeping inventories of byproduct materials and sealed sources throughout the facility.
- Follow-up of rules and guidance and establishment of procedures for use, shipping, storage, and disposal of byproduct materials.
- Establishing procedures for ordering, receiving, surveys, and delivery of byproduct materials.
- Implementing the Department of Transportation regulations in shipping byproduct material.
- Investigation of incidents involving radioactive materials and making corrective action.
- Annual audit of the entire program and all record keeping.
- Making amendments and renewals on a timely manner to keep the license up-to-date.

The management of the licensee shall grant the RSO sufficient authority, organizational freedom, time, resources to carry out the above functions. The licensee and the RSO shall retain a record of all actions taken. If necessary, the licensee's management may appoint one or more Associate Radiation Safety Officers (ARSO) to support the RSO. The RSO may assign duties and tasks to the ARSO, as appropriate. However, the ultimate responsibility of the program remains with the management.

6.5.2 Radiation Safety Committee

A Radiation Safety Committee (RSC) is not required for the use of byproduct materials for uptake and dilution (10CFR35.100) and for imaging and localization (10CFR35.200) in nuclear medicine, when either alone or both are used by a licensee. If two or more types of medical use of byproduct materials are allowed in a license, the management of the licensee is required to appoint an RSC. An example is the therapeutic use of unsealed byproduct material (10CFR35.300) and manual brachytherapy (10CFR35.400) in radiation therapy. For Type A broad scope licensee, an RSC is mandatory.

The RSC consists of, at a minimum, an authorized user for each type of use permitted in the license, the RSO, a nurse representative, and a management representative. Members of other disciplines may be added as appropriate. The management appoints a chairman from among the members of the committee. The RSC reviews the material related to the radiation protection program presented at the meeting by the RSO. Under the broad scope license in an institution, the committee approves applicants from the institution as authorized users or medical physicists who meet the NRC requirements.

Pursuant to 10 CFR 33.13(c)(3)(iii), the Committee approves or disapproves an application for new projects submitted by an authorized user after deliberations by the committee members. Changes in permits (quantity of activity, change of work area, use of new byproduct material, addition of new personnel, etc.) of authorized users are

approved or disapproved by the committee based on the merit of the proposal and training and experience of the applicant in the specific use of byproduct material.

Personnel exposures of radiation workers are reviewed by the RSC, and if a worker receives exposure above the NRC limit, circumstances are investigated by the RSO. With the RSO's report, the RSC recommends corrective action, if necessary. The committee reviews the results of required radiation surveys and any significant incidents, including spills, contamination, and medical events and recommends corrective actions, if needed. The committee meets as frequently as needed and the minutes of the meeting are recorded, although the NRC does not make any definite recommendation for the frequency of meetings.

6.6 Supervision

According to 10CFR35.27, the licensee must give thorough instructions on radiation safety, license conditions, written directive procedures, and appropriate use of byproduct materials, to individuals working in the facility under the supervision of an authorized user or a nuclear pharmacist. Practically this is performed by the RSO or ARSO in medical institutions. Periodic review of the supervised individuals is not required; however, the licensee is responsible for any omission or wrongful acts of the supervised individuals.

6.7 Training, Retraining, and Instructions to Radiation Workers

All workers in nuclear medicine who are likely to receive 100 mrem (1 mSv) in a year must be trained and instructed in radiation safety, all operating procedures, emergency procedures, and principles of ALARA to provide appropriate care to the patients and human research subjects. These instructions are given in-person, or on-line in large institutions where the materials are stored in computers for the workers to peruse and sign off. The licensee shall provide radiation safety instructions, initially on recruitment and then at least annually, to all radiation workers including personnel caring for patients or human research subjects. These personnel must be cognizant of regulations as to visitation of the confined patients, contamination problems, and waste disposal. They must be instructed to notify the RSO in the case of a medical emergency or death. All training and instructions are recorded and maintained for each worker.

6.8 Written Directives

According to 10CFR35.40, a written directive is required, dated, and signed by an authorized user before a dosage of greater than 30 μCi (1.11 MBq) of $^{131}\text{I-NaI}$ or a therapeutic dosage of an unsealed byproduct material other than $^{131}\text{I-NaI}$ can be administered to a patient or a human research subject. It must contain the patient's name, the identity and dosage of the drug, and the route of administration. If

necessary, a revision or changes in the written directive can be made by the authorized user prior to administration. Also, in the case of emergency, oral revision of the directive can be made, which must be followed by a written directive within 48 h.

10CFR35.41 stipulates that the licensee shall develop a systematic procedure for the written directives and retain a copy of them. Prior to administration of byproduct material, the patient's identity shall be verified by the name, driver's license, birthday, hospital ID number, or social security number, and the administration of the dosage is made in accordance with the written directive. The licensee shall retain a copy of the directive for each patient.

6.9 Authorization for Calibration, Transmission, and Reference Sources

Per 10CFR35.65, sealed sources manufactured, labeled, packaged, and distributed in accordance with the NRC or an Agreement State license regulations, or transferred from a NRC licensee or an Agreement State, and not exceeding 30 mCi (1.11 GBq) may be received, possessed, used, and redistributed by an authorized user for checking calibration, transmission, and reference purposes. Any unsealed byproduct material with $t_{1/2}$ less than 120 days may not exceed 15 mCi (0.56 GBq) and $t_{1/2}$ longer than 120 days may not exceed 200 μ Ci (7.4 MBq) or 1000 times the quantities in Appendix B of 10CFR30 for these purposes. However, any amount of ^{99m}Tc can be used. These sources need not be listed on the license.

6.10 Requirements for Possession of Sealed Sources

According to 10CFR35.67, the licensee is required to leak test the sealed sources of byproduct material with a half-life greater than 30 days at intervals of 6 months, unless it has been tested by the manufacturer within the last 6 months prior to possession by the licensee. The activity limit for leak tests of the sealed sources is $>100 \mu\text{Ci}$ (3.7 MBq) of β^- or γ -emitting radionuclide and $> 10 \mu\text{Ci}$ (370 kBq) of α -emitters. The sensitivity of the leak test is $0.005 \mu\text{Ci}$ (185 Bq). If the test is positive, the source is taken out of service, and stored, disposed, or repaired. A report must be filed with the NRC within 5 days of the leak test describing the source, the test results, and the action taken. Sealed sources of byproduct material with a half-life of less than 30 days and gaseous material need not be leak tested. A licensee shall make an inventory of all sealed sources every 6 months and keep a record of it.

6.11 Sterile Preparation of Radioactive Drugs

To prevent infection from contaminated drugs, sterile preparation of drugs is essential. The US Pharmacopeial Convention (USP), in concurrence with the US FDA, has introduced the USP General Chapter <797>, "Pharmaceutical Compounding—Sterile Preparations" setting the standards for sterile preparations. One of the requirements is

to compound drugs in a sterile and clean environment. Environmental air quality is monitored by measuring the particles in the environment. In nuclear medicine, drugs are prepared in a laminar flow hood fitted with a HEPA filter. The air quality of these hoods deems to be sterile and particulate free.

International Organization for Standardization (ISO) classifies the environment based on the number of particles per cubic meter in an area (Table 6.1). The USP Chapter <797> requires that compounding of radiopharmaceuticals should be carried out in an ISO Class 5 environment within an ISO Class 8 or cleaner environment. Radionuclide Generators can be eluted in an ISO Class 8 or cleaner environment. Cell labeling should be carried out in an ISO Class 7 environment. In nuclear pharmacy, dosage dispensing is carried out in a lead-lined enclosed

Table 6.1 ISO classification of particulate matter in room air

ISO Class	Particle count ^a /m ³
3	35.2
4	352
5	3520
6	35,200
7	352,000
8	3,520,000

^aLimits are given in particles of 0.5 μm and larger, per cubic meter (ISO)

Fig. 6.2 USP Chapter <797> compliant dosage dispenser chamber (Courtesy of Pinestar Technology, Inc.)



chamber (Fig. 6.2), which are commercially available. The interior space of the chamber is maintained sterile with the use of a HEPA filter and continuous air circulation. These small size chambers are compliant with Chapter <797> regulations of US pharmacopeia and are extremely useful for small facilities.

Laminar flow hoods are required to be certified annually for ISO Classification, and vendors are available to provide these services on an annual basis.

6.12 Measurement of Dosage of Radiopharmaceutical for Patients

According to 10CFR35.63, each dosage of a radiopharmaceutical for administration to human patient or research subject must be measured in a well calibrated dose calibrator. The calibration of dose calibrators is described in Chap. 2. In an in-house operation, bulk quantity of a radiopharmaceutical is prepared in a vial from which unit dosages are drawn in syringes for patients for a specific study using the dosage chart adopted by the department of nuclear medicine. Often for convenience, dosages are drawn precalibrated in syringes ahead of administration using decay factors of the radionuclide, and the syringes are properly labeled with the name of radiopharmaceutical and the time of injection, and then placed in cylindrical or tray type lead-shield carriers. The cylindrical ones are stored on a rack for use by the technologists for administration to patients at scheduled times.

Activity of unit dosages can be determined by direct measurement in the dose calibrator or by a mathematical combination of volume and concentration of the activity in the vial supplied by the manufacturer, or the PET drug producer, or prepared in the nuclear medicine facility. The unit dosages supplied by the manufacturer with calibrated activity need not be measured again.

Normally, authorized users establish a tabular chart of prescribed dosages or dosage ranges for different routine procedures in nuclear medicine. Unless otherwise directed by an authorized user, a licensee may not use a dosage, if it does not fall within the prescribed dosage range or if it differs from the prescribed dosage by more than 20 percent.

6.13 Permissible Concentration of ^{99}Mo , ^{82}Sr , and ^{85}Sr in Radionuclide Generators

According to 10CFR35.204, a licensee is required to do the following:

- (a) A licensee using the $^{99\text{m}}\text{Tc}$ - ^{99}Mo generator for preparing $^{99\text{m}}\text{Tc}$ radiopharmaceuticals shall measure ^{99}Mo concentration after each elution to comply with limits below.
- (b) A licensee is required to determine the ^{82}Sr and ^{85}Sr concentration in the eluate of the ^{82}Sr - ^{82}Rb generator prior to the first use of ^{82}Rb for patients on the day of use to comply with limits below.

- (c) The licensee shall report any measurement exceeding the limit to the manufacturer and the NRC or the Agreement State.

⁹⁹Mo limit: 0.15 kBq of ⁹⁹Mo ($t_{1/2} = 66$ h) per MBq of ^{99m}Tc ($t_{1/2} = 6$ h) or 0.15 μ Ci ⁹⁹Mo per mCi of ^{99m}Tc at the time of administration.

Note that the expiration time of ^{99m}Tc eluate is 12 h after elution. Because of the difference in half-lives of ⁹⁹Mo and ^{99m}Tc, ⁹⁹Mo decays slowly, whereas ^{99m}Tc decays faster so that the eluate would exceed the limit of 15 μ Ci of ⁹⁹Mo/mCi of ^{99m}Tc (0.15 kBq of ⁹⁹Mo/MBq of ^{99m}Tc) long before 12 h expiration time, and the eluate cannot be used. It can be shown that a value of 0.043 μ Ci of ⁹⁹Mo/mCi of ^{99m}Tc (0.043 kBq ⁹⁹Mo/MBq ^{99m}Tc) at the end of an elution results in 0.15 μ Ci ⁹⁹Mo/mCi ^{99m}Tc (0.15 of kBq of ⁹⁹Mo/MBq of ^{99m}Tc) 12 h later and the eluate can be used. Conventionally, one considers the value of 0.043 μ Ci or 0.043 kBq breakthrough of ⁹⁹Mo as the limit, which allows the use of the eluate 12 h later in compliance with the NRC requirement.

Determination of ⁹⁹Mo breakthrough: The activity in the elution vial after elution of the ⁹⁹Mo-^{99m}Tc generator on a given day is measured (A) usually in MBq or mCi in a dose calibrator, which contains mostly ^{99m}Tc and insignificant amount of ⁹⁹Mo. Next, the vial is placed inside a lead container, the thickness of which is so designed to stop 140 keV photons of ^{99m}Tc and allow 740 keV and 780 keV photons of ⁹⁹Mo, albeit the latter are partly attenuated. The dose calibrator setting for ⁹⁹Mo is already adjusted by the manufacturer to correct for the attenuation of the photons of ⁹⁹Mo in the lead container. So the ⁹⁹Mo activity in the shielded vial is measured (B) (usually in kBq or μ Ci), and the ratio B/A gives the ⁹⁹Mo breakthrough in kBq or μ Ci of ⁹⁹Mo per MBq or mCi of ^{99m}Tc.

⁸²Sr and ⁸⁵Sr limit: 0.02 μ Ci of ⁸²Sr ($t_{1/2} = 25.6$ days) per mCi of ⁸²Rb ($t_{1/2} = 75$ s) (0.02 kBq of ⁸²Sr per MBq of ⁸²Rb, and 0.2 μ Ci of ⁸⁵Sr ($t_{1/2} = 64.8$ days) per mCi of ⁸²Rb (0.2 kBq of ⁸⁵Sr per MBq of ⁸²Rb) at the time of administration.

Determination of ⁸²Sr and ⁸⁵Sr breakthrough: Prior to a patient study on a given day, the ⁸²Sr-⁸²Rb generator is eluted with 50 mL of 0.9% NaCl solution (saline) and the eluate is discarded. After 10 min wait, the generator is eluted again with 50 mL saline and the time at end of elution (EOE) is noted. The activity of the eluate is immediately measured in a dose calibrator. This is the total ⁸²Rb + ⁸²Sr + ⁸⁵Sr activity, considered to contain total ⁸²Rb activity (usually in MBq or mCi), because the ⁸⁵Sr and ⁸²Sr activity in it is relatively negligible. The measured activity is corrected for decay from EOE to time of measurement to get corrected ⁸²Rb activity (A) in MBq or mCi. The activity A is allowed to decay for 1 h, whereby all ⁸²Rb ($t_{1/2} = 75$ s) activity decays almost completely, leaving the residual ⁸²Sr + ⁸⁵Sr activity (B), which is measured usually in kBq or μ Ci in the dose calibrator.

The manufacturer provides ⁸²Sr/⁸⁵Sr ratio (R) on the calibration date on the generator label and correction factors F in a chart in the package insert for each of the days until the expiration of the generator (typically 4–6 weeks). Corrected ratio R_c on the day of use is calculated as

$$R_c = R \times F$$

The ^{82}Sr activity P is calculated in kBq or μCi as

$$P = \frac{B}{[1 + R_c \times 0.478]}$$

where the factor 0.478 (suggested by the manufacturer) is used to compensate for contribution of ^{85}Sr to ^{82}Sr activity. The ^{82}Sr breakthrough is calculated as P/A in kBq of ^{82}Sr per MBq of ^{82}Rb , or μCi of ^{82}Sr per mCi of ^{82}Rb at EOE.

6.14 Use of Unsealed Byproduct Material not Requiring Written Directive

According to 10CFR35.200, a licensee is required to use unsealed byproduct material not requiring written directive, which are:

1. Obtained from a manufacturer licensed by the NRC or an Agreement State or from a PET drug center.
2. (a) Prepared by an authorized nuclear pharmacist.
(b) Prepared by an authorized user.
(c) Prepared by someone under the supervision of an authorized pharmacist or an authorized user.
3. Prepared under an FDA-approved RDRC research protocol.

6.15 Minimizing Radiation Exposure from Nuclear Medicine Procedures

- Use γ -emitting radionuclides for imaging studies for diagnosis.
- Use correct and appropriate dosage of radiopharmaceuticals.
- Use a syringe shield during administration of a radiopharmaceutical, if not contraindicated.
- Block critical organs with cold agents such as with iodine for thyroid.
- Use well-calibrated instruments.
- Spend minimum time near the radioactive patient.

6.16 Labeling of Vials and Syringes

According to 10CFR35.69, vials and syringes that contain radioactive material must be labeled stating the identity and quantity of radionuclide and the date and time of measurement. If the label is not visible due to the shielded container, then the label with the same information must be placed on the outside of the container. The NRC does not require a syringe shield for administration of a radiopharmaceutical to a patient. However, it is highly recommended to use one to maintain the ALARA principle.

6.17 Possession and Calibration of Survey Meter

A licensee is required to have a survey instrument properly calibrated prior to first use, annually and after repair. Calibration is performed with a NIST traceable radioactive source (commonly ^{137}Cs) of known activity with deviation of $\pm 5\%$. The source is collimated in the form of a cone to minimize the scattered radiations. All scales are calibrated with readings up to 1000 mrem (10 mSv) per h, and two separate readings (usually 20% and 80% of the full scale) are obtained on each scale of use. A check source (typically ^{137}Cs source of 0.25 μCi to 10 μCi (92.5 kBq to 370 kBq)) is affixed to the body of the survey meter to test if the meter is functioning properly. The exposure value of the check source is posted on a label placed on the meter. On the day of measurement, if measured exposure rate differs from the calibrated exposure rate by more than 20 percent, the survey meter cannot be used and must be repaired.

The date of calibration is noted on the meter and a record of calibration must be kept.

6.18 Survey of Ambient Exposure Rate

According to 10CCR20.1501 and 10CFR35.70, surveys of ambient radiation exposure are required in the following areas where:

- Radiation workers are likely to be exposed in excess of 10% of the occupational dose limit.
- An individual is likely to receive more than 2.5 mrem (25 μSv)/h [5 rem (50 mSv)/year divided by 2000 h/year].
- The TEDE to the public is likely to exceed 0.1 rem (1 mSv)/year.
- The dose from external sources in an unrestricted area is likely to exceed 2 mrem (20 μSv)/h.

The NRC requires that all areas and rooms where radioactive material is stored, prepared, and administered are surveyed for ambient radiation exposure rate at the end of the day. The areas include almost all rooms in a nuclear medicine department, except office areas. In unrestricted areas at least monthly surveys are required. The trigger level for ambient dose rate is 0.1 mrem (1 μSv)/h for unrestricted areas and 5 mrem (50 μSv)/h for restricted areas.

Prior to survey, the calibrated G-M meter is checked if it is functioning properly. First, the control knob is turned on and positioned on the battery check position. If the needle moves to the “Bat Test” area, batteries are good. Otherwise, they need to be replaced. Second, a background count is taken with the meter in a low-background area to check if the meter is contaminated from unknown sources. If contaminated, it is decontaminated or another survey meter is used. Then proper functioning of the meter is checked by placing the detector of the meter as close as possible to the check source and comparing the reading with the calibration exposure value posted

on the survey meter on a given scale. A survey meter may not be used for surveying if the measured exposure rate differs from the calibration value by 20%. If all is well, then the counter is used for surveying.

For survey of a facility, a schematic diagram of all areas where radioactivity is used needs to be chalked out (Fig. 6.3) and a tabular list is made of these areas by assigning numbers to them (Table 6.2). The survey of each area is carried out with a calibrated survey meter (e.g., G-M counter), and the survey reading is recorded in a column corresponding to the area shown in Fig. 6.3. Survey is not required in rooms where patients administered with radiopharmaceuticals are confined, because the readings are usually high, and the room is surveyed after the patient is released.

The survey readings must be recorded along with the date of survey, the type of survey meter, and the name of the individual performing the survey.

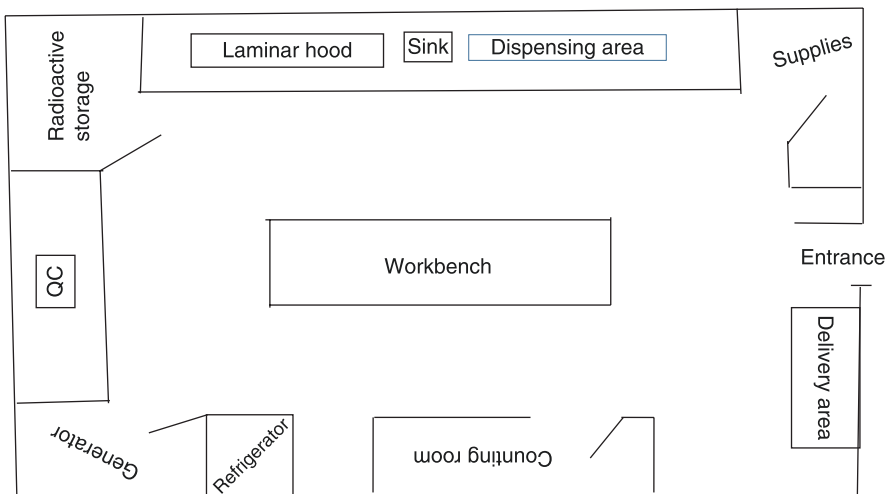


Fig. 6.3 Schematic layout of a nuclear pharmacy laboratory to identify areas to be surveyed. Similar layout should be drawn for all other areas of nuclear medicine

Table 6.2 List of areas by numbers for survey corresponding to Fig. 6.3

Areas	Number	Survey reading
Delivery area	1	
Supply room	2	
Dispensing area	3	
Sink	4	
Laminar hood	5	
Radioactive storage	6	
QC station	7	
Refrigerator	8	
Counting room (several areas)	9 (10, 11)	
Workbench	12	
Floor (several spots)	13	

6.19 Survey for Removable Contamination

The frequency of survey for removable contamination in the different areas in nuclear medicine is given below:

- Weekly—1. Areas where generator elution, drug preparation, assay, and patient administration are made. 2. Also storage areas of radionuclides and radioactive waste should be wipe tested.
- Monthly—Areas where small quantities of photon-emitting radionuclides are handled, e.g., research laboratories.

Wipe tests are performed by wiping an area of the contaminated area (larger than 100 cm²) with a piece of absorbent paper and counting it in a low-background area in a well counter giving counts per min (cpm). The cpm is then converted to disintegration per minute (dpm) by correcting for background, efficiency, and geometric factors. The recommended limits of wipe test (dpm or Bq/100 cm²) for restricted and unrestricted areas for common radionuclides are given in Tables 6.3 and 6.4,

Table 6.3 Suggested surface contamination limits in restricted areas^a

Area, clothing	Restricted areas, protective clothing used only in restricted areas (dpm/100 cm ²)
Alpha emitters	200
P-32, Co-58, Fe-59, Co-60, Se-75, Sr-85, Y-90, In-111, I-123, I-125, I-131, Sm-153, Yb-169, Lu-177, Au-198	2000
Cr-51, Co-57, Ga-67, Tc-99m, Hg-197, Tl-201	20,000

^aData are taken from NUREG 1556, vol 9, revision 3; 2019

Table 6.4 Suggested surface contamination limits for certain radionuclides in unrestricted areas (dpm (Bq)/100 cm²)^{a,d}

Radionuclide	Average ^{a,c} ((dpm/Bq))	Maximum ^{b,c} ((dpm(Bq))	Removable ^c (dpm(Bq))
I-125, I-129, Ra-226	100 (1.7)	300 (5.0)	20 (0.3)
I-126, I-131, I-133, Ra-223, Sr-90, Th-232	1000 (16.7)	3000 (50.0)	200 (3.3)
Other alpha emitters	500 (8.33)	1500 (50)	100 (1.67)
Beta-gamma emitters (nuclides with decay modes other than alpha emission or spontaneous fission) except those noted above	5000 (83.3)	15,000 (250)	1000 (16.7)

^aMeasurements of average contaminants should not be averaged over more than 1 square meter. For objects of less surface area, the average should be derived for each such object.

^bThe maximum contamination level applies to an area of not more than 100 cm².

^cThe average and maximum radiation levels associated with surface contamination resulting from beta-gamma emitters should not exceed 0.2 mrad/h at 1 cm and 1.0 mrad/h at 1 cm, respectively, measured through not more than 7 mg per square centimeter of total absorber.

^dData are taken from NUREG 1556, vol 9, revision, 3: 2019

respectively. If an area cannot be completely decontaminated, it should be covered with a lead sheet of appropriate thickness for decay to background, or restricted from use until acceptable contamination.

6.20 Medical Mobile Service

Per 10CFR35.80, to provide a mobile medical service in nuclear medicine, an agreement is required with particular emphasis on the relationship between service provider and the client (normally a hospital or private practice).

- A letter of agreement (MOU-memorandum of understanding) must be signed by both parties to provide services at the client's address with clear delineation of authority and responsibility between the licensee and the client.
- Instruments used for measuring activity and survey must be checked for proper functioning on the day of service.
- Client shall have the license for receiving and possession of byproduct material.
- All areas of use must be surveyed for contamination before leaving the client's address.
- The letter of agreement and records of all survey data must be retained.

6.21 Medical Uses of Byproduct Materials

Except for quantities that require a written directive under 10CFR35.40(b), a licensee may use any unsealed byproduct material prepared for uptake, dilution, or excretion (10CFR35.100), imaging and localization (10CFR35.200), and radionuclide therapy (10CFR35.300) studies, which is

- (a) Obtained from a manufacturer or a PET radioactive drug producer licensed by the NRC or an Agreement State, or prepared by (1) an authorized nuclear pharmacist; (2) an authorized user; or (3) an individual under the supervision of either an authorized nuclear pharmacist or an authorized user *or*
- (b) Prepared in accordance with a Radioactive Drug Research Committee-approved protocol or an Investigational New Drug (IND) protocol approved by the FDA.

6.22 Special Medical Uses of Byproduct Material

According to 10CFR35.1000, a licensee may use byproduct material approved for medical use, which is not specifically addressed in 10CFR35, provided the licensee receives approval of its use from the NRC following submission of the details of the use of the byproduct material to the Commission.

6.23 Use of Radioactive Material in Animal Research

Use of animals in biomedical research is a century-old practice for the sole purpose of discovery of drugs and devices to alleviate and mitigate human health problems. Drug development has been the cornerstone of animal research for centuries. Human diseases are induced in mice, rats, guinea pigs, dogs, and many others by administering disease cells. When the symptoms of the disease appear in the animal over time, the drug of interest is administered to the animal to assess its treatment effect. Over the decades, numerous experimental drugs have been evaluated and finally translated into successful human drugs for specific diseases.

Over the years, some scientific groups have cast doubt on the human benefit from animal research stating that the diseases induced in animals are not true replica of human diseases. Also what works in animals may not work in humans and vice versa. Computer models have been developed, which predict the *in vivo* behavior of many drugs in treating human diseases, resulting in realistic drug design. However, even today many animal experiments are carried out to evaluate the efficacy of numerous drugs including radiopharmaceuticals.

Investigators use radioactive materials in animals for various purposes. Like investigators for human-use radiopharmaceuticals, the animal users are required to have authorization from the Radiation Safety Committee for the use of radioactive material in animals. While requirements for human-use investigators are very stringent, the animal-use investigators need only some basic instructions in radiation safety. These instructions include knowledge in decay of radioactivity, safe handling of radioactivity, and disposal of radioactivity. The Radiation Safety Officer, or his designee provides these instructions to the animal-use researchers.

A researcher must apply to the Radiation Safety Committee through the RSO office for authorization to use radioactive material in animals by submitting an application specially designed for this purpose. A typical form is illustrated in Fig. 6.4.

The RSO or his designee will make a preliminary review of the application and the workspace, to find any deficiency. Then the application is deliberated at the RSC meeting and rejected or approved by the RSC.

Note that the applicant is also required to be authorized by the Institutional Animal Care and Use Committee (IACUC) for the use of animals in research, and both authorizations must be synchronized for approval before starting the experiment.

Name of Institution
Application for Use of Radioactive Material in Animal or In Vitro Studies

Name _____ Mail Code _____

Lab Locations _____ Phone _____ e-mail _____

New application _____ Amendment _____

Radionuclide _____ Chemical form _____ Solid, gas or liquid _____

If gas, you must agree to work in the fumehood and location of fumehood _____

Animal _____ IACUC approval # _____ In vitro _____

Maximum quantity of radionuclide to be used per experiment _____ # expt /month _____

Briefly describe your protocol:

Types of radioactive waste generated:

Dry waste (Paper, plastic, glass etc.)

Aqueous liquid

Non-aqueous liquid

Liquid scintillation vials

Is any radioactive waste:

Biohazardous or infectious

Hazardous

What survey equipment would you use? _____

Where will you store radioactive waste and/or animal? _____

Who will do the experiments? If different from AU, name them and their experience _____

Signature of Applicant Date _____

Date received by Rad Safety _____ Approved _____ or Rejected _____ by RSC

Date _____

Note: The RSO will review the application with the applicant prior to RSC meeting.

Fig. 6.4 Typical application form for authorization to use radioactive material in animals

6.24 Report and Notification of a Medical Event

Per 10CFR35.3045, a medical event occurs when the dose to a patient exceeds 5 rem (0.05 Sv) effective dose equivalent, or 50 rem (0.5 Sv) to an organ, tissue, or 50 rem (0.5 Sv) skin dose equivalent from any of the following situations:

1. Administration of a wrong radioactive drug.
2. Administration of a radioactive drug by wrong route of administration;
3. Administration of a dose or dosage to a wrong patient or human research subject;
4. Administration of a dose (absorbed dose) or dosage (radioactivity) delivered by wrong mode of treatment;
5. A leaking sealed source;
6. Total dose delivered differs from the prescribed dose by 20% or more;
7. Total dosage administered differs from the prescribed dosage by 20% or more, or falls outside the prescribed dosage range;
8. Unintended permanent damage to an organ or physiological system from the administration of a byproduct material, as determined by a physician.

The licensee shall report by telephone to the NRC Operation Center no later than one calendar day after the discovery of the medical event, followed by a written report to the NRC Regional Office within 15 days. The written report includes the licensee's name, the name of the prescribing physician, a brief description and the cause of the event, its effect on the individual, and corrective action taken. The affected individual's name may not be included in the report.

The licensee is required to notify the referring physician and the affected individual of the occurrence of the event within 24 h, unless the referring physician deems it unnecessary based on medical judgment, or he or she takes the responsibility to inform the individual. If the individual is not immediately available, a close relative or guardian may be notified. Immediate medical care should be provided to the affected individual, if needed, even if prompt notification cannot be made. If a verbal notification is made, the licensee informs the individual of the availability of the written report upon request.

In addition, the licensee shall annotate a copy of the report filed with the NRC or Agreement State with the name and social security number or other identification number of the affected individual and provide a copy of the annotated report to the referring physician, if other than the licensee, within 15 days of occurrence of the event.

6.25 Report and Notification of Dose to Embryo/Fetus or Nursing Child

According to 10CFR35.3047, the licensee shall report to the NRC or the Agreement State an event in which an embryo/fetus receives a dose equivalent of more than 5 rem (0.05 Sv) from the administration of a byproduct material to a pregnant woman, unless the dose is specifically approved by the authorized user. A similar report also is required to be made to the NRC or the Agreement State if a nursing

child receives a total effective dose more than 5 rem (0.05 Sv) or an unintended damage occurs to an organ or physiological system of the child due to the administration of a byproduct material to the breast-feeding woman.

The conditions, timing, notification, and descriptions of the report are identical to those of the medical event given in Sect. 6.24 above.

6.26 Record Keeping

Record keeping in nuclear medicine is one of the most essential requirements as mandated by the NRC or the Agreement State. Prior to the advent of computers, it was carried out by entering all information in handwriting in a record logbook.

Information to record includes, among others,

Dosages for Patients

- Ordering and receiving unit dosages or bulk dosages in a vial from commercial vendors
- Surveying the received radioactive packages
- Yield and quality control of ^{99m}Tc eluate and ^{82}Rb eluate
- Verifying the received dosages by measuring in the dose calibrator
- Preparing bulk radiopharmaceuticals using kits and their quality control
- Drawing the pre-calculated unit dosages from the kit vial for patients on a day
- Identity of the patients on a given day
- Administering the dosages to patients
- Date and time of administration of dosage to a patient
- Storage and disposal of syringes containing residual activity
- Name of the individual performing a given chore

Calibration of Equipment

- Dose calibrator (constancy, accuracy, linearity, and geometry)
- Survey meter (G-M counter, ionization chamber)
- Well counter
- Liquid scintillation counter
- Thyroid uptake counter
- Spectrometer

Quality Control of Imaging Equipment

- Positioning of photopeak
- Intrinsic or extrinsic uniformity
- Special resolution and linearity
- Center of rotation (SPECT)
- High count uniformity calibration

Radiation Protection

- Survey of work area
- Wipe test of work area

All software packages have many features in common with some specific differences attributable to the design of each program. Ordering of the dosages for patients for a specific study on a given date and time, bulk dosages, receiving the dosages, dispensing of dosage to the patient, storing and disposal of radioactive wastes are common items to document by the program in the computer. All programs keep track of patient's identity, type of study, name, and dosage of drug administered, date and time of administration, etc. with a few strokes of computer keys. Some programs are interfaced with the dose calibrators to record the dosage readings, while others have barcodes, which provides the data with a barcode reader thus reducing data entry error. After administration, the residual activity in the syringe is measured, the administered dosage is determined, and the syringe is stored for disposal—all these information are stored by the software. Software programs can store survey and wipe test data for packages, work areas, spill contamination, and bioassay. These have provisions for storing personnel radiation exposure dosimetry data.

Most software interfaces with HL7 and DICOM to transport back and forth RIS/HIS information on patient demographics and scheduling information. Many of them are HIPPA compliant due to multiple levels of security applied. Some software also can generate Standard Operating Procedures (SOP) for different studies. Timely calibration data of dose calibrators, survey meters, and counting instruments are stored by most software programs. Annual or semiannual instructions to radiation workers on principles of radiation protection in handling radioactive materials can be stored in the format of a module in the computer using the software program, which can be used on-line on a computer by the workers. Similarly, the elements of DOT requirements to train employees in handling hazmat are formatted in the form of a module by the software for presentation to the employees on a timely basis, as needed.

The intriguing part of these software programs is that once the initial data (e.g., dosage) is entered in the program, the subsequent data are generated automatically in a seamless workflow and displayed on the screen. All essential data can be navigated over the computer screen by the keyboard, a mouse, or a touchpad. The data can be printed out, if needed, and stored in a separate folder for future reference. The programs are mostly web-based and can be accessed from any computer within the department. Access to the program is secured by a log-in process requiring a user ID and a password.

6.26.2 Duration of Record Keeping

The NRC or an Agreement State requires a licensee to keep the records of all relevant activities performed in nuclear medicine for a specified time. Table 6.5 is a list of activities that require documentation and the time period the records need to be retained.

Table 6.5 Record keeping of various activities related to radioactive materials^a

Type of operation	Information needed	Time to maintain Records
Written directives (10CFR35.2040)	Copy of written directives	3 years
Procedures requiring written directive (10CFR35.2041) copy of procedures	Duration of license	3 years
Dosage of radiopharmaceuticals dispensed (10CFR35.2063)	Name, lot number, expiration date, patient's name or identification number prescribed dosage and dispensed dosage, date and time of administration, name of individual	3 years
Calibration of dose calibrator (10CFR35.2060)	Model, serial number of dose calibrator, date and results of test, and name of individual doing the test	3 years
Calibration of survey meters (10CFR35.2061)	Model and serial number of instrument, date and results of calibration, and name of individual	3 years
Semiannual leak tests and inventory of sealed sources (10CFR35.2067)	Model and serial number of each source and its radionuclide, estimated activity, measured activity in μCi (Bq), date of test, location of source (inventory), name of individual	3 years
Moly breakthrough (10CFR35.2204)	μCi (kBq) of ^{99}Mo per mCi (MBq) of ^{99m}Tc , date and time of measurement, name of individual	3 years
^{82}Sr and ^{85}Sr breakthrough (10CFR35.2204)	μCi (kBq) of ^{82}Sr and ^{85}Sr per mCi (MBq) of ^{82}Rb , date and time of measurement, name of individual	3 years
Thyroid bioassay and whole body counting (10CFR20.2106)	Name of individual having bioassay, date of reading, and the individual taking the measurement	Until NRC terminates license
Personnel exposure monitoring records (10CFR20.2106)	Must be on NRC-5 form according to items described on the form	Until NRC terminates license
Radioactive waste disposal by decay-in-storage (10CFR35.2092)	Date of disposal, instrument used, background reading, and surface reading of waste container and name of individual	3 years
Planned special exposures (10CFR20.2105)	Circumstances, name of authorizing individual, doses expected	Until NRC terminates license
Survey (10CFR35.2070)	Date, area, trigger level (mR/h), survey data, instrument used, and name of individual	3 years
Medical mobile service (10CFR35.2080)	Copies of agreement between clients and service provider	3 years
Release of patients with unsealed byproduct material (10CFR35.2075)	Basis of calculation to release patient, such as retained activity, occupancy factor less than 0.25 at 1 m, using T_p or T_e , or considering shielding by tissue	3 years

(continued)

Table 6.5 (continued)

Type of operation	Information needed	Time to maintain Records
Instructions given to breast-feeding (10CFR25.2075)	Instructions given if dose to infant exceeds 0.5 rem (5 mSv)	3 years
Actions taken by the licensee in radiation protection program ^b (10CFR35.2026)	Copy of actions taken and management's signature	5 years
Authority, duty and responsibility of RSO, and ARSO ^b (10CFR35.2024)	Copy of these elements with signatures of management and RSO and ARSO	5 years
Changes in radiation program ^b (10CFR35.2026)	Copy of old and new programs, date, approval, signature of management	5 years
Disposal of byproduct material ^b (10CFR20.2108)	Date and method of disposal, amount and type of activity, person disposing of	Duration of license
Transfer of byproduct material ^b	Date, amount, type of activity transferred, names of transferor and recipient	3 years. after transfer
Prior occupational dose ^b (10CFR20.2104)	Prior doses from previous employers	Duration of license
Release of radioactive effluents to environment (10CFR20.2013) ^b	Date, concentration of effluents	Duration of license
Dose to members of the public (10CFR20.2107) ^b	Date of record, dose values	Duration of license
Receipt of byproduct of material ^b	Date of receipt, type and quantity of activity, name of receiver	Duration of possession

^aReprinted with permission from Springer Nature, *Physics and Radiobiology of Nuclear Medicine* by Saha GB (2013)

^bAdded later

Questions

- Medical use of radioactive material in humans is regulated by
 - Food and Drug Administration
 - Environmental Protection Agency
 - Nuclear Regulatory Commission
 - Department of Transportation
- Who is accountable for the radiation safety program in an institution?
 - Radiation Safety Officer
 - Chief Executive Officer
 - Chairman of Nuclear Medicine
 - Medical Physicist
- For a large institution, which of the following NRC licenses is required?
 - Type A broad scope
 - Type B broad scope
 - Type C broad scope
 - general in vitro testing license
- Elucidate the responsibilities of a radiation safety officer.

5. The ^{99m}Tc breakthrough in ^{99m}Tc eluate is limited to
 - (a) 10 μCi of ^{99}Mo /mCi of ^{99m}Tc (10 Bq of $^{99}\text{Mo}/\text{MBq}$ of ^{99m}Tc)
 - (b) 0.15 μCi of ^{99}Mo /mCi of ^{99m}Tc (0.15 Bq of $^{99}\text{Mo}/\text{MBq}$ of ^{99m}Tc)
 - (c) 1.5 μCi of ^{99}Mo /mCi of ^{99m}Tc (1.5 Bq of $^{99}\text{Mo}/\text{MBq}$ of ^{99m}Tc)
 - (d) 15 μCi of ^{99}Mo /mCi of ^{99m}Tc (15 Bq of $^{99}\text{Mo}/\text{MBq}$ of ^{99m}Tc)
6. The ^{99m}Tc eluate needs to be tested for ^{99}Mo breakthrough
 - (a) for every patient receiving ^{99m}Tc
 - (b) daily, even if no patient study is performed with ^{99m}Tc
 - (c) after each elution of the ^{99}Mo - ^{99m}Tc generator
 - (d) only once upon receipt of the generator from the vendor
7. How often and when ^{82}Sr - ^{85}Sr breakthrough needs to be determined in a ^{82}Rb generator?
 - (a) daily for every patient
 - (b) only once upon receipt of the generator
 - (c) every alternate day of use
 - (d) only once before the first patient use of the day
8. Indicate the following individuals who cannot prepare the radiopharmaceuticals for medical use in humans:
 - (a) authorized user
 - (b) radiation safety officer
 - (c) individuals supervised by an authorized user
 - (d) nuclear pharmacist
9. For which of the following conditions is a written directive needed?
 - (a) a radiopharmaceutical for diagnostic purpose
 - (b) administration of less than 30 μCi of ^{131}I -NaI
 - (c) administration of therapeutic dosage of an unsealed radiopharmaceutical
 - (d) administration of ^{99m}Tc -MDP for bone scan
10. Survey of a nuclear medicine facility is performed
 - (a) daily
 - (b) weekly
 - (c) never
 - (d) biweekly
11. At what time is the daily survey of a radiation area carried out?
 - (a) at the beginning of the day
 - (b) after administration of every patient
 - (c) at lunch time
 - (d) at the end of the workday
12. Indicate if the following conditions for area survey are True or False:
 - (a) radiation worker likely to be exposed to more than 10% of occupational dose
 - (b) an individual likely to receive more than 2.5 mrem (25 $\mu\text{Sv}/\text{h}$)
 - (c) TEDE to the public likely to exceed 0.1 rem (1 mSv)/year
 - (d) dose from external sources in unrestricted area is more than 2 mrem (20 $\mu\text{Sv}/\text{h}$)

13. The leak test for sealed sources is performed
 - (a) on first possessing, provided the manufacturer performed the test within last 6 months
 - (b) every 6 months
 - (c) every month
 - (d) only if it is leaking
14. How often is the wipe test performed in the nuclear medicine area?
 - (a) monthly
 - (b) biweekly
 - (c) weekly
 - (d) daily
15. Describe the situations when a medical event occurs.
16. A medical event must be reported by telephone to the NRC Operating Center
 - (a) within 24 h of discovery of the event
 - (b) 15 days after discovery of the event
 - (c) a week after discovery of the event
 - (d) whenever it is convenient for the licensee
17. A written report for a medical event must be submitted to the NRC within
 - (a) 10 days after phone report
 - (b) a week after phone report
 - (c) 15 days after phone report
 - (d) whenever the RSO decides
18. A report must be made to the NRC in the event a fetus or a nursing child receives an effective dose equivalent of
 - (a) 0.5 rem (0.005 mSv)
 - (b) 1.5 rem (0.015 mSv)
 - (c) 10 rem (0.1 mSv)
 - (d) 5 rem (0.05 mSv)
19. Match the following activities with the period of record keeping:

A. Written directives	A. 3 years
B. Disposal of byproduct material	B. 3 years
C. Decay-in-Storage	C. Until NRC terminates the license
D. Thyroid bioassay	D. Duration of license
E. Dosage to patients	E. 3 years
20. Which of the following statements are true:
 - (a) A dosage of a radiopharmaceutical can be used for a patient if it differs from the prescribed dosage by $>20\%$
 - (b) The sensitivity of the leak test for sealed sources is $0.1 \mu\text{Ci}$ (37 kBq)
 - (c) Written directive is not needed for administration of $>33 \mu\text{Ci}$ (1.221 MBq)

- (d) Survey instruments need to be calibrated annually
21. Radiation workers are required to be given instructions on radiation safety principles
- (a) on recruitment only
 - (b) annually
 - (c) semiannually
 - (d) never
-

References and Suggested Reading

NRC 10CFR35. Medical use of byproduct material; 2019.

NRC NUREG 1556. Consolidated guidance about materials licenses: program—specific guidance about medical use licenses. Vol. 9, Rev 3; 2019.

US Pharmacopeial Convention (USP), 2022. USP General Chapter <797>, Pharmaceutical Compounding – Sterile Preparations.



Training and Experience of Authorized Personnel

7

7.1 Introduction

The NRC mandates that individuals using radioactive materials (RAM) in humans or otherwise must have sufficient training and experience in the respective use. The NRC has established criteria of classroom and laboratory training and experience for different types of RAM use. The Agreement States adopt the similar requirements of training and work experience for individuals for the use of RAMs in humans. Physicians, Radiation Safety Officers (RSOs), medical physicists, nuclear pharmacists, and researchers must fulfill these requirements prior to their approval by the NRC to use radioactive materials in respective areas. Authorization of individuals to use byproduct material for specific purposes is granted by the NRC or the Agreement States in two major pathways: (a) certification by a specialty board in the specific discipline and (b) laboratory training and work experience in the specific discipline. In the past, either authorization required attestation by a preceptor as to the competency of the individual to function independently in a discipline. Now such preceptor attestation is not required in specialty board authorization, because the NRC recognizes that these boards meet the NRC requirements of laboratory training and work experience including all elements of preceptor attestation. These topics are described in detail in NRC 10CFR35. However, as of January 14, 2019, a few changes in requirements for authorization along with other changes have been made that are incorporated in the current 10CFR35.

Many national professional organizations such as the American Board of Radiology (ABR), the American Pharmaceutical Association (APhA), the American Board of Nuclear Medicine (ABNM), the American Board of Science in Nuclear Medicine (ABSNM), etc. are involved in the use of radiation and have established specialty boards to certify individuals to practice in their respective specialty. To be certified, the candidates are required to fulfill a set period (years) of training and practical work experience in respective specialties in an accredited program and must pass the board examination. The NRC and the Agreement States recognize these specialty boards for authorization of individuals for respective use of RAMs,

provided the training and experience requirements of these board certifications match those of the NRC, and authorize these board-certified individuals to practice in respective specialties. The NRC has published the list of recognized specialty boards and occasionally updates them on their webpage, NRC's Medical Uses Licensee Toolkit. Different professional boards that are recognized by the NRC or Agreement States for various medical uses of byproduct material are listed in Table 7.1. The basic NRC requirements of classroom and laboratory training and work experience are presented in Table 7.2.

The topic of training and experience required for the NRC authorization is quite comprehensive and is beyond the scope of this book. The following is a brief outline of the NRC requirements for certification of professionals for the use of RAMs.

Table 7.1 Specialty board certification recognized by the NRC under 10 CFR 35 for professionals and specific use of byproduct materials

Specialty Boards ^{a,b,c}	Professionals or type of byproduct material use
1. American Board of Health Physics (ABHP)	Radiation Safety officer (RSO)
2. American Board of Science in Nuclear Medicine (ABSNM) in (a) Nuclear Medicine Physics and Instrumentation (b) Radiation Protection	
3. American Board of Radiology (ABR) in Diagnostic Radiologic Physics, Medical Nuclear Physics, Diagnostic Medical Physics and Nuclear Medical Physics specialties certificate containing insignia "RSO Eligible" appearing above the ABR seal	
4. American Board of Medical Physics (ABMP) with experience in Medical Health Physics and certificate containing "RSO Eligible"	
1. ABR in Therapeutic Radiology Physics, and Therapeutic Medical Physics with certificate containing "AMP eligible," Canadian College of Physicists in Medicine(CCPM)	Authorized medical physicist (AMP)
1. Board of Pharmaceutical Specialties and Nuclear Board of Pharmacy Specialties (BPSNBPS)	Authorized Nuclear Pharmacist (ANP)
1. American Board of Nuclear Medicine (ABNM) with certificates containing "United States"	Uptake, dilution, and excretion (AU)
2. Certification Board of Nuclear Endocrinology (CBNE)	Imaging and localization
1. Certification Board of Nuclear Cardiology (CBNC) with certificate containing "for physicians residing in the United States"	
2. CBNC under Council for Certification of Cardiovascular Imaging (CCCI) with wording "for Physicians Trained in the United States" on the certificate	
3. ABNM containing the words "United States" on the certificate	
4. American Osteopathic Board of Radiology (AOBR) with diagnostic radiology specialty with "AU Eligible" appearing above D.O. symbol on the certificate	
5. American Osteopathic Board of Nuclear Medicine (AOBNM)	
6. ABR With words "AU Eligible" appearing above the ABR seal on the certificate	

Table 7.1 (continued)

Specialty Boards ^{a,b,c}	Professionals or type of byproduct material use
1. ABNM containing the words “United States” on the certificate	Unsealed byproduct material, oral administration of less than or more than 33 mCi (1.22 GBq) ¹³¹ I- NaI for which a written directive is required
2. ABR certification for Radiation Oncology Specialty with words “AU Eligible” appearing above the ABR seal	
3. American Osteopathic Board of Radiology directive is required (AOBR) with Radiation Oncology Specialty with “AU Eligible” appearing above D.O. seal on the certificate	

^aSome specialty boards have been omitted because their relationship to nuclear medicine is minimal.

^bThe NRC has time restriction on certification of several specialty boards for authorization of individuals, so refer to the NRC’s toolkit webpage

^cNote that preceptor attestation is not required for authorization, if an individual is authorized by way of specialty board certification, provided the specialty boards meet the NRC requirements of training and work experience

Table 7.2 Basic NRC requirements of classroom and laboratory training and work experience

Classroom and laboratory training	Work experience
1. Radiation physics and instrumentation	1. Ordering, receiving, shipping, and surveying the radioactive packages
2. Radiation protection	2. Performing quality control of dose calibrator and survey
3. Mathematics pertaining to the use and measurement of radioactivity	3. Calculating, measuring, and safely preparing dosages for patients or human subjects
4. Chemistry of byproduct material for medical use	4. Administering dosage to patients (AU)
5. Radiation dosimetry (RSO)	5. Administrative control of medical event involving the use of byproduct material
6. Radiation biology	6. Management of spill and contamination
	7. Emergency procedure (RSO)
	8. Securing and disposing of radioactive material (RSO)
	9. Sealed source leak test and inventory (AMP)

Note: For specific use of byproduct material, additional training and experience may be required. For example, to be an authorized user for imaging and localization, knowledge of eluting the ⁹⁹Mo-^{99m}Tc generator and quality control of the eluate is required.

7.2 Radiation Safety Officer and Associate Radiation Safety Officer

Per 10CFR35.50, an applicant is authorized to be a Radiation Safety Officer (RSO) by one of the following six ways, provided the individual:

1. Is certified by a specialty board recognized by the NRC or an Agreement State (Table 7.1) that requires that the candidate

- (a) Holds a bachelor's or graduate degree from an accredited institution in physical science or engineering or biological science with a minimum of 20 college credits in physical science; *and*
 - (b) Has 5 or more years of professional experience in health physics (graduate training may be substituted for no more than 2 years of the required experience) including at least 3 years in applied health physics; *and*
 - (c) Passes an examination administered by the specialty board to assess knowledge and competence in radiation safety; *or*
2.
 - (a) Holds a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university; *and*
 - (b) Has 2 years of full-time practical training and/or supervised experience (Table 7.2) in medical physics under the supervision of a specialty board-certified medical physicist; or in clinical nuclear medicine facilities under the direction of authorized physicians; *and*
 - (c) Passes an examination, administered by the specialty board to assess knowledge and competence in radiation safety; *or*
3. Has completed a structured educational program consisting of both
 - (a) 200 h of classroom and laboratory training in radiation physics and radiation safety; *and*
 - (b) 1 year of full-time radiation safety experience (Table 7.2) under the supervision of an RSO or an eligible ARSO who is approved on an NRC or an Agreement State license for type(s) of use(s) of byproduct material involving radiation safety; *and*
 - (c) Has obtained a written attestation, signed by a preceptor RSO or ARSO who has radiation safety experience in RAM use similar to those the applicant has applied for, that the individual has satisfactorily completed the radiation safety experience requirements in radiation safety and achieved sufficient radiation safety knowledge to function independently as a RSO or as an ARSO for a medical use licensee; *or*
4. Is a medical physicist who has been certified by a specialty board (Table 7.1) recognized by the NRC under 10CFR35.51 or an equivalent Agreement State regulation and has experience in radiation safety for similar types of use of byproduct material; *or*
5. Is an authorized user, authorized medical physicist, or authorized nuclear pharmacist who is identified on an NRC license or permit, and has experience in radiation safety aspects of similar types of use of byproduct material; *or*
6. If an individual seeks simultaneous approval for both RSO and authorized user on the same license, he/she must have relevant training and experience for both entities.

The individual is required to have training in radiation safety, regulatory issues, and emergency procedures for the types of byproduct use for which a licensee seeks approval. This training requirement may be satisfied by completing training that is

supervised by an RSO, ARSO, authorized medical physicist, authorized nuclear pharmacist, or authorized user, as appropriate, who is authorized for the type(s) of use for which the licensee is seeking approval.

7.3 Training for Authorized Medical Physicist

Per 10CFR35.51, an applicant is approved as an authorized medical physicist (AMP) by one of the following two pathways, if the individual:

1. Is certified by a specialty board (Table 7.1) recognized by the NRC or an Agreement State that requires all candidates for certification to:
 - (a) Hold a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university; *and*
 - (b) Have 2 years of full-time practical training and/or supervised experience in medical physics under the supervision of a medical physicist certified by a specialty board recognized by the NRC or an Agreement State; or in clinical radiation facilities providing high-energy, external beam therapy, and brachytherapy services under the direction of authorized physicians; *and*
 - (c) Pass an examination administered by diplomates of the specialty board in the respective specialty; *or*
2.
 - (a) Hold a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university; *and*
 - (b) Have 2 years of full-time practical training and/or supervised experience in medical physics (a) under the supervision of a medical physicist who is certified in medical physics by a NRC-approved specialty board or (b) in clinical radiation facilities providing high-energy, external beam therapy (photon and electron energies greater than 1 MeV) and brachytherapy services under the direction of authorized physicians in these modalities; this experience includes leak tests of sealed sources, calibration, spot checks of, and radiation survey around the external beams, stereotactic radiosurgery units, and remote afterloading units; *and*
 - (c) Obtain a written attestation signed by a preceptor authorized medical physicist, stating that the individual has achieved sufficient competency to function independently in the management and use of external beam treatment units, stereotactic radiosurgery units, and remote after loading units.

In both cases (1) and (2), the applicant must have training in the type(s) of RAM use for which authorization is sought that includes hands-on device operation, safety procedures, clinical use, and the operation of a treatment planning system under a training program provided by the vendor or under the supervision of an authorized medical physicist.

7.4 Training for Authorized Nuclear Pharmacist

Per 10CFR35.55, an applicant (a pharmacist) is approved as an authorized nuclear pharmacist (ANP) by one of the following two ways, if the individual:

1. Is certified by a specialty board in nuclear pharmacy recognized by the NRC or the Agreement State (Table 7.1), which requires the candidate to:
 - (a) Have graduated from an accredited pharmacy program; *and*
 - (b) Be currently licensed to practice pharmacy; *and*
 - (c) Have acquired at least 4000 h of training/experience (Table 7.2) in nuclear pharmacy practice (academic graduate training may be substituted for a maximum of 2000 h of the required training and experience); *and*
 - (d) Pass an examination in nuclear pharmacy administered by the specialty board that assesses knowledge and competency in nuclear pharmacy practice; *or*
2.
 - (a) Has completed 700 h of structured pharmacy program consisting of (a) 200 h of classroom and laboratory training and (b) supervised practical experience in nuclear pharmacy practice (Table 7.2); *and*
 - (b) Has obtained a written attestation, signed by a preceptor authorized nuclear pharmacist, stating that the candidate has sufficient competence to function independently in nuclear pharmacy practice.

7.5 Authorized Users (Physicians, Dentists, and Podiatrists)

7.5.1 7.5.1 Training for Uptake, Dilution, and Excretion Studies

Per 10CFR35.190, a physician is approved as an authorized user (AU) in this category by one of the following three pathways, provided the physician

1. Is certified by an NRC-recognized specialty board (Table 7.1) that requires 60 h of training and experience in radiation safety, radionuclide handling and quality control, and passing of an examination conducted by the specialty board; *or*
2. Is already an authorized user on an NRC license under 10CFR35.290 or 10CFR35.390 or equivalent Agreement State approved license; *or*
3.
 - (a) Has 60 h of training and experience (Table 7.2) that include a minimum of 8 h of classroom and laboratory training in basic aspects of radiation safety, and the remaining 52 h of work experience in handling RAMs under the supervision of an authorized user; *and*
 - (b) Obtains a written attestation from a preceptor authorized user or a residency program director that he/she has achieved sufficient competence in independently fulfilling the radiation safety-related duties in handling RAM to conduct uptake, dilution, and excretion studies.

7.5.2 Training for Use of Unsealed Byproduct Material for Imaging and Localization Studies

Per 10CFR35.290, authorization in this category is granted to a physician by one of the following three ways, provided the physician:

1. Is certified by an NRC-recognized specialty board (Table 7.1) that requires 700 h of training and experience in radiation safety, radionuclide handling and quality control, and passing a specialty board examination; *or*
2. Is already an authorized user on an approved NRC or Agreement State license; *or*
3. (a) Has 700 h of training and experience that include a minimum of 80 h of classroom and laboratory training in basic aspects of radiation safety, the remaining 620 h of work experience in safe handling of RAMs under the supervision of an authorized user or an authorized nuclear pharmacist; *and*
(b) Obtains a written attestation from a preceptor authorized user or a Residency Program Director that he/she has achieved sufficient competence in independently fulfilling the radiation-safety-related duties and acting as an authorized user

7.5.3 Training for Use of Unsealed Byproduct Material for which a Written Directive Is Required

Per 10CFR35.390, authorization in this category is granted to a physician by one of the following two pathways, provided the physician:

1. Is certified by an NRC-recognized specialty board (Table 7.1) that requires
 - (a) residency training in radiation therapy or nuclear medicine or a program in a related medical specialty approved by the Accreditation Council for Graduate Medical Education, the Royal College of Physicians and Surgeons of Canada, or the Committee on Post-Graduate Training of the American Osteopathic Association; *and*
 - (b) 700 h of training and experience (Table 7.2) in radiation safety, radionuclide handling, and clinical use of unsealed byproduct material requiring a written directive; *and*
 - (c) Passing an examination administered by the specialty board; *or*
2. Has completed 700 h of training and experience (Table 7.2) that includes
 - (a) A minimum of 200 h of classroom and laboratory training in basic radionuclide handling in the medical use of unsealed byproduct material requiring a written directive; *and*
 - (b) The remaining 500 hours of work experience under the supervision of an authorized user. The work experience, in addition to radioactive handling, management, and quality control, must include administration of a radioactive drug to a minimum of three patients or human research subjects in each of the following categories:
 - Oral administration of less than or equal to 33 mCi (1.22 GBq) of $^{131}\text{I-NaI}$ for which a written directive is required

- Oral administration of greater than 33 mCi (1.22 GBq) of $^{131}\text{I-NaI}$
 - Parenteral administration of any beta emitter, alpha emitter, or a photon-emitting radionuclide with photon energy less than 150 keV, for which a written directive is required; *and*
- (c) Obtains a written attestation from a preceptor authorized user or an eligible Residency Program Director that he/she has achieved sufficient competence in independently fulfilling the radiation-safety- related duties in handling RAM.

7.5.4 Training for Oral Administration of $^{131}\text{I-NaI}$ Requiring a Written Directive in Quantities Less than or Equal to 33 mCi (1.22 GBq) (per 10CFR35.392) and Greater than 33 mCi (1.22 GBq)(per 10CFR35.394)

Authorization in either category is granted to a physician by one of the following three pathways, provided the physician:

1. Is certified by a medical specialty board (Table 7.1) whose certification process has been recognized by the NRC or an Agreement State; *or*
2. Is already an authorized user on an NRC or Agreement State license fulfilling the requirements of this section; *or*
3. (a) Has successfully completed 80 h of classroom and laboratory training in medical use of $^{131}\text{I-NaI}$ for procedures requiring a written directive; *and*
(b) Has work experience (Table 7.2) under supervision of an authorized user in this category; *and*
(c) Specifically must have experience of administering dosages of less than 33 mCi (1.22 GBq) (10CFR35.392) or greater than 33 mCi (1.22 GBq) (10CFR35.394) to three patients or human research subjects in each category; *and*
(d) Must have a written attestation, signed by a preceptor authorized user or a Residency Program Director, stating that the applicant is sufficiently competent to function independently to carry out radiation safety-related duties in the intended medical use

7.5.5 Training for the Parenteral Administration of Unsealed Byproduct Material Requiring a Written Directive

Per 10CFR35.396, authorization in this category requiring a written directive is granted to a physician who

1. Is certified by medical specialty board (Table 7.1) that is recognized by the NRC or an Agreement State; *or*
2. Is an authorized user under NRC 10FR35.390 or an Agreement State requirements; *or*

3. (a) Has successfully completed 80 h of classroom and laboratory training (Table 7.2), applicable to parenteral administration of any beta emitter, alpha particle emitter, or any photon-emitting radionuclide with a photon energy less than 150 keV for which a written directive is required; *and*
 - (b) Additionally, has work experience under the supervision of an authorized user in this category of medical use of byproduct material; *and*
 - (c) Has a written attestation, signed by a preceptor authorized user in this category or a Residency Program Director, stating that the applicant is sufficiently competent to function independently in the parenteral administration of the byproduct material

7.5.6 Training for Use of Manual Brachytherapy Sources

Per 10CFR35.490, authorization in this category is given to a physician in one of two pathways, provided he or she:

1. Is certified by a medical specialty board (Table 7.1) recognized by the NRC or an Agreement State, based on the requirement of (a) 3 years of residency in radiation oncology program, which is approved by the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada, or the Committee on Post-Graduate training of the American Osteopathic Association and (b) passing a specialty board examination that tests knowledge and competence in radiation safety, radionuclide handling, treatment planning, quality assurance, and clinical use of manual brachytherapy; *or*
2. (a) Has completed a structured educational program of 200 h of classroom and laboratory training in basic handling of byproduct material applicable to manual brachytherapy; *and*
 - (b) 500 h of work experience under the supervision of an authorized user in this category; *and*
 - (c) Has completed 3 years of supervised clinical experience in radiation oncology, under an authorized user in this category, as part of a formally approved training program. Items 2(a) and 2(c) can be accomplished simultaneously; *and*
 - (d) Has a written attestation, signed by a receptor authorized user in this category, must be obtained stating that the applicant is sufficiently competent to function independently as an authorized user in manual brachytherapy.

7.5.7 Training for Use of Sealed Sources for Diagnosis

Per 10CFR35.590, authorization in this category is given to a physician, dentist, or podiatrist in one of the following three ways, provided the individual:

1. Is certified by a medical specialty board (Table 7.1) in this category recognized by the NRC or an Agreement State; *or*

2. Is authorized on an NRC or Agreement State license; *or*
3. Has completed 8 h of classroom and laboratory training in basic radionuclide handling techniques and a training specific to the use of the device.

7.6 Exemptions for Experienced RSO, AMP, AU, and ANP

Per 10CFR 35.57, the following exemptions are approved by the NRC for experienced RSO, AMP, AU, and ANP:

1. Individuals identified as an RSO, AMP, or ANP on an NRC or Agreement State license prior to January 14, 2019 are exempt from the training requirements of Sect. 7.2–7.4 for byproduct materials they used before. However, the RSOs and AMPs must meet training program for byproduct use for which they were not authorized prior to this date.
2. Individuals certified by ABHP, ABR, ABNM, ABSNM, BPSNP, ABMP, RCPS (Canada) and American Osteopathic Boards of Radiology (AOBR) and Nuclear Medicine (AOBNM) before October 24, 2005 are exempt from the training requirements of Sect. 7.2 for being an RSO or an ARSO for byproduct materials they used before.
3. Individuals certified by ABR in therapeutic radiology or ABMP in radiation oncology on or before October 24, 2005 are exempt from the training requirements of Sect. 7.3 to be an AMP for materials they used before.
4. Physicians, dentists, or podiatrists who were authorized users of RAMs under a NRC or Agreement State license prior to January 14, 2019 and seek to use only those byproduct materials they used before, need not comply with training requirements of Sect 7.5.1–7.5.6.
5. Physicians dentists or podiatrists not identified as AU on an NRC or Agreement State license, but certified by ABR, ABNM, AOBR, AOBNM, and RCPS (Canada) on or before October 24, 2005 for uses of byproduct material, are exempt from the training requirements of Sect. 7.5.1 for uptake, dilution, and excretion studies (10CFR35.100); Sect. 7.5.2 for imaging and localization studies (10CFR35.200); Sect. 7.5.3 for administration of unsealed byproduct requiring written directive(10CFR300), and Sect. 7.5.6 for manual brachytherapy therapy (10CFR35.400); and Sect. 7.5.7 for use of sealed sources for diagnosis(10CFR35.500). However, physicians certified by AOBR after1984 only are exempt from training for 10CFR 35.300.
6. Physicians who used only accelerator-produced RAMs before August 8, 2009 are exempt from training requirements of Sects. 7.5.1–7.5.4.
7. The above physicians can serve as preceptors and supervisors for the specified uses of byproduct materials for which they are authorized.

7.7 Recentness of Training

The training and experience specified in 10CFR35 must have been obtained within the 7 years preceding the date of application, or the individual must have had related continuing education and experience since the required training and experience were completed.

Questions

1. An individual was approved as an RSO on an Agreement State license until recently when he joined your institution for a similar position. Does he need to provide the fulfillment of requirement of training and work experience?
 Yes
 No
2. A physician intends to be an authorized user for RAM for imaging and localization studies in patients. If he is not certified by a specialty board (a) how many hours of classroom and laboratory training and (b) how many hours of work experience does he need to be an authorized user?
(a) _____
(b) _____
3. An authorized user is certified by the specialty board for RAM use for which a written directive is required. He now joins a new hospital and asks to be an authorized user. Does he need a written preceptor attestation?
 Yes
 No
4. A physician was identified as an RSO on an NRC or an Agreement State license prior to January 19, 2019, and now applies for the position of RSO in a new hospital. Does he need to comply with training requirements to be an RSO?
 Yes
 No
5. For physicians authorized by certification by ABNM and ABR on or before October 24, 2005 for RAM use under uptake, dilution, and excretion and imaging and localization categories do not need to comply with training requirement.
 Yes
 No
6. When is a preceptor's written attestation required for approval of an individual to be an authorized user or RSO?
7. The training and experience of an individual requesting authorization for the use of RAMs must be obtained within 7 years preceding the date of application.
True _____
False _____

References and Suggested Reading

NRC 10CFR35. Medical Use of Radioactive Material; 2019.

NRC medical uses licensee toolkit web page. Specialty Board(s) Certification recognized by NRC under 10 CFR Part 35; 2017.

8.1 Introduction

Radioactive spills and incidental contamination can happen during handling of radioactive material despite meticulous preventive measures adopted. Radioactive spills may be minor or major depending on variables such as the type and quantity of radionuclide, the number of individuals contaminated, spread of contamination, and types of surfaces contaminated as well as the radiotoxicity of the spilled material. A spill may be considered minor if it is contained properly without the spread of radioactivity around and with limited contamination of personnel, if any. On the other hand, a major spill entails extensive spread of radioactivity involving the facility, personnel, and equipment, even if the level of radioactivity is only reasonable and not so high. Table 8.1 presents the arbitrary limits differentiating between minor and major spills suggested by the NRC for common radionuclides used in nuclear medicine. Spills above the limit are considered major spills, and those below the limit minor spills. However, the licensee may choose different but appropriate limits. Spill kits containing essential items for radiation protection procedures should be available in all radiation facilities including nuclear medicine. The typical contents of a minor spill kit are given below and are illustrated in Fig. 8.1:

Table 8.1 Arbitrary limits delineating minor and major spills suggested by the NRC

Radionuclide	mCi (MBq)	Radionuclide	mCi (MBq)
Fluorine-18	10 (370)	Strontium-85	10 (370)
Phosphorus-32	10 (370)	Technetium-99 m	100 (3700)
Chromium-51	100 (3700)	Indium-111	10 (370)
Cobalt-57	10 (370)	Iodine 123	10 (370)
Iodine-125	1 (37)	Iodine-131	1 (370)
Gallium-67	100 (3700)	Thallium-201	100 (3700)
Samarium-153	10 (370)	Carbon-14	10 (370)

Fig. 8.1 Contents of a typical minor spill kit (Courtesy of Pinestar Technology)



- 5 pr Disposable gloves
- 1 pr Housekeeping gloves
- 3 ea Disposable isolation gowns
- 2 ea Disposable head covers
- 5 pr Disposable shoe covers
- 5 ea Roll of absorbent paper with plastic backing,
- 1 roll Masking tape
- 1 roll Yellow tapes with “Caution: Radioactive Material”
- 5 ea Plastic trash bags with twist ties
- 1 ea “Radioactive Material” labeling tape
- 1 ea Marking pen
- 5 ea Pre-strung “Radioactive Material” labeling tag
- 1 pkg Contamination wipes
- 1 ea Instructions for “Emergency Procedures,”
- 1 ea Clipboard with a radioactive spill report form
- 1ea 32 oz bottle bind-it decontaminant spray cleaner
- 1ea 32 oz bottle bind-it decontaminant hand soap
- These spill kits are commercially available without the battery and survey instrument or can be custom-arranged. Appropriate survey instruments, including batteries, should be in possession in case of a radioactive spill for measuring the level of decontamination.

8.2 Basic Procedures for Containment of a Spill

The cardinal principle of managing a radioactive spill is containment to prevent the spread of radioactivity. In the case of a radioactive spill, one needs to stay calm and the following steps should be followed:

1. Cordon off the area of spill so that contamination does not spread and restrict other people to enter the area.
2. Warn all around the area that a spill has occurred.
3. Notify the radiation safety officer for appropriate action, particularly if it is a major spill.
4. Don a coverall in case of a major spill; otherwise, a lab coat is good enough. In all cases, wear gloves and disposable booties and also wear safety eyeglasses, if needed.
5. If it is a liquid spill, spread absorbent paper over the area.
6. If it is a volatile spill, put on a mask to avoid inhalation.
7. If convenient and appropriate, use tongs to decontaminate and collect waste.
8. Use RADIACWASH to remove radioactive contaminants.
9. If personnel are contaminated, wash the contaminated area of the body with non-abrasive soap and cold water. Warm water facilitates the absorption of radioactivity through the skin.
10. After each decontamination step, monitor the area, equipment, and personnel with an appropriate counter (G-M counter, scintillation counter, liquid scintillation counter, wipe test, etc.), to determine if contamination is removed within the NRC limit.
11. If contamination is found to be non-removable by wipe test, it is advisable to cover the area with a lead sheet of appropriate thickness (depending on the radiation energy of the radionuclide in question) until the radioactivity decays to an acceptable level. Also signs alerting the presence of radioactivity must be posted.
12. Collect and segregate the contaminated waste in a plastic bag.
13. Tag the bag with information about the type of radioactivity, survey meter reading, the survey meter used, date of storage, and store for decay.
14. After decay, collect the personal items, if any, and dispose of the waste appropriately.
15. Make an incident report for record for review by the radiation safety officer. If it is a medical event, notify the NRC or the Agreement State.

8.3 Radiation Incidents and Accidents

Radiation accidents occur for a variety of reasons. These can happen by a road accident with a car or truck during transportation of radioactive material on a highway. Natural calamity, fire, or intentional malicious terror acts involving radiation sources can cause widespread radiation exposure. According to the International Nuclear and Radiological Event Scale (INES) (IAEA, 2008), radiation events are categorized on seven levels based on their magnitudes and damage they cause, with Levels 1–3 being termed “incidents” and Levels 4–7 “accidents”. The severity of the event increases tenfold with each level increase. The Chernobyl nuclear reactor explosion in Russia in 1986 is considered a Level 7 accident, because of high radiation exposure causing death over time. Similarly the breakdown in the nuclear reactor at Three Mile Island, USA in 1979 is considered as Level 5 accident.

Incidents involve less radiation damage to humans and properties compared to accidents. The breakdown of a sealed source used in radiation therapy causing exposure to operators is considered an incident. Readers should consult Reference (IAEA, 2008) for more details.

8.3.1 Management of Major Accidents

For radiation emergency situations, a response team should be established in every institution and facility, consisting of radiation experts, physicians, technologists, firefighters, police, etc. Facilities should have designated areas for decontamination furnished with all appropriate equipment. The Joint Commission requires each medical facility to establish protocols assigning responsibilities to each responder in appropriate order and organizing the triage in a major accident involving injuries and fatalities. Responders include a team of physicians, nurses, and radiation safety officers and his team. A team leader should be selected a priori to avoid confusion in managing the accident. In case the accident occurs in places outside hospital facilities, ambulatory individuals should be transported to the hospital using appropriate vehicles, whereas a temporary tent should be considered for holding the non-ambulatory patients for decontamination prior to moving them to the hospital facility. All liquid and solid waste from decontamination must be retained and stored for decay and final disposal.

- Saving life is more important than radioactive decontamination; hence in the case of life-threatening situations, *first aid administration and medical management of the exposed individual must be offered immediately*, followed by decontamination. Treatment depends on the severity of syndromes from radiation exposure such as nausea, vomiting, diarrhea, skin burn, etc. Attending physicians should decide on the appropriate treatment.
- Notify the authorities (e.g., police, environmental protection agency, etc.) immediately who should help and act appropriately.
- Responders should wear radiation monitoring badges.
- Always wear double gloves prior to survey and decontamination of radiation-exposed individuals, and change the outer glove as often as needed to minimize the spread of contamination and store it for decay or disposal.
- Collect all jewelry, personal items, wallets in plastic bags and let them decay, if contaminated, for giving back later to the owner.
- Survey the injured individuals with a G-M survey meter or an ion chamber.
- Decontamination of personnel starts with removal of contaminated clothing and placing them for decay in storage. This removes maximum contamination (~95%). Surveys are made after each decontamination.
- Wherever possible, a shower should be given to the affected individuals in a designated facility, e.g., fire house, school locker room, etc.
- Burns or wounds that are not contaminated should be covered with waterproof dressings.

- The contaminated skin and hair of the injured person should be washed thoroughly several times before transferring to the ambulance, each time monitoring the level of decontamination. If needed, hair may be cut.
- After permissible decontamination, the individuals should be provided with hospital gowns, scrubs, sheets, etc. prior to leaving the decontamination area.
- Often psychological advice and counseling to the affected individuals are appropriate.
- After the medical care and decontamination of the individuals, remove all waste from the triage area and check the area for residual decontamination. If there is any residual contamination found in the room and the work area, decontamination must be continued until the permissible level is achieved so that it can be used for future emergencies. If items in the room cannot be decontaminated, they may be disposed of appropriately.

If patients are internally contaminated, their treatment is radionuclide specific. For example, when internal contamination is due to ^{131}I , the FDA and the NRC recommend oral administration of potassium iodide (KI) to the exposed individuals to block the thyroid uptake of ^{131}I that may cause thyroid cancer. It should be administered within a few hours of exposure. The recommended daily dosage is 130 mg of KI for adults, 65 mg for 3-18 year old, 32 mg for children 1 month to 3 year old, and 16 mg for less than 1 month old infants (Mettler and Voelz, 2002).

Similarly, 500 mg Prussian blue tablet can be administered to adult patients, pregnant women and children (2–12 years old) to remove the internal contamination of ^{137}Cs by excretion through bowel movement.

If there is a death of an individual involved in the radiation accident, ideally the cadaver should be decontaminated to the permissible lowest level of radioactivity prior to transfer to a funeral home for burial or cremation. Autopsy is discouraged, but if it is absolutely necessary, precaution is needed to avoid undue radiation exposure. A survey should be made of the cadaver and an estimate of the radioactivity in it is reported to the funeral director. While cremation is not expressly recommended due to atmospheric contamination, burial is acceptable with proper precaution. All personnel handling cadaver should be provided personal protective equipment (PPE) and a personal dosimeter.

Annual or biannual emergency drills should be held to ensure the validity and emergency preparedness of the triage protocol in radiation emergencies. In these cases, simulated patients are used.

8.4 Radiological Dispersal Device

Radiological dispersal device (RDD), also called the Dirty Bomb, is normally used by the perpetrators for explosion to disrupt human life by creating fear and panic. RDD is a mix of explosives like dynamite with long-lived radioactive materials such as ^{60}Co , ^{137}Cs , ^{90}Sr and ^{192}Ir , ^{238}Pu , ^{241}Am , and ^{131}I , which are commonly used in hospitals, research facilities, and industries. If stolen or otherwise acquired, these radionuclides could be used to make RDD.

These radionuclides in liquid and powder form are used as potent ingredients in RDDs, which can result in widespread contamination following explosion. While nuclear bombs or weapons of mass destruction (WMD) cause havoc after explosion covering hundreds of square miles because of extremely high explosive power, RDDs spread the radioactivity over a much smaller area (may be a few blocks or buildings). Most RDDs would not release enough radiation to kill people or cause severe illness. Besides exploding them in residential areas, miscreants can hide them in a bus, train, and subway station, where passengers unknowingly can receive high exposure to radiation. The extent of dispersion depends on a number of factors, namely,

- Amount of radioactive material dispersed.
- How it is dispersed (explosion, fire, spraying).
- Physical and chemical form of the radioactive material.
- Weather condition (direction of wind). If the dispersion occurs in the form of fine particles, the particles will flow in the wind direction and spread further.

Exposure originates from the RDD source itself and the surrounding contaminated area. While external exposure comes from staying close to the source, internal exposure occurs due to inhalation, ingestion, and skin contamination from contaminated surrounding. Exposure and consequential damage depend on:

- The amount of radiation absorbed in 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

Subsequent decontamination of areas and exposed personnel after explosion require a considerable time and careful effort. Prompt detection of these devices is extremely essential to avoid unnecessary radiation exposure to the public, and meticulous security measures can prevent them.

8.4.1 Measures to Take Following Explosion of Radiological Dispersal Device

In case of an explosion of a RDD, one should take the following actions for self-protection, and the safety of loved ones and pets:

8.4.1.1 Get Inside

In a radiation emergency, you may be asked to get inside a building and take shelter for a period of time, preferably 24 h as the radioactivity decays with time. Walls, closed doors, and windows can block harmful radiations.

- This action calls for “Get to the middle of the building or a basement,” away from doors and windows.
- This action is called “sheltering in place.”
- Bring pets inside.

8.4.1.2 Stay Inside

Staying inside will reduce your exposure to radiation.

- Close and lock windows and doors.
- If there is a possibility of contamination, take off the first layer of your clothing and take a shower or wipe exposed parts of your body with a damp cloth. Store the removed clothing for decay or dispose properly.
- Drink bottled water and eat food from sealed containers.
- Wash the packages lest they are contaminated.

8.4.1.3 Stay Tuned

Emergency officials (police, firefighters, etc.) are trained to respond to disaster situations and will provide specific actions to help keep people safe.

- Get the latest information on radio, television, Internet, mobile devices, etc.
- Emergency officials will provide information on where to go to be screened for contamination.

8.4.1.4 Other Protection Steps

- Implement the basic principles of radiation protection, TDS (Time-Distance-Shielding): less time near the radiation source, distance away from the radiation source, and shielding of the radiation source.
- Cover the nose and the mouth of personnel nearby to avoid ingestion and inhalation of radioactive debris.
- If clothing and shoes are contaminated, remove them and wear new ones.
- A shower is advisable for removing any dust contamination.
- The windows and doors of the nearby residences should be shut immediately to prevent contamination by airborne radioactivity.
- Turn off air conditioner or heating system in the room to prevent circulation of radioactivity.
- Avoid the contaminated food and water, if any, and wait for the guidance from the local authorities as to when to start consumption.

8.4.2 Effects of RDD Dispersion

Common health effects arise from the dispersed materials, heat, and radioactive materials. Immediate health effects may be minimal because of the low level of radioactivity used in RDDs. The factors such as the type and amount of radiation absorbed by the body, means of external or internal absorption, and length of

exposure determine the extent of effects on health. If the exposure is very high, the absorbed dose is consequently expected to be high. Acute radiation syndromes such as diarrhea, vomiting, and decreased blood cell count are unlikely to occur with RDDs. However, there may be slight probability of the late effect of radiation exposure such as cancer long after the RDD exposure. It is to be noted that exposed individuals may suffer from psychological effects due to radiation exposure and should seek medical advice.

8.4.3 Measures to Prevent RDD

Prevention of theft and controlling access to restricted areas containing radioactive materials are the most important steps in controlling their use in RDDs. The licensees are required to secure and restrict the access to the areas where radioactive materials are stored. Loss of radioactive materials that may pose risk to the public must be reported promptly to the NRC or the Agreement State. However, it is estimated that the total stolen radioactive material not reported so far over the years is not enough to make one RDD. Different international, federal, and state agencies such as the NRC, Agreement States, the Department of Energy (DOE), and the Department of Homeland Security (DHS), the International Atomic Energy Agency (IAEA) along with the licensees have established a strong safety framework to prevent theft and unauthorized access to radioactive material. A joint NRC-DOE database has been created to track the location and movement of certain special nuclear materials. In 2009, the NRC established a National Source Tracking System for continuous tracking of high-risk sources in the USA.

Questions

1. What is the cardinal rule of handling radioactive spill?
2. A ^{99m}Tc -DTPA sample accidentally is spilled on the floor. Which of the following instruments would you need to monitor decontamination?
 - (a) a dose calibrator
 - (b) a G-M counter
 - (c) a film badge
 - (d) a calculator
3. If the spill is difficult to remove by common decontamination process, what is the next logical step to follow?
 - (a) place an absorbent paper to cover the area
 - (b) cover the area with a lead sheet of appropriate thickness until decay
 - (c) wash and wipe with paper
 - (d) notify RSO to clean it
4. A Radiological Dispersal Device or Dirty Bomb causes extensive damage to humans and properties equivalent to nuclear bomb: True _____ or False _____.

5. The common radionuclides used in Radiological Dispersal Device (RDD) are ^{131}I (A) and ^{137}Cs (B). What are the drug chemicals given to public exposed to these radiations from the explosion of an RDD?
 - (a) _____
 - (b) _____
6. An individual exposed to radiation exposure from a radiation accident has heart attack. What would you do first?
 - (a) decontamination
 - (b) cardiopulmonary resuscitation (CPR)
 - (c) wait for the medical team to arrive
7. A radioactive spill has occurred in a patient room involving the patient on the scanning table. The patient is contaminated on the head. What are the sequence of following measures would you take to manage the spill?
 - (a) remove the outer clothing of the patient and let him get out of bed
 - (b) survey the table and the patient with a G-M counter to locate the areas of contamination
 - (c) make an incident report
 - (d) decontaminate the table and the patient up to background level
8. What is “sheltering in place”?
9. A $^{99\text{m}}\text{Tc}$ spill has occurred in the hallway outside the nuclear medicine area. After the decontamination process, what should be the wipe test reading?
 - (a) 5 mrem/h
 - (b) 3 mrem/h
 - (c) 0.1 mrem/h
 - (d) 2 mrem/h
10. If a patient dies following contamination with radioactivity, what are the steps to take for the cadaver prior to burial or cremation?

References and Suggested Reading

- Federal Emergency Management Agency (FEMA). Protective action guides for Radiological Dispersal Device (RDD) and Improvised Nuclear Device (IND) Incidents. ID: FEMA-2004-0004-0088; 2008.
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Management and Release of Patients Administered with Radioactivity

9

Administration of radioactivity to patients for diagnosis or treatment of diseases raises concern for radiation exposure to family, caregivers, and the public. Strict radiation safety procedures should be established and followed to minimize such exposure. The following is a brief outline of the essential steps in the management of patients administered with radioactivity, while in the hospital.

9.1 Diagnostic Patients

Patients in nuclear medicine undergo diagnostic tests with administration of short-lived radionuclides to detect diseases in different parts of the body. The amount of radioactivity administered is small, and radiation exposure to nuclear medicine personnel and the public is minimal. So all diagnostic patients are discharged after the procedures without any specific instruction as to radiation exposure to the family members or the public. However, the following precautions should be adopted to minimize undue exposure from the patient.

1. During the procedure (scanning), the technologist or the nurse should not be too close to the patient and maintain an optimal distance from the patient to minimize the exposure.
2. For compromised or incontinent patients, care should be taken to avoid contamination of the patient's bed or stretcher. If contaminated, decontamination should be performed. Otherwise, these items should be removed from the room and let the radioactivity decay.
3. If the floor of the scanning room or injection room is contaminated, they must be decontaminated using general principles of decontamination described in Chap. 8, prior to admitting the next patient.

9.2 Therapeutic Patients

Management of therapeutic patients is quite different from diagnostic patients because of the higher level of exposure involved. Therapeutic treatment is given by either sealed sources (brachytherapy with ^{103}Pd , ^{125}I , or ^{192}Ir) or unsealed sources (^{131}I , ^{32}P , ^{153}Sm , ^{177}Lu) for specific diseases, which are briefly discussed below.

9.2.1 Therapy with Sealed Sources

The therapy sources are made in different shapes and sizes (rods, seeds, pellets, etc.) with varying quantities of radionuclides inside. Common radionuclides used for sealed sources for treatment and their characteristics are given below in Table 9.1.

The common use of these sealed sources is in brachytherapy for treatment of a variety of cancers, namely prostate, pancreatic, breast, etc. Treatment can be temporary or permanent. In temporary treatment, typically ^{137}Cs and ^{192}Ir sources of low radioactivity are inserted interstitially into the tumor area in the patient under fluoroscopic or ultrasonic guidance. This procedure is considered Low-Dose Rate (LDR) brachytherapy because of the low radioactivity used. The sources are kept in position for 20–50 h, depending on the dose to be delivered, and then removed. The patient is hospitalized overnight. Since the sources contain high energy γ radiation, no visitor and underage individuals (<18 years) are allowed to visit the patient for long and at less than 6 ft (183 cm) away. Appropriate portable lead shielding barriers should be placed beside the patient's bed to minimize the radiation exposure to caregivers or visitors. A signage placard displaying "Caution: Radioactive Material" should be posted on the door of the patient room. Nurses and technologists should be instructed in radiation safety procedures and be given radiation personal monitors.

In another temporary treatment, delivery devices (needle, catheter) containing sealed sources of high ^{192}Ir radioactivity are positioned and held for 10–20 min over the tumor target area and then removed. The procedure is repeated for several days depending on the dose to be delivered. After each procedure, the device is taken out of the room and stored in the designated storage area. This procedure is termed the High Dose Rate (HDR) brachytherapy. Since the procedure is short in time, any special radiation safety precaution is not necessary except for safe handling of the sealed sources.

Table 9.1 Characteristics of radionuclides used in sealed sources

Radionuclide	Half-life	Decay mode (%)	γ radiations emitted	
			(keV)	%
Palladium 103	17 days	EC (100)	20.1	65
Iodine-125	60 days	EC (100)	35	7
			x-rays (27–32)	140
Cesium-137	30 years	β^- (100)	662	85
Iridium-192	73.8 days	β^- (96)	296	30.0
			316	82.8
			468	47.8
			604	8.1
Yttrium-90	64.1 h	β^- (100)	–	–

Permanent implants of low-level radioactivity of ^{125}I and ^{103}Pd are made for the treatment of prostate cancer. Seeds of these radionuclides are permanently implanted into the tumor bed in the patient using fluoroscopic or ultrasound guidance. Because the energy of the radiation is very low, they penetrate the tumor tissues locally and kill them, while they hardly escape the patient body causing minimal radiation exposure beyond the tissue. However, a side effect of this category of treatment is that some normal tissues surrounding the prostate (urinary bladder and lower part of the bowel) are damaged by these implants causing incontinence and uncontrollable bowel movement.

^{90}Y -microspheres are administered through intrahepatic artery to treat hepatic tumors. Radiation exposure to the public from ^{90}Y is also insignificant due to β^- radiations. Accordingly, no special radiation safety precaution is necessary in the management of these low-dose-treated patients, except for safe handling of the seeds to avoid contamination.

9.2.2 Therapy with Unsealed Sources

Unsealed radionuclides in liquid form are administered orally or intravenously to treat cancers in patients. Common radionuclides in this category are ^{131}I -sodium iodide for hyperthyroid or thyroid cancer, ^{32}P -sodium phosphate for leukemia, ^{153}Sm -samarium ethylenediamine tetramethylene phosphonic acid (EDTMP) for bone pain palliation, ^{177}Lu -DOTATATE for treating neuroendocrine tumors, and ^{223}Ra -radium chloride for prostate cancer. The characteristics of these radionuclides are given in Table 9.2.

Patients are treated for cancer by intravenous administration of ^{32}P , ^{153}Sm , ^{177}Lu , and ^{223}Ra on an outpatient basis. Because of the particulate radiation, radiation exposure from the patient to the caregiver or the family members is insignificant. Also, in the case of treatment of hyperthyroid patients with ≤ 33 mCi (1.22 GBq) ^{131}I -NaI, radiation exposure from the patients is not deemed hazardous (see later). Therefore, these patients are allowed to leave the facility following treatment and only general radiation safety precautions are advised.

On the other hand, thyroid cancer patients are treated after thyroidectomy with oral administration of hundreds of millicuries (GBqs) of ^{131}I -NaI. Radiation exposure from these patients increases by many orders of magnitude necessitating an

Table 9.2 Characteristics of radionuclides used as unsealed sources

Radionuclide	Half-life	Decay mode (%)	γ radiations emitted	
			(keV)	(%)
^{131}I	8 days	β^- (100)	284	6
			364	81
			637	7
^{32}P	14 days	β^- (100)	–	–
^{153}Sm	1.9 days	β^- (100)	103	28
			70	5
^{177}Lu	6.65 days	β^- (100)	–	–
^{223}Ra	11.4 days	α (95.3)	–	–
		β^- (3.4)	–	–

effective measure of radiation protection and hospitalizing the patient until the activity decays below the limit permitted by the NRC or the Agreement State. The following steps need to be taken for these patients while in the hospital.

1. The patient is assigned a designated private room away from common traffic in the hospital.
2. Signs such as “Caution: Radioactive Material” and “No Unauthorized Entry” should be posted on the entrance door of the treatment room.
3. A separate toilet and a sink in the room are for patient’s use only.
4. Trash baskets must be lined with plastic liner.
5. The floor of the patient’s room, toilet seat, chairs, etc. must be covered with absorbent paper to remove accidental spillage of radioactivity.
6. Caregivers must wear gloves, lab coat, and booties to avoid contamination from handling the patient.
7. Since iodine is eliminated by urinary excretion to the extent of ~50% in 24 h, the urine is highly contaminated and so is discharged through the designated toilet by several flashings after each discharge.
8. The feces is minimally contaminated and flushed in the toilet.
9. The contaminated clothing, linen, bedding, etc. should be collected by well-instructed nursing personnel or the radiation safety personnel for proper decay and cleaning.
10. Disposable plastic plates and cups are used by the patients, which are then disposed of as contaminated items.
11. The type and quantity of radionuclide, date of administration, exposure at 1 m, and the name of the technologist must be entered in the patient’s chart.
12. Adult visitors are allowed no more than 30 min per 24 h at a distance of not less than ≤ 6 ft. (183 cm) from the patient.
13. Pregnant women and children younger than 18 years of age are not allowed in the room.
14. If the patient has life-threatening condition (e.g., heart attack), cardiopulmonary resuscitation (CPR) should be initiated without regard to radioactivity in the patient. The RSO and the physician should be contacted without delay.
15. If the patient dies, a report of the estimated activity in the patient, among other considerations, should be submitted to the funeral director.

A survey meter reading is obtained immediately following administration of radioactivity to establish the initial exposure at 1 m from the patient and then daily monitoring is performed to estimate the reduction in exposure by physical decay and biological elimination so that the patient can be released when the exposure is at a safe level permissible by the NRC (see later). All pertinent measurements (exposure and disposal) must be recorded and retained.

9.3 Release of Patients Treated with ¹³¹I-Nal and Other Radionuclides

The primary concern for the release of patients administered with radioactivity is the exposure to the public and the family members. The NRC has established limits (Table 9.3) of exposure from such patients for their release from the licensee's facility. According to 10CFR35.75(a), a licensee can release a patient administered with a radiopharmaceutical or a permanent radioactive implant, if the TEDE to other individuals from exposure to the patient is not likely to exceed 0.5 rem (5 mSv). Recordkeeping of the release of the patient is not required for these patients. If the administered activity exceeds the limit listed in the table, the patient can only be released when the activity has decayed to the limit level (Table 9.3), and then a record is required, because the discharge is based on residual activity rather than administered activity.

Further, the licensee is required to give the patient written instructions on radiation safety to manage himself to follow the ALARA principle so that the TEDE to other individuals is not likely to exceed 100 mrem (1 mSv) (10CFR35.75 (b)). In the case of a breast-feeding infant or child who is likely to receive the TEDE in excess of 100 mrem (1 mSv) from continuous breast-feeding from the mother administered with radioactivity, instructions for the duration of complete cessation or interruption and the consequences for non-compliance must be given. In addition, according to 10CFR35.75(c), records of the release of the patient and instructions given must be retained for 3 years.

9.3.1 Calculation of Administered Activity to Release a Patient

In nuclear medicine, patients administered with radiopharmaceuticals are released based on one of the two criteria: activity at the time of release or measured exposure rate at the time of release. The pertinent equation for exposure rate per hour, X , from

Table 9.3 Activities and dose rates for authorizing patient release^a

Radionuclides	Column 1		Column 2	
	Activity at or below which patients may be released		Dose rate at 1 m or below which patients may be released	
	(MBq)	(mCi)	(mSv/h)	(mrem/h)
⁶⁷ Ga	8.7	240	0.18	18
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
¹⁵³ Sm	26	700	0.3	30
^{99m} Tc	28	760	0.58	58
²⁰¹ Tl	16	430	0.19	19

^a The activity values were computed based on 0.5 rem (5 mSv) total effective dose equivalent

activity A_r of a radionuclide in the patient (considered a point source) at a distance d centimeter is

$$X = \frac{A_r \times \Gamma}{d^2} \quad (9.1)$$

where Γ is exposure rate constant in R-cm²/mCi-h at 1 cm. The cumulative exposure $D(t)$ from retained activity A_r in the patient at the time of release (not the initial administered activity in the patient) for a period of time t after release is

$$D(t) = \frac{A_r \times \Gamma}{d^2} \int_0^t e^{-0.693t/T_p} \quad (9.2)$$

where T_p is the physical half-life of the radionuclide in days. On integration, the cumulative exposure rate per day (24 h) is

$$D(t) = \frac{24 \times A_r \times \Gamma \times (1 - e^{-\lambda t})}{\lambda \times d^2} \quad (9.3)$$

where $D(t)$ is the cumulative exposure at d centimeter away from the patient over t days and λ is the decay constant of the radionuclide given by $0.693/T_p$, where T_p is given in days. Thus, inserting $0.693/T_p$ for λ in Eq. (9.3)

$$D(t) = \frac{34.6 \times A_r \times \Gamma \times T_p (1 - e^{-0.693xt/T_p})}{d^2} \quad (9.4)$$

The maximum possible activity at which patients can be released so that the exposure to other individuals (TEDE), i.e., $D(t)$ does not exceed 0.5 rem (5 mSv). In such situations, complete decay of the activity due to physical decay is assumed, i.e., the decay factor $(1 - e^{-0.693xt/T_p})$ is unity assuming no shielding by body tissues. Thus assuming only physical decay, the activity A_r that the patient can have at the time of release to give TEDE of 0.5 rem (5 mSv) to others can be calculated as

$$A_r = \frac{0.5 \times d^2}{34.6 \times \Gamma \times T_p} \quad (9.5)$$

Note that A_r is the activity in the patient at the time of release, which will give the exposure to the family members and the public after complete decay.

For radionuclides with a physical half-life greater than 1 day and no biological excretion, an *occupancy factor* (E) is introduced, which states that an individual exposed to such a released patient would receive a dose of 25% (0.25) of the dose to total decay at 1 m. The choice of an occupancy factor 0.25 in the above circumstances is supported by the regulatory analysis in NRC NUREG 1492 and the estimated dose seems to be conservative in most normal situations, discussed in detail later in Sect. 9.4.

For radionuclides with half-life shorter than or equal to 1 day, a long-term averaging of behavior is difficult to assume and so an occupancy factor of 0.25 cannot be justified; instead a value of 75% (0.75) or 100% (1.0) is assumed.

Using the above occupancy factors, Eq. (9.4) becomes

$$\text{For half-life} \leq 1 \text{ d, } D(t) = \frac{34.6 \times A_r \times \Gamma \times T_p \left(1 - e^{-\frac{0.693t}{T_p}}\right) \times 1}{d^2} \quad (9.6)$$

$$\text{For half-life} \geq 1 \text{ d, } D(t) = \frac{34.6 \times A_r \times \Gamma \times T_p \left(1 - e^{-\frac{0.693t}{T_p}}\right) \times 0.25}{d^2} \quad (9.7)$$

Similarly, Eq. (9.5) becomes

$$\text{For half-life} \leq 1 \text{ day, } A_r = \frac{0.5 \times d^2}{34.6 \times \Gamma \times T_p \times 1} \quad (9.8)$$

$$\text{For half-life} \geq 1 \text{ day, } A_r = \frac{0.5 \times d^2}{34.6 \times \Gamma \times T_p \times 0.25} \quad (9.9)$$

As an example, one can calculate the ^{131}I -NaI activity that a patient can have who can be released by the licensee, based on information such as $D(t) = 0.5$ rem at 1 m ($d = 100$ cm), $T_p = 8$ days, $\Gamma = 2.2$ R-cm²/mCi-h at 1 cm, and occupancy factor 0.25 and assuming only physical decay. Thus, using Eq. (9.9)

$$A_r = \frac{0.5 \times 10000}{34.6 \times 2.2 \times 8 \times 0.25}$$

$$\sim 33 \text{ mCi (1.221 GBq)}$$

This is the value given in column 1 of Table 9.3 for ^{131}I , and similarly, activities for other radionuclides are also calculated and included in the table. If the administered activity is greater than the listed value for release of a patient given in column 1 of Table 9.3, the patient can only be released when the activity decays to values in column 1. In this case a record must be made as to the basis for the release because it is based on the retained activity instead of on the administered activity (see Sect. 9.6 below).

9.3.2 Measured Dose Rates from a Patient Administered with Radioactivity to Release

The dose rates (D) at distance d (1 m or 100 cm) below which a patient administered with a radionuclide can be released is calculated using $D = (A_r \times \Gamma) / d^2$, where Γ is the exposure rate constant and A_r is the activity of the radionuclide in the patient at the time of release given in column 1 of Table 9.3, which would give the TEDE of 0.5 rem to an individual exposed to the released patient. For example, if a patient has 33 mCi (1.22 GBq) ^{131}I at the time of release, the dose rate at 1 m comes to ~ 7.3 mrem/h. (which is given in column 2 of Table 9.3). So a licensee can release a patient

administered with $^{131}\text{I-NaI}$ if the measured dose rate at 1 m from the patient's body surface is no greater than 7 mrem/h. (7 mSv/h). This dose rate would be reduced to 0.5 mrem/h. (5 mSv) (NRC limit of patient release) after complete decay of the activity in the patient. Similar dose rates for other radionuclides are listed in column 2 of Table 9.3. The licensee cannot release a patient with a higher dose rate until the dose rate from the patient's body surface falls below the value given in Table 9.3.

Note that several assumptions made for patient release using Eqs. (9.6) and (9.7) are quite conservative. Use of a point source and the inverse square law neglects the attenuation of radiation in the body. Use of a non-void period of less than 8 h is difficult to justify for hydrated patients. Also, patient-specific conditions can be invoked to justify an early release of patients from the licensee's control.

9.4 Release of Patients Treated with $^{131}\text{I-NaI}$ Based on Patient-Specific Factors

This section discusses the issues of ^{131}I treatment because of its predominant use in thyroid therapy in nuclear medicine and potential radiation hazard to the public. However, regulations in 10CFR35.75 apply equally to other medical radionuclide therapies such as ^{90}Y , ^{125}I , ^{177}Lu , and ^{223}Ra , and dose calculations for patient release after radionuclide treatment with these radionuclides can be made accordingly.

Equation (9.4) is valid only for physical decay of the radionuclide. If there is biological elimination of the tracer as well, then the effective half-life, $T_e = (T_p \times T_b) / (T_p + T_b)$, must be used, where T_p is the physical half-life and T_b is the biological elimination half-life. Also if the tracer is localized in different organs, the fractional accumulation in these organs must be taken into account. Taking these factors into account, Eq. (9.4) can be expressed as

$$D(t) = \frac{34.6 \times f \times A_r \times \Gamma \times T_e (1 - e^{-0.693t/T_e})}{d^2} \quad (9.6)$$

where f is the fraction of activity in an organ. The total dose rate is calculated by summing the dose rates of individual organs.

However, the above exponential decay equation does not take into account of several biological processes (e.g., absorption of ^{131}I from bowel into the blood, accumulation of ^{131}I in the bladder), which could underestimate the calculated dose from the patient to other individuals. Based on regulatory analysis in the NRC Regulatory Guide 8.39, a conservative assumption is made that during the first 8 h after administration, 80% of the ^{131}I activity is excreted with a physical half-life of 8 days. Thus, three components of ^{131}I decay after administration for thyroid cancer treatment contribute to the dose, namely the first component (80%) comes from 8 h (0.33 day) of physical decay. The second component of the dose comes from 8 h to total decay of the extrathyroidal activity. The third component is the dose from the thyroidal activity for 8 h to total decay.

As mentioned above, based on regulatory analysis in NRC Regulatory Guide 8.39, an *occupancy factor* (E) has been introduced in the equation, which is related to the effective half-life or physical half-life and whether instructions are given to

the released patient to follow at home after release. Patient-specific occupancy factors are selected as follows:

1. For radionuclides with physical half-life shorter than 1 day, the occupancy factor E is chosen to be 0.75 or 1.0 at 1 m. The rationale for this value of E is that for a given period of exposure, the short-lived radionuclides always result in higher exposure dose than long-lived ones. So individuals (family members, etc.) are likely to spend in close proximity to the patient at home immediately after his or her release and receive a large fraction of the total dose from the short-lived radionuclide.
2. For radionuclides with effective half-life greater than 1 day, the occupancy factor E of 0.25 at 1 m is assumed. The assumption is based on the condition that the patient will not be in close proximity to other individuals for several days and the patient is given the following verbal as well as written instructions:
 - (a) Maintain a prudent distance from others for at least the first 2 days.
 - (b) Sleep alone in a room for at least the first night.
 - (c) Do not travel by airplane or public transportation for at least the first day.
 - (d) Do not travel on a prolonged automobile trip with others for at least the first 2 days.
 - (e) Have sole use of a bathroom for at least the first 2 days.
 - (f) Drink plenty of fluids for at least the first 2 days.
3. For radionuclides with effective half-life greater than 1 day, the occupancy factor E is assumed to be 0.125 at 1 m, provided the following instructions are given to the patient:
 - (a) Follow the instructions for $E = 0.25$ above.
 - (b) Live alone for at least the first 2 days.
 - (c) Have few visits by the family or friends for at least the first 2 days.

So for the calculation of the dose from the patient, the occupancy factors of 0.75, or 1.0 at 1 m for effective half-life less than 1 day and 0.25 at 1 m for effective half-life greater than 1 day are chosen and included in Eq. (9.4) as follows:

$$D(t) = \frac{34.6 \times A \times \Gamma \times T_e (1 - e^{-0.693t/T_e})}{d^2} \times 0.75 \text{ or } 1.0 \text{ for } T_e \text{ less than 1 day} \quad (9.7)$$

$$D(t) = \frac{34.6 \times A \times \Gamma \times T_e (1 - e^{-0.693t/T_e})}{d^2} \times 0.25 \text{ for } T_e \text{ greater than 1 day} \quad (9.8)$$

Let us take an example of a thyroid cancer patient who is treated with $^{131}\text{I-NaI}$ after thyroidectomy.

Problem 9.1

Determine if a patient can be released from the licensee's confinement if the patient receives 300 mCi (11.1 GBq) of $^{131}\text{I-NaI}$ for thyroid cancer treatment after total thyroidectomy. Given data are: $T_{e\text{extrathyroid}} = 0.32$ day, $T_{e\text{thyroid}} = 7.3$ days (NRC Reg Guide 8.39); uptake fraction (extrathyroid), $f_1 = 98\%$ and uptake fraction (thyroid), $f_2 = 2\%$.

Answer

In solving this problem, as Regulatory Guide 8.39 suggests that three components of ^{131}I decay after administration for thyroid cancer treatment contribute to the dose. The first component comprises 80% of the dose from 8 h (0.33 day) of physical decay. The second component of the dose comes from 8 h to total decay of the extrathyroidal activity. The third component is the dose from the thyroidal component for 8 h to total decay. Data given in Regulatory Guide 8.39 are:

Extrathyroidal fraction $f_1 = 0.98$.

Thyroidal fraction, $f_2 = 0.02$.

T_e for thyroid = 7.3 days.

T_e for extrathyroidal = 0.32 days.

$\Gamma = 2.2 \text{ R-cm}^2/\text{mCi-h}$ at 1 cm.

$$D(\infty) = \frac{34.6 \times 2.2 \times 300}{10000} \left\{ 0.75 \times 8 \times 0.8 \left(1 - e^{\frac{-0.693 \times 0.33}{8}} \right) + e^{\frac{-0.693 \times 0.33}{8}} \times 0.25 \times 0.98 \times 0.32 + e^{\frac{-0.693 \times 0.33}{8}} \times 0.25 \times 0.02 \times 7.3 \right\}.$$

$$D(\infty) = 0.519 \text{ rem (5.19 mSv)}.$$

Since the dose is more than 0.5 rem at 1 m, the licensee may not release the patient, and one can calculate the additional holding time prior to release.

Assuming only physical decay

$$0.5 / 0.519 = e^{\frac{-0.693 \times t}{8}}$$

$$0.03723 = 0.08662 \times t$$

$$t = 0.43 \text{ day} = 10.3 \text{ hrs}$$

The patient can be released from the licensee's control after about 10 h.

9.5 Written Instructions to the Patient to Follow after Release

As already mentioned, written instructions must be given to the released patient if the dose to others is likely to exceed 100 mrem (1 mSv). To achieve this goal, the patient is recommended to adopt ALARA principles at home and around, so that the dose to

others from exposure does not exceed 100 mrem (1 mSv). This is accomplished if the patient follows a set of instructions given to him/her, which vary with the circumstances of the patient at home. The common elements of instructions are:

1. Sleep alone or, better yet, live alone.
2. Use disposable gloves, flushable wipes, and frequent hand washing.
3. Use disposable paper plates and bowls.
4. Maintain a distance of minimum 3 ft. from others.
5. Do not travel by airplane or mass transportation.
6. Do not travel in cars with others.
7. Drink plenty of water.
8. Have the sole use of a bathroom.
9. Do wash the clothing separately from others.
10. Collect all contaminated items in plastic bags for decay.
11. Limit visits by others.
12. If woman, postpone pregnancy for at least 6 months after treatment.
13. Have a contact number from the care provider to contact in emergency.

The activity and dose rate limits of different radionuclides for which instructions to patients are required are listed in Table 9.4. One can use the activity values in column 1 of the table, above which the licensee needs to give instruction to the released patient. Column 2 of the table gives the corresponding dose rates, above which the licensee is required to give the patient written instructions. If the patient is mentally or physically too compromised to follow the instructions, he/she may be held in the hospital until the time when instructions are no longer required. A female patient of child-bearing age who may not know the status of her pregnancy in the early stage at the time of treatment is often given a pregnancy test. If the test is positive, the physician has the discretion to treat or postpone the treatment.

Additional instructions are required to be given to breast-feeding patients who are administered with radiopharmaceuticals and released, if the dose to the breast-fed infant or child is likely to exceed 100 mrem (1 mSv) on the assumption of

Table 9.4 Activities and dose rates above which instructions should be given to patients prior to release^a

Radionuclide	Activity above which Instructions are required		Dose rate at 1 m above which Instructions are required	
	GBq	mCi	mSv/h	mrem/h
¹²³ I	1.2	33	0.05	5
⁶⁷ Ga	1.7	47	0.04	4
¹³¹ I	0.24	7	0.02	2
¹¹¹ In	0.47	13	0.04	4
^{99m} Tc	5.6	150	0.12	12
²⁰¹ Tl	3.1	85	0.04	4

^aNRC NUREG 1556, vol. 9, Rev. 3; 2019

continuous breastfeeding. The instructions include discontinuation of breast-feeding for a period of time for the current infant or child depending on the radionuclide administered and a warning on the consequences of failure to follow the guidance that may result in permanent damage to the thyroid gland of the nursing infant or child. However, she can breastfeed future children assuming she is not having radionuclide treatment at the time. Records of instructions and guidance must be retained for 3 years. The activity limits of different radionuclides above which instructions

Table 9.5 Activities of radiopharmaceuticals that require instructions and records when administered to patients who are breast-feeding an infant or a child

Radiopharmaceutical	Column 1		Column 2		Column 3
	Activity above which instructions are required		Activity above which a record is required		Recommended duration of interruption of breast-feeding
	(MBq)	(mCi)	(MBq)	(mCi)	
¹³¹ I- NaI	0.01	0.0004	0.07	0.002	Complete cessation (for this infant or child)
¹²³ I- NaI	20	0.5	100	3	3 d
¹²³ I MIBG	70	2	400	10	24 h for 370 MBq (10 mCi)
^{99m} Tc DTPA	1000	30	6000	150	24 h
^{99m} Tc MAA	50	1.3	200	6	24 h
^{99m} TcO ₄ ⁻ 100	3		600	15	24 h
^{99m} Tc DISIDA	1000	30	6000	150	24 h
^{99m} Tc MDP	1000	30	6000	150	24 h
^{99m} Tc-MIBI	1000	30	6000	150	24 h
^{99m} Tc red blood cell in vivo labeling	400	10	2000	50	24 h
^{99m} Tc sulfur colloid	300	7	1000	30	24 h
^{99m} Tc DTPA aerosol	1000	30	6000	150	24 h
^{99m} Tc MAG3 0	1000	30	6000	150	24 h
^{99m} Tc white blood cells	100	4	600	15	24 h
⁶⁷ Ga citrate	1	0.04	7	0.2	28 d
¹⁸ F-FDG	–	–	–	–	4 h
¹¹¹ In octreotide	–	–	–	–	6 d
¹¹¹ In white blood cells	10	0.2	40	1	6 d
²⁰¹ Tl chloride	40	1	200	5	4 d
¹⁷⁷ Lu-Octreotate (diagnostic or therapeutic)	–	–	–	–	Complete cessation (for this infant or child)
²²³ Ra and all alpha emitters	–	–	–	–	Complete cessation (for this infant or child)

The duration of interruption of breast-feeding is selected to reduce the maximum dose to a newborn infant to less than 1 millisievert (0.1 rem). Of course, the physician may use discretion in the recommendation, increasing or decreasing the duration of interruption. Details of the calculations are shown in NUREG-1492, "Regulatory Analysis on Criteria for the Release of Patients Administered Radioactive Material"

to breast-feeding patients are required, and activity limits for cessation of breast-feeding and duration of cessation are given in Table 9.5.

9.6 Internal Dose

It is obvious that individuals around the released patient may receive internal dose due to ingestion through the mouth or skin. A few studies have shown that the radioactivity intakes by individuals exposed to patients administered with ^{131}I were generally of the order of 1 millionth of the dosage administered to the patient. Internal doses calculated from these intakes were shown to be much lower than the external exposure dose. So the NRC Reg guide 8.39 suggests that internal doses may be ignored in the calculations if they are likely to be less than 10 percent of the external dose, because the internal dose would be significantly less than the uncertainty in the external dose.

9.7 Record Keeping

When patients administered with the amount of radioactivity listed in Table 9.3 are released, no record is required to be kept, because no patient-specific factor is considered in the dose calculation. However, if patient-specific factors such as effective half-life that includes biological elimination, residual activity in the body, shielding by body tissues, occupancy factors, etc. are used in the calculation of activity at or below which a patient administered with radionuclide is released, then a record is required. The content of the record varies with the situation; however, the basic contents include the patient identifier (not traceable to the patient by name for privacy concern), radioactive material administered, the administered dosage, and the date of administration. If the patient is released based on the calculation of decayed activity in the patient, the results of the decay calculation, the time of administration, the date and time of release must be recorded. If the patient is released immediately or later following treatment based on dose rate measurement, a record is made of the result of measurement, the type of survey instrument used, date, and the individual performing the measurement.

In addition, records must be made if instructions are given to breast-feeding patients. If a patient's failure to interrupt or discontinue breast-feeding could result in a dose to the infant or child in excess of 5 mSv (0.5 rem) or permanent damage to the child, 10CFR35.2075 (b) requires a record that the licensee gave instructions to the patient. In this case, the licensee is required to report the dose to the NRC National Operation Center within 24 h after the discovery followed by a written report submitted to the NRC Regional Office within 15 days. Furthermore, the licensee is required to inform within 24 h the patient and her referring physician about the event except when the physician may decide not to tell the patient for reasons of any harm or he himself wants to tell. A relative or a guardian in the

absence of the mother may be notified. A written report may be given, if requested by the mother or guardian.

Table 9.5 lists activities of radiopharmaceuticals that require instructions and record keeping, when administered to patients who are breast-feeding an infant or a child. The contents of the record include patient's identifier (not traceable), the radiopharmaceutical administered, the administered dosage, the date of administration, and whether instructions were provided to the patient who could be breast-feeding an infant or child.

Questions

1. A patient has been injected with 20 mCi (740 MBq) ^{99m}Tc – MDP for bone scanning. Can he be discharged soon after scanning? Yes _____, No _____.
2. The exposure dose limit for releasing a patient administered with a byproduct material without instructions is
 - (a) 0.1 mrem (1 μSv)
 - (b) 0.5 rem (5 mSv)
 - (c) 15 rem (0.15 Sv)
 - (d) 5 rem (50 mSv)
3. The maximum activity of ^{131}I -NaI that can be administered to a hyperthyroid patient who can be released without instructions is
 - (a) 12 mCi (444 MBq)
 - (b) 55 mCi (2.035 GBq)
 - (c) 30 mCi (1.11GBq)
 - (d) 33 mCi (1.221 GBq)
4. Written instructions are required to be given to a released patient following administration of radioactivity when
 - (a) exposure to the radiation workers from the patient is 0.5 rem (5 mSv)
 - (b) exposure to an individual from the patient exceeds 0.1 rem (1 mSv)
 - (c) G-M survey meter reading at 1 m from the patient is 10 mR/h
 - (d) the patient does not understand verbal instruction
5. A patient is administered with 200 mCi (7.4 GBq) of ^{131}I -NaI for thyroid cancer treatment. Calculate how long the patient will be held prior to release assuming a biological elimination half-life of 1 day when the patient can be released. (Hint: Look for the release activity in Table 9.1).
6. A female patient who is nursing a child is given 55 mCi (2.035 GBq) ^{131}I -NaI for hyperthyroid treatment. She should discontinue breast-feeding:
 - (a) until her exposure rate is less than 7 mR/h. at 1 m
 - (b) until the activity is less than 33 mCi (1.221 GBq) in the body
 - (c) completely for that child, but may nurse a future child, provided no radiation treatment is given at the time
 - (d) completely for that child and all future children
7. Should written instructions be given to the patient in Question 6? Yes _____, No _____.

8. Elucidate the common elements of instructions for releasing a patient administered with a radionuclide for treatment.
9. If a patient dies following ^{131}I treatment, what are the basic steps required to be taken prior to burial or cremation?
10. What is the radiation dose to an unborn child that requires reporting to the NRC?
 - (a) 0.1 rem (1 mSv)
 - (b) 0.15 rem (1.5 mSv)
 - (c) 0.5 rem (5 mSv)
 - (d) 5.0 rem (50 mSv)
11. A radionuclide with a physical half-life of 10 days is administered to a patient for treatment. Its exposure rate constant is $3.1 \text{ R}\cdot\text{cm}^2/\text{mCi}\cdot\text{h}$ at 1 cm. What is the maximum activity of the radionuclide that can be administered for immediate release from the licensee's confinement? (Occupancy factor = 0.25).

References and Suggested Reading

- NRC 10CFR35.75. Release of individuals containing unsealed byproduct material or implants containing byproduct material; 2019.
- NRC, NUREG-1492, Regulatory Analysis on Criteria for the Release of Patients Administered Radioactive Material; 1997.
- NRC NUREG1556. Consolidated Guidance about Materials Licenses: Program—Specific Guidance about Medical Use Licenses, vol. 9, Rev 3; 2019.
- Regulatory Guide 8.39, Rev 1. Release of patients administered radioactive materials; 2020.



10.1 Introduction

Several federal agencies such as the US Department of Transportation (DOT), the US Environmental Agency (EPA), the US Postal Service (USPS), and the NRC regulate the shipment and transfer of hazardous materials including radioactive materials among different sites and facilities, based on their respective primary functions. However, in nuclear medicine, the DOT and the NRC are the major regulators for implementing rules and regulations for packaging and shipment of radioactive materials via ground, air or waterways. The DOT regulations are given in 49CFR173, and the NRC regulations are described in 10CFR71, which provide specific guidelines on types of packaging, limits of radioactivity in a package, and exposure limit from the package. The DOT and NRC regulations and guidelines are similar and both are referred to as appropriate in the following discussion.

10.2 Definition

The DOT has adopted several classifications regarding the transportation of radioactive materials. Only a few are relevant in nuclear medicine and these are given below.

Class 7 (radioactive) material: any material containing radionuclides whose activity concentration and total activity in a consignment exceed the exempt values given in 49CFR173.436.

Special Form Class 7 (radioactive) material: An indispersible solid radioactive material or a sealed capsule containing radioactive material that has a dimension not less than 0.2 in (5 mm) and meets all test requirements of packaging.

Normal Form Class 7 (radioactive) material: Class 7 (radioactive material) that does not qualify as Special Form Class 7 (radioactive) material.

10.3 Packaging

Packaging is an important part of transportation of radiopharmaceuticals via ground, air or waterways. In nuclear medicine, two categories of packaging are relevant: Type A and Type B.

Type A: Type A packages are allowed to contain Type A quantity of Class 7 (radioactive) materials up to a limit of A_1 for Special Form Class 7 (radioactive) material or of A_2 for Normal Form Class 7 (radioactive) material listed in DOT 49CFR173.435 and in Appendix A to NRC 10CFR71. For radionuclides not listed in 49CFR173.435, A_1 and A_2 values are calculated by formulas given in DOT 49CFR173.433 and 10CFR71. Some pertinent values of A_1 and A_2 applicable to nuclear medicine are listed in Table 10.1. Type A packaging is most commonly used in nuclear medicine.

Type B: Type B packages are used for activity exceeding the limit of activity for Type A packages and are required to be more sturdy. There would be no loss or dispersal of radioactive contents and no significant increase in external surface radiation levels. There should be no external radiation dose rate exceeding 1 rem/h (10 mSv/h) at 40 inches (1 m) from the external surface of the package. In addition, a Type B package containing more than $10^5 A_2$ must be designed so that its undamaged containment system can withstand an external water pressure of 2 MPa (290 psi) for a period of not less than 1 h without collapse, buckling, or leakage of water.

Table 10.1 A_1 and A_2 values for selected radionuclides in nuclear medicine for Type A and Type B packages from DOT 49CFR173.435

Radionuclide	A_1 (TBq)	A_1^a	A_2 (TBq)	A_2^a
^{14}C	4.0×10^1	1.1×10^3	3	8.1×10^1
^{67}Cu	1.0×10^1	2.7×10^2	7.0×10^{-1}	1.9×10^1
^{18}F	1	2.7×10^1	6.0×10^{-1}	1.6×10^1
^{67}Ga	7	1.9×10^2	3	8.1×10^1
^{68}Ga	5.0×10^{-1}	1.4×10^1	5.0×10^{-1}	1.4×10^1
^{153}Gd	1.0×10^1	2.7×10^2	9	2.4×10^2
^{68}Ge	5.0×10^{-1}	1.4×10^1	5.0×10^{-1}	1.4×10^1
^{123}I	6	1.6×10^2	3	8.1×10^1
^{125}I	2.0×10^1	5.4×10^2	3	8.1×10^1
^{131}I	3	8.1×10^1	7.0×10^{-1}	1.9×10^1
^{111}In	3	8.1×10^1	3	8.1×10^1
^{177}Lu	3.0×10^1	8.1×10^2	7.0×10^{-1}	1.9×10^1
^{99}Mo	1	2.7×10^1	6.0×10^{-1}	1.6×10^1
^{32}P	5.0×10^{-1}	1.4×10^1	5.0×10^{-1}	1.4×10^1
^{223}Ra	2.0×10^{-1}	5.4	3.0×10^{-3}	8.1×10^{-2}
^{82}Sr	2.0×10^{-1}	5.4	2.0×10^{-1}	5.4
^{99m}Tc	1.0×10^1	2.7×10^2	4	1.1×10^2
^{201}Tl	1.0×10^1	2.7×10^2	4	1.1×10^2

^a The values of A_1 and A_2 in curies (Ci) are approximate and for information only; the regulatory standard units are Terabecquerels (TBq)

The general design requirements for these packages for radiopharmaceutical transportation are given in detail in 49CFR173.410 and NRC 10CFR71. Here only a brief summary and salient points are elucidated.

- The smallest external dimension of the package must not be less than 4 inches (10 cm).
- The package must be well-secured in the transport vehicle, easily liftable without any possibility of damaging the package, and is capable of withstanding vibration during transport.
- It should have a smooth surface for easy decontamination and to prevent any water accumulation.
- For air transportation, the surface temperature will not exceed 50 °C (122 °F) at an ambient temperature of 38 °C (100 °F), and the containment will withstand a temperature of -40 °C (-40 °F) to 55 °C (131 °F).
- The package containing liquid must withstand an internal pressure of 95 kPa (13.8 psi). Packages must have a sturdy seal, which is not breakable unintentionally.
- The radiation level must not exceed 200 mrem/h (2 mSv/h) at any point on the external surface of the package, and the transport index must not exceed 10 (see later).
- The removable contamination on the external surface of the package must not exceed 240 dpm/cm² for β , γ emitters and low-energy α emitters, and 24 dpm/cm² for other α emitters.

Packages exceeding the radiation level of 200 mrem/h. (2 mSv/h) are allowed a higher level of 1000 mrem/h (10 mSv/h), provided the packages are well-secured and transported in a closed vehicle without any interruption of loading or unloading between the beginning and end of the transportation. For such shipments, the shipper shall provide specific written instructions to the carrier for exclusive use control of the shipment, along with shipping paper, to avoid any delivery delay and unnecessary radiation exposure to transport workers or the public.

According to 49CFR173.412, for Type A packages of liquid, either absorbent material is placed inside to absorb the liquid in the event of leakage, or the containment system is composed of a primary inner component to store the liquid and a secondary outer component to ensure containment of liquid in the event of leakage. Type A packages for gas will be able to prevent loss or dispersal of contents when subjected to free drop test and penetration test defined below.

10.3.1 Stability Tests for Packages

All packages for transportation of Class 7 radioactive materials must undergo stringent tests for their sturdiness and integrity for specific purposes. There are several tests (10CFR71), and only pertinent ones are described here.

Water spray test: A package must endure a water spray test simulating exposure to rainfall of 5 cm/h. (2 in/h) for 1 h.

Free drop test: For nuclear medicine shipments, the package weighing less than 11,000 lbs. (5000 kg) must endure a free drop from a vertical distance of 4 ft. (1.2 m). For Type A packages for liquid and gas transportation, a height of 30 ft. (9 m) is used (49CFR173.466). This test is performed 1.5 to 2.5 h after the water spray test.

Corner drop test: This test involves the free drop onto each corner of the package from a height of 1 ft (0.3 m) and applies to rectangular fiberboard and wood packages weighing no more than 110 lbs. (50 kg) and to cylindrical packages weighing no more than 220 lbs. (100 kg).

Compression test: For packages weighing up to 11,000 lbs. (5000 kg), a compressive load greater of 5 times the weight of package or the equivalent of 13 kilopascals (1.9 psi) multiplied by the vertically projected area of package is applied to the top and bottom of the package, which should not cause any damage to the package.

Penetration test: Impact of the hemispherical end of a vertical steel cylinder of 1.25 in (3.2 cm) diameter weighing 13 lbs. (6 kg), dropped from a height of 40 in (1 m) onto the exposed surface of the package should not cause any damage to the package. For Type A packages for liquid and gas, the drop is made from a height of 5.5 ft. (1.7 m) (49CFR173.466).

10.3.2 Labeling of Packages

Radioactive packages must be labeled properly prior to transportation. Whereas a variety of labeling requirements are mandated in 49CFR172 for different materials, for nuclear medicine, however, there are three types of labels used for transportation of radioactive material based on *transport index* (TI), which is defined as the exposure reading in mrem/h. (mSv/h) at 1 m from the surface of the package. In addition, the surface reading of any package must not exceed 200 mrem/h. (2 mSv/h). The three categories of labels used in nuclear medicine are White-I, Yellow II, and Yellow III, which are illustrated in Fig. 10.1 and the criteria for their use are given in Table 10.2. The labels are diamond-shaped with upper half containing a three-blade fan-type symbol and the lower half containing the term “Radioactive” and other information such as the type of radionuclide, quantity of radioactivity in curies or becquerels, and transport index.

One of these labels with pertinent information about the radionuclide of interest must be affixed on the opposite sides of the package for transportation. The maximum TI value allowed for any package is 10, whereas it is limited to three for passenger-carrying aircraft. For liquids, a label or a sign “THIS SIDE UP” is placed on the outside of the package corresponding to the vertical orientation of the liquid container inside the package. If the package contains biohazard radioactive material, then a biohazard symbol also must be attached on both sides (49CFR172.323).



Fig 10.1 Three types of US Department of Transportation labels required for transportation of radioactive material. (Reprinted by permission from Springer Nature, *Physics and Radiobiology of Nuclear Medicine* by Saha GB, 2013)

Table 10.2 Labeling categories for packages containing radioactive materials

Exposure (mrem/h)		
Type of label	At surface	At 1 m
White I	< 0.5	–
Yellow II	> 0.5 ≤ 50	< 1
Yellow III	> 50 ≤ 200	> 1 ≤ 10

No package shall exceed 200 mrem (2 mSv)/h at the surface of the package or 10 mrem/h at 1 m. Transport index(TI) is the reading in mrem (mSv)/h. at 1 m from the package surface (10CFR71)

A shipping certificate bearing the identity, amount, and chemical form of the radioactive material and TI must be placed inside the package. It must be attested and signed by the shipper indicating that it contains radioactive material for research, or medical diagnosis or treatment.

Placards are required on transport vehicles carrying yellow III-labeled packages and must be displayed on four sides of the vehicle (49CFR172.504 and 49CFR172.556).

10.4 Exemption for Limited Quantity of Radioactive Material

According to 49CFR173.421, radioactive shipments are exempted from packaging, labeling, and marking requirements, provided the following conditions are met.

1. The radioactivity in the package does not exceed the limit of $10^{-4}A_2$ for liquid, $10^{-3}A_1$ for special form of solid and gas, and $10^{-3}A_2$ for normal form of solid and gas, where A_1 and A_2 are given in 49CFR173.435. The limited quantities of certain common radionuclides used in nuclear medicine have been obtained from 49CFR173.425 and are given in Table 10.3.
2. The radiation level on the surface of the package does not exceed 0.5 mrem/h. (5 μ Sv/h).

3. The contamination on the external surface of the package does not exceed 240 dpm/cm².
4. The outside of the inner packaging or, if there is no inner packaging, the outside of the packaging itself bears the marking "RADIOACTIVE -Limited Quantity."
5. A notice must include the names of the shipper and the consignee and contain the statement "This package conforms to the conditions and limitations specified in 49CFR173.421 for radioactive material, excepted package – limited quantity of material, UN2910."
6. A UN identification number, displayed as UN XXXX, where Xs are four assigned digits, is marked on the outside of the package. Several UN numbers for different types of radioactive materials are given in Table 10.4 (49CFR172.101). For example, radioactive Type A packages containing exempt limited quantity from labeling requirement are marked UN2910.

Table 10.3 Limited quantities of several radionuclides that are exempt from packaging and labeling requirements, according to 49CFR 173.425

Radionuclides ^a	Quantity	
	(mCi)	(MBq)
⁵⁷ Co (s)	270	10,000
⁶⁷ Ga (t)	8.1	300
¹²³ I (t)	8.1	300
¹²⁵ I (t)	8.1	300
¹³¹ I (t)	1.9	70
⁸⁹ Sr (t)	1.6	60
¹¹¹ In (t)	8.1	300
³² P (t)	1.4	50
^{99m} Tc (t)	11	400
²⁰¹ Tl (t)	11	400
¹³³ Xe (g)	270	10,000
¹⁸ F(t)	1.6	60

^a s solid, t liquid, g gas

Table 10.4 UN ID number for packages of different types of exempted radioactive materials

Types of packages	Hazard class ^a	UN ID No	Package group
Radioactive material, excepted package- empty packaging	7	UN2908	Empty
Radioactive material, excepted package-limited quantity of material	7	UN2910	Limited
Radioactive material, low specific activity (LSA-I) non-fissile	7	UN2912	7
Radioactive material, low specific (LSA-II) non-fissile	7	UN3321	7
Radioactive material, low specific activity (LSA-III) non-fissile	7	UN3322	7
Radioactive material, under special arrangement, fissile or non-fissile-excepted	7	UN2119	7
Radioactive material, Type A package, special form, fissile	7	UN3333	7

^aNumber 7 indicates the DOT classification of hazardous material for Class 7 (radioactive) material

10.5 Empty Packaging

When packages that contained radioactive material previously are emptied as practically as possible, they are exempted from packaging, labeling, and marking requirements, except that the UN number UN2908 (Table 10.4) is marked on the package. Internal contamination must not exceed 100 times 240 dpm/cm² (4 Bq/cm²) for β and γ emitters, and 10 times less these values for α emitters. Any previous labels and markings must be removed or defaced, and an “EMPTY” label must be pasted on the package.

No shipping paper is required for limited quantity packages and empty packages.

10.6 Vehicles for Transportation of Radioactive Material

Vendors use vehicles for transportation of radioactive packages to the customers. So the vehicles must be monitored for contamination with radioactivity. Each transport vehicle used for transporting Class 7 (radioactive) materials as an exclusive use shipment whose non-fixed contamination level does not exceed 10 times the normal DOT limit (240 dpm/cm²) must be surveyed after each use. A vehicle may not be used for service until the radiation dose rate at each accessible surface is 0.5 mrem/h (5 μ Sv/h) or less, and there is no significant removable (non-fixed) radioactive surface contamination.

This condition does not apply if the vehicle is solely used for transportation of radioactive materials and a survey of the interior surfaces of the empty vehicle shows that the radiation dose rate at any point does not exceed 10 mrem/h (0.1 mSv/h) at the surface or 2 mrem/h (0.02 mSv/h) at 3.3 ft. (1 m) from the surface. Furthermore, the vehicle must display the sign, “For Radioactive Materials Use Only” in letters at least 3 in (76 mm) high on both sides of the exterior of the vehicle and it is kept closed except for loading or unloading.

10.7 Exemption for Licensed Physician

Any physician licensed by a State to dispense drugs in the practice of medicine is exempt from all packaging, labeling, and marking requirements for transportation of licensed material for use in the practice of medicine. However, the physician must be licensed under 10CFR35 or the equivalent Agreement State regulations.

10.8 Employee Training

The DOT requires that hazmat employees handling hazardous materials (hazmat) must be trained in the specific functions they carry out. Emergency response, measures to protect employees from exposure to hazardous materials in the workplace, and avoidance of accidents are parts of safety training. Training includes the

awareness of security risks and possible threats during transportation of hazardous materials and specific actions to be taken by the employee in the event of a security breach.

Initial training of an employee involves performing the specific functions dealing with hazardous materials under the direct supervision of a properly trained and knowledgeable hazmat employee and must be completed within 90 days after employment. The training is repeated every 3 years for each hazmat employee to enhance the in-depth security knowledge. Hazmat training from a previous employer may satisfy the requirements of the present employer. The employer is responsible for compliance with the requirements and keeping records of each employee's training. The record must include hazmat employee's name, date of training, elements of training, the name and address of the trainer, and a certificate attesting to the training of the employee.

10.9 Transportation of Radioactive Materials Within Hospital

All personnel involved in the transportation of radioactive materials are trained by radiation safety officer in rules and regulations to transport radioactive materials from one area to another area within a hospital. The recipient area must be approved for receiving and use of radioactive material. The container (vials, syringes, etc.) of radioactive material must be labeled properly identifying the radionuclide, quantity, date and, if needed, patient information. Vials, syringes, etc. must be placed in a lead container that provides sufficient shielding to minimize radiation exposure to the public during transportation. The outside of the lead container must be labeled with radioactive sign, identity of radionuclide, quantity, and date. If residual activity has to be returned to the sender, follow the above procedure.

10.10 Record Keeping

The NRC mandates that records of transportation of radioactive material except limited quantity packages must be kept and maintained for 3 years for audit by the appropriate authority. The content of the record includes, among others, type and quantity of the radioactive material, addresses of both shipper and recipient, and date of shipment.

Questions

1. The transport index (TI) for shipping a radioactive package is defined by
 - (a) 10 mrem (0.1 mSv)/h at 1 cm from the package
 - (b) 200 mrem (2 mSv)/h at 1 m from the package
 - (c) 10 mrem (0.1 mSv)/h at 1 m from the package
 - (d) 10 mrem (0.1 mSv)/h on the surface of the package

2. The survey reading on the surface of a radioactive shipping package should not exceed:
 - (a) 1 mrem/h (10 μ Sv/h)
 - (b) 10 mrem/h (0.1 mSv/h)
 - (c) 50 mrem/h (0.5 mSv/h)
 - (d) 200 mrem/h (2 mSv/h)
3. The smallest dimension of a radioactive package should not be less than
 - (a) 10 inches (25 cm)
 - (b) 4 inches (10 cm)
 - (c) 1 ft. (30 cm)
 - (d) it depends on the quantity of radioactivity in the package
4. A Yellow II label is required to be pasted on a radioactive package if
 - (a) the surface survey reading of the package is less than 60 mrem (0.6m Sv)/h
 - (b) the surface survey reading of the package is more than 200 mrem (2 mSv)/h
 - (c) the surface survey reading of the package is less than 10 mrem (0.1 mSv)/h
 - (d) the surface survey reading of the package is less than 50 mrem (0.5 mSv)/h
5. A radioactive package reads 100 mrem/h at the surface and 9 mrem/h at 1 m from the package. Which DOT label has to be fixed on the package for shipping?
 - (a) White I
 - (b) Yellow II
 - (c) Yellow III
6. The radiation exposure at the surface of a limited quantity radioactive package should not exceed
 - (a) 10 mrem (0.1 mSv)/h
 - (b) 0.5 mrem (5 μ Sv)/h
 - (c) 200 mrem (2 mSv)/h
 - (d) 50 mrem (0.5 mSv)/h
7. Does a limited quantity radioactive package need a Yellow label?
8. All radioactive packages must be wipe tested prior to shipment. What is the limit of these wipe tests for β^- and γ radiation contamination?
 - (a) 100 dpm
 - (b) 240 dpm
 - (c) 24 dpm
 - (d) no limit
9. Name the stability tests for the package containers for radioactive shipment.
10. Placards are required on four sides of a transportation vehicle carrying Yellow III—labeled packages. True _____ False _____.
11. An employee handling hazardous material (Hazmat) must have hazmat training:
 - (a) prior to employment
 - (b) within 90 days of employment
 - (c) within 1 year of employment
 - (d) training not needed

12. How often does an employee require to renew hazmat training?
- (a) every year
 - (b) biannually
 - (c) every 5 years
 - (d) every 3 years

References and Suggested Reading

Department of Transportation 49CFR173 and 49CFR172. Shippers-general requirements for shipments and packaging. Washington, DC; 2011.

NRC 10CFR71. Packaging and transportation of radioactive material. Washington, DC; 2010.



11.1 Rationale for Radioactive Waste Disposal

Use of radioactivity for various purposes is likely to generate radioactive waste that needs to be disposed of properly to prevent unnecessary spread of radioactivity and minimize the exposure to personnel and the public. There are two broad categories of radioactive waste—high-level waste (HLW) and low-level waste (LLW). The former is generated in power plants and nuclear bomb manufacturing facilities in the defense department and contains a very high level of radioactivity presenting a daunting challenge to dispose of radioactive waste. However, this category of waste is not encountered in nuclear medicine at the hospitals and other institutions, and hence disposal of HLW will not be discussed here. LLW originates from medical use of radioactivity and tracer use in industry and research and typically consists of contaminated materials such as paper, rags, plastic bags, clothing, cardboard, residual fluids, vials, syringes, etc. It is obvious that disposal of LLW is less challenging than that of HLW. By virtue of its scope and nature of operation, nuclear medicine generates only LLW making it easier to dispose of. Low-level waste is typically stored onsite by licensees, either until it has decayed to background level and is disposed of as ordinary trash, or until the accumulated amount becomes large enough to warrant shipment to a low-level waste disposal site.

11.2 Management and Storage of Radioactive Waste

In different facilities, low-level radioactive waste can be generated from various uses of radioactive materials, namely radioactive drugs for diagnosis and treatment in humans, radioactivity in research animals, and in vitro experiments with radioactivity. These wastes may be solid, liquid, or gaseous, and their storage and disposal are managed differently. Following is a brief guideline to storage of different types

of radioactive wastes generated in facilities such as hospitals, industries, and academic institutions. The disposal methods will be discussed in detail later in the chapter.

In general, the storage area should have an exhaust fitted with a filter in the vent to trap contaminated vapor and also properly shielded to minimize the external exposure. Often they are built with thick concrete walls for shielding. Small facilities often fail to afford such separate shielded and ventilated areas for financial and practical reasons. However, these facilities use only short-lived radionuclides such as ^{99m}Tc and ^{18}F , and the storage time for decay is significantly short. They use lead-shielded containers for storage and can dispose of the waste after short holding period for decay.

11.2.1 Storage of Dry Solid Waste

- Segregate wastes according to half-lives (group of ^{99m}Tc , ^{18}F , ^{123}I and group of ^{131}I , ^{67}Ga , and ^{111}In) for the convenience of disposal (see later).
- Collect all dry waste (contaminated tissue paper, gloves, wipes, etc.) in a lead-lined foot-controlled container fitted inside with a plastic bag.
- Do not put in any sharp items such as needles in these containers.
- When full, remove the inner plastic bag and replace it with a new one.
- Tie firmly the full bag, and attach a yellow tag (with radioactive insignia) with information as to survey reading on the surface of the bag, model of the survey meter, date of storage, identity of radionuclides, and initials of the individual who stores.
- Place the bag in the designated storage area for disposal later.

11.2.2 Storage of Liquid Waste

- Liquid waste is mostly generated from liquid scintillation counting in research. Nowadays the liquid scintillation cocktail is mostly biodegradable.
- ^{14}C ($t_{1/2} = 5730$ years) and ^3H ($t_{1/2} = 12.3$ years) are the common radionuclides used in research in low concentrations (μCi). Other radionuclides include ^{32}P ($t_{1/2} = 14$ days) and ^{125}I ($t_{1/2} = 60$ days), which are not as common.
- Empty the liquid scintillation cocktail from vials into a large plastic container with a lid, and store it in a secured place until disposal.
- Store the empty vials in a separate plastic container to dispose of later.
- Store water-soluble and non-aqueous liquid waste in separate containers.
- Identify the contents of the containers with tags with information on the type and estimated amount of radionuclide.

11.2.3 Infectious or Biohazard Radioactive Waste

- Keep infectious radioactive waste separate from other waste, as it is biohazard.
- Package the waste according to categories such as solid, liquid, sharps, etc.
- Attach biohazard and radiation hazard tag with the type and amount of radioactivity.
- Store in the designated area until disposal.

11.2.4 Sharps and Glass Container

- Sharps mostly originate from syringes and needles used in nuclear medicine. Specially designed red boxes are used to collect these items, which are placed at different stations of nuclear medicine and research areas.
- Place all syringes and needles in the sharp box after injection of radioactive drugs into patients.
- Do not place syringes containing any liquid into the sharp box.
- When boxes are full, cap them with attached lid.
- Survey the box and attach a radioactive tag with the information on survey reading, instrument used to survey, type of radionuclide and date.
- Store the boxes in the designated place.

11.2.5 Radioactive Animal

- Radioactive materials are used in animal experiments, and waste generated from them falls into three categories, namely (a) carcass, (b) blood, urine, etc., and (c) contaminated items like bedding.
- Keep animals administered with radioactivity in cages labeled with radioactive sticker and place the cages in a segregated area in the animal quarter of the facility.
- If tissues are dissected, preserve them until the intended experiment is completed.
- Place the carcass in a plastic bag and tie a radioactive tag on it. Store in a cold freezer until disposal.
- If biological samples are collected, place them in appropriate containers and store them with identification in the cold freezer until disposal.
- After the completion of experiment, the preserved tissues are packaged in a bag and stored in the freezer for disposal later.
- Discharge animal excreta (urine, feces) in the sanitary sewer according to the NRC limit.

11.3 Radioactive Waste Disposal

The NRC has established criteria for disposal of radioactive waste based on the physical condition of the waste (liquid, solid, and gas) and the half-life of the radionuclide. Listed below are the common methods of disposal of radioactive waste.

- Decay-in-storage
- Incineration
- Discharge in sewerage
- Transfer to authorized recipient

11.3.1 Decay-in-Storage

This method is applicable to short-lived radionuclides, which decay in a relatively short time to insignificant level and are disposed of in regular nonradioactive trash. According to NRC 10CFR35.92, radionuclides with $t_{1/2}$ less than 120 days can be allowed to decay-in-storage until the survey reading of the storage bag is indistinguishable from the background, when the waste can be disposed of in regular non-radioactive trash.

Common radionuclides used in nuclear medicine are short-lived (^{99m}Tc ($t_{1/2} = 6$ h), ^{99}Mo ($t_{1/2} = 66$ h), ^{123}I ($t_{1/2} = 13.2$ h), ^{32}P ($t_{1/2} = 14.3$ days), ^{131}I ($t_{1/2} = 8$ days), ^{111}In ($t_{1/2} = 2.8$ days), ^{67}Ga ($t_{1/2} = 3.3$ days), ^{201}Tl ($t_{1/2} = 3$ days), ^{18}F ($t_{1/2} = 110$ min), ^{90}Y ($t_{1/2} = 2.7$ d), etc.) and fall into the disposal category of decay-in-storage. For convenience of timely disposal, waste of these radionuclides is bagged in plastic bags according to similar half-lives; for example, group of ^{99m}Tc , ^{18}F and ^{123}I ; group of ^{67}Ga , ^{111}In , ^{201}Tl , ^{99}Mo , and ^{90}Y ; and group of ^{131}I and ^{32}P . The storage bags are tagged with information as to the radionuclide, date of storage, exposure reading on the surface of the bag, model of the survey meter, and initials of the individual who stores.

After estimated decay, bags are removed from the storage to a background area (such as the hallway) to measure the exposure rate from the bag with a G-M survey meter. If the meter reading is indistinguishable from the background, the tags from the bag are removed and the bag is placed in a regular garbage bag, which is disposed of in regular trash. If the survey reading is still higher than the background, the bag is returned to the storage for further decay. Following disposal, records are made of information as to the radionuclide, date of storage, exposure reading on the surface of the bag, model of the survey meter, and initials of the individual who stores.

11.3.2 Disposal by Incineration

Incineration of solid or liquid waste, and carcasses of research animals containing radioactivity are allowed by this method, provided the effluent radioactivity released in the atmosphere meets the limit set by the NRC and the EPA. The NRC limit is given in Table 2 of Appendix B to 10CFR20. These limits of some radionuclides used in nuclear medicine are included in Table 11.1. Incineration reduces the bulk

Table 11.1 Values of concentration limits for air effluent and sewer release of several radionuclides used in nuclear medicine (obtained from Appendix B to 10CFR20^a)

Radionuclide	Chemical form	Table 1		Table 2
		Effluent concentrations		Release to sewers
		Col 1 Air ($\mu\text{Ci/mL}$)	Col 2 Water ($\mu\text{Ci/mL}$)	Monthly average concentration ($\mu\text{Ci/mL}$)
^3_1H	Water	1E-7	1E-3	1E-2
$^{14}_6\text{C}$	Monoxide	2E-6	–	–
	Dioxide	3E-7	–	–
$^{99m}_{43}\text{Tc}$	Compounds	3E-9	3E-5	3E-4
	All compounds except those given for	2E-7	1E-3	1E-2
	Oxides, hydroxide halides, and nitrates	3E-7	–	–
$^{111}_{49}\text{In}$	All compounds except those given for	9E-9	6E-5	6E-4
	Oxides, hydroxides, halides, and nitrates	9E-9	–	–
$^{123}_{53}\text{I}$	All compounds	2E-8	1E-4	1E-3
$^{131}_{53}\text{I}$	All compounds	2E-10	1E-6	1E-5
$^{67}_{31}\text{Ga}$	All compounds except those given for	2E-8	1E-4	1E-3
	Oxides, hydroxides, carbides, halides, and nitrates	1E-8	–	–
$^{201}_{81}\text{Tl}$	All compounds	3E-8	2E-4	2E-3
$^{133}_{54}\text{Xe}$	Submersion	5E-7	–	–
$^{18}_9\text{F}$	Fluorides of H, Li, Na, K, Rb, Cs, and Fr except those given below	–	7E-4	7E-3
	Fluorides of Be, Mg Ca, Sr, Ba, Ra, Al, Ga, In, Tl, As, Sb, Bi, Fe, Ru, Os, Co, Ni, Pd, Pt, Cu, Ag, Au, Zn, Cd, Hg, Sc, Y, Ti, Zr, V, Nb, Ta, Nm, Tc, La, and Re	1E-7	–	–

Table 1 lists concentration limits (maximum permissible concentration, MPC) for airborne and liquid effluents released in the environment

Table 2 shows the limits (maximum permissible concentration, MPC) for discharges of radioactive material to sanitary sewer systems

Refer to Appendix B to 10CFR20 for explanation of how different values in Tables 1 and 2 are calculated

of insoluble liquid waste from liquid scintillation studies to a small volume of ash, which is then disposed of as solid waste in appropriate manner depending on the level of activity. Liquid scintillation media and animal tissue containing 0.05 μCi (1.85 kBq) or less of ^3H or ^{14}C per gram of medium or animal tissue (averaged over the whole body of the animal) can be incinerated or disposed of in the regular trash.

Plastic sharp containing contaminated needles and vials are monitored in the same way as the bags in decay-in-storage, which are then disposed of by incineration after appropriate decay. Some facilities install monitoring counters and a conveyor belt between them. The waste boxes or containers pass through a conveyor belt. If there is any detectable radioactivity in any box or container, it will trigger the monitor and the item is then removed and stored for more decay. Some facilities run their own incinerators for this purpose, otherwise they are sent to authorized facilities who burn them in their incinerators.

11.3.3 Disposal of Radioactive Material into Sewerage

According to NRC 10CFR20.2003, water-soluble radioactivity may be discharged into the sewer, provided the concentration of radioactivity in the sewer is less than the MPCs listed in Table 3 of Appendix B to 10CFR20 and for convenience, MPCs of some radionuclides used in nuclear medicine are given in Table 11.1. The water concentrations are derived by dividing the most restrictive occupational stochastic oral ingestion ALI by 7.3×10^7 . The factor of 7.3×10^7 (mL) is the product of 50, 2, and a quantity 7.3×10^5 (mL), which is the annual water intake of “Reference Man.” Here the factor of 50 is assumed to relate the 5-rem (0.05 Sv) annual occupational dose limit to the 0.1 rem (1 mSv) limit for members of the public, and the factor of 2 is assumed to adjust the occupational values (derived for adults) so that they are applicable to other age groups.

The monthly average concentrations of radionuclides for release to sanitary sewers are derived by taking the most restrictive occupational stochastic oral ingestion ALI and dividing it by 7.3×10^6 (mL). The factor of 7.3×10^6 (mL) is composed of a factor of 7.3×10^5 (mL), the annual water intake by “Reference Man,” and a factor of 10, such that the concentrations, if the sewage released by the licensee is the only source of water ingested by a “Reference Man” during a year, would result in a committed effective dose equivalent of 0.5 rem (5 mSv).

When more than one radionuclide is discharged, the fractional limit for each radionuclide is calculated by dividing the actual annual average activity discharged, by the limit in Table 3 of Appendix B to 10CFR20, and the sum of the fractions of all radionuclides must not exceed unity.

The annual limit of sewer disposal of radioactive materials is 5 Ci (185 GBq) of ^3H , 1 Ci (37 GBq) of ^{14}C , and 1 Ci (37 GBq) of all other radioactive materials combined. Note that human excreta from radioactive patients and the items (linen, diapers, etc.) contaminated with human radioactive excreta are excluded from this limit.

11.3.4 Transfer to Authorized Recipients

Congress established a policy in 1980 followed by an amendment in 1985 that charged different states to form regional “Compacts” to share a disposal facility to dispose of low-level radioactive waste. By 1998, 42 states formed 10 compacts to share the common disposal facility, but so far no full-pledged compact facility has yet been developed, primarily due to complexity of public education, acceptance, and financial costs. However, the NRC has approved and licensed four locations for disposal of low-level radioactive wastes: Energy Solutions Barnwell Operations in Barnwell, South Carolina; US Ecology in Richland, Washington; Energy Solutions Clive Operations in Clive, Utah; and Waste Control Specialists, LLC in Andrews, Texas. Each Compact location is licensed by the NRC to accept low-level wastes (albeit long-lived) from specific member states and disposes of specific categories of waste from these states (10CFR61). These Compact facilities in the US accept from designated states for a fee radioactive waste for burial or incineration, particularly long-lived radionuclides such as ^3H , ^{14}C , etc. So, many institutions and investigators adopt this method and send the long-lived radioactive waste to these Compact facilities after paying the appropriate fee. An important point of consideration is to compact solid waste as much as possible to reduce the volume prior to shipment.

Radioactive waste intended for ultimate disposal at a licensed land disposal facility involves three entities: *waste processor* whose job is to process, repackage and to treat low-level waste (LLW) prior to sending to land disposal facility; *waste collector* whose job is to collect radioactive waste from others and transfer to disposal facility without processing or repackaging; and *waste generator* who possesses radioactive material as waste and transfers the material to a licensed land disposal facility or to a licensed waste collector or processor for ultimate disposal. Any of these individuals must prepare a Manifest on NRC Form 540—Uniform Low-Level Radioactive Waste (Shipping Paper) and Form 541—Uniform Low-Level Radioactive Waste (Container and Waste Description). These forms are available from the NRC. Form 540 must physically accompany the shipment. NRC 541 may be transmitted or stored electronically for later transmission to the intended consignee in accordance with Appendix G to 10CFR20. All entities must be approved and licensed by the NRC or the Agreement State for their respective activities and responsibilities.

The shipper shall provide the following information on the uniform manifest:

- Name, facility address, telephone number of the shipper, designation of the shipper (waste generator, collector, or processor or combination of them)
- The name, address, and phone number of the transporting carrier
- The date of waste shipment
- Number of packages/disposal containers

- Disposal volume and weight of the shipment
- Total activity in the shipment
- Identifying number of each container
- Type, volume, weight of container
- Radiation level on the surface of each disposal container
- Physical and chemical form of the waste
- Identities and activities of individual radionuclides in each container

Each shipment manifest must include a certification by the waste generator as specified in section II of Appendix G to 10CFR20. An authorized representative of the waste generator, processor, or collector shall certify by signing and dating the shipment manifest that the transported materials are properly classified, described, packaged, marked, and labeled and are in proper condition for transportation according to the applicable regulations of the DOT and the NRC. A collector concurs with the waste generator's certification by signing the certification.

Appropriate measures must be taken to track and control of the shipment. The manifest must be forwarded to the consignee prior to shipment or delivered to the consignee along with the shipment. Acknowledgment of the receipt of the manifest by a collector must be documented. If the shipment is not received by the collector within 60 days after receipt of the advance manifest, the collector shall notify the shipper and the administrator of the NRC Regional Office. The land disposal facility operator shall acknowledge the receipt of the shipment within one week of receipt by returning the signed copy of the NRC Form 540 to the shipper. All manifests are copied and stored electronically in computers until the NRC terminates the license.

The columns of ^{99}Mo – $^{99\text{m}}\text{Tc}$ generators containing ^{99}Mo with a short half-life of 66.2 hrs may be decayed to background level for disposal to normal trash. However, the generator manufacturers have a policy of accepting these spent generators and letting them decay at their sites for disposal. The carrier normally picks up the old generator to return to the vendor, while delivering a new generator to the customer. ^{82}Sr – ^{82}Rb generators also are returned to the manufacturers in a similar procedure. Proper packaging of shipment including surveying, wipe testing, and labeling is the licensee's responsibility.

11.3.5 Other Disposal Methods

Methods different from the above methods may be employed with the approval from regulatory agencies (NRC, EPA, Agreement State). Approval of such methods is obtained by submitting an application to the NRC or the Agreement State detailing the method of disposal. Major considerations in approval are the impact of the disposal on the environment, neighborhood, and population.

11.4 Special Situations for Disposal of Radioactive Waste

In addition to the above methods of radioactive waste disposal, some specific radioactive waste needs special attention for their disposal, namely gaseous waste, sealed sources, and cadaver containing radioactivity, and they are discussed below.

11.4.1 Disposal of Gaseous Waste

The method can be employed for the release of radioactive gases such as ^{133}Xe and ^{127}Xe through vents, provided the concentration of the effluent does not exceed the maximum permissible limit (MPC) set by the NRC in Table 2 of Appendix B to 10CFR20. For convenience, the values of MPCs of some of the radionuclides used in nuclear medicine are listed in Table 11.1.

Volatile radioactive samples such as ^{131}I and ^{125}I release radioactive vapors which are typically discharged into the atmosphere following a principle of dilute and disperse. The effluent must not exceed the MPC established by the NRC. These radionuclide samples should be handled in a fume hood connected with a duct to the outside atmosphere at the highest rooftop exit. The vapors should pass through charcoal and particulate air filters installed in the duct to trap most of radioactive particles. Also laminar flow hoods fitted with HEPA filters are helpful in minimizing the exposure from these radionuclides. Filters in the hood must be replaced as frequently as possible to prevent blockage and maintain proper air flow. Other gaseous radioactivities such as $^{14}\text{CO}_2$, ^3H gas, and $^{99\text{m}}\text{Tc}$ aerosol are handled and disposed of by this method.

11.4.2 Disposal of Sealed Sources

Radioactive sealed sources of various activities are used in hospitals for a variety of applications, namely equipment calibration, brachytherapy, blood irradiation, etc. The activity level is generally low for many sources (a few to several hundred millicuries (MBqs) for calibration, brachytherapy), whereas in teletherapy and blood irradiation, the sources contain many orders of radioactivity (multi-curies). Over time, these sources decay to low levels of activity such that they become unusable for the intended purpose, prompting their removal and replacement with new ones. Facilities using these sources typically enter into contractual agreement with the vendors for safe removal and replacement of these sealed sources. Normally, the Radiation Safety Officer of the facility should be consulted for such contracts and his recommendation should be taken into consideration.

11.4.3 Management of Cadavers Containing Radioactive Materials

Occasionally patients containing radioactivity pass away at home or in the hospital. For example, thyroid cancer patients are treated with a high level of ^{131}I activity and if they die in the course of treatment, they may contain high levels of radioactivity in the body. Burial or cremation of these corps becomes hazardous to the public and is illegal. An optimal course of action is to survey the whole body of the deceased patient to identify any localized activity in an organ, such as ^{131}I activity in thyroid glands or metastatic sites following treatment with ^{131}I . If activity is found, these organs are removed and disposed of by appropriate methods such as incineration or as biohazard materials.

The cadavers still containing high activity are retained in the morgue until the level reduces to the safe limit. If the level of activity is less than the recommended safe level set by the authority, the corpse may be buried or cremated. The entire situation must be supervised by the radiation safety officer and the nuclear physicians.

11.4.4 Disposal of Radioactive Animals

Radioactive animal carcasses are either incinerated or buried. While incineration is widely accepted for animal carcass disposal, burial is very limited due to local regulations and other logistic problems. The Barnwell Compact in South Carolina employs both methods and accepts radioactive waste only from member states, and animal carcasses from these states are buried. All other states do not have access to this facility, so they are left with the option of incineration of animal carcasses.

- Remove the animal carcasses and tissues stored in the freezer.
- Survey all items and note the survey reading.
- If the reading is below background, place the bag in a new outer garbage bag. Otherwise, leave the carcass and tissues in the freezer.
- Call the radiation safety offices to pick up the bags, who will incinerate them following the established method.

11.5 Record Keeping

Records of disposal must be kept in a logbook for all radionuclides as to the date and time of storage and disposal, quantity and identity of the radionuclide along with the name of the individual disposing of the waste. The units used in the record must be in curie, rad, rem, and their multiples and fractions, although SI units can be used in parenthesis. These records must be retained until the NRC terminates the license for a reason.

Questions

- Describe the step-by step decay-in-storage method of radioactive waste disposal.
- What is the NRC recommended half-life of a radionuclide below which it can be disposed of by the decay-in-storage method in the regular trash?
 - 10 days
 - 10 half-lives
 - 120 days
 - 12 h
- Radioactive waste generated in nuclear medicine is Low-Level Waste (LLW) _____; High-Level Waste (HLW) _____.
- The common method of disposal of the ^{99}Mo - $^{99\text{m}}\text{Tc}$ generator is
 - incineration
 - decay-in-storage
 - return the generator to the vendor
 - transfer to an authorized recipient
- When several radionuclides are disposed of in sewerage, what are the regulations to calculate the quantity of each radionuclide to dispose?
- The sewerage disposal limit of
 - ^3H _____
 - ^{14}C _____
 - all other radionuclides _____.
- What are the elements of a record of radioactive waste disposal?
- What is a manifest in transferring radioactive waste?
- The NRC licensed four “Compacts” comprising regional States to dispose of low-level radioactive waste, but only one is currently operational. Which of the following Compacts is operational?
 - Waste Control Specialists, LLC in Andrews, Texas
 - US Ecology in Richland, Washington
 - Energy Solutions Clive Operations in Clive, Utah
 - Energy Solutions Barnwell Operations in Barnwell, South Carolina
- How long does the licensee need to retain the record of disposal of radioactive waste?
 - 3 years
 - 5 years
 - until the license terminates
 - 10 years
- Human and animal excreta disposal in the sewer is limited by the NRC.
 - True _____.
 - False _____.
- The background reading in the hallway is 0.01 mR/h. A bag containing $^{99\text{m}}\text{Tc}$ reads 10 mR/h. How long will it take to dispose of it in the regular trash?

References and Suggested Reading

10CFR20 Standards for protection against radiation; 2015.

American Nuclear Society. Disposal of low-level radioactive waste. Revised, February; 2009.

NRC 10CFR61. Licensing requirements for land disposal of radioactive waste; 2020.



Biological Effects of Radiation on Humans

12

Radiation causes damage to human tissues leading to untoward health problems of various diseases. It is logical that the radiation workers have appropriate knowledge of these effects to adopt precautionary measures to minimize the radiation exposure at the workplace and to the public. This chapter is a synopsis of radiation biology dealing with effects of radiation on humans.

12.1 Cell Structure and its Function

Cells are basic units of living bodies carrying out all essential functions for survival. There are millions of cells in the human body. The cell is enclosed by a plasma membrane, which permits the essential nutrients to enter and waste products to leave out of the cell (Fig. 12.1). Inside the cell exists a nucleus that contains a nucleolus to produce a ribosome and proteins inside, and a jelly-like liquid called the cytoplasm in which thousands of miniscule structured organelles exist to carry out a variety of specific functions. Most cells have one nucleus, whereas some have several nuclei such as skeletal cells, and yet a few cells such as red blood cells do not contain any nucleus.

The nucleus is composed of genes, which are composed of deoxyribonucleic acid (DNA) molecules that have a ladder-like double-stranded helical structure (Fig. 12.2) and encode genetic and hereditary information required to sustain life in living organisms. DNAs are made up of nucleotides, which contain a phosphate group, a sugar group, and one of the four nitrogen bases, namely adenine (A), thymine (T), guanine (G), and cytosine (C). The two strands of the DNA molecule are connected to the base of each rung through hydrogen bonds thus giving a ladder-like structure. In human cells, many genes group together to form a thread-like structure called the chromosome. Abnormal genes and chromosomes are considered progenitors of many diseases such as cancer, inflammation, fibrosis, Down's syndrome, multiple sclerosis, immune disease, etc.

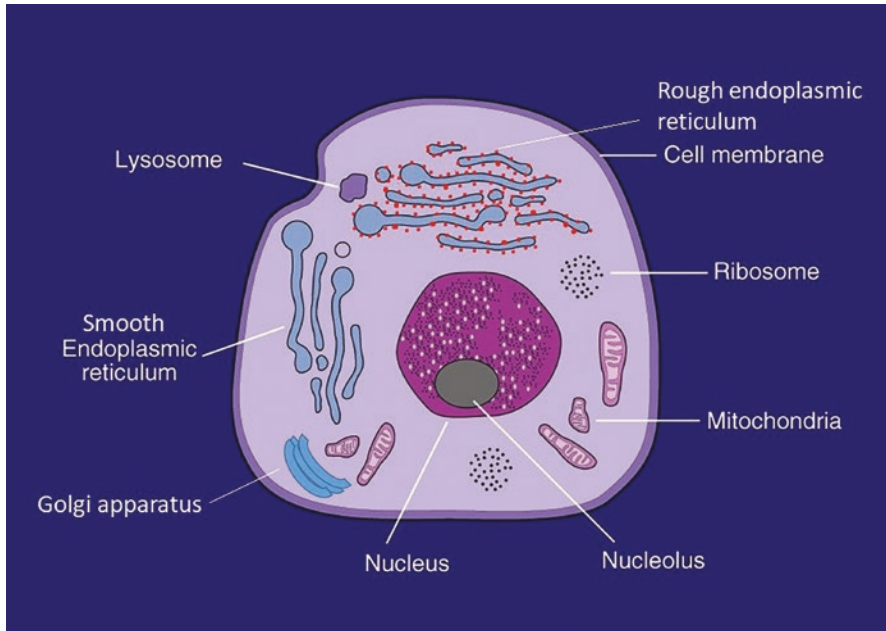


Fig. 12.1 Structure of a mammalian cell. (Reprinted by permission from Springer Nature, *Physics and Radiobiology of Nuclear Medicine* by Saha GB, 2013)

Besides the nucleus, other major organelles in the cell include (a) **mitochondria**, carrying out the function of the energy production by enzymatic oxidation of carbohydrate and lipid necessary for cell survival; (b) the rough and smooth **endoplasmic reticulum** (ER), the rough one having ribosome on it synthesizing necessary proteins for cellular function, and smooth ER synthesizing lipids, phospholipids as in plasma membranes, and steroids; (c) the **Golgi apparatus** serving as a reservoir in which ER proteins are sorted and transported to the specific destinations such as lysosomes, the plasma membrane, or secretion; and (d) **lysosomes**, which lyse unwanted materials within the cell.

There are two types of cells based on the number of chromosomes they contain: germ cells and somatic cells. Human germ cells such as spermatozoa and oocytes contain 23 chromosomes and are called *haploids*, which are responsible for reproduction. All other human cells are somatic cells, each containing 23 pairs of chromosomes (46 chromosomes), with each parent contributing a chromosome to each pair. These cells are termed *diploids* and are responsible for maintenance of physiological functions in the body.

The life of a cell is characterized by cell growth and cell division. Cell growth begins with undifferentiated or immature cells with no specific function but to grow into mature or differentiated cells, which carry out specific functions to sustain life. Cell division is essential for physical growth from infancy to old age in living species and also for genetic reproduction. There are two types of cell division: mitosis

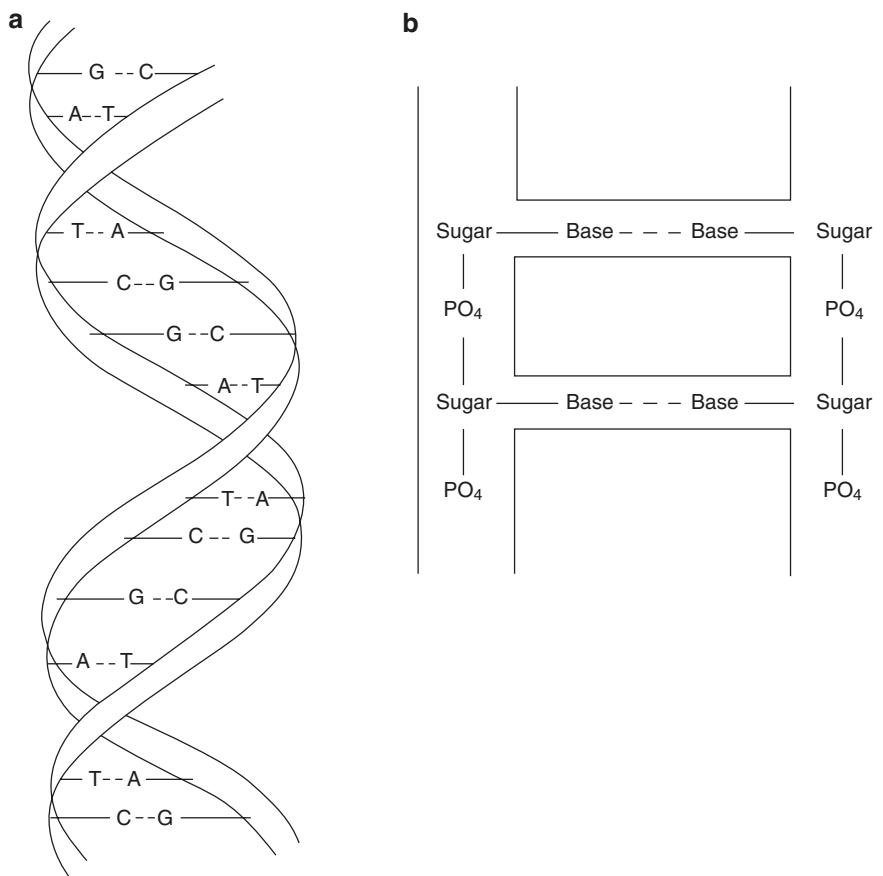
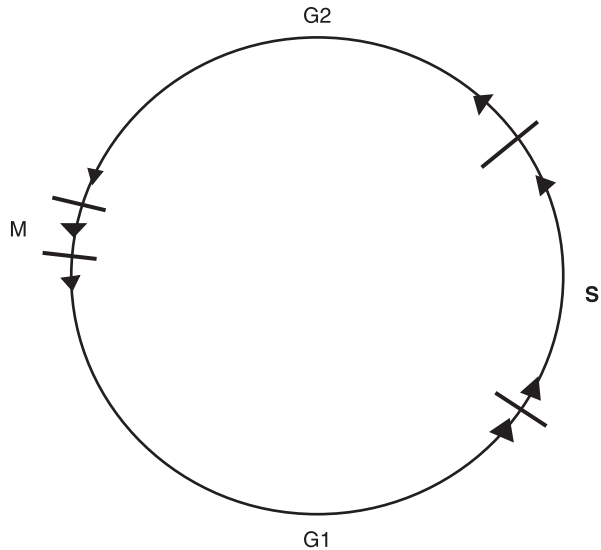


Fig. 12.2 (a) Double-helical structure of DNA molecule composed of four bases: adenine (A), guanine (G), thymine (T), and cytosine (C). (b) Configuration of a DNA molecule: strands are formed by sugar molecules bonded by phosphate groups. The rungs of the ladder-like structure are formed by bases connected to each other by hydrogen bond (dashed line) and to the sugar molecule on the strands on both sides. (Reprinted by permission from Springer Nature, *Physics and Radiobiology of Nuclear Medicine* by Saha GB, 2013)

and meiosis. Mitosis occurs in somatic cells, where cell division occurs with the duplication of DNAs and chromosomes in the cell to produce two new identical daughter cells. The daughter cells contain the same number of chromosomes as the parent. In meiosis, however, a single germ cell (sperm or ovum) divides into two cells, which divide again resulting in total four new cells, each containing half the chromosome of the parent cell. Meiosis differs from mitosis in that in meiosis, for a given series of cell division, every alternate cell division skips DNA synthesis, thus keeping the number of chromosomes the same in germ cells.

The cell goes through a cycle of events, which take place in the cell causing it to divide into two daughter cells. This cell cycle consists of four distinct stages, namely

Fig. 12.3 The cell cycle. S is the DNA synthesis phase. M is the period of mitosis during which the prophase, metaphase, anaphase, and telophase take place. G1 is the period between the telophase and S, and G2 is the period between S and the prophase



Gap 1 (G1), synthesis (S), Gap 2 (G2), and mitosis (M), in which the cell grows and divides (Fig. 12.3). The initial three phases (G1, S, and G2) are collectively called the interphase, which is the longest period in the cell cycle. In the synthesis phase, the DNAs and chromosomes are replicated and copied by the cell, and the cell then heads into the G2 phase, where the genetic material is condensed and the cell gets ready to divide. In the mitosis phase, the cell division occurs producing two identical daughter cells, which by their own right goes through the interphases and mitosis to begin a new round of the cell cycle.

12.2 Apoptosis

Apoptosis is a well-regulated programmed cell death in living species and plays a critical role in maintaining a balance between cell death and cell division. It can be triggered by a number of stimuli such as drugs, chemicals, infections, high temperature, immune reactions, radiation exposure, and various disease states. Following initiation of apoptosis, a series of biochemical events take place in which changes such as cell shrinkage, nuclear fragmentation, chromatin condensation, DNA fragmentation, etc. occur, which ultimately lead to apoptosis. The stimuli may be extracellular or intracellular. The former include physical agents such as physical trauma, chemotherapeutic drugs, infectious agents, and viruses, whereas the latter are internal imbalances, such as glucocorticoid treatment, oxidative stress, oncogenes, direct DNA damage by radiation, hypoxia, and treatment with cytotoxic drugs.

In most cases, apoptosis involves the activation of a protein, cysteinyl aspartate-specific proteases (caspases) by stimuli, which breaks down the chromatin in the nucleus essential for cellular functions. Cells then condense to form membrane-enclosed apoptotic bodies, which are then phagocytosed by surrounding macrophages resulting in apoptosis. A deregulation of apoptosis results in the uncontrolled multiplication of cells leading to different diseases such as cancer and neurodegenerative disease.

A parallel term, necrosis, also alludes to cell death. However, there is a notable difference between apoptosis and necrosis. Necrosis typically induces an inflammatory reaction in the adjacent viable tissues, whereas apoptosis does not. Unlike apoptotic cells, necrotic cells are not removed by macrophages to clean the cellular debris.

12.3 Radiation Damage in Human Cells

When radiation interacts with the human tissue, cells are damaged. The primary mechanism of cellular damage is the breakdown of the strands of helical structure of the DNA molecule, which is called *mutation*. Mutations are reflected in the genes by adversely altering the genetic codes and ultimately in the chromosomes. The altered genes and chromosomes are replicated in daughter cells through mitosis (cell division), and proliferation of damaged cells causes various diseases. The number of mutations increase with increasing radiation exposure. At low radiation exposure, usually the single-strands of the DNA molecule break down, and over time, the broken components can join to repair forming the original structure. At high radiation exposure, however, double-strand breakage occurs and the odds for rejoining the broken strands to repair the DNA molecule decrease. Radiation damage can be induced by direct interaction of radiation with the DNA molecule by breaking its structure, or by indirect interaction in which radiation interacts with other molecules in the cytoplasm such as water (70% content) and organic molecules producing free radicals like $\text{HO}_2\bullet$ and alkoxy ($\text{RO}_2\bullet$) that are toxic to the DNA molecules.

Functionally, cells are categorized as undifferentiated or differentiated. Undifferentiated cells are immature cells having no specific function except to develop into mature cells through mitosis. Differentiated cells, however, are mature cells and carry out specific physiologic functions in the body. For example, erythroblasts are undifferentiated cells that develop into mature red blood cells, whereas red blood cells are differentiated cells performing as oxygen carriers. Differentiated cells are radiation resistant, whereas the undifferentiated cells are most sensitive to radiation, particularly in active mitosis phase.

12.4 Factors Affecting Radiation Damage in Genes and Chromosomes

Various factors affect the radiosensitivity of cells, namely dose and dose rate, the linear energy transfer (LET) of the radiation, chemical molecules present in the vicinity, and the stage of the cell cycle.

12.4.1 Dose and Dose Rate

Dose rate is the dose delivered per unit time. Low dose and low-dose rate imply single-strand breakage of DNA molecules, which have a greater likelihood of cell repair over time, whereas at higher doses and dose rates, double-strand breakage is likely to occur implying less repair of the DNA molecules. In radiation therapy, the dose-rate effect is well appreciated, because fractionated radiation doses are given to the patient in short intervals over a period of time to minimize cell repair and thus to achieve maximum effect on cell killing in tumors.

12.4.2 Linear Energy Transfer

High LET radiations such as α particles are short-range radiations and cause more damage than the low LET radiations such as β^- and γ radiations, because of a greater deposition of energy in a localized area by the former. Similarly, β^- radiations are more damaging than γ radiations.

12.4.3 Radiosensitizer and Radioprotector

Chemicals present during radiation exposure may increase (radiosensitizers) or decrease (radioprotectors) the effect of radiation. Oxygen is a well-known radiosensitizer, and oxygenated cells are highly radiosensitive. It has been postulated that radiation interacts with cell constituents and produces $R\bullet$ free radicals. Oxygen present in the cell combines with $R\bullet$ to form $RO\bullet_2$, which causes more damage to the DNA molecules than $R\bullet$ alone, thus enhancing the tumor cell killing. The oxygen effect is predominant with β^- and γ radiations and is practically absent for high LET radiations such as α particles. In radiation therapy, the oxygen effect plays an important role. It is known that hypoxic cells are resistant to radiation and exist in tumors to a varying extent. In view of this, it has been suggested that the tumor cells are oxygenated first, followed by radiation treatment. Chambers with oxygen pressure at 2–3 times the atmospheric pressure have been used for oxygenation, in which patients are allowed to breathe inside the chamber for a certain time, followed by radiation treatment.

Other chemicals such as pyrimidines, actinomycin D, 5-fluorouracil, etc. have been used as radiosensitizers with varying levels of success in tumor treatment,

whereas substances containing –SH group work like radioprotectors that protect cells from radiation damage. Cysteine and cysteamine are examples of radioprotectors, which combine with free radicals formed by radiation to neutralize their damaging effect, thereby protecting the cells from radiation damage.

12.4.4 Stage in the Cell Cycle

In the cell cycle, the mitosis phase is most radiosensitive, and the S phase is the least radiosensitive. Thus the extent of radiation damage depends on the stage of the cell cycle at the time of radiation exposure. Cells in the mitosis phase may die at high radiation exposure, whereas at low exposure they may survive. Radiation damage may delay the DNA replication in the S phase.

12.5 Acute Effects of Total-Body Irradiation

Due to varying radiosensitivity of different tissues of the human body, the tissues respond to radiation exposure differently, and various disease syndromes are manifested depending on the type of tissues and the dose applied. Whole-body exposure is likely to occur in nuclear accidents (atomic explosion, nuclear spill, etc.) and accidental radiation exposure during radiation treatments. Effects of whole-body irradiation are characterized by the survival time of the species and various stages of acute syndromes caused by radiation. The survival time is generally expressed by the term, lethal dose $LD_{50/60}$, defined by the dose that kills 50% of the species in 60 days. For humans, the $LD_{50/60}$ is 400–600 rad (400–600 cGy).

Acute syndromes caused by radiation appear in four stages: prodromal, latent, manifest illness, and recovery or death. In the prodromal stage, nausea, vomiting, and diarrhea occur at a dose of about 50 rad (50 cGy). In the latent stage, internal cellular damage occurs with no visible syndrome, whereas in the manifest illness stage, specific syndromes appear making the species ill. In the last stage, the subject either recovers or dies. All four stages occur at a minimum dose of 200–300 rad (200–300 cGy). There are three tiers of syndromes in manifest illness, based on the dose applied.

12.5.1 Hematopoietic Syndromes

These syndromes appear at a total-body irradiation with a dose of 250–500 rad (250–500 cGy), which largely damages the erythrocytes, white blood cells, platelets, and lymphocytes. Loss of blood counts is noticed at a dose of 10–15 rad (10–15 cGy). The immunity of the body is compromised, and infection, fever, and bleeding set in, and ultimately death may occur in 10–21 days. At a low dose of radiation, appropriate medical treatment with antibiotics and steroids may help recovery. In some cases, bone marrow transplantation helps survival, depending on the dose.

12.5.2 Gastrointestinal Syndromes

These syndromes appear at whole-body dose of 500–1000 rad (500–1000 cGy). Initial prodromal syndromes of severe nausea, vomiting, and diarrhea appear within hours of exposure, followed by loss of crypt cells in the intestine that renders the gut nonfunctional. Ulceration of the stomach and the intestine, loss of nutrients, and infection lead to death in 3–10 days. Aggressive treatment rarely helps the species survive at the low end of the dose exposure.

12.5.3 Cerebrovascular Syndromes

These syndromes require a total-body dose of greater than 5000–10,000 rad (5000–10,000 cGy) to appear, because the nerve cells are radiation resistant. They appear in a few minutes after radiation exposure and consist of prodromal syndromes of nausea, vomiting, and burning sensation of the skin, followed by motor incoordination, stupor, coma, and ultimately death in 2–3 days.

12.6 Long-Term Effects of Radiation

The long-term effects of radiation on living species appear long after the radiation exposure, delayed by possible years and decades. The exposure may be a single large exposure causing acute syndromes followed by late effects, or fractionated small exposures over a period of time. Both somatic cells and germ cells are affected by the late effects of radiation exposure. Carcinogenesis, cataractogenesis, and embryogenic damage are caused by mutation of somatic cells, whereas genetic effects result in hereditary abnormalities such as Down's syndromes, cystic fibrosis, etc.

12.6.1 Carcinogenesis

Cancer is caused by proliferation of abnormal cells, which are mutated by various agents such as chemicals, radiations, and viruses. In general, radiation-induced cancers are late somatic effects of radiation exposure and can result from very low doses of radiation exposure such as occupational and diagnostic exposures, or from high radiation exposure such as exposure to nuclear accidents, spill, etc. In the latter case, initially the subject suffers from acute radiation syndromes described above, depending on the exposure dose, and when the syndromes disappear over time, carcinogenesis sets in as delayed effects.

Normal cells contain two important genes, proto-oncogenes and suppressor genes, of which the former promotes cell growth and the latter suppresses it. When proto-oncogenes are mutated, they become oncogenes that cause excessive proliferation of cancer cells. Suppressor genes such as p53 gene do not promote cell growth but control it and protect the cells against carcinogenic agents. Radiation can

inactivate suppressor genes and thus favor cell proliferation leading to malignancy. As many as 50% of human tumors have been found to contain mutated p53 genes. Radiation may also promote proliferation of tumor cells by immunosuppression.

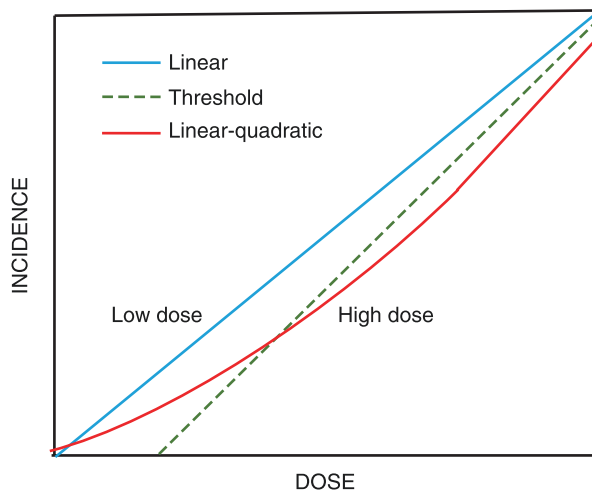
Leukemia, most lymphomas, and germ cell tumors are very sensitive to radiation. The majority of epithelial cancers (carcinomas) have only moderate radiosensitivity. Some cancers, such as renal cell cancer and melanoma, are highly radioresistant, requiring higher doses for radiation treatment.

12.6.2 Dose–Response Relationship

The risk of carcinogenesis is assessed mostly from experimental data of radiation exposures on living species and is expressed by a dose–response relationship. Many national and international organizations, namely the United Nations Scientific Committee of the Effects of Atomic Radiations (UNSCEAR), the Committee on the Biological Effects of Radiations (BEIR), the International Commission on Radiological Protection (ICRP), and the National Council on Radiation Protection and Measurement (NCRP), assess the risk estimates and establish the dose–response relationships, based on the data from the Japanese survivors of the Atomic bomb attacks on Hiroshima and Nagasaki, epidemiologic data, and animal and in vitro studies. Most low-dose exposure data are difficult to assess and inconclusive and are essentially obtained by extrapolation from high-dose exposure data.

A contentious debate continues for a long time as to whether there is a threshold dose of radiation exposure (minimum dose) for cancer induction, or a very insignificant dose can cause cancer. One group of experts advocate a linear-non-threshold (LNT) dose–response theory based on the extrapolation of high-dose data to low-dose risks (Fig. 12.4), arguing that even a single hit by radiation can cause mutation of a cell that can lead to cancer as late effect. The BEIR VII (2005) strongly supports

Fig. 12.4 Dose response curves based on three concepts proposed by different groups. Low-dose data are obtained by extrapolation of high-dose data



the LNT theory. Opponents of the LNT theory argue that the mechanism of cell damage at low doses may be quite different from that at high doses, thus nullifying the justification of extrapolation. These experts believe that the immune system is enhanced at a low-dose exposure, whereby cancer cells are fought off and the risk of cancer is reduced. This situation is called radiation hormesis. Support for hormesis comes from people living in high background radiation areas (e.g., Colorado) who do not show any increased risks of cancer compared to those living at sea level. Cataractogenesis is an example, which requires a threshold dose of 200 rad (200 cGy) to occur.

A group of experts obtained a linear-quadratic curve (Fig. 12.4) from the data of Japanese Atomic bomb survivors, which is linear at low doses and becomes proportional to D^2 (quadratic) at higher doses. Yet another group believe that there is a threshold dose below which there is no risk of carcinogenesis and above which the dose response curve becomes linear or quadratic. There is a contention that the linear response model holds good for solid tumors, whereas the linear-quadratic model fits well with leukemia.

Based on the LNT theory and various epidemiological studies (Japanese Atomic bomb survivors, medical, and occupational radiation exposures, etc.), the BIER VII (2005) has estimated that 1 in 100 persons exposed to a low dose of 10 rem (100 mSv) is expected to develop solid tumor or leukemia. In contrast, approximately 42 of 100 individuals who are not exposed to radiation would develop cancers from other causes such as smoking, exposure to chemicals, pollution, etc.

12.6.3 Specific Cancers

Leukemia: Radiation exposure can induce leukemia and its risk varies with age, the younger persons being more susceptible to radiocarcinogenesis. It accounts for 1 in 5 mortalities due to radiation-induced cancers. Leukemia appears in 2–3 years after exposure and peaks in approximately 12 years after radiation exposure.

In statistics, a term *person-year* is often cited for expressing incidence rate, which is defined by the number of people in the study times the number of years each person spends in the study. For example, a study that follows 1000 people for 2 years would contain 2000 person-years of data. According to the BIER VII (2005), 1–2.6 per 100 person-years per rad (1–2.6 per 10,000 person-years per Gy) will have an excess risk of radiocarcinogenesis.

Thyroid cancer: Radiation-induced thyroid cancer appears mostly as papillary adenocarcinoma almost 5–35 years after the exposure. In the past, children were treated with external radiation for enlarged thymus glands, skin angiomas, adenoids or neck lymph nodes, acne, otitis, or tinea capitis. These high-dose radiation exposures cause thyroid cancer in later years. The excess relative risk of thyroid cancer at age 60 after exposure at 1Gy at age 10 was estimated as 1.28. Radiation also can

induce thyroiditis and hypothyroidism. External exposure is more effective than internal irradiation in causing thyroid cancer. Ironically, ^{131}I treatment is used for killing the residual thyroid cancer cells after ablation.

Breast Cancer: Breast cancer is the common cancer in women accounting for nearly 200,000 new incidences per year in the USA and one in 30 breast cancer patients has the risk of dying. Various factors such as age, estrogen level, race, demographics, number of offspring, breast-feeding, etc. affect radiocarcinogenesis in the breast. The BIER VII estimate of the absolute risk of breast cancer is 10 per 100 person-years per rad (10 per 10,000 person-years per Gy) at age 50.

In the past, there was a risk of breast cancer from radiation exposure from mammography, and frequent mammography in women, particularly at younger age, was not recommended. Nowadays, the mammography equipment is well designed and shielded, so the risk of cancer is minimized. The American College of Radiology recommends that women over age 40 should have annual mammography screening for breast cancer, outweighing the benefit over risk of cancer.

12.6.4 Skin Damage

Radiation can cause damage to skin because of radiosensitive hair follicles and sebaceous glands, and the severity of damage depends on the extent of exposure. A minimum of 100 rad (100 cGy) is required to induce any noticeable erythema symptoms on the skin. Common radiation exposure is encountered in radiation therapy of cancer patients, in which the radiation beam projected to a cancer location crosses the skin causing radiation dermatitis or burn. General symptoms of skin burn include erythema (redness), itching, soreness, flaking, blistering, fibrosis, pigmentation change, and ulceration. Initial erythema appears in a few hours to a few days after exposure, followed by dry desquamation characterized by atrophy of epidermis, and red, tender, and edematous skin reappears a few weeks later. Temporary hair loss (epilation) may occur at this stage. The normal skin may reappear in 2–3 months after exposure.

Radiation effects on skin depend on the dose, dose rate, and LET of radiation. Also younger people are more prone to skin damage by radiation exposure. Rarely, skin cancer is caused by radiation exposure.

12.6.5 Cataractogenesis

Ionizing radiation can cause cataract in the eyes due to the sensitivity of the lens to radiation. However, it requires a threshold dose of about 200 rad (2 Gy) to occur in humans, and its incidence increases with high dose and high-LET radiation. The latent period for cataractogenesis is about a year.

12.7 Radiation Damage to Embryo and Fetus

During the gestational period, the embryo develops into a fetus in three stages and the effects of radiation in each stage are described below.

12.7.1 Preimplantation Period

It is the period of 8–10 days when an embryonic egg is formed by fusion of a male sperm and a female ovum, which is then attached to the uterus wall. Cells in this embryonic stage are extremely radiosensitive and the embryonic death is certain at a dose of 200 rad (200 cGy).

12.7.2 Major Organogenesis

In this period, all major organs are developed during the next 2–6 weeks, and radiation affects the central nervous system and skeleton resulting in growth retardation, microcephaly, and neonatal death at a dose of ~200 rad (~200 cGy). Often, therapeutic abortion is suggested if the embryo receives ~10 rad (10 cGy) during first 6 weeks of gestation.

12.7.3 Fetal Stage

It is the remaining period of pregnancy when all organs are fully developed to sustain life after birth. Because fetal cells are differentiated and hence relatively radio-resistant, radiation effects are not as deleterious. However, in utero irradiation during the fetal stage with a dose of 1–2 rad (1–2 cGy) increases the risk of leukemia in the offspring by a factor of 1.5 to 2 during the first 10–15 years of life. Loss of IQ has been noted in individuals born after fetal irradiation. Mental retardation has been reported with a dose as low as 10–50 rad (10–50 cGy) if given within 8–15 weeks of gestation.

Because of the adverse effects of radiation on embryo and fetus, radiological procedures are contraindicated in pregnant women. It is a common practice for the practitioners to confirm, prior to radiological procedures if the patient of childbearing age is pregnant or not. If pregnant, the risk versus benefit must be weighed to continue with the procedure.

12.8 Genetic Effects

Germ cells are mutated by radiation due to damage to the DNA structure. Mutated cells undergo meiosis (germ cell division) in the irradiated individual but no genetic defect appears in the individual. However, delayed effects appear in future

generations with a frequency of 1 in 10,000. *Spontaneous mutation* happens to occur in normal cells by various mutagens such as chemicals and viruses. Genetic mutations themselves do not produce any visible abnormalities, but increase the frequency of spontaneous mutations.

The risk of genetic mutation is expressed in terms of a parameter called the *doubling dose*. It is defined as the radiation dose that would cause additional mutations equal in number to those that already occur naturally from all other causes, thereby doubling the rate of mutation. Attempts have been made to estimate the doubling dose for humans, but all studies are based on animal experiments or follow-up of the offspring of Japanese survivors of atomic bombs and non-exposed population. While animal data are variable, no excess risk of genetic disorder was evident in the descendants of the Japanese survivors. However, the most plausible estimate for the doubling dose for humans has been 100 rem (1 Sv), but it depends on the gender and the dose rate.

Because of the repair process in the affected genes, genetic adverse effects are mitigated over time after radiation exposure. For these reasons, it is advisable for both men and women that conception be deferred for at least 6 months particularly following radiation therapy or radiation accidents involving high gonadal exposure. For diagnostic procedures involving radiations, such delay in conception is not warranted.

12.9 Risk Versus Benefit in Diagnostic Radiology and Nuclear Medicine Procedures

Millions of procedures involving X-rays, CT, fluoroscopy, dental X-rays in radiology and using radionuclides in nuclear medicine are performed for the diagnosis and treatment of human diseases. The number is ever increasing over time, as new procedures such as CT angiography, PET/CT, etc. are being introduced. However, many health organizations, the US FDA, the NRC are making a concerted effort to minimize the radiation exposure without compromising the efficacy of the test. Manufacturers of the equipment are diligently working to improve the quality of the equipment. Despite all these efforts, there is always some risk involved with any radiological and nuclear medicine procedures.

Dental and chest X-rays give low radiation exposure causing minimal somatic and genetic damage. On the other hand, CT and fluoroscopy provide the highest radiation exposure and hence the highest cell damage. However, the position of the organ in radiologic imaging determines the genetic risk. For example, radiological procedures involving the hip and the pelvis provide a very high gonadal dose, whereas those of upper extremities contribute very negligible gonadal dose due to their position farther away from gonads. In the former procedures, protective lead shields over the gonads are employed to minimize the exposure.

The absorbed doses to different organs from different nuclear medicine procedures are given in Table 3.7 (Chap. 3), and the effective doses from each procedure are listed in Table 3.10 (Chap. 3). Procedures using long-lived and β -emitting

radionuclides give higher dose to the organs than using the X-rays or γ radiations. Overall, nuclear medicine procedures cause less somatic and genetic damage than radiological procedures, except some therapeutic procedures with α and β^- particle-emitting radionuclides because of their high LET effect.

Even though the risk is low from diagnostic procedures involving radiation, based on the LNT theory, there is no reason to believe that there is no risk even at very low radiation exposures. The acute syndromes may not be evident at low doses, but late long-term effects such as carcinogenesis and teratogenesis from fetal exposure, etc., may still appear years later. Genetic risk is even more elusive in expression at low doses, as they may appear in generations later.

Diagnostic tests in radiology and nuclear medicine are essential for immediate assessment of human diseases despite some risks involved so that appropriate treatment can be instituted. Risk vs benefit should be analyzed and a judicious decision be made as to whether the test should be conducted. In the absence of any alternative, the test should be performed with a technique that offers minimum radiation exposure. Reasonable use of radiological tests should be adopted for screening procedures too. In screening, many individuals are exposed to radiation, but only a small number benefit from it, as many turn out negative. For example, the American College of Radiology recommends annual mammography for women over 40 years., sparing younger women from unnecessary radiation exposure, because they are more susceptible to radiation damage.

Diagnostic tests involving radiation are contraindicated in pregnant women because of the deleterious effects on the embryo and fetus. Embryos are more affected even at low doses, whereas higher doses are needed for fetal damage, because fetal cells are relatively radioresistant. Nuclear medicine procedures are more damaging, because the radiotracer resides in the body for a relatively longer time and can cross the placenta causing fetal damage. It is, therefore, a prudent and common practice to confirm the pregnancy prior to a radiological test on women and to avoid the procedure, if positive. The woman should be asked if she is pregnant or when she had the last menstrual period. Radioiodine administered orally to pregnant women during the gestation period of 15–22 weeks can cross the placenta and localize in the fetal thyroid to the extent of 50–75%. The fetal thyroid dose at 6 weeks of gestation is of the order of 7.8 rad/mCi (2.1 Gy/MBq) (Watson 1991).

At times, it is discovered after the test that the woman is pregnant. In that situation, the fetal dose is calculated and a decision needs to be made as to continuing with pregnancy or terminating it. Some experts suggest abortion at a fetal dose of 10 rad (10 cGy). However, abortion depends on a number of social, legal, and familial issues.

Radionuclide therapy of pregnant women is absolutely prohibited because of deleterious effects on the fetus. Radioiodine used for treating hyperthyroidism in pregnant women can localize in the fetal thyroid and cause thyroid cancer in later years.

Questions

1. Radiation causes damage to cells by breaking the DNA structure. True _____, or False _____.
2. No level of exposure to ionizing radiation can be considered to be without risk because:
 - (a) there may be no threshold dose for some cancers
 - (b) genetic effects may be caused by single ionizing events
 - (c) all cells pass through mitosis
 - (d) acute radiation symptoms have been observed at mrad doses
3. The cell replication cycle consists of the G1, S, G2, and M phases. The most variable phase in time is
 - (a) G1
 - (b) S
 - (c) G2
 - (d) M
4. Match the following:

(a) DNA replication	(a) endothelial reticulum
(b) Protein synthesis	(b) Lysosome
(c) Energy production	(c) Nucleus
(d) Disposal of unnecessary	(d) Mitochondria material
5. Match the following:

(a) Hematopoietic syndrome	(a) 500–1000 rad
(b) Cerebrovascular syndrome	(b) 400–600 rad
(c) Gastrointestinal syndrome	(c) 250–500 rad
(d) LD _{50/60} for humans	(d) 5000–10,000 rad
6. In the BIER VII (2005) estimate, _____ in 100 persons exposed to a low-dose of 10 rem (100 mSv) is expected to develop solid tumors or leukemia.
 - (a) 3
 - (b) 4
 - (c) 1
 - (d) 6
7. What are the three stages in gestation period considered for radiation damage?
8. Estimates are that an *in utero* exposure of 1 to 2 rad of external radiation increases the risk of leukemia by a factor of _____.
 - (a) 0.5 to 1.5
 - (b) 1.5 to 2.0
 - (c) 2.0 to 2.5

- (d) 2.5 to 3.0.
9. The Committee on Biological Effects of Ionizing Radiation (BEIR) of the National Academy of Sciences now uses the _____ model for evaluating the somatic effects of low-level ionizing radiation.
- (a) linear-quadratic, no threshold
 - (b) linear, threshold
 - (c) linear, no threshold
 - (d) linear-quadratic, threshold
10. Which of the following is/are most likely to result from irradiation during the preimplantation period of embryonic development?
- (a) malformations
 - (b) growth retardation
 - (c) intrauterine death
 - (d) death in the first year of life
11. The BIER VII estimate of the absolute risk of breast cancer per 100 person-years per rad (cGy) at age 50 is
- (a) 30
 - (b) 10
 - (c) 15
 - (d) 25
12. Mutated cells undergo meiosis (germ cell division) in the irradiated individual but no genetic defect appears in the individual. However, delayed effects appear in future generations with a frequency of
- (a) 10 in 1000
 - (b) 3 in 1000
 - (c) 20 in 1000
 - (d) 1 in 10,000
13. The most likely consequence of an acute radiation dose of 50 rad (0.5 Gy) during the 8 to 15 week of gestation period is
- (a) fetal death
 - (b) mental retardation
 - (c) childhood malignancy
 - (d) congenital heart disease
14. Describe (a) apoptosis and (b) hormesis.

References and Suggested Reading

- American Cancer Society. Radiation exposure and cancer. Atlanta, GA; 2003.
- BEIR VII. Phase 2. Health risks from exposure to low levels of ionizing radiation. Washington, DC: National Academy of Sciences/National Research Council; 2005.
- Hall E, Giaccia AJ. Radiobiology for the radiologist. 8th ed. Philadelphia: Wolters Kluwer; 2018.
- Watson EE. Radiation absorbed dose to the human fetal thyroid. 5th international radiopharmaceutical dosimetry symposium. Oak Ridge, TN; 1991.

Appendix A: Characteristics of Common Radionuclides

Nuclides	Physical half-life	Mode of decay (%)	γ -ray energy (MeV)	Abundance (%)
^3_1H	12.3 y	β^+ (100)	–	–
$^{11}_6\text{C}$	20.4 min	β^+ (100)	0.511 (annihilation)	200
$^{13}_7\text{N}$	10 min	β^+ (100)	0.511 (annihilation)	200
$^{14}_6\text{C}$	5730 y	β^+ (100)	–	–
$^{15}_8\text{O}$	2 min	β^+ (100)	0.511 (annihilation)	200
$^{18}_9\text{F}$	110 min	β^+ (97) EC(3)	0.511 (annihilation)	194
$^{32}_{15}\text{P}$	14.3 d	β^+ (100)	–	–
$^{51}_{24}\text{Cr}$	27.7 d	EC(100)	0.320	9
$^{52}_{26}\text{Fe}$	8.3 h	β^+ (56)	0.165	100
		EC(44)	0.511 (annihilation)	112
$^{57}_{27}\text{Co}$	271 d	EC(100)	0.014 0.122 0.136	9 86 11
$^{58}_{27}\text{Co}$	71 d	β^+ (14.9) EC(85.1)	0.511 (annihilation) 0.811	30 99.5
$^{59}_{26}\text{Fe}$	45 d	β^+ (100)	1.099 1.292	56 43
$^{60}_{27}\text{Co}$	5.2 y	β^+ (100)	1.173 1.332	100 100
$^{62}_{29}\text{Cu}$	9.7 min	β^+ (97)	0.511 (annihilation)	194
$^{64}_{29}\text{Cu}$	12.1 h	EC(3)		
		β^+ (17.9)	0.511 (annihilation)	36
		β^+ (39)		
		EC(43)		

Nuclides	Physical half-life	Mode of decay (%)	γ -ray energy (MeV)	Abundance (%)	
⁶⁷ ₂₉ Cu	2.6 d	β^- (100)	0.185	49	
			0.92	23	
⁶² ₃₀ Zn	9.3 h	β^+ (8)	0.420	25	
			EC(92)	0.511 (annihilation)	16
				0.548	15
				0.597	26
⁶⁷ ₃₁ Ga	78.2h	EC(100)	0.093	40	
			0.184	20	
			0.300	17	
			0.393	5	
			0.511 (annihilation)	178	
⁶⁸ ₃₁ Ga	68 min	β^+ (89) EC(11)	0.511 (annihilation)	178	
⁶⁸ ₃₂ Ge	270.8 d	EC(100)	–	–	
⁸² ₃₇ Rb	75 s	β^+ (95) EC(5)	0.511 (annihilation)	190	
			776	13	
⁸² ₃₈ Sr	25.5 d	EC(100)	–	–	
⁸⁹ ₃₈ Sr	50.6 d	β^- (100)	–	–	
⁹⁰ ₃₈ Sr	28.6 y	β^- (100)	–	–	
⁹⁰ ₃₉ Y	2.7 d	β^- (100)	–	–	
⁸⁹ ₄₀ Zr	78.1 h	β^+ (23) EC(77)	0.511 (annihilation)	46	
			909	100	
⁹⁹ ₄₂ Mo	66 h	β^- (100)	0.181	6	
			0.740	12	
			0.780	4	
^{99m} ₄₃ Tc	6.0 h	IT(100)	0.140	90	
¹¹¹ ₄₉ In	2.8 d	EC(100)	0.171	90	
			0.245	94	
^{113m} ₄₉ In	100 min	IT(100)	0.392	64	
¹²³ ₅₃ I	13.2 h	EC(100)	0.159	83	
¹²⁴ ₅₃ I	4.2 d	β^+ (23) EC(77)	0.511 (annihilation)	46	
¹²⁵ ₅₃ I	60 d	EC(100)	0.035	7	
			X ray (0.027–0.032)	140	
¹³¹ ₅₃ I	8.0 d	β^- (100)	0.284	6	
			0.364	81	
			0.637	7	
¹³³ ₅₄ Xe	5.3 d	β^- (100)	0.081	37	

Nuclides	Physical half-life	Mode of decay (%)	γ -ray energy (MeV)	Abundance (%)
$^{137}_{55}\text{Cs}$	30.0 y	β^{-} (100)	0.662	85
$^{153}_{62}\text{Sm}$	1.9 d	β^{-} (100)	70	5
			103	28
$^{153}_{64}\text{Gd}$	241.6 d	EC (100)	97	28
			103	20
$^{177}_{71}\text{Lu}$	6.65 d	β^{-} (100)	–	–
$^{186}_{75}\text{Re}$	3.8 d	β^{-} (92) EC(8)	137	9
$^{188}_{74}\text{W}$	69.8 d	β^{-} (100)	155	15
$^{201}_{81}\text{Tl}$	73 h	EC(100)	167	9.4
			X ray (0.069–0.083)	9.3
$^{223}_{88}\text{Ra}$	11.4 d	α (95.3) β^{-} (3.6)		

Appendix B: Units and Constants

Energy

- 1 electron volt (eV) = 1.602×10^{-12} erg
1 kiloelectron volt (keV) = 1.602×10^{-9} erg
1 million electron volts (MeV) = 1.602×10^{-6} erg
1 joule (J) = 10^7 ergs
1 watt (W) = 10^7 ergs/s
= 1 J/s
1 rad = 1×10^{-2} J/kg = 100 ergs/g
1 gray (Gee) = 100 rad
= 1 J/kg
1 sievert (Svi) = 100 rem
= 1 J/kg
1 horsepower (HP) = 746 W
1 calorie (call) = 4.184 J

Charge

- 1 electronic charge = 4.8×10^{-10} electrostatic unit (so)
= 1.6×10^{-19} coulomb
1 coulomb (C) = 6.28×10^{18} charges
1 ampere (A) = 1 C/s

Mass and Energy

- 1 atomic mass unit (amu) = 1.66×10^{-24} g
= 1/12 the atomic weight of ^{12}C
= 931 MeV
1 electron rest mass = 0.511 MeV

Appendix C: Answers to Questions

Chapter 1

1. b
3. mass defect; binding energy
4. c
5. True
6. c
7. False; True; False; False
8. False; True; True; False
9. b, c, e
10. d
13. 1.9×10^{12} dps
14. 3.25 min
15. 4.96 mCi
16. 1.34 d
17. c
18. c
19. c
20. $N/4$ atoms
21. b
22. c
23. b
24. a
25. d
26. a
27. b
28. d
29. b.c.d
30. b
31. c
32. 13.3 HVLs

Chapter 2

1. True
3. d
6. d
7. c
8. d
10. c
11. c
12. a
13. d
14. c
16. c
17. c
20. d
21. 43.7%; hyperthyroid
22. d

Chapter 3

2. 0.15 gray; 0.15 rem; 0.0015 Sv
4. 0.5 mrem/h ($5\mu\text{Sv/h}$)
5. c
6. c
7. d
8. a
9. b
10. d
11. d
12. c
13. b
14. c
15. c
16. c
17. b
18. a
19. b
20. 0.8 mR/h
21. 1.25 rad or cGy
22. a – 6.6; b – 3.52; c – 0.33
23. 4430 rad
24. 2.67 rad/mCi

Chapter 4

- 2. c
- 3. c
- 4. 73 mR; 7.3 μ Gy
- 5. 10%
- 6. 0.87 cm
- 9. 10.7 cm
- 10. d
- 13. d
- 16. c

Chapter 5

- 1. c
- 3. c

Chapter 6

- 1. c
- 2. b
- 3. a
- 4. b
- 6. c
- 7. d
- 8. b
- 9. c
- 10. a
- 11. d
- 13. b
- 14. c
- 16. a
- 17. c
- 18. d
- 20. d
- 21. b

Chapter 7

- 2. (a) – 80 h; (b) – 620 h
- 7. True

Chapter 8

2. b
 3. b
 4. False
 5. a. potassium iodide for ^{131}I uptake
b. prussian blue for ^{137}Cs uptake
 6. b
 7. a, b, d, c
 9. d
-

Chapter 9

1. Yes
 2. b
 3. d
 4. b
 5. 2.31 d
 6. c
 7. Yes
 10. d
 11. 18.6 mCi
-

Chapter 10

1. c
 2. d
 3. b
 4. d
 5. c
 6. b
 8. b
 10. True
 11. b
 12. d
-

Chapter 11

2. c
4. c
9. d
10. c

- 11. False
- 12. 59.8 h

Chapter 12

- 1. True
- 2. a
- 3. a
- 6. c
- 8. b
- 9. c
- 10. c
- 11. b
- 12. d
- 13. d
- 14. b

Appendix D: Terms Used in the Text

Absorption	A process by which the energy of a radiation is removed by an absorber through which it passes.
Accuracy	A term used to indicate how close a measurement of a quantity is to its true value.
Annihilation radiation	γ -Radiations of 511 keV energy emitted at 180° after a β^+ -particle is annihilated by combining with an electron in matter.
Atomic mass unit (amu)	By definition, one twelfth of the mass of $^{12}_6\text{C}$, equal to 1.66×10^{-24} g or 931 MeV.
Atomic number (Z)	The number of protons in the nucleus of an atom.
Attenuation	A process by which the intensity of radiation is reduced by absorption and/or scattering during its passage through matter.
Attenuation coefficient	The fraction of γ -ray energy attenuated (absorbed plus scattered) per unit length of an absorber (linear attenuation coefficient, μ_l) or per gram of an absorber (mass attenuation coefficient, μ_m).
Auger electron	An electron ejected from an energy shell, instead of a characteristic X-ray emission, carrying the energy equal to that of the X-ray minus its binding energy.
Average life (τ)	<i>See</i> Mean life.
Becquerel (Bq)	A unit of radioactivity. One becquerel is equal to 1 disintegration per second.

Binding energy	The energy to bind two entities together. In a nucleus, it is the energy needed to separate a nucleon completely from other nucleons in the nucleus. In a chemical bond, it is the energy necessary to separate two binding partners by an infinite distance.
Biological half-life (T_b)	The time by which one half of an administered dosage of a substance is eliminated by biological processes such as urinary and fecal excretions.
Bremsstrahlung	γ -Ray photons produced by deceleration of charged particles passing near the nucleus of an absorber atom.
Committed dose equivalent ($H_{T,50}$)	The dose equivalent to organs or tissues of reference (T) that will be received from an intake of radioactive material by an individual during the 50-year period following intake.
Compton scattering	In this process, a γ -ray transfers only a partial amount of its energy to an outer orbital electron of an absorber which is ejected, and the photon itself is deflected with less energy. The scattered photon may exit from the medium, may be absorbed by the photoelectric effect, or may undergo another Compton scattering depending on the energy.
Conversion electron (e^-)	<i>See</i> Internal conversion.
Curie (Ci)	A unit of activity. A curie is defined as 3.7×10^{10} disintegrations per second.
Dead time	The period of time that a counter remains insensitive to count the next after a count.
Decay constant (λ)	The fraction of atoms of a radioactive element decaying per unit time. It is expressed as $\lambda = 0.693/t_{1/2}$, where $t_{1/2}$ is the half-life of the radionuclide.
Deep-dose equivalent (H_d)	Dose equivalent at a tissue depth of 1 cm (1000 mg/cm^2) resulting from external whole-body exposure.
Dosage	The term for administered activity.
Dose	The energy of radiation absorbed by any matter.

Dosimeter	An instrument to measure the cumulative dose of radiation received during a period of radiation exposure.
Dosimetry	The calculation or measurement of radiation absorbed doses.
Effective dose	The sum of the products of the committed dose equivalent to each of the body organs and tissues and the weighting factor of the corresponding organ or tissue. ($H_e = \sum W_T \times H_T$, 50).
Effective half-life (T_e)	Time required for an initial administered dosage to be reduced to one half as a result of both physical decay and biological elimination of a radionuclide. It is given by $T_e = (T_p \times T_b)/(T_p + T_b)$, where T_e is the effective half-life, and T_p and T_b are the physical and biological half-lives, respectively.
Electron (e^-)	A negatively charged particle rotating around the atomic nucleus. It has a charge of 4.8×10^{-10} electrostatic unit and a mass of 9.1×10^{-28} g, equivalent to 0.511 MeV, or equal to 1/1836 of the mass of a proton.
Electron capture (EC)	A mode of decay of a proton-rich radionuclide in which an orbital electron is captured by the nucleus, accompanied by emission of a neutrino and characteristic X-rays or Auger electrons.
Electron volt (eV)	The kinetic energy gained by an electron when accelerated through a potential difference of 1 V.
Energy resolution	Capability of a detecting system to separate two γ -ray peaks of different energies. It is given by the full width at half maximum (FWHM) of a given photopeak.
Erg	The unit of energy or work done by a force of 1 dyne through a distance of 1 cm.
Free radical	A highly reactive chemical species that has one or more unpaired electrons.
Gray (Gy)	The unit of radiation absorbed dose in SI units. One gray is equal to 100 rad.
Half-life ($t_{1/2}$)	A unique characteristic of a radionuclide, defined by the time during which an initial activity of a radionuclide is reduced to one half. It is related to the decay constant λ by $t_{1/2} = 0.693/\lambda$.

Half-value layer (HVL)	The thickness of an absorbing material required to reduce the intensity or exposure of a radiation beam to one half of the initial value when placed in the path of the beam.
Internal conversion	An alternative mode to γ -ray decay in which nuclear excitation energy is transferred to an orbital electron, which is then ejected from the orbit.
Isobars	Nuclides having the same mass number, that is, the same total number of neutrons and protons. Examples are $^{57}_{26}\text{Fe}$ and $^{57}_{27}\text{Co}$.
Isomeric transition (IT)	Decay of the excited state of an isomer of a nuclide to a lower excited state or the ground state.
Isomers	Nuclides having the same atomic and mass numbers but differing in energy and spin of the nuclei. For example, ^{99}Tc and ^{99m}Tc are isomers.
Isotones	Nuclides have the same number of neutrons in the nucleus. For example, $^{131}_{53}\text{I}$ and $^{132}_{54}\text{Xe}$ are isotones.
Isotopes	Nuclides having the same atomic number, that is, the same number of protons in the nucleus. Examples are $^{14}_6\text{C}$ and $^{12}_6\text{C}$.
Kerma	The sum of kinetic energies of all charged particles liberated by an uncharged ionizing radiation passing through per unit mass of material. It is identical to rad for all practical purposes but measures only energy liberated rather than energy absorbed.
$\text{LD}_{50/60}$	A quantity of a substance that, when administered or applied to a group of living species, kills 50% of the group in 60 days.
Linear energy transfer (LET)	Energy deposited by a radiation per unit length of the matter through which the radiation passes. Its usual unit is $\text{keV}/\mu\text{m}$.
Mass defect	The difference between the mass of the nucleus and the combined masses of individual nucleons in the nucleus of a nuclide.
Mass number (A)	The total number of protons and neutrons in a nucleus of a nuclide.

Mean life (τ)	The average expected lifetime of a group of radionuclides before disintegration. It is related to the half-life and decay constant by $\tau = 1/\lambda = 1.44 t_{1/2}$.
Metastable state (m)	An excited state of a nuclide that decays to a lower excited or the ground state by isomeric transition with a measurable half-life.
Neutrino (ν)	A particle of no charge and mass emitted with variable energy during β^+ , and electron capture decays of radionuclides.
Nucleon	An antineutrino ($\bar{\nu}$) is emitted in β^- decay. A common term for neutrons or protons in the nucleus of a nuclide.
Pair production	γ -Rays with energy greater than 1.02 MeV interact with the nucleus of an absorber atom, and a positron and an electron are produced at the expense of the photon.
Photoelectric effect	A process in which a γ -ray, while passing through an absorber, transfers all its energy to an orbital electron, primarily the <i>K</i> -shell electron of the absorber, and the photoelectron is ejected from the shell.
Physical half-life (T_p)	<i>See</i> Half-life.
Precision	A term used to indicate the reproducibility of the measurement of a quantity when measurements are made repeatedly.
Quality factor (QF)	A factor dependent on linear energy transfer that is multiplied by absorbed doses to calculate the dose equivalents in rem. It is used in radiation protection to take into account the relative radiation damage caused by different radiations. It is 1 for X-, γ -, and β -rays, 10 for protons, and varying values for neutrons of different energies.
Rad	The unit of radiation-absorbed dose. One rad is equal to 100 ergs of radiation energy deposited per gram of any matter, or 10^{-2} J/kg of any matter.
Radiation weighting factor (W_r)	A factor that depends on the types of radiation and is used to convert rad to rem in radiation protection. $\text{Rem} = \text{rad} \times W_r$.
Range	The straight-line distance traversed by a charged particle in an absorber.

Relative biologic effectiveness (RBE)	A factor used to calculate the dose equivalent in rem from rad. It is defined as the ratio of the amount of a standard radiation that causes certain biological damage to the amount of radiation in question that causes the same biological damage.
Roentgen	The quantity of x - or γ -radiations that produces one electrostatic unit of positive or negative charge in 1 cm ³ of air at 0 °C and 760-mm Hg pressure (standard temperature and pressure, STP). It is equal to 2.58×10^{-4} C/kg air.
Roentgen equivalent man (rem)	A dose equivalent defined by the absorbed dose (rad) times the relative biological effectiveness or quality factor of the radiation in question.
Shallow-dose equivalent (H _s)	Dose equivalent at a tissue depth of 0.007 cm (7 mg/cm ²) averaged over an area of 1 cm ² from external exposure to the skin.
Specific ionization	The number of primary and secondary ion pairs produced by an incident radiation per unit path length in an absorber.
Tissue weighting factor (W _T)	The weighting factor of an organ or tissue is the proportion of risk of stochastic effects resulting from irradiation of that organ or tissue to the total risk of stochastic effects when the total body is irradiated uniformly.

Appendix E: Abbreviation Used in Text

ABHP	American Board of Health Physics
ABMP	American Board of Medical Physics
ABNM	American Board of Nuclear Medicine
ABR	American Board of Radiology
ABSNM	American Board of Science in Nuclear Medicine
ACR	American College of Radiology
AEC	Atomic Energy Commission
ALARA	As low as reasonably achievable
ALI	Annual limit on intake
AMP	Authorized medical physicist
ANP	Authorized nuclear pharmacist
AOBR	American Osteopathic Board of Radiology
AOBNM	American Osteopathic Board of Nuclear Medicine
ARSO	Associate Radiation Safety Officer
AU	Authorized user
BPSNP	Board of Pharmaceutical Specialties in Nuclear Pharmacy
CBNC	Certification Board of Nuclear cardiology
CBNE	Certification Board of Nuclear Endocrinology
CCPM	Canadian College of Physicists in Medicine
d	day
DAC	Derived air concentration
DOT	Department of Transportation
EC	Electron capture
FDA	Food and Drug Administration
GM	Geiger-Muller
h	Hour
HVL	Half-value layer
IAC	Intersocietal Accreditation Commission
ICRP	International Committee on Radiation Protection
IND	Notice of Claimed Investigational Exemption for a New Drug
IRB	Institutional Review Board
IT	Isomeric transition
keV	Kilo electron volt

LET	Linear energy transfer
m	meter
MDA	Minimum detectable activity
MeV	Million electron volt
min	minute
MIRD	Medical internal radiation dose
mo	month
MPC	Maximum permissible concentration
NARM	Naturally occurring and accelerator-produced radioactive materials
NCRP	National Council on Radiation Protection and Measurement
NDA	New Drug Application
NEMA	National Electrical Manufacturers' Association
NRC	Nuclear Regulatory Commission
PET	Positron Emission Tomography
PM	Photomultiplier (tube)
OSLD	Optically stimulated luminescence dosimeter
QF	Quality factor
RDRC	Radioactive Drug Research Committee
RBE	Relative biologic effectiveness
RCPS	Royal College of Physicians and Surgeons of Canada
RSO	Radiation Safety Officer
TEDE	Total effective dose equivalent
TLD	Thermoluminescent dosimeter
TVL	Tenth-value layer
USP	US Pharmacopeia
W_r	Radiation weighting factor
W_T	Tissue weighting factor
yr	year

Appendix F: Typical NRC Notification and Reporting Requirements for Different Situations

Event	Telephone notification	Written report	Regulatory requirement
Theft or loss of licensed material	Immediate	30 d	10CFR 20.2201(a)(1)(i) 10CFR22.2201(b) (1)
Whole body dose greater than 25 rem (0.25 Sv)	Immediate	30 d	10CFR 20.2202(a)(1)(i) 10 CFR 20.2203(a)(1)
Extremity dose greater than 250 rad (2.5 Gy)	Immediate	30 d	10 CFR20.2202(a)(1)(iii) 10 CFR 20.2203(a)(1)
Whole body dose greater than 5 rem (0.05 Sv) in 24 h	24 h	30 d	10 CFR 20.2202(b)(1)(i) 10 CFR 20.2203(a)(1)
Extremity dose greater than 50 rem (0.5 Sv) in 24 h	24 h	30 d	10CFR20.2202(b)(1)(iii) 10CFR 0.2203(a)(1)
Whole body dose greater than 5 rem (0.05 Sv)	None	30 d	10 CFR 20.2203(a)(2)(i)
Dose to individual member of public greater than 0.1 rem (1 mSv)	None	30 d	10 CFR0.2203(a)(2)(iv)
Defect in equipment that could create a substantial safety hazard	2 d	30 d	10 CFR 21.21(d)(3)(i) & (ii)
Unauthorized entry resulting in an actual sabotage, or diversion of radioactive material	As soon as possible	30 d	10 CFR 37.57(a) & (c)
Medical event	1 d	15 d	10 CFR 35.3045(c) 10 CFR 35.3045(d)
Dose to an embryo/fetus is greater than 5 rem (50 mSv)	1 d	15 d	10 CFR 35.3047(c) 10 CFR 35.3047(d)
Dose to a nursing child greater than 5 rem (50 mSv) or resulting in unintended permanent functional damage	1 d	15 d	10 CFR 35.3047(c) 10 CFR 35.3047(c)
Eluate exceeding permissible molybdenum-99, strontium-82, or strontium-85 concentrations	7 d	30 d	10 CFR 35.3204

*NRC NUREG1556, vol. 9, Rev 3. Consolidated Guidance about Materials Licenses: Program—Specific Guidance about Medical Use Licenses; 2019

Appendix G: Radioactive Decay of ^{99m}Tc

The decay factor is $e^{-\lambda t}$. The decay constant λ is calculated as $(0.693/6) \text{ h}^{-1}$. The percentage remaining is calculated as $100 \times e^{-\lambda t}$.

Time	Percentage remaining	Time	Percentage remaining
0 h	100		
10 min	98.1	4 h	63.0
20	96.2	10	61.8
30	94.4	20	60.6
40	92.6	30	59.4
50	90.8	40	58.3
1 h	89.1	50	57.2
10	87.4	5 h	56.1
20	85.7	10	55.0
30	84.1	20	54.0
40	82.5	30	53.0
50	80.9	40	51.9
2 h	79.4	50	50.9
10	77.8	6 h	50.0
20	76.4	20	48.1
30	74.9	40	46.3
40	73.5	7 h	44.6
50	72.1	8 h	39.7
3 h	70.7		
10	69.3		
20	68.0		
30	66.7		
40	65.5		
50	64.2		

Appendix H: Radioactive Decay of ^{131}I

The decay factor is $e^{-\lambda t}$. The decay constant λ is calculated as $(0.693/8) \text{ d}^{-1}$.
The percentage remaining is calculated as $100 \times e^{-\lambda t}$.

Time (d)	Percentage remaining
1	91.8
2	84.1
3	77.1
4	70.7
5	64.8
6	59.5
7	54.5
8	50.0
9	45.8
10	42.1
11	38.6
12	35.4
13	32.4
14	29.7
15	27.3
16	25.0
17	22.9
18	21.0
19	19.3
20	17.7

Appendix I: Radioactive Decay of ^{18}F

The decay factor is $e^{-\lambda t}$. The decay constant λ is calculated as $(0.693/110) \text{ min}^{-1}$.
The percentage remaining is calculated as $100 \times e^{-\lambda t}$.

Time (min)	Percentage remaining
10	93.7
20	88.1
30	82.8
40	77.7
50	73.0
60	68.5
70	64.3
80	60.4
90	56.7
100	53.3
110	50.0
120	47.0
130	44.1
140	41.1
150	38.9
160	36.5
170	34.3
180	32.2
190	30.2
200	28.4

Appendix J: Frequency of Essential Chores in Nuclear Medicine

Chores	Frequency
Survey of radiation work area	Daily at the end of the day
Survey of the radioactive storage	Weekly
Survey of research area (low activity use) and office area	Monthly
Survey of radioactive patient room	As needed (after patient release)
Wipe test of routine work area	Weekly
Leak test of sealed source	Every 6 months
Inventory of all sealed sources	Every 6 months
⁹⁹ Mo breakthrough in ⁹⁹ Mo- ^{99m} Tc generator	After every elution
⁸² Sr + ⁸⁵ Sr breakthrough in ⁸² Sr- ⁸² Rb generator	Before the first patient use of the day
Calibration of dose calibrator	
Constancy	Daily at the beginning of the working day
Accuracy	At installation, after repairs or adjustment and annually
Linearity	At installation, after repairs or adjustment and quarterly
Geometry	At installation, and after repairs or adjustment
Calibration of survey meter	Annually
Functioning of well counter	As needed at the time of counting
Calibration of well counter	At installation and after repairs
Airflow monitoring in laminar hood	Annually
Radiation safety training to radiation workers	Annually or as needed
DOT training	Within 90 days of employment, and then every 3 years
Notification of medical events and exposure to embryo/fetus or nursing child	Within 24 h by phone followed by a written report in 15 days

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