Radiation Safety Review for Radiation Therapy 2017

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Topics

• Quantities and Units for Radiation Protection
• Fundamental Principles (ALARA; Time, Distance, and Shielding)
• Radiation Dose Limits
• Personnel Monitoring for Radiation Dose
• Facilities Controls
• Operational Safety
• Radioactive Materials Controls
• Preventing Medical Events
Radiation Quantities and Units

Dose; rad and rem; etc.

Unit Systems

• “Historical” (sometimes called “Traditional”) units [still in use in some countries/contexts, e.g., “gallons” for volume, “feet” for distance]

• “Systeme Internationale” (SI) Units [widely adopted international system of units and measures, used for nearly all scientific purposes, e.g., “liters” for volume, “meters” for distance]
Radioactivity Units

- The rate at which nuclear transformations take place indicates “how much” radioactivity is present.
- The rate of radioactive decay (or transformation rate) in a sample, measured at a given time, is a quantity known as activity.
- Radioactive “decays” or “transformations” are commonly called “disintegrations”.
- Decay rates (activity) can therefore be given as dpm, tpm, dps, tps, etc.

Special Units of Activity

- The traditional curie (Ci) unit is based on the disintegration rate of 1 gram of radium (in equilibrium with its daughters).
- That rate is
  - $3.7 \times 10^{10}$ disintegrations per second (dps)
- 1 curie defined as equaling $3.7 \times 10^{10}$ dps
- In the international system (SI), the unit for activity is the becquerel (Bq)
- 1 Bq = 1 dps
Activity Unit Conversions

- 1 curie = 2.22 x 10^{12} dpm = 3.7 x 10^{10} dps
- 1 millicurie = 2.22 x 10^9 dpm = 3.7 x 10^7 dps
- 1 microcurie = 2.22 x 10^6 dpm = 3.7 x 10^4 dps

Conversions: Activity Units

- 1 Bq = 1 dps = 60 dpm = 0.000027 \mu Ci
- 1 MBq = 10^6 dps = 27 \mu Ci
- 1 TBq = 10^{12} dps = 27 Ci
- 1 Ci = 37 GBq
- 1 mCi = 0.037 GBq = 37 MBq
- 1 \mu Ci = 0.037 MBq = 37 kBq
Radiation ‘Intensity’
(Quantities and Units)

• ‘Intensity’ meaning how much radiation energy is present (e.g., how ‘strong’ a radiation beam is, what the level of the ‘radiation field’ around a source is, etc.)

The Quantity “Exposure”

• Electrical charge produced in air by photons of < 3 MeV (can be relatively easily measured)
Exposure Units

• The roentgen (R) [“historical” unit]
  – Only defined for photons of up to 3 MeV energy, in the terms of the charge that these photons produce in air
  – 1 R = 1 esu/cc_{air} at STP; or; 2.58 x 10^{-4} coulombs/kg_{air}
  – Many radiation detection instruments read out in “R” units
  – There is no special SI exposure unit; “exposure” is measured directly in coulombs/kg.

Radiation Absorbed Dose
[AKA: “ABSORBED DOSE”]

Amount of radiation energy deposited in a material (any type or form of radiation in any type of material).
The quantity “absorbed dose” is independent of the type of radiation depositing the energy.

Caution: The term “dose” by itself can be used generically to refer to any of a number of dose or dose equivalent quantities. One needs to be alert to the context in which the term “dose” is used.
“KERMA”

• “Kinetic Energy Released in Material (or “Matter”, or “per unit Mass)”
• Energy “released” within a given volume of material
• Differs from absorbed dose (not all released energy will be deposited within the same volume of material)
• Same units (e.g., gray)
• For more information:

Absorbed Dose Units

• 1 rad [traditional unit] = 100 erg/gram
• 1 gray (Gy) = 100 rad = 10,000 erg/gram
• 1 rad = 0.01 Gy
• gray is the SI unit, routinely used in the practice of radiation therapy
Problem:

“Radiation absorbed dose” does not account for differences in the ability of different types of radiation to produce biological effects, for the same amount of energy deposited. The quantity “absorbed dose”, therefore, does not in and of itself convey the level of biological risk incurred.

Dose Equivalent (A Radiation Protection Quantity)

To convey a uniform measure of “risk”, doses from different types of radiation are adjusted (normalized) to be equivalent to each other in terms of biological effectiveness. The resulting quantity is called dose equivalent. Dose equivalent is used in practice to apply to non-deterministic (stochastic) effects below levels where cell killing takes place.
Dose equivalent (sometimes called “equivalent dose”) is obtained by multiplying the radiation absorbed dose (in rad or gray units) by a quality factor (aka “radiation weighting factor”), derived from the relative biological effectiveness (RBE) of different radiations, for biologic endpoints of concern in radiation in humans

[NOTE: other modifying factors are used for certain dose equivalent quantities.]

“Dose Equivalent (HT)’’
[US regulatory definition in 10 CFR 20.1003]

• “The product of absorbed dose in tissue, quality factor, and all other necessary modifying factors” [Units: rem or sievert]
Some Current Quality Factors Specified in U.S. Regulations (10 CFR 20)

<table>
<thead>
<tr>
<th>RADIATION TYPE</th>
<th>QUALITY FACTOR</th>
</tr>
</thead>
<tbody>
<tr>
<td>X-ray, gamma, beta</td>
<td>1</td>
</tr>
<tr>
<td>Alpha</td>
<td>20</td>
</tr>
<tr>
<td>Neutrons of unknown energy*</td>
<td>10</td>
</tr>
</tbody>
</table>

*Note: for neutrons of known energy, refer to table in 10 CFR 20

Please note also that other factors have been published by advisory groups and/or in peer reviewed journals

Dose Equivalent

- Equals: Dose x Quality Factor
- Example:
  - For 1 rad or 1 gray alpha, the dose equivalent is:
    - 1 rad x 20 = 20 rem
    - 1 gray x 20 = 20 sievert
• The unit of dose equivalent still appearing in U.S. regulations is the **rem** (rad equivalent man)
• The SI unit is the **sievert (Sv)**
• 100 rem = 1 Sv
• 1 rem = 0.01 Sv
• Dose equivalent is essentially a radiation protection quantity
• There are a number of specific dose equivalent terms (see following slides)
• “Dose equivalent” is only meaningful for:
  - Dose to living humans
  - Dose levels below or slightly above occupational dose limits (i.e., below levels where cell killing is significant)

### “Effective Dose Equivalent (\(H_E\))” [10 CFR 20.1003 definition]

• “Sum of the products of the dose equivalent to each irradiated organ or tissue (\(H_T\)) and the weighting factor (\(W_T\)) for each organ or tissue”
• \(H_E = \sum w_T H_T\)
• Employed for non-uniform radiation exposure
• Often abbreviated as EDE
“Committed Dose Equivalent ($H_{T,50}$)” [10 CFR 20.1003 definition]

• Dose equivalent to any reference organ or tissue due to an intake of RAM during the 50 years following an uptake of radioactive material into the body
• Also abbreviated as CDE

“Committed Effective Dose Equivalent ($H_{E,50}$)” [10 CFR 20.1003 definition]

• “Sum of the products of weighting factor and committed dose equivalent for each of the irradiated organs or tissues”
• $H_{E,50} = \sum w_T H_{T,50}$
• Also abbreviated as CEDE

NOTE: Weighting factors are also defined, and specific factors provided in a table, within 10 CFR 20.1003 definitions
“Deep-Dose Equivalent ($H_d$)”  
[10 CFR 20.1003 definition]

- Radiation dose equivalent from external sources, determined for 1 cm tissue depth
- Also abbreviated as DDE

“Total Effective Dose Equivalent (TEDE)”  
[10 CFR 20.1003 definition]

- Sum of deep-dose equivalent and committed effective dose equivalent
- External ($H_d$) + Internal ($H_{E,50}$)
- Abbreviated as TEDE
“Shallow Dose Equivalent (H_s)” [10 CFR 20.1003 definition]

- Applies to external exposure to the skin
- Is the dose equivalent at 0.007 cm tissue depth
- Abbreviated as SDE, also often referred to as “skin dose”

“Lens - Dose Equivalent (LDE)” [10 CFR 20.1003 definition]

- Applies to external exposure to the lens of the eye
- Is the dose equivalent at 0.3 cm tissue depth
- Abbreviated as LDE
Fundamental Principles of Radiation Protection

The “ALARA” Concept

ALARA

• Stands for “as low as reasonably achievable”
• Is a radiation protection philosophy that is applied to the protection of workers and the general public (both individuals and populations)
• While elements of ALARA philosophy may apply, “ALARA” as it is generally stated should not be applied to the clinical application of radiation to patients. [The concept of applying the “optimal” and “justifiable” radiation dose should be used.]
Formal Statement of “ALARA”  
[10 CFR Definition] 
• “ALARA” (as low as reasonably achievable) means making every reasonable effort to reduce (radiation dose) as far below the dose limits…as is practical consistent with (the purpose for which the radiation is used), taking into account the state of technology, the economics of improvement in relation to (the state of technology and to the benefits to public health and safety, and to the radiation’s use in the public interest), and other societal and socioeconomic considerations…” 

Regulatory Requirement  
[§20.1101(b)]: 
• “The licensee shall use, to the extent practical, procedures and engineering controls based upon sound radiation protection principles to achieve (occupational and public) doses that are (ALARA).”
The Thinking Behind “ALARA”

• Even low dose levels assumed to carry stochastic risk
• (Therefore) one should make every reasonable effort to keep doses as far below regulatory limits as is practical

Applying ALARA Principles Means Considering:

• Benefits gained from the radiation use
• Current state of technology
• Economic factors (cost/benefit)
• Other societal considerations
• It does NOT mean doing everything possible to reduce already ‘low’ doses!
Fundamental Principles of Radiation Protection (cont’d)

Time, Distance, and Shielding

Basics of Dose Reduction

• DOSE = DOSE RATE x TIME
• Limit dose by lowering dose rate or time of exposure (use “time, distance, and shielding” principles)
• Lower dose rate also by minimizing strength or output of the source used (where feasible)
Radiation Protection by Time

The longer you are exposed to radiation, the higher your radiation dose. To minimize radiation dose, minimize the time exposed.

Control Time

- Limit personnel around radiation sources to those necessary
- Pre-plan procedures (to minimize source “on” or “out-of-shielding” times)
- Practice source handling and procedure techniques without the active radiation source (use “dry runs” with mock sources, for example)
Radiation Protection by Distance

Double the distance and the dose drops by a factor of 4; triple the distance and it drops by a factor of 9.

It was a dark and stormy night.

Maximize Distance

• Take advantage of the inverse square law (radiation intensity decreases with the square of the distance from a “point” source)

• $I_1d_1^2 = I_2d_2^2$
Inverse Square Law
Calculation Example:
The dose rate at 3 meters is 4 mrad/hr. What is it at 5 meters?

Use: \( \frac{I_1}{I_2} = \frac{d_2^2}{d_1^2} \) or: \( I_1 d_1^2 = I_2 d_2^2 \)

Designate \( I_2 = 4 \text{ mrad/hr}, \ d_2 = 3 \text{ m}, \ d_1 = 5 \text{ m}; \) solve for \( I_1 \)
Answer: 1.44 mrad/hr

Shielding

Shielding is simply placing radiation attenuating material between people and the source of radiation.
Use Shielding To The Extent Practical (apply “ALARA”)

- Lead for photons (other materials possible)
- Low density materials for charged particles
- High neutron cross-section materials (Boron, concrete) for neutrons
- Shield (where applicable)
  - Treatment rooms
  - Radioisotope storage areas and/or containers
  - Radioisotope transport containers
  - Areas around implant patients
  - Individuals (with shielding garments)

Radiation Dose Limits

Dose Limiting Recommendations and Regulations
Recommendations vs. Regulations

• Recommendations (made by advisory bodies like the NCRP and ICRP) are just that - recommendations. They are **not** enforceable!
• Regulations are enacted under the provisions of government statutes. They **are** legally enforceable!!!

Published dose limits address:

• Occupational doses (for adults and minors)
• The general public
• The embryo/fetus
• Other non-occupational situations
• Effective (“whole body”) doses
• Individual organs and tissues or body parts
• Doses from sources outside or inside the body
Regulatory Dose Limits
(As found in US Federal Regulations: 10 CFR 20)

Adult Occupational* Annual Limits

TEDE (i.e., DDE + CEDE): 0.05 Sv (5 rem)
LDE: 0.15 Sv (15 rem)
SDE: 0.5 Sv (50 rem)
Any other organ or tissue: 0.5 Sv (50 rem)

*Note: “Occupational” dose results when an individual’s assigned duties involve exposure to radiation. It does not include dose received from background radiation, as a patient, as a member of the general public, or as any other non-occupational dose.
Occupational Dose Limits for Minors (Workers <18 Years Old)

- 10 percent of any of the annual dose limits specified for adult workers

[Note: In the US, OSHA regulations prohibit persons under age 16 from working with ANY hazardous substance, so in reality the above only applies to 16 or 17 year old workers]

Note re Extremity Limits:

There is no specific limit for the extremities in US federal regulations (10 CFR 20). The 0.5 Sv (50 rem) annual limit for shallow dose equivalent (“skin”) of the extremities (at 0.007 cm tissue depth) is the limiting dose.
Dose Limits for the Embryo/Fetus (§20.1208)

- Dose limit applies only to the embryo/fetus of a “Declared Pregnant Woman”
- “Declared Pregnant Woman” is defined in regulation §20.1003
- Means a woman who has voluntarily informed the employer, in writing, of her pregnancy and the estimated date of conception. The declaration remains in effect until the declared pregnant woman withdraws the declaration or is no longer pregnant.

- The dose limit to the embryo/fetus applies only to radiation from the occupational exposure of the declared pregnant woman.
- The dose limit is **0.005 Sv** (5 mSv, or 0.5 rem, or 500 mrem) during the entire pregnancy [§20.1208(b)].

*Note: there are advisory group recommendations for a monthly limit of 0.0005 Sv, or 50 mrem*
“Public Dose” [for regulatory purposes]

• Dose to a member of the public from sources released by, or under the control of, a specific licensee (or registrant)

• “The dose that a member of the public can receive from activities conducted by each licensee shall not exceed 0.1 rem (1 mSv) per year” [§20.1301(a)(1)].

• Notice that this a restriction on each licensee (i.e., 1 mSv per person per licensee), and NOT a total annual limit for a specific individual

“Public Dose” does not include:

• Occupational dose
• Background radiation dose
• Dose received for medical purposes
• Dose from patients released under provisions of 10 CFR 35.75 (5 mSv per person per patient limit)
• Dose from participation in a voluntary medical research program
Comparison to NCRP Recommendations

<table>
<thead>
<tr>
<th>NCRP</th>
<th>NRC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Occupational: 50 mSv/y effective</td>
<td>Adult 50 mSv/y TEDE [same]</td>
</tr>
<tr>
<td>Occupational: 10 mSv x age effective</td>
<td>No cumulative limit</td>
</tr>
<tr>
<td>Occupational: 150 mSv/y eye lens</td>
<td>Adult 150 mSv/y [same]</td>
</tr>
<tr>
<td>Occupational: 500 mSv/y skin, extremities</td>
<td>Adult 500 mSv/y skin or skin of extremities [same]</td>
</tr>
<tr>
<td>Non-medical: 0.5 mSv/month embryo/fetus</td>
<td>5 mSv/gestation period (only declared pregnant worker)</td>
</tr>
<tr>
<td>Public: 1 mSv/y continuous or frequent; 5 mSv/y infrequent exposure</td>
<td>1 mSv/y from any one licensee; 5 mSv/y from exposure to radioactive patients in certain cases</td>
</tr>
<tr>
<td>Public: 50 mSv/y lens of eye, skin, extremities</td>
<td>Not directly addressed</td>
</tr>
<tr>
<td>Education/training: 1 mSv/y</td>
<td>Covered under Public Dose limit</td>
</tr>
<tr>
<td>Minor, occupational: none (public)</td>
<td>10% of adult limit</td>
</tr>
<tr>
<td>NID: 0.01 mSv</td>
<td>None</td>
</tr>
</tbody>
</table>
Personnel Monitoring

Assessing Dose to Workers and Others

Why Monitor?

• Show compliance with dose limiting and related regulations
• Identify issues where dose reduction could be obtained through intervention (e.g., personnel training, improved procedures, better engineering controls, etc.)
• Validate effectiveness of existing practices

Note: The 2nd and 3rd reasons above are the reasons why many individuals are issued dosimeters even though the regulations would not specifically require them.
Individual Monitoring Devices (Radiation Dosimeters)

- 10 CFR 20 definition: “Device designed to be worn by a single individual for the assessment of dose equivalent…”
- Dosimeters (“radiation badges”) record the (cumulative or integrated) dose accumulated over some period of time (‘wear period’)
- Regulatory requirement for wearing found in 10 CFR 20.1502 (“conditions requiring individual monitoring or external and internal occupational dose”)
- “Body badge” dosimeters will provide readings for DDE, LDE, and SDE; “rings” for hand/finger dose

Wearing of individual monitoring devices required by regulation for:

- Adults likely to exceed 10% of any occupational dose limit
- Minors likely to exceed 0.1 rem DDE; 0.15 rem LDE; or 0.5 rem SDE or extremities
- Declared pregnant women likely to exceed 0.1 rem over the entire pregnancy
- Anyone entering a high or very high radiation area
Wearing Dosimeters

• Whole body types should be on front torso or collar toward midline of the body, label facing away from the body
  – Collar
  – Shirt pocket
  – Lapel
  – Belt [all dosimeters for tracking pregnancy dose should be on abdomen]
• Ring dosimeters on dominant hand; label oriented toward radiation source

What if you wear x-ray protective garments?

• If the wearer is issued a single badge, wear outside garment at collar level
• Persons routinely exposed while wearing lead may be issued two dosimeters (one for outside at collar, one for under garment at waist)
• Declared pregnant women who wear protective garments need 2 dosimeters (‘fetal’ badge to be worn under garment at waist level)
NOTE (especially for therapists)

• Avoid leaving dosimeters in treatment rooms!!!!
• Wear them at all times in proximity to therapy machines or devices!!! (The only real dose likely to ever be recorded from a medical accelerator, HDR, or GSR source would result from an accident, e.g., beam activated while staff member is in the treatment room.)

The Dosimetry Report
Standard Report Information:

- Wearer identification (ID numbers, name etc.)
- Processing notes (e.g., to indicate damaged, contaminated, or unable to read)
- Radiation Quality (type and energy)
- Dosimeter type designation (e.g., code meaning TLD, film, etc.)
- Wear location (e.g., finger, collar, “whole-body”)
- Dose Equivalent
Dose Reported For:

- Wear period
  - Deep
  - Shallow
  - Lens of the eye
- Calendar quarter to date
  - Deep
  - Shallow
  - Lens of the eye
- Year to date
  - deep
  - shallow
  - lens of the eye
- Lifetime-accumulated “deep” dose shown on standard reports

Readings Reviewed* For:

- Unusual readings (dose to an individual or group higher than for his/her peers; dose higher than historical, etc.)
- Trends (e.g., dose increasing among a group?)
- Readings above “ALARA Investigation Levels”

*Reviewed by Radiation Safety Officer or other designated personnel with radiation safety responsibilities.
Prior Doses

- Accumulated occupational dose information obtained by or provided to any employer is to be added to the worker's lifetime dose history.

Dosimetry Reports to Workers

10 CFR 19.13 requires reports of occupational doses to workers be furnished:

- Annually
- At the request of a former worker (written, signed request to protect worker’s confidential information)
- Anytime a dose has resulted that requires notification to NRC or state agency
- Year-to-date dose to a worker who is terminating employment (at the request of that worker)

Note: Some State regulations may go beyond the above requirements.
Facilities and Area Controls

Area Classification, Posting, and Physical Safety Measures

“Restricted Area” [10 CFR 20.1003 definition]

• “…an area, access to which is limited by the licensee for the purpose of protecting individuals against (undue radiation risks)” [emphasis added]
“Controlled Area” [10 CFR 20.1003 definition]

• “…an area outside a restricted area but inside a site boundary, access to which can be limited by the licensee for any reason” [emphasis added]
• [Note: The NCRP (an advisory body) defines a controlled area as one where access must be approved by the RSO or other individual responsible for radiation protection.]

“Unrestricted Area” [10 CFR 20.1003 definition]

• “…an area, access to which is neither limited nor controlled by the licensee”
Dose Rate Limit

• Regulation §20.1301(a)(2) limits radiation dose in unrestricted areas to no more than 2 millirem (0.02 mSv) in any one hour!
• NOTE: the dose limit of “2 mrem in any one hour” does not necessarily mean that a measured instantaneous dose rate of “2 mrem/hr” is a violation. Duration of occupancy, or the source “on-time” within any one hour, can be considered.

Relevant Exception to §20.1301(a) Dose Rate Limit

• Visitors to patients hospitalized under provisions of §35.75 may be in areas where they may receive > 2 mrem in an hour. They may get up to 500 mrem for total visitation times if the authorized user determines that the visitation is appropriate.
“Radiation Area”

- (§20.1003 Definition): An accessible area where (external radiation) levels could result in someone getting >5 millirem in 1 hour at 30 cm from a source or 30 cm from any surface that the radiation penetrates

“High Radiation Area”

- (§20.1003 Definition): An accessible area where (external radiation) levels could result in someone getting >100 millirem in 1 hour at 30 cm from the source or 30 cm from any surface that the radiation penetrates
“Very High Radiation Area”*

- (§20.1003 definition) An area where external radiation levels could be encountered at 500 rads or more in 1 hour at 1 meter from a source or any surface through which the radiation penetrates

*Not encountered in medical use. Note that spending an hour at the 1 meter distance in a very high radiation area would result in better that 50% chance of death from the acute radiation syndrome.

Area Posting Requirements

- Very High Radiation Area: **Posting required**
- High Radiation Area: **Posting required**
- Radiation Area: **Posting required**
- Restricted Area: no specific requirement
- Unrestricted Area: no requirement
- Radioactive materials use or storage location: **Posting required**
Exception to Posting Radioactive Materials Room

• Hospital room containing a radioactive patient who does NOT require hospital confinement under the 10 CFR 35.75 regulation does not require a “Caution – Radioactive Materials” sign
Container Labeling Requirements – 10 CFR 20.1904

- Containers of RAM must have durable visible labels that include:
  - Radiation symbol
  - “Caution” (or “danger”) – “Radioactive Material”
  - Isotope information (isotopes, activities, date(s) activity determined, radiation levels, or any other information sufficient to allow persons handling, using, or working near the container to take appropriate precautions

Security of Radioisotopes

- Regulations require that radioactive sources to be secured against unauthorized access or theft at all times, either by…
  - Keeping sources in storage locked up, or,
  - Maintaining constant surveillance of the sources
- Part 35 requires additional security measures for control panels of HDR afterloading devices and GSR units
- New 10 CFR 37 or state issued ‘Increased Controls’ orders require additional security measures for GSR, teletherapy units, and other specified source/quantity combinations.
Basic Survey Requirements in Part 20

• Part 20 survey requirements are very non-specific
• Requires performance of such surveys as are appropriate and necessary to show compliance with the other regulations in Part 20 (e.g., need to perform surveys to show dose rates in unrestricted areas are within limits)
• Examples include surveys of source storage areas and radiation levels around patients undergoing brachytherapy
• Part 35 also includes a specific requirement to survey patients AFTER sources are removed

Physical Radiation Safety Items

Thermaphy treatment rooms (e.g., HDR, GSR, or accelerator rooms)
- Interlocks and beam interrupt switches
- Visual monitors
- 2-way audio
- Room radiation monitors
- Warning lights and indicators
- Availability of portable survey instruments
- Written procedures
- Radiation barriers (shielding)
Notes About Room Shielding

• Determined by Qualified Experts
• Determine shield material and thickness to attenuate radiation to “design” or “target” levels in occupied, adjoining space. Select ‘target’ (e.g., mSv/week) to meet dose limits, with additional ALARA factors
• Considerations: Occupational vs. non-occupational; area occupancy; primary vs. secondary barrier; radiation source workload; barrier utilization (“use” factor, for primary barriers)

Barrier Shielding Terminology

• Primary barrier – a barrier struck by the primary radiation beam
• Secondary barrier – a barrier struck only by scatter and leakage radiation
• Occupancy factor (T) – fraction of time that the area to be shielded is occupied (e.g., T = 1 [i.e., 100%] for a control booth
• Workload – reflects amount of time and operating parameters that a device will be used (e.g., MU/week)
• Use factor – for primary barriers, the fraction of time that the barrier would be struck by the primary beam
Practical (Operational) Safety Procedures

- Last person leaving room prior to initiating treatment is the person to close the door
- Never initiate treatment without visually accounting for everyone who had been involved in patient set-up within the treatment room
- Never initiate treatment without visually checking the viewing monitors (both to check patient position and re-confirm no one else is in the room)
- Make an announcement over the audio system that “treatment is about to start” (alerts anyone left in room)
- (Persons inside room) Be alert to radiation monitors, etc. Exit room immediately at any sign that beam might be about to be turned on or is already on; and/or hit emergency interrupt buttons

Environmental Issues

Disposal of Radioactive Wastes
Disposal Methods

- Decay-in-storage (decay-to-background)
- Transfer to authorized recipient (i.e., to another licensee)
- Discharge to sewer
- Discharge to atmosphere

Note: Radioactive materials once implanted or administered permanently to a patient effectively become 'unlicensed' and no longer a part of a licensee's inventory.

10 CFR 35.92 Requirements For D-I-S

- Isotope must have <120 day half-life (some states permit longer half-lives)
- May be disposed of “without regard to its radioactivity” IF:
  - Licensee monitors the material at its surface with an appropriate survey meter, set on its most sensitive scale, with no interposed shielding; and
  - Determines that the RAM cannot be distinguished from background; and
  - Obliterates all radiation labels (except those within containers that will be managed as biomedical waste after they are released by the licensee)
Records To Show Compliance With §35.92 Must Include:

- Date of disposal
- Instrument used for survey
- The background radiation level
- The (maximum) radiation level at the surface of each waste container
- Name of person who performed the survey

Transfer To Authorized Recipient (i.e., another licensee]

- Transfer to an authorized radioactive waste disposal facility (usually for RAM with >120 day half-life)
- ‘Return-to-vendor’ of used sources (e.g., unused seeds, decayed HDR sources)
- Shipments must be prepared in accordance with DOT and NRC shipping regulations
Patient Protection

Preventing Medical Events

Patient Protection: Basic Intent
(Goals)

• Limit radiation dose to that necessary
  – Prevent “medical events”
  – Prevent other medication errors involving radiation sources
Human Use Categories for Therapy In Part 35

- §35.300 - unsealed RAM, written directive needed
- §35.400 - manual brachytherapy
- §35.600 - photon emitting remote afterloading, teletherapy, gamma stereotactic radiosurgery
- §35.1000 – other, not covered above

Example: $^{90}$Yttrium-labelled microspheres for treatment of metastatic liver disease

• **NOTE**: Sources can only be used for the types of human use specifically authorized in an NRC or state issued radioactive materials license
• Written Directives, where required, can only be signed by a physician approved as an Authorized User for that specific modality
Re Machine-Produced Radiation Therapy

• Regulated by individual states
• Regulations highly variable from state to state
• Regulations regarding prevention of medical errors may be similar in principle to the federal regulations that apply to radioactive materials sources

Manual Brachytherapy Safety Precautions (10 CFR 35.415)

• Do not quarter patient in room with non-brachytherapy patient
• Post radiation signs and precautions, visitor stay times
• Have emergency equipment for dislodged source or source remaining in patient
Written Directive Requirement (10 CFR 35.40)

- Required for any therapeutic administration of radiation from RAM sources.
- Must be signed and dated by authorized user (AU)
- Must be completed before administration (limited exceptions for emergent medical situations)
- Must identify patient by name
- Modifications to a Written Directive can only be made by an AU and must be documented (with signature) by the AU

Written Directive (continued)

- For HDR brachytherapy, must contain:
  - Treatment site
  - Dose per fraction
  - Number of fractions
  - Total dose
Written Directive (continued)

- For NRC-regulated teletherapy, must contain:
  - Total dose
  - Dose per fraction
  - Number of fractions
  - Treatment site

Note: State regulations regarding machine sources vary, and may or may not specify what appears in a written directive or equivalent “prescription”; or may differ in what elements of the prescription are required.

Written Directive (continued)

- For gamma stereotactic radiosurgery (GSR), must contain:
  - Total dose
  - Treatment site
  - “Values for target coordinate settings per treatment for each anatomically distinct site”
Written Directive (continued)

• For all other brachytherapy, must contain (before administration):
  – Treatment site
  – Radionuclide
  – Dose

• After implantation, but before completion of treatment, must contain:
  – Treatment site
  – Radionuclide
  – Number of sources
  – Total source strength and exposure time (or, total dose)

Medical Events and Medication Errors – Categories:

• Administration to wrong patient
• Administration of wrong material
• Administration of wrong amount (wrong dose)
• Administration by wrong route
Medical Event (1-Wrong Amount)

• Resulting dose to patient differs from the dose that would have occurred from the administration as prescribed by more than 5 rem TEDE, 50 rem to any single organ or tissue, or 50 rem SDE, and...
  – Total dose or dosage delivered differs from prescribed by ≥ 20%, or
  – A single fraction of a fractionated dose differs by ≥ 50% from the fractionated dose prescribed

Medical Event (2)

• A dose that exceeds 5 rem TEDE or 50 rem SDE to any organ tissue from any of the following:
  – Administration of the wrong radiopharmaceutical
  – Administration to the wrong individual
  – Administration by the wrong route of administration
  – Administration by the wrong mode of treatment
  – From a leaking sealed source
Medical Event (3)

- Dose to skin or organ outside the treatment site exceeds 50 rem and is 50% or more larger than would have been expected from the administration defined in the written directive (excluding permanently implanted seeds that migrate from the treatment site after they were implanted in the correct site)

Note: These are NRC definitions for radionuclide sources that do not necessarily apply to state regulated machine sources.

Preventing Medical Events & Medication Errors

- Ensure proper identification of patients
- Ensure correct radiopharmaceutical or radiation source (and settings)
- Ensure use of proper administration methods and procedures (patient set-up, etc.)
- Ensure proper amounts
Preventing errors…

• Is primarily a matter of developing and following good procedures

• Regulations require written procedures to provide “high confidence” that treatments are administered to the correct patient in accordance with the written directive or prescription

• The concept of “defense-in-depth” should be applied (multiple layers of independent checks so that a “single point failure” does not result in an incorrect administration)

Resources: A link to some self-study lectures and practicals that the student may find helpful in preparing for registry exams:

• https://rpop.iaea.org/RPOP/RPoP/Content/AdditionalResources/Training/1_TrainingMaterial/Radiotherapy.htm
End Review