Refresher Training for X-Ray Equipment Operators

Developed for the

Department of Environmental Protection
Bureau of Radiation Protection

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Outline of Course

- Part 1: Introduction and Overview of the Training Program
- Part 2: Fundamentals of Radiation Science
- Part 3: Review of X-ray Imaging
- Part 4: Safety Plan, Documentation and QA
- Part 5: Regulations

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Part 1

Introduction and Overview of Training Program

Introduction and Background

- X-rays a key component of diagnostic medicine for many years
- BUT will result in exposure of patient and staff to ionizing radiation
- Food and Drug Administration (FDA) recommends two steps for medical X-rays:
  - Justification of procedure
  - Optimization of procedure

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Justification of Imaging Procedure

- Imaging procedure should do more good than harm; therefore, exams should be performed only when necessary to:
  - Answer a medical question
  - Treat a disease
  - Guide a procedure

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Optimization of Imaging Procedure

- Exams should use techniques that are adjusted to:
  - Administer lowest radiation dose that yields image quality adequate for diagnosis or intervention
- That is, radiation doses should be "As Low As Reasonably Achievable," referred to as the ALARA Principle

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Purpose of Training

- According to the National Council on Radiation Protection and Measurements (NCRP Report No. 134) there are four major reasons for training:

1. Development of worker skills so that tasks may be performed efficiently and with confidence

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Purpose of Training

2. Individuals aware of risk of exposure become active participants in accepting and, where possible, reducing those risks

3. Number and seriousness of accidents can be reduced

4. Workers will be aware of regulatory requirements involved with radiation exposure

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State Requirements for Training

- Pennsylvania Department of Environmental Protection (DEP) regulations require individuals operating X-ray equipment to:
  - Receive initial instructions in safe operating procedures
  - Be competent in the safe use of equipment
  - Receive continuing education

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State Requirements for Continuing Education

PA Title 25 Chapter 221 Appendix A lists the following topics for continuing education:

- Basic properties of radiation
- Units of measurement
- Sources of radiation exposure
- Methods of radiation protection
- Biological effects of radiation exposure

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Topics for Continuing Education

- X-ray equipment
- Image recording and processing
- Patient exposure and positioning
- Procedures
- Quality assurance program
- Regulations

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Training Goal

To provide the generic portions of this training for operators performing low-risk medical procedures

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Part 2

Fundamentals of Radiation Science

Fundamental Properties of Radiation for X-ray Imaging

- Properties of Radiation
- Units of Measurement
- Sources of Radiation
- Biological Effects of Radiation

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Ionizing Radiation

- High energy particles or electromagnetic (EM) energy
- Capable of removing orbital electrons from atoms
- Effect called ionization
- Resulting atom and electron called ion pair

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Particulate vs. EM Ionizing Radiation

Particulate

- Includes alpha, beta, neutrons
- Usually easier to shield
- Not used in diagnostic medicine (some applications in therapy)

EM

- Includes gamma, and X-rays
- Generally more difficult to shield
- X-rays are major tool in diagnostic medicine

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Types of EM Radiation

- Most EM radiation is non-ionizing
- Common names for various energies of EM radiation:
  - Radio waves (very low energy, non-ionizing)
  - Microwaves (non-ionizing despite common perception)
  - Infra-red, visible, and Ultraviolet (non-ionizing, though intense forms may damage skin or eyes)
  - X-rays (ionizing)
  - Gamma rays and cosmic rays (ionizing)

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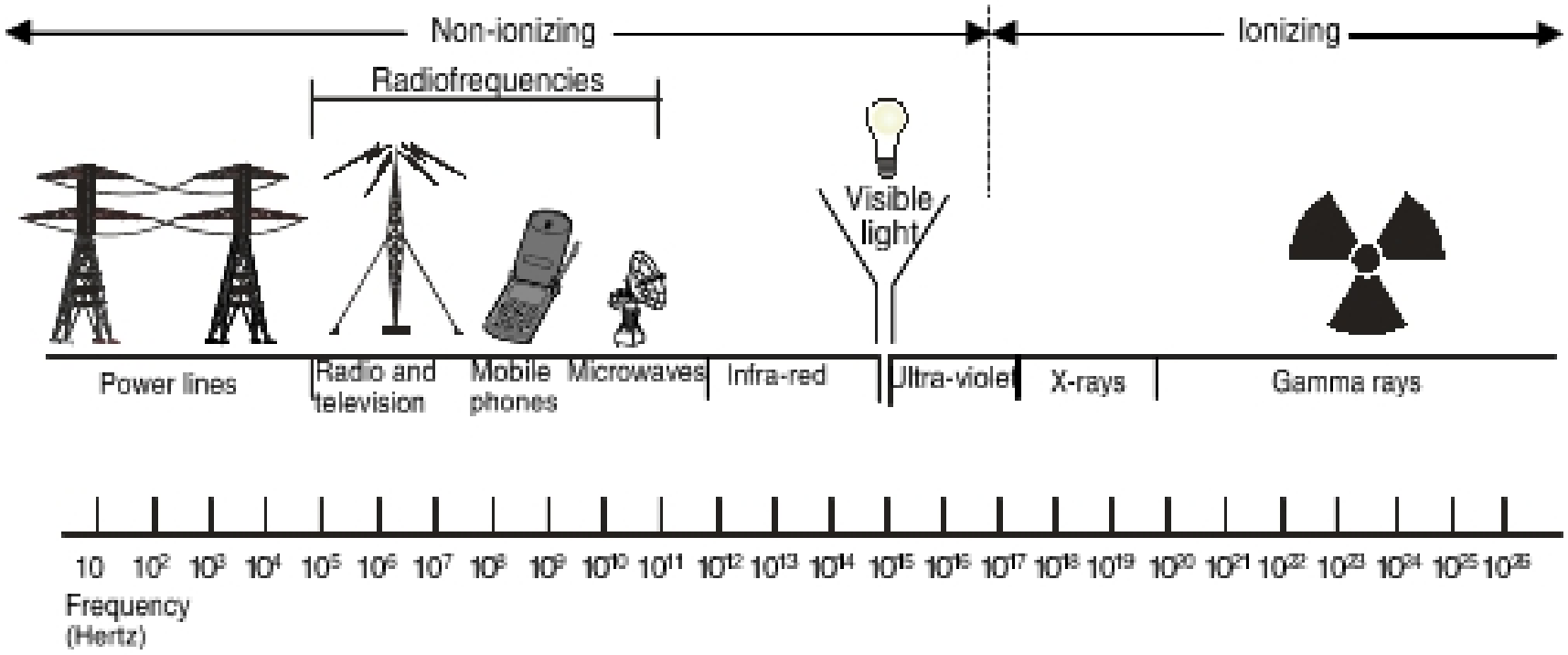
EM Radiation Types



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X-rays vs. Other Forms of Ionizing Radiation

- X-rays (with some minor exceptions) are produced by machines.
- Particulate radiations and gamma rays primarily come from radioactive materials.
- X-rays cannot make a person radioactive and cannot result in contamination (loose radioactive materials).

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X-rays vs. Other Forms of Ionizing Radiation

- X-ray machines have an on-off switch
- They can be immediately turned off, removing the source of radiation

Quantities & Their Units of Measurement

- Three Basic Quantities
  - Exposure – measure of charge in air produced by X-ray or gamma radiation
  - Absorbed Dose – measure of energy deposited by any type of ionizing radiation in any material
  - Equivalent Dose – measure of biological damage to the human caused by various types of ionizing radiation

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Why Three Quantities?

- Exposure
  - Easy to measure using inexpensive instruments
  - Can be related to other two quantities
- Absorbed Dose
  - Widely applicable to measuring effects of radiation
  - Often difficult to measure
- Equivalent Dose (or Dose equivalent)
  - Allows for biological differences in humans for different types of radiations
  - Used for regulatory limits

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Exposure Units

- Roentgen
  - Oldest unit, defined as 0.000258 coulombs/kg in air
  - Still widely used in USA but not defined in the current international scientific unit system (SI)
  - Symbol: R
- Air kerma (closest SI equivalent)
  - Defined as 1 joule/kg in air
  - Symbol: Gy_a (grays in air – see absorbed dose)
- To a close approximation 1R = 0.01 Gy_a

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Absorbed Dose Units

- rad
  - Traditional unit defined as 100 ergs/g of energy deposited by any type of ionizing radiation in any mass (g) of material
- Gray (Gy)
  - SI unit defined as 1 joule/kg of energy deposited by any type of ionizing radiation in any mass (kg) of material
- 1 rad = 0.01 Gy

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Effective Dose Equivalent Dose Units

- rem – traditional unit defined as absorbed dose in rad multiplied by modifying factors to account for responses in the human
- Sievert (Sv) – SI unit defined as absorbed dose in gray multiplied by modifying factors to account for responses in the human
- 1 rem = 0.01 Sv

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Relationship of Units

- For X-ray radiation, to a close approximation we can assume that:
  - 1 R = 1 rad = 1 rem

    and
  - 1 Gy_a = 1 Gy = 1 Sv

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Common Numerical Prefixes

Numeric Value	Prefix	Symbol
10^{6}	mega-	M
10^{3}	kilo-	k
10^{-2}	centi-	c
10^{-3}	milli-	m
10^{-6}	micro-	μ
10^{-9}	nano-	n

Dose and Dose Rate

- Radiation often measured as a dose rate (dose per time) so dose received is calculated as follows:
- Dose received = Dose Rate x Time exposed

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Example of Dose Rate & Conversions

Exposure rate in area is 2 mR/hr.

Is yearly limit of 5 rem exceeded?

(Assume occupancy of 40 hours/week and 50 work weeks in year).

- Exposure = 2mR/hr x 40 hr/wk x 50 wks/yr
- Exposure = 4000 mR/yr = 4 R/yr
- Assume 1R = 1 rad = 1 rem, so
- Equivalent dose = 4 rem/yr; limit not exceeded

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Sources of Radiation

- Radiation exposure to the general public comes from a number of sources:
  - Natural background radiation (in soil, air, our bodies, etc.)
  - Medical procedures
  - Occupational exposures
  - Consumer products
- Following slide shows breakdown of exposures and recent trends

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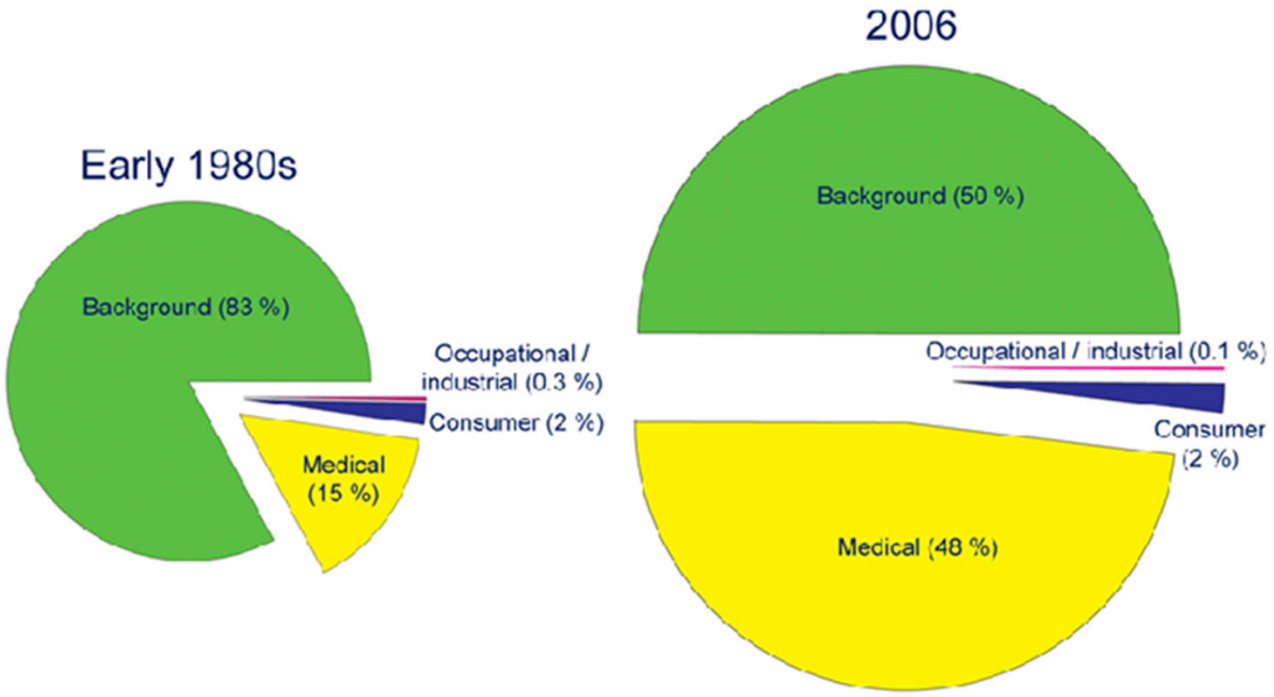
NCRP Report No. 160, *Ionizing Radiation Exposure of the Population of the United States*



	Early 1980s	2006
Collective effective dose (person-Sv)	835,000	1,870,000
Effective dose per individual in the U.S. population (mSv)	3.6	6.2

So what has happened?

- Background levels are the same, but in % they have decreased to only about half of the total average exposure
- Occupational and consumer product levels have remained very low
- Medical exposures have increased significantly (on the average)
- Why?

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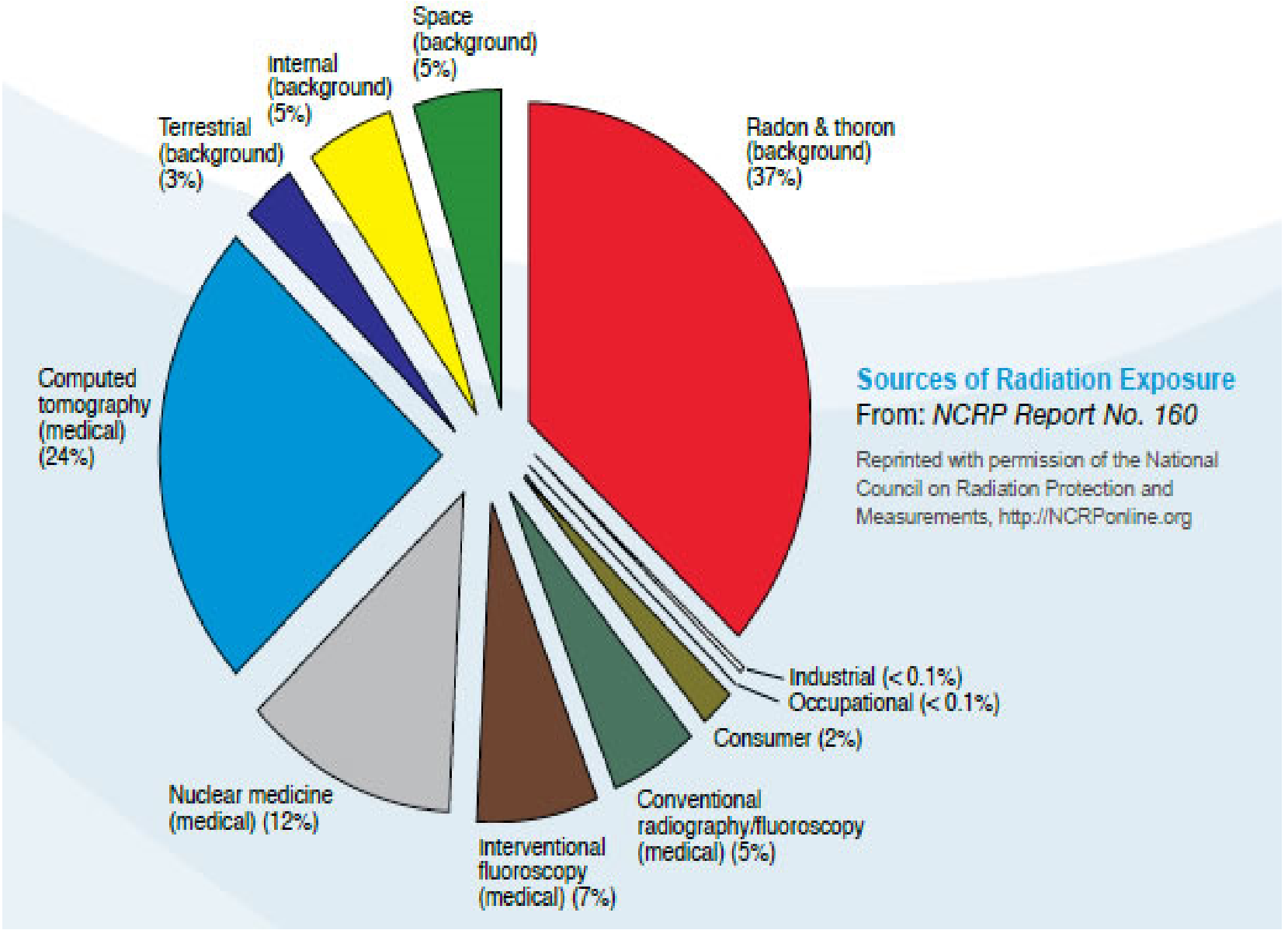
Space (background) (5%)
Internal (background) (5%)
Terrestrial (background) (3%)
Radon & thoron (background) (37%)
Computed tomography (medical) (24%)
Sources of Radiation Exposure
From: NCRP Report No. 160
Reprinted with permission of the National Council on Radiation Protection and Measurements, http://NCRPonline.org
Industrial (< 0.1%)
Occupational (< 0.1%)
Consumer (2%)
Conventional radiography/fluoroscopy (medical) (5%)
Interventional fluoroscopy (medical) (7%)
Nuclear medicine (medical) (12%)

So what has changed?

- Large increase in number of CT scans
- Increase in nuclear medicine procedures
- Newer techniques involve higher doses to the patient

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High-Risk vs. Low-Risk Procedures

Pennsylvania has divided X-ray medical procedures into two risk classes:

- High-risk procedures – utilize energies of < 1 MeV that could exceed skin doses of 200 rads (2 Gy).
  - Examples: CT scans, interventional radiography
- Low-risk procedures – any radiologic procedure that is not a "high-risk" procedure.
  - Examples: conventional x-rays, dental, podiatry, chiropractic, and veterinary

High-risk results in more dose per patient, but many more patients receive low-risk procedures (especially children and young adults).

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Biological Effects of Radiation

- Harmful effects discovered very early
  - (Thomas Edison ceased work on X-rays in 1904 following a serious injury and subsequent death of his assistant due to radiation)
- "Law of Bergonie and Tribondeau" developed in France in 1906:
  - "The more rapidly a cell is dividing, the greater the sensitivity to radiation"
  - Not always true but helpful in explaining effects on certain organs such as skin, blood-forming organs, gonads and unborn children.

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What is the primary biological effect?

- Research has found that the primary hazard is to DNA
- Can result in cell death leading to organ failure, illness, and possible death of exposed person
- Or can result in cell mutations leading to cancer in exposed person and possible genetic effects to future generations
- Greatest risk at low doses is cancer to exposed person – regulations based on this risk

Acute vs. Delayed Effects

- Acute effects (also referred to as early effects or deterministic effects)
  - Typically occur at high doses and appear within days or weeks of exposure
  - Examples: skin burns, sterility, loss of hair, etc.
- Delayed effects (also referred to as late effects or stochastic effects)
  - Occur at low doses over long periods of time
  - Cancer is greatest concern

Goal of Radiation Regulations

- Prevent acute effects to exposed person
  - Shield sensitive organs such as lens of eye, thyroid, unborn child
- Reduce likelihood of delayed effects
  - Keep doses low and make sure they are justified
- In other words, ALARA:

  As low as reasonably achievable

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Part 3

Review of X-ray Imaging

Basic Components of X-ray Tube

- Cathode – heated wire to produce large source of electrons and focusing cup to direct them
- Anode – target of high atomic number struck by electrons to produce X-rays
- Voltage supply – high voltage supply to accelerate electrons from cathode to anode
- Envelope – glass or metal vacuum tube containing anode and cathode
- Tube housing – shielding around envelope to protect tube and shield unwanted X-rays

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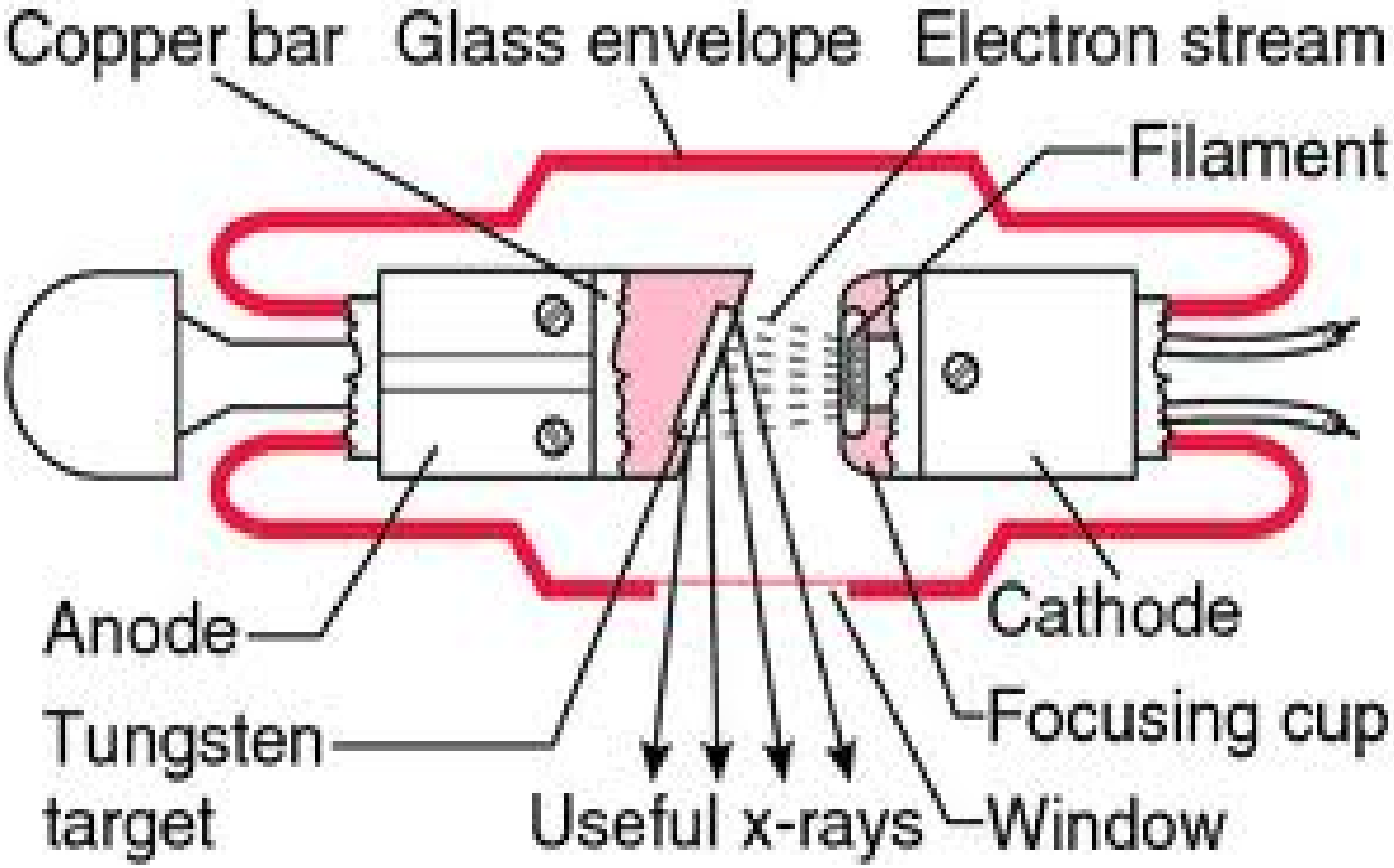
Copper bar
Glass envelope
Electron stream
Filament
Anode
Tungsten target
Useful x-rays
Cathode
Focusing cup
Window

Other Parts of X-ray Machine

- Collimator – restricts X-ray beam to only the area of interest
- Filtration – removes unwanted low energy X-rays
- Transformer – converts low voltage to high voltage needed for tube
- Rectifier – converts AC input voltage to DC needed for X-ray tube

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Primary Settings on X-ray Tube

- Current to cathode – measured in milliamps (mA)
- Timer for current in seconds
  - Current and timer together are measured in mAs
- Voltage across the cathode and anode – measured in kVp (kilovoltage peak, the maximum possible energy a photon exiting the X-ray tube can reach)
  - kVp determines the energy of electrons which is directly related to energy of X-rays produced

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Quantity and Quality of X-rays

- Medical X-rays characterized by quantity and quality
- Quantity – number of X-rays reaching the patient
- Quality – penetrability or ability of X-ray beam to pass through tissue

  (low quality X-rays have little chance of penetrating so they deliver dose to patient while providing no useful medical information)

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Factors Affecting Quantity

mAs	when increased	Increases quantity proportionately
kVp	when increased	Increases quantity by square law
distance	when increased	Decreases quantity by inverse square law
filtration	when increased	Decreases quantity

Factors Affecting Quality

mAs	when changed	does not change quality
kVp	when increased	improves quality
distance	when changed	does not change quality
filtration	when increased	increases quality

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Impact of Digital Imaging

- Digital (computer) imaging replacing conventional (film) systems
  - Images immediately available, can be stored and transmitted electronically and post processed to improve image after the fact
- Should result in lower dose to patients due to fewer retakes

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Dose Creep in Digital Imaging

- In some cases doses increased in digital systems
- Effect called dose creep
  - Digital resulted in good images without changing factors, even if patient dose was higher, so factors were not optimized to lower dose.
  - Also, techniques were used to reduce signal noise that resulted in increased dose.
- Manufacturer's recommendations should be reviewed to minimize dose to patient

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Reducing Patient (and employee) Dose from Medical X-rays

- Sources of radiation in Medical X-ray Imaging:
  - Primary beam – also called the useful beam; the X-ray beam coming from the tube, through the patient, to the image receptor.
  - Scatter radiation – radiation resulting from the primary beam interacting with other materials. The patient is often the largest source of scatter.
  - Leakage radiation – leakage radiation from tube housing, generally a minor source from a properly housed tube.

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Administrative Controls for Reducing Radiation Doses

- Chapter 221.11 of the Pa. Code, Title 25 - Environmental Protection, has a list of responsibilities for registrants to ensure doses are ALARA
- These responsibilities are summarized in the following tables:

Section Number	Summary of Requirement	Additional Comments and Clarifications
221.11(a)	Registrant is responsible for directing operation and assuring requirements are met.	
221.11(b)	Operator(s) shall be instructed in safe operating procedures and competent to use equipment. (1) The operator or the individual who supervises the operation of a high-risk procedure shall have additional instruction, which may include certification or registration in the applicable specialty by a professional organization recognized by the Department. Continuing education for high-risk procedures shall occur, at a minimum, every 2 years. (2) Continuing education for all other (low-risk) procedures shall occur, at a minimum, every 4 years.	Instructions shall include items in Appendix A of this section.
221.11(c)	Protocol Information for examinations performed with system shall be provided in vicinity of control panel. The protocol shall include information pertinent to the particular examination, such as: (1) The patient's body part and anatomical size, or body part thickness, or age (for pediatrics), versus technique factors to be utilized. (2) The type and size of the image receptor or film-screen combination. (3) The type of grid, if any. (4) The type and location of placement of patient shielding, for example, gonad, and the like. (5) For mammography, indication of kVp/target/filter combination. (6) Source to image receptor distance to be used, except for dental intraoral radiography.	Chart (or protocol information) should contain pertinent information to particular exams.

Section Number	Summary of Requirement	Additional Comments and Clarifications
221.11(d)	Written safety procedures and rules shall be available- including restrictions for safe use.	Operator shall be able to demonstrate familiarity with these rules.
221.11(e)	Only staff and others required for procedure or training shall be in room during the exposure.	Exception may be made for other patients in room that cannot be moved out (see 221.11(e)(3) below).
221.11(e)(1)	Except for patient, individuals shall be positioned so that no body part will be struck by the useful beam unless protected by 0.5 mm lead equivalent material.	Lead equivalent of material determined at 60kV.
221.11(e)(2)	Personnel required for exam shall be protected by protective aprons or barriers of at least 0.25 mm lead equivalent or not in direct line of useful beam and at least 2 meters away	Two meter distance is based on nearest portion of body from both tube head and nearest edge of image receptor
221.11(e)(3)	Other patient(s) in room that cannot be moved shall be protected by barriers of at least 0.25 mm lead or equivalent material; positioned out of direct line of the useful beam; and at least 2 meters away.	Again, two meter distance is based on nearest portion of body from both the tube head and nearest edge of image receptor.
221.11(e)(4)	No individual except patient being examined may be in useful beam, unless required to conduct procedure	
221.11(f)	When patient's gonads are in useful beam, gonad shielding of at least 0.5 mm lead equivalent shall be used unless it interferes with procedure.	
221.11(g)	Individuals may not be exposed to useful beam except for healing arts purposes or approved research (see 221.15)	Specifically prohibited are exposures for: training, demonstrations, other non-healing purposes. Exposures for screening purposes must be approved (see 221.13)
221.11(h)	If patient or image receptor requires auxiliary support during exposure: (1) Mechanical holding devices shall be used when technique permits, (2) Human holder shall be protected per 221.11(e), (3) Individual may not be used to routinely hold image receptors or patients.	
221.11(i)	Procedures and auxiliary equipment for minimizing patient and personnel exposure commensurate with needed diagnostic information shall be utilized.	

Section Number	Summary of Requirement	Additional Comments and Clarifications
221.11(j)	Screen and film systems used shall be spectrally compatible.	Defective screens may not be used for diagnostic screening.
221.11(k)	Film may not be used without intensifying screens for routine diagnostic imaging.	An exception to this is for intraoral radiography.
221.11(l)	Shall have a documented QA program in accordance with guidelines established by DEP or by appropriate organization recognized by DEP. At a minimum, QA program shall address: (1)Repeat rate, (2)DRL's (3)Image recording, processing, and viewing, (4)Image quality and artifacts (5)Maintenance and modifications to QA program. For CT, each study shall be checked. If an artifact is present, the registrant shall take corrective action as appropriate.	Records shall be maintained for inspection by DEP for 5 years. DEP's guidelines and list of recognized organizations are available on DEP's website and on request.
221.11(m)	Neither X-ray tube housing nor collimating device may be handheld during the exposure unless specifically designed to be handheld.	

Additional Techniques for Reducing Dose

- kVp and mAs settings
  - Generally lowest dose is achieved when kVp settings are increased and mAs settings decreased within the limits of obtaining a good image.
  - Prevent dose creep by “technique creep” – gradually increase kVp while decreasing mAs over successive exams as long as image quality remains satisfactory until optimum reached.

Additional Techniques for Reducing Dose

- Use of grids
  - While grids can reduce scatter radiation and increase image quality, they increase dose to patient.
  - Use only as necessary and avoid on children.
- Reducing Dose from scatter radiation
  - Workers should increase distance from patient, especially from beam side.
  - Use carbon fiber or similar material for cassettes, grids and tables.

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Additional Techniques for Reducing Dose

- Collimation and Beam Size
  - Primary beam should be sized to cover area of interest but not overly exceed it.
  - Collimation to the clinical region of interest should be performed prior to patient exposure.

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Special Cases - Children

- Historically, children have been imaged with settings similar to adults – resulting in unnecessary dose.
- IMAGE GENTLY campaign designed to make medical staff and parents aware of potentially unnecessary exposure to children.
- See website at: https://www.imagegently.org/

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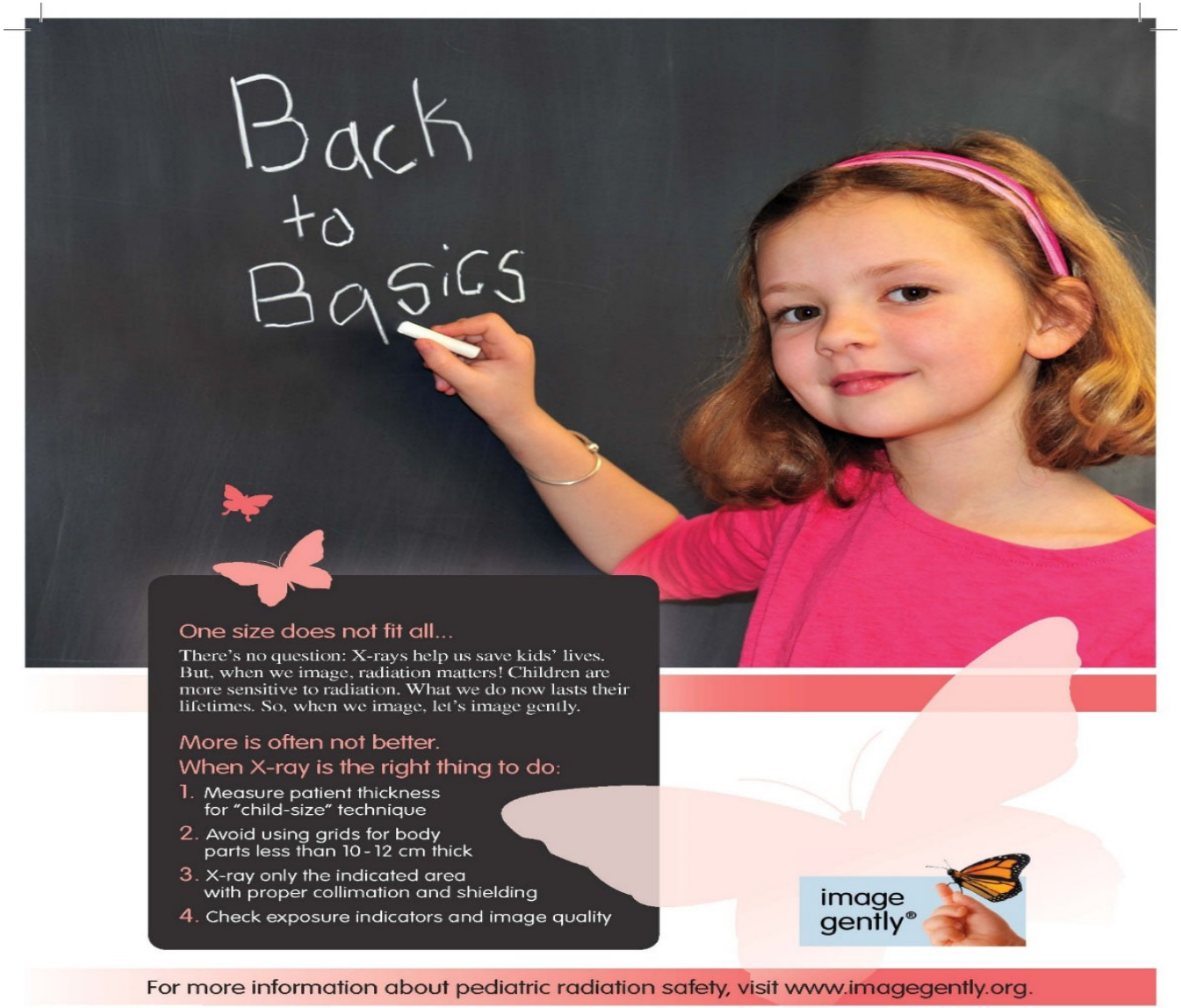

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BASICS: Image Analysis Tool

Beam:

- Was the x-ray beam centered on the area of interest?
- Was the tube angled correctly?
- Was equipment properly aligned to body part?

Artifacts:

- Is there anything obstructing the area of interest?
- Are positioning aids obscuring the anatomy?
- Is there excess quantum mottle/noise?
- Are there CR/DR processing errors present?

Shielding:

- Was gonadal protection indicated/ properly utilized?
- Was last menstrual period documented (when appropriate)?

Immobilization and Indicators:

- Was the selected technique based on measured body size?
- Are the Exposure Indicators/Deviation Index (EI/DI) in the appropriate range?
- How can you adjust for the next similar patient?
- Are artifacts, AEC, or field size changing the EI/DI?
- Could the baby, toddler, or child follow instructions?
- Could immobilization be used more effectively?
- Should our facility seek immobilization advice and training from a pediatric imaging facility?

Collimation:

- Was collimation appropriate?
- Was digital electronic post-collimation avoided?

Structures:

- Is all necessary anatomy included?
- Is there rotation present?
- Was the distance used appropriate?
- Is there evidence of patient motion?
- Were markers used correctly?
- Were grids used appropriately?

For more information about pediatric radiation safety, visit www.imagegently.org

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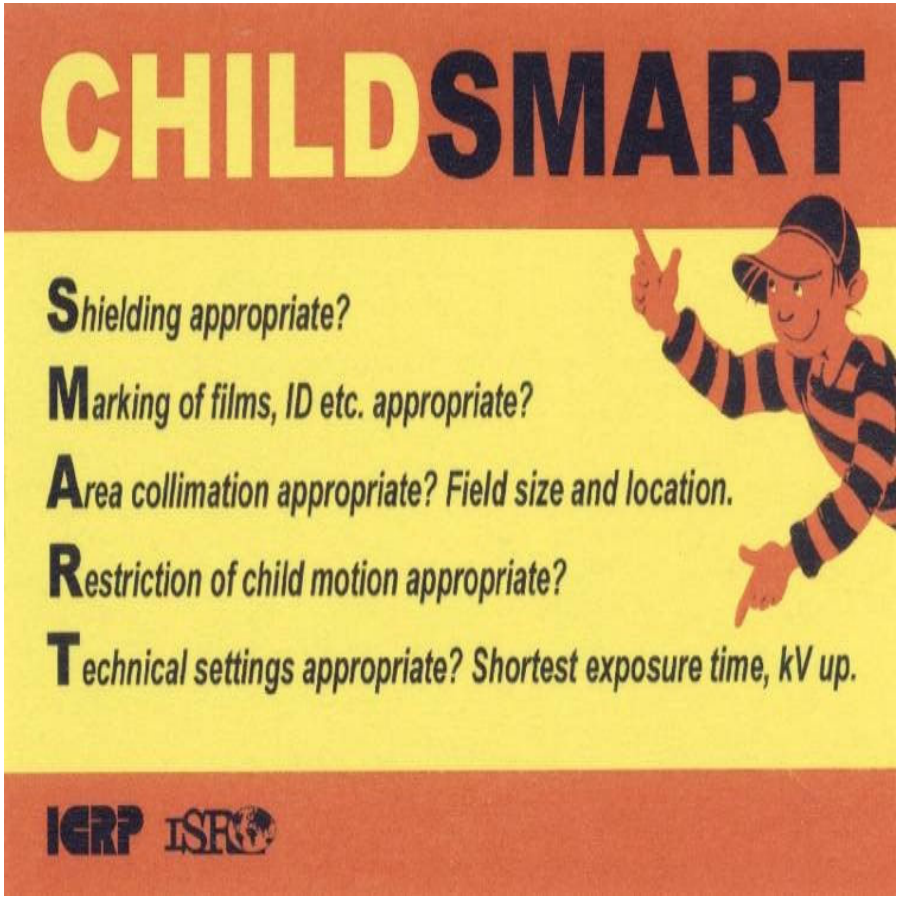
Additional Sources of Information

- International Atomic Energy Agency has PowerPoints available for free:
- http://rpop.iaea.org/RPOP/Content/AdditionalResources/Training/1TrainingMaterial/PaediatricRadiology.htm
- Poster from site:



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Other Special Cases – Patient Size

- Larger patients often require adjustments to kVp and mAs that result in higher dose.
- Example: An increase of body thickness from 16 to 24 cm increases scatter 5X.
- Staff should take additional precautions such as increasing distance from patient or use of portable shields.

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Pregnant Patients

- Special care should be taken to reduce dose to fetus:
  - Females of child-bearing age should be informed of risks.
  - Warning signs should be posted.
  - If X-ray is necessary, efforts should be made to reduce dose to fetus through shielding and/or positioning.

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Pregnant Workers

- Female medical staff required by federal and state regulations to be instructed on risks.
- Special limits apply to “declared” pregnant female (woman has option to declare pregnancy).
- NRC Regulatory Guide 8.13 provides information on risks, instructions on declaring pregnancy, and lower limits that then apply.

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Part 4

Radiation Safety Plan, Documentation and QA/QC

Radiation Safety Plan

Mechanism that ensures registrant properly directs X-ray program.

Guidance for Diagnostic & Interventional X-ray Procedures

From Federal Guidance Report No. 14

- Plan should ensure that:
  - Radiation activities are performed in accordance with existing laws and regulations.
  - Staff are equipped with knowledge of available options regarding risk vs. benefit determinations and appropriate examinations.
  - X-ray users and surrounding public receive adequate protection.

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Documentation of Medical X-ray Program

- Charts, records, procedures and other documentation are essential for safety and compliance.
- Pennsylvania regulations require certain documentation.

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Pennsylvania Requirements for Documentation

- 25 Pa. Code § 221.11(d)
  - Written safety procedures and rules available at facility.
  - Operators able to demonstrate familiarity with rules.
  - Procedures and rules should be specific for particular applications planned at facility.

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Pennsylvania Requirements for Documentation

- 25 Pa. Code § 221.11(c)
  - Protocol Information provided in vicinity of control panel specifying techniques for exams on that system.
- 25 Pa. Code § 221.12
  - Registrant shall maintain records of surveys, calibrations, maintenance, and modifications including names of person performing service.
  - Records kept for inspection for minimum of 5 years.

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Pennsylvania Requirements for Documentation

See 25 Pa. Code, Chapter 221 (X-rays in the Healing Arts) for other documentation requirements for specific applications.

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Quality Assurance

- According to FDA Regulations, Quality Assurance is defined as:

  "…the planned and systematic actions that provide adequate confidence that a diagnostic X-ray facility will produce consistently high-quality images with minimum exposure of the patients and healing arts personnel."

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FDA Statement on QA Actions

- Should include both “quality control” techniques and “quality administration” procedures:
  - QC techniques – techniques used in monitoring or testing and maintenance. Concerned directly with equipment.
  - QA procedures – management actions intended to guarantee monitoring techniques are properly performed and evaluated and corrective actions taken.

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Pennsylvania Regulatory Requirements for QA Program

25 Pa. Code, § 221.11(l) states:

"…the registrant shall have a quality assurance program. This quality assurance program shall be documented and in accordance with guidelines…"

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Guidelines for Developing QA Program

Available on DEP's website at:

https://www.dep.pa.gov/Business/RadiationProtection/RadiationControl/X-rayMachineProgram/Pages/Quality.aspx

- Pennsylvania guidelines and links to guidelines developed by appropriate professional organizations
- Fact sheets on:
  - "Minimum QA Requirements for Healing Arts Radiography"
  - "Model QA Guidelines for Dental, Diagnostic Radiology and Mammography"

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Part 5

Regulations

Brief History and Overview of Radiation Regulations

- X-ray machines regulated by states since their early development.
- Shortly after WW II, most radioactive materials and all nuclear reactors assigned to be regulated by federal government.
  - Originally under the Atomic Energy Commission (AEC) and later under the Nuclear Regulatory Commission (NRC).

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Agreement State Status

- Because of overlap of many regulatory issues regarding X-rays and radioactive materials, Agreement State arrangements were made.
- Federal agency (AEC and later NRC) would allow state regulatory oversight of most radioactive materials.
- Federal government maintained control over reactors and certain materials dealing with defense.

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Pa. Agreement State Status

- Pennsylvania became Agreement State in 2008.
- State regulations found in 25 Pa. Code – Environmental Protection, Chapters 215-240.
- Federal regulations from Title 10 of the Code of Federal Regulations (or more commonly: 10 CFR) incorporated into some Pennsylvania regulations by reference.

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Role of FDA

- Federal Food and Drug Administration (FDA) responsible for protecting public from hazardous or unnecessary exposure to radiation-emitting electronic products.
- Oversees manufacturer compliance and studies biological effects of radiation.
- FDA regulations found in 21 CFR.

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FDA, DEP and the MQSA

- FDA also regulates mammography facilities under the Federal Mammography Quality Standards Act (MQSA).
- In Pennsylvania, DEP's Bureau of Radiation Protection contracts with FDA to perform annual inspections of mammography facilities.
- Pennsylvania also maintains list of certified mammography facilities.

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Regulations Related to Use of Diagnostic X-rays

- Following slides briefly review regulations regarding diagnostic X-rays in 25 Pa. Code and the incorporated section of 10 CFR.
- Not intended to be comprehensive; registrants should always refer directly to the regulations for issues at their facilities.

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Registration of Radiation-Producing Machines

25 Pa. Code Chapter 216

- Provides requirements for registration, renewal, expiration, or termination of certificate of registration and transfer or disposal of machine.
- Applications for renewal sent out at least 2 months prior to expiration.
- DEP must be notified of transfer or disposal of X-ray devices.

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Standards for Protection Against Radiation

25 Pa. Code Chapter 219

- Largely parallels federal regulations in 10 CFR Part 20, which are incorporated by reference.
- Many sections not relevant to X-ray facilities since they apply to radioactive materials.
- Will highlight those that apply to medical X-ray devices.

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Occupational Dose Limits

25 Pa. Code §§ 219.21-22

- Applies only to occupational workers – individuals exposed in course of their work.
- Does not include background radiation, medical administration to the worker, or other exposures as a member of the public.

Note: this means that radiation doses to an individual from medical procedures performed on them do not fall under these regulations – a frequent concern of radiation workers.

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Annual Occupational Dose Limits for Diagnostic X-ray Workers with no Other Occupational Exposure

Effective Dose Equivalent to Whole Body	5 rem (0.05 Sv)
Lens of Eye Dose Equivalent	15 rem (0.15 Sv)
Shallow dose equivalent to skin of whole body or extremity	50 rem (0.5 Sv)
Dose limits for minors (occupational) (< 18 years old)	10 % of adult limits
Dose equivalent to embryo/fetus of declared pregnant female (See NRC Reg. Guide 8.13)	0.5 rem (5 mSv) during entire pregnancy (See 10CFR20.1208 for additional information and guidelines)

Dose Limits for Public

25 Pa. Code § 219.51

- Shall not exceed 0.1 rem (1 mSv) in a year.
- Excludes background radiation or medically administered radiation.

Example: This limit applies to a patient (or other family member) in a waiting room, but not to the medical treatment of the patient.

Note: Value was changed from 0.5 rem in 1990s; Pennsylvania does not require retrofitting of shielding for installations existing before Nov. 18, 1995 as long as similar equipment is used.

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Shielding of X-ray Facilities

- X-ray facilities are shielded to protect individuals in adjoining areas and are based on expected use of those areas outside the X-ray room.
- Major renovations of facilities or replacement of machines resulting in higher workloads may require a review of the shielding in-place to ensure that it is still adequate.

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Storage and Control

25 Pa. Code §§ 219.131-132

- Sources of radiation (including X-ray machines) shall be secured from unauthorized removal or access while in storage or available for use.

Posting Requirements

25 Pa. Code §§ 219.159-160

Radiation-producing machines are required to be labeled indicating that radiation is produced when energized:

CAUTION – RADIATION

THIS EQUIPMENT PRODUCES RADIATION WHEN ENERGIZED

(Caution signs based on radiation level not required for rooms with machines used solely for diagnosis in the healing arts).

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Reporting Requirements

25 Pa. Code §§ 219.221,222,229

- Report shall be made to the state of stolen, lost or missing sources of radiation including radiation-producing machines.
- Report required to state if determination by physician of actual or suspected damage to organ or system of patient exposed to therapeutic or diagnostic radiation.

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Notices, Instructions & Reports to Workers; Inspections &Investigations

- Registrants required to post:
  - Pa. Code Chapters 219 and 220
  - Certificate of Registration
  - Applicable operating procedures
  - Notices of violations
- Alternatively, registrant may post notice describing documents and where they may be examined.

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Notices to Employees"

- DEP Form 2900-FM-RP0003 "Notice to Employees" required to be posted.
- Available on DEP's website.
- Outlines employer's and worker's responsibilities, items covered by regulations, reports on workers' radiation history and inspections.
- Provides contact information for DEP's Bureau of Radiation Protection.

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2900-FM-BRP0003 Rev. 1/2017

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COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF ENVIRONMENTAL PROTECTION
BUREAU OF RADIATION PROTECTION

NOTICE TO EMPLOYEES

STANDARDS FOR PROTECTION AGAINST RADIATION; NOTICES, INSTRUCTIONS AND REPORTS TO WORKERS; INSPECTIONS; EMPLOYEE PROTECTION

In Title 25 of its Rules and Regulations, the Pennsylvania Department of Environmental Protection has established standards for your protection against radiation hazards and has established certain provisions for the options of workers engaged in work under a Department license or registration.

YOUR EMPLOYER'S RESPONSIBILITY

Your employer is required to:

1. Apply these Department of Environmental Protection regulations and any conditions of your employer's radioactive materials license to all work involving radiation sources.
2. Post or otherwise make available to you a copy of the Department of Environmental Protection regulations, licenses, and operating procedures which apply to work in which you are engaged, and explain their provisions to you.
3. Post Notice of Violation involving radiological working conditions, proposed imposition of civil penalties and orders.

YOUR RESPONSIBILITY AS A WORKER

You should familiarize yourself with these provisions of the Department of Environmental Protection regulations and operating procedures which apply to the work in which you are engaged. You should observe their provisions for your own protection and protection of your co-workers. If you observe a violation or possible safety concern, you should report it immediately to your supervisor or contact DEP. You may be personally subject to enforcement action if through deliberate misconduct you cause or attempt to cause a violation of DEP requirements or deliberately provide inaccurate or incomplete safety information to DEP or your employer.

WHAT IS COVERED BY THESE REGULATIONS

1. Limits on exposure to radiation and radioactive materials in restricted and unrestricted areas.
2. Measures to be taken after accidental exposure.
3. Personal monitoring, surveys, and equipment.
4. Caution signs, labels, and safety interlock equipment.
5. Exposure records and reports.
6. Options for workers regarding Department inspections.
7. Related matters.

REPORTS ON YOUR RADIATION HISTORY

1. The Department of Environmental Protection regulations require that your employer give you a written report if you receive an exposure in excess of any applicable limit as set forth in the regulations or the license. The basic limits for exposure to employees are set forth in Chapter 219 of the regulations. This chapter specifies limits on exposure to radiation and exposure to concentrations of radioactive material in air.
2. If you work where personal monitoring is required pursuant to Chapter 219:
   (a) Your employer must advise you annually of your exposure to radiation, and
   (b) You may request a written report of your radiation exposure when you leave your job.

INSPECTIONS

All activities involving radiation are subject to inspection by representatives of the Pennsylvania Department of Environmental Protection. In addition, any worker or representative of workers who believes that there is a violation of the Department regulations of the terms of the employer's license or registration with regard to radiological working conditions in which the worker is engaged may request an inspection by sending a notice of the alleged violation to the Bureau of Radiation Protection. The request must set forth the specific grounds for the notice and must be signed by the worker as the representative of the workers or the worker's self. During inspections, Department inspectors may confer privately with workers, and any worker may bring to the attention of the inspectors any past or present condition which that worker believes contributed to or caused any violation as described above.

INQUIRIES

Inquiries dealing with matters outlined above or other reports and correspondence can be sent to the Bureau of Radiation Protection, Pennsylvania Department of Environmental Protection, P.O. Box 8469, Harrisburg PA 17105-8469.

Telephone (717) 787-2480
Facsimile (717) 783-8965
Off-hours emergency, call PEMA: (717) 651-2001

POSTING REQUIREMENTS

Copies of this notice must be posted in a sufficient number of places in every establishment where activities covered by the regulations are conducted to permit employees working in or frequenting any portion of a restricted area to observe a copy on the way to or from their place of employment.

X-rays in the Healing Arts

Chapter 221 provides detailed information on requirements for medical X-rays

- General Provisions (§§ 221.1 and 221.2) discuss purpose and scope of this chapter and provide extensive list of definitions.
- Administrative Controls (§§ 221.11-221.15) cover registrant responsibilities, reports, records, applicability and associated information. These controls have largely been covered during the section on X-ray machines.

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X-rays in the Healing Arts

- Diagnostic Installations General Requirements (§§ 221.21-221.50) provide specific regulations for operation, maintenance, and control of X-rays used in healing arts.
- Registrant should review these regulations for their specific facility to determine application.
- A table of the section titles and a brief review of the requirements follows:

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Section Number and Title	Abbreviated summary of section requirements (See Regulations for Additional Details)
221.21 Diagnostic equipment requirements	Certified components shall comply with relevant regulations of the Food and Drug Agency (21CFR 1020.30 – 1020.33) Diagnostic systems incorporating one or more certified components shall comply with 21 CFR 1020.30—1020.33. Equipment registered after January 24, 2019, must comply with 21 CFR 1010.2 (relating to certification).
221.22 Battery charge indicator	Control panels on battery powered x-ray generators shall visually indicate proper battery operation
221.23 Leakage radiation from diagnostic source assembly	May not exceed 100 mR in one hour at 1 meter
221.24 Radiation from components other than diagnostic source assembly	May not exceed 2 mR in 1 hour at 5 cm from accessible surface
221.25 Beam Quality	Table I gives minimum filtration requirements based on operating voltage. Table II gives minimum HVL values that will meet these requirements
221.26 Multiple tubes	When multiple tubes are controlled by one switch, indicators on the control panel and at or near the tube housing assembly shall indicate which tube has been selected

Section Number and Title	Abbreviated summary of section requirements (See Regulations for Additional Details)
221.27 Mechanical support of tube head	Tube housing assembly shall remain stable during exposure (unless movement is a designed function of system)
221.28 Technique indicators	Technique factors shall be indicated (except for automatic exposure controls in which case mAs shall be indicated). Equipment having fixed technique factors may indicate them with permanent marking on equipment
221.29 Kilovoltage (kV) accuracy	Output for variable kV units may not vary from set-indicated value by more than 10% Output for fixed kV units may not vary from set-indicated value by more than 20%
221.30 Exposure reproducibility for noncertified systems	Coefficient of variation of exposure reproducibility may not exceed 0.1 when technique factors held constant. (See definitions in 221.2 for formula for this calculation)
221.31a Locks	Position locking, holding and centering devices shall function as intended
221.32a Radiographic beam limitations	Useful beam shall be limited to area of clinical interest. Specifics are given for beam limiting devices regarding accuracy, adjustment, and alignment. Intraoral dental system requirements for beam limitation are specified

Section Number and Title	Abbreviated summary of section requirements (See Regulations for Additional Details)
221.33a Radiation from capacitor energy storage equipment in standby status	When switch or timer not activated, may not exceed 2 mR/hour at 5 cm from accessible surface when fully charged and beam limiting device fully open
221.34a Radiation exposure control	Requirements to ensure exposure controls are given including switch operations, visible and audible signals and other requirements for manual and automatic exposure control. Also stationary systems shall have controls in protected area and require operator to remain there; mobile and portable units shall be designed so operator is at least 2 meters from patient and x-ray tube head when operating system.
221.35a Fluoroscopic x-ray systems	Fluoroscopic X-ray systems shall use an image intensifier and, in addition to the requirements of § § 221.1—221.34a, shall meet the requirements of § § 221.36a—221.38a (relating to limitation of useful beam of fluoroscopic equipment; activation of fluoroscopic tube; and entrance exposure rate). In addition to the applicable sections of these regulations, the operation of a fluoroscopic unit for clinical purposes can only be operated by individuals with specific qualifications. § 221.35a(b)
221.36a Limitation of useful beam of fluoroscopic equipment	Requirements are given for primary protective barrier placement, adjustment and size of the x-ray field, minimum source to skin distance, and spot image device requirements

Section Number and Title	Abbreviated summary of section requirements (See Regulations for Additional Details)
221.37a Activation of fluoroscopic tube	Dead-man switch and means to terminate serial images shall be provided
221.38a Entrance Exposure Rate	Entrance exposure rates, frequency of measurements and compliance requirements are given Entrance exposure rates are: 10 R/min. for systems without high level control 20 R/min. for systems with high level control activated 10 R/min. for systems with high level control, but not activated
221.39a Barrier transmitted radiation rate limits	Protective barrier may not transmit >2mR/hr at 10 cm from accessible surface of fluoroscopic imaging assembly for each R/min. of entrance exposure rate
221.40a Indication of tube voltage and current	During fluoroscopy and cinefluorography, voltage and current shall be indicated
221.41a Fluoroscopic timer	Timing device activated by fluoroscopic switch shall be provided. It shall provide audible signal or temporary/permanent interruption when preset limit not exceeding 5 minutes is reached
221.42a Control of scattered radiation	Limits for scatter radiation originating either under or above the table top are specified
221.43a Mobile fluoroscopes	In addition to other fluoroscopic requirements, shall provide image intensification

X-rays in the Healing Arts

- Remainder of Chapter 221 deals with radiation therapy simulations systems, therapeutic X-rays systems with energies less than 1 MeV and computed tomography X-ray systems and are beyond the scope of this training program.

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Conclusion

- This section has presented an overview of the regulations that apply to medical X-rays used in low-risk procedures. Registrants should directly consult the applicable regulations or contact the Pennsylvania Department of Environmental Protection, Bureau of Radiation Protection, for questions or concerns.

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Online Continuing Education Radiation Safety Quiz

- The Online Continuing Education Radiation Safety Quiz is found at:

http://www.dep.pa.gov/Business/RadiationProtection/RadiationControl/X-rayMachineProgram/Pages/Continuing-Education-In-Radiation-Safety-Quiz.aspx

- Upon successful completion of the quiz, print out the confirmation webpage and retain in your records.

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Contact Information

Pa. Department of Environmental Protection

Bureau of Radiation Protection

P.O. Box 8469

Harrisburg, PA 17105-8469

Telephone (717) 787-3720

Email: RA-EPRadiationContro@pa.gov

Off-hours emergency call PEMA (717) 651-2001

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