Temple University
Environmental Health and Radiation Safety

TEMPLE UNIVERSITY

RADIATION SAFETY GUIDE FOR DIAGNOSTIC IMAGING X-RAY PRODUCING EQUIPMENT

Published by
Temple University
Environmental Health & Radiation Safety
November 2019

Table of Contents

Introduction

The purpose of this Radiation Safety Guide for X-ray Producing Equipment is to inform Temple University and Temple Health System (collectively referred to herein as Temple) X-ray users and supervisors of the policies in place to ensure the safe and compliant application of X-ray producing machines and equipment. For more information on analytical X-ray units, cabinet X-ray units, please refer to the Temple X-ray Analytical Guide.

Radiation Fundamentals

Among the various types of radiation, this guide will focus solely on X-rays. X-rays are photons capable of producing ions both directly or indirectly. This phenomenon, referred to as ionization, is known to be hazardous and is subsequently regulated.

Radiation Quantities

In order to effectively communicate the amount of radiation, we need to provide units in conjunction with a numerical value. Typically exposure, absorbed dose and dose equivalent are used with X-ray producing machines.

Exposure is a measure of the ionization produced in air by radiation. The conventional unit for exposure is roentgen (R). In general practice the radiation exposure is paired with a time measurement (i.e. R/hr).

Absorbed dose is the amount of energy deposited in any material from the ionizing radiation. Absorbed dose is measured in the conventional unit rads. A rad is a measure of energy absorbed per gram of material. The SI unit of absorbed dose is the gray (Gy), which is 0.01 rad.

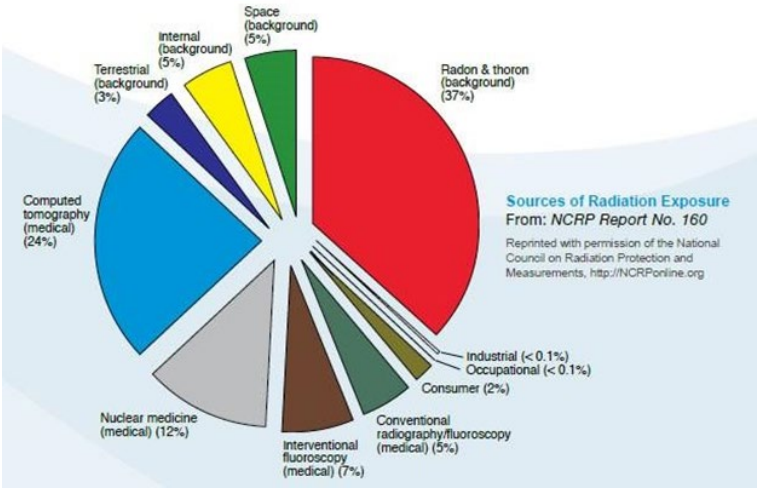
Dose equivalent is a measure of the effectiveness of the absorbed dose. It expresses the effect of all radiation on a common scale for calculating the effective absorbed dose. The conventional unit of dose equivalent is rem, which is defined as the product of absorbed dose, rad, and the quality factor (Q; Q=1 for X-rays/gammas) for the type of radiation. The SI unit of dose equivalent is Sievert (Sv) which is equivalent to 0.01 rem.

Terminology	Conversion
Dose	1 Gy = 100 rad
Dose Equivalent	1 Sv = 100 rem

Background Radiation

Radiation occurs naturally in the world we live in. We are exposed from space, the earth, the air we breathe and the food we eat. This natural phenomenon is commonly referred to as background radiation.

In the United States, we receive about half (300 mrem) of our radiation exposure from natural sources of radiation and the remaining half from man-made sources. Totaling our average annual radiation dose to approximately 600 millirem (mrem) per year. This exposure to man-made sources is primarily a result of diagnostic imaging used to provide a level of standard care to the public and could be higher or lower based on an individual's health. It should be noted that these published values from the National Council on Radiation Protection (NCRP) Report No. 160 are averages to the general public and do not include any occupational exposures.



Biological Effect of Radiation

The fact that ionizing radiation causes biological damage has been known for many years. The first case of human injury was reported in literature just a few months following Roentgen's discovery of X-rays in 1895.

Biological effects of ionizing radiation on living cells may result in three common outcomes:

- Cells repair themselves, resulting in no damage;
- Cells die, much like millions of body cells do every day, being replaced through normal biological processes; or

- Damaged cells (mutations) that are not repaired may still be able to reproduce mutated progeny. (Even though this potential does exist, it is the least likely of the scenarios due to the inherent repair mechanisms in place.)

The biological effects of radiation can vary greatly from no adverse effects to death. This is dependent on the amount of radiation a person is exposed to. The amount received is determined from the duration exposed to a particular rate. A very short exposure, typically minutes to hours, is commonly referred to as an acute exposure. Whereas a chronic exposure is defined for longer exposure times.

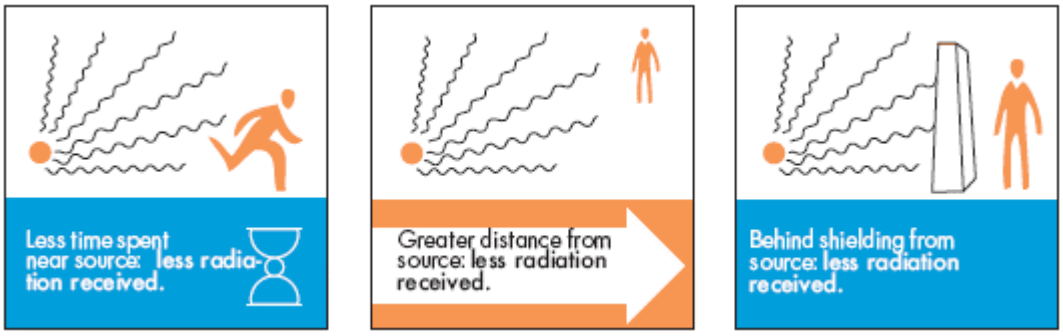
The biological effects observed may be classified as prompt or delayed effects. Prompt effects can appear in a matter of minutes to as long as a few months after exposure. Prompt effects are typical due to very high acute doses of radiation and can be commonly referred to as deterministic effects. This means that the biological effects are generally observed once a certain exposure is received. Although this threshold may vary from one person to the next, there is a defined dose range for which a particular biological effect may be observed from an acute exposure to radiation. Generally speaking, an acute exposure to the skin of 200-600 rem (2-6 Gy) could promptly result in erythema.

Delayed biological effects take many years to appear and are typically an outcome from chronic low dose exposures. Genetic effects and the development of cancer are the primary biological health concerns. The length of time before the effect is observed, the latency period, increases the degree of uncertainty. Since this uncertainty is so great, the effects of chronic radiation exposure are stochastic. This means that the biological effects manifest randomly and are not a definitive outcome for a particular individual.

Current studies of a population exposed to chronic low-levels of radiation above background have shown no biological effects. This population includes occupationally exposed radiation workers and people living in areas having high levels of background radiation above 1,000 mrem per year.

Radiation Protection

Radiation protection is a term applied to concepts, requirements, technologies and operations related to protection of radiation workers, members of the public, and patients against the harmful effects of radiation. This requires trained and experienced workers using good radiation safety practices and equipment. The three basic principles of ionizing radiation protection are time, distance and shielding.



The three principles regarding the use of radiation are justification, optimization and dose limitation. These terms are defined below as:

- *Justification:* No practice involving exposures to radiation should be utilized unless it produces sufficient benefit to the exposed individuals to offset the detriment it may cause.

- *Optimization:* Once a practice has been justified, it is necessary to consider how best to use resources in reducing the radiation risk to individuals. The objective is to keep doses as low as reasonably achievable, ALARA, while achieving an image sufficient for clinical diagnosis.

- *Limitation:* Exposure of individuals are subject to dose limits, or to some control of risk in the case of potential exposure. These are aimed at ensuring that no individual is subject to radiation risks deemed to be unacceptable by the regulatory agency, applicable guidance, institutional policies and goals.

Since radiation has been widely used, dating back to the 1940s-1950s, it became quickly apparent that it needed to be regulated. However, available data on the radiation hazard was sparse and posed a unique challenge to the regulatory pioneers. Thus they were ultra conservative in their regulations. Specifically, the regulating agencies have decided to accept a linear-no-threshold (LNT) response model to chronic exposures and limit the annual exposure of an adult occupational radiation worker to 5,000 mrem.

This LNT concept means that there is some risk regardless of the exposure. The increased risk of cancer to a population, as published by the International Council of Radiation Protection (ICRP), for an adult is approximately 4.1% per Sievert[1] from chronic low dose rate exposures. ICRP states that there is no evidence to any radiation induced heritable diseases in humans.

To define the meaning of this risk, a comparison is made between other common circumstances in society. The average life expectancy of a population in the United States is considered to diminish

[1] ICRP Publication 103, 2007.

by: 2,400 days to those who smoke 20 cigarettes per day; 200 days by auto accidents; 130 days by alcohol consumption; 30 days for those exposed to 1 rem/year for 30 years. In comparison, the risk from exposure to low levels of radiation is less than these other life events.

Employee Protection

Registration of Radiation Workers

The Commonwealth of Pennsylvania (PA) Department of Environmental Protection (DEP) regulations require that individuals who work with or in the presence of radioactive materials or radiation are provided training prior to working. Adult workers who have the potential of receiving a dose in excess of 10% of the regulatory limit (500 mrem/yr.) and minors or declared pregnant worker who are likely to receive 50 mrem are required to be monitored for occupational exposure. In addition, Temple Policy requires that all radiation workers register with the Environmental Health and Radiation Safety (EHRS) Department and be at least 18 years of age.

A Radiation Worker Registry (RWR) is maintained by EHRS and requires employee's social security numbers in order to ensure that the regulatory requirements are met. Managers are required to register workers who are using X-ray producing machines under their supervision and give them task specific training. This RWR Form can be found on the EHRS webpage or at the EHRS office (3307 N. Broad St., # B-49).

If at any time during the course of employment an individual works at another site or facility and will be exposed to radiation within or outside of the Temple Organization, he or she must notify EHRS. EHRS is responsible for compiling radiation workers' occupational exposure regardless of where it is received.

Training

EHRS provides radiation safety training to all employees working with or in the presence of radiation. Individuals who operate or supervise operators of an X-ray producing machine must complete annual training and demonstrate competence in compliance with all Federal Regulations, Commonwealth of Pennsylvania's Regulations (§ 221.16) and The Joint Commission.

Occupational Dose Limit

The annual dose limit for an occupational radiation worker is 5,000 mrem for whole body, 15,000 mrem for the lens of the eye and 50,000 mrem for organs (e.g. breast, lung, and skin) and extremities.

Badging and Dosimetry

EHRS provides personal monitoring devices (dosimetry; badges) to determine the radiation exposure of a particular worker. The proper use of dosimetry can be used to evaluate whether proper radiation safety practices and controls are in place. Some individuals who are not required to be monitored may be discretionarily monitored as a means of good work practice. If you have any reason to believe you should be monitored and currently are not, please contact EHRS directly at 215-707-2520.

Individuals assigned a dosimeter must only wear their badge at the assigned Temple location. For information regarding your particular scenario, please contact EHRS.

All unreturned and unused badges will be subject to an administrative fee determined by EHRS and the Radiation Safety Committee (RSC) per wear period. Repeated non-compliance will be referred to the RSC for further action.

Successful interpretation of the measured dose depends on the proper placement of the dosimeter. All personnel must wear their dosimeters correctly. The following list indicates where the dosimeters are to be worn:

- For protective garment users, the whole body badge must be worn outside of the protective garment at the collar level.

- For users not wearing protective garments, the whole body badge should be worn centered on the torso.

- The ring dosimeter must be worn on the hand most likely to be exposed and oriented in the direction that receives the maximum exposure.

Dosimeters are sensitive to extreme heat. Store dosimeters in an area away from any radiation source. Your department supervisor should have a designated location in a cool low background area for the storage of dosimeters when not in use.

Exposure of a monitoring device to deceptively indicate a dose delivered to an individual is prohibited and is a violation of PA DEP regulation (PA Code § 215.28 & § 215.25).

Declared Pregnant Worker

The PA DEP has set limits for radiation exposure to the embryo/fetus of a declared pregnant woman. The PA DEP requires that the dose to an embryo/fetus during the entire pregnancy, from occupational exposure of a declared pregnant worker, be reduced to not exceed 500 mrem. Efforts must be made to assure that this dose is distributed uniformly over the entire period of pregnancy and do not exceed the exposure limit.

A pregnant employee is encouraged to voluntarily inform the employer, in writing, of the pregnancy and the estimated date of conception. Employees interested in declaring pregnancy should contact EHRS at 215-707-2520 to schedule a meeting. During this confidential meeting, the pregnant worker will receive information regarding concerns about radiation exposure during pregnancy.

The meeting will include:

- Evaluate the exposure history of the individual and equivalent tasked employees;
- Provide information concerning risk and precautions;
- Evaluate the working environment with respect to radiation exposure;
- Make recommendations for reducing radiation exposure;
- Monitor monthly radiation exposure with respect to the PA DEP limits; and
- The employee can then decide to make the declaration of pregnancy. A monthly fetal dosimeter will be issued upon completion of the Declaration of Pregnancy Form.

Exposure Reports

All individuals who are badged receive their respective exposure reports annually. Individual exposure reports are available by contacting the EHRS Department during normal business hours for individuals who wish to review their exposure history. EHRS reviews all exposure reports. High and unusual exposures are investigated and reported to the RSC along with the result(s) of the investigation.

As Low as Reasonably Achievable (ALARA)

This policy provides specific guidance and data on Temple's approach to implement the *as low as reasonably achievable* (ALARA) principle. ALARA is achieved through the use of: training; engineering controls; administrative controls and limits; Image Wisely and Image Gently Campaigns; and personal protective equipment.

To evaluate the effectiveness of Temple's ALARA program, EHRS reviews personnel exposures on a regular basis. A written report is provided to the RSC that includes any abnormal exposures, those exceeding ALARA Level I and II, and the results of the subsequent investigation by EHRS of such exposures. ALARA Level I and II are stated below:

	ALARA Notification	ALARA Level I		ALARA Level II		
	mrem/month	mrem/qtr.	mrem/yr.	mrem/mo.	mrem/qtr.	mrem/yr.
Whole Body Non Protective Garment(s) User	40	120	480	120	480	1440
Lens of the Eye	125	375	1500	375	1125	4500
Extremities	400	1200	4800	1200	3600	14400
Whole Body Lead Equivalent Garment(s) User*	125	375	1500	375	1125	4500
Whole Body Interventional Radiologists & Cardiologists**	450	1400	5600	1150	3500	14000
Extremities Interventional Radiologists & Cardiologists	1000	3000	12000	3000	9000	36000

* For fluoroscopy guided users, the reported deep dose equivalent may be multiplied by 0.3 to determine the effective dose equivalent when the dosimeter is worn outside the garment at collar level, NCRP 122.

** For fluoroscopy guided interventional procedures, the reported deep dose equivalent may be divided by 5.6 to determine the effective dose equivalent when the dosimeter is worn outside the garment at collar level, NCRP 168.

EHRS evaluates the cause of radiation exposure above ALARA limits through an interview with the responsible individual and presents their findings to the RSC, with the request to provide guidance to EHRS for possible corrective actions. EHRS in turn, implements the recommendations on behalf of the RSC. In every case, the individual will be asked to take steps to reduce the radiation exposure unless the individual can demonstrate that all reasonable measures were utilized to keep the radiation exposure ALARA.

Shielding

Shielding is a physical object that will attenuate or terminate the X-rays impinging upon it. It is used to protect employees, patients and others from unintended stray radiation. The shielding can be incorporated in walls or other barriers, such as protective garments.

Protective Garments

Protective garments are worn by those who must be in an area where X-rays are used. The garments can be made of either lead or lead free materials. Regardless, all garments will be marked with its *lead equivalency (Pb eq.)*, a measure of the amount of protection offered.

When choosing an appropriate level of protection, the intended use or uses of the garment must be carefully considered. The style, proper sizing and weight of the garment are additional factors for consideration. For general X-ray usage, protective garments must have at least 0.25 mm Pb eq. Since there is a possibility that some body parts may be exposed to the useful/primary beam during interventional or other procedures with high beam-on times, garments protecting those body parts must have at least 0.5 mm Pb eq., and at least 0.35 mm Pb eq. would be recommended for individuals participating in these procedures who are not at risk of being struck by the useful/primary beam. Thyroid shields should be 0.5 mm Pb eq. for optimal protection.

To ensure a long usable life, garments must be cared for properly. Specifically garments must always be hung, never folded. Do not clip dosimeters directly onto a garment. Routinely clean with a hospital approved disinfectant, and implement manufacturer recommendations.

Garments must undergo annual inspections or whenever damage is suspected. Additionally, newly added garments to the Temple institution must undergo a documented initial inspection prior to use. Protective glasses, goggles, gloves, shields and barriers must be visually inspected by the user before each use.

Structural Shielding

Shields/barriers (whole protective barriers) placed in procedure rooms must be at least 0.25 mm Pb eq. or positioned to prevent individuals from being in the direct line of the useful/primary beam and such that the nearest portion of the body is at least 2 meters from both the tube head and the nearest edge of the image receptor.

Procedure rooms have been designed with sufficient shielding in the walls to provide protection to anyone outside of the room or at the control areas. The integrity of the shielded walls should not be tampered with. If structural changes are intended or made, such as holes drilled into walls

(hanging pictures, etc.), notify EHRS or the individual responsible for radiation protection of the facility as soon as possible.

A structural radiation shielding design assessment is conducted prior to imaging equipment installation or room modification. A radiation survey is conducted after installation of imaging equipment or construction. The survey must be performed prior to clinical use. Contact EHRS with intent to install equipment, construct or modify procedure rooms.

Patient Protection

Protection of Patients or Human Research Subjects

Patients and human subjects are individuals who willfully consent and are authorized by a licensed practitioner of the healing arts to receive a particular procedure. Exposure of an individual for the purpose of research must additionally be approved by the Institutional Review Board (IRB), RSC and meet the PA Code (§ 221.15) requirements. Approval must be obtained before initiation of any research study.

The order by the physician is documented on the prescription form and must be verified by the technologist performing the study prior to exposure. Particularly the technologist must ensure the correct patient, correct site and correct position prior to exposure as authorized by the licensed practitioner.

Sensitive body organs such as the gonads and the lens of the eye should be shielded with at least 0.5 mm and 0.2 mm lead equivalent respectively if these organs are in the primary beam, provided such shielding does not interfere with the diagnostic procedure or medical treatment.

The equipment must be routinely maintained in proper working condition. Protocols must be setup to provide diagnostic quality to the physicians, while yielding the lowest practical dose to the patients. This method adheres to the Image Wisely & Image Gently Campaigns.

Radiation Protection During Pregnancy

Special consideration must be given to protect the embryo or fetus of patients known to be, or potentially, pregnant. A patient of childbearing age should be questioned and/or tested to ascertain the likelihood of pregnancy. The purpose of screening patients for the possibility of pregnancy is to reasonably minimize the exposure to the patient and the embryo or fetus.

If the patient is found to be pregnant or likely to be pregnant and the embryo or fetus may be in the primary beam, the procedure is considered to be a high risk to the embryo or fetus. For these high risk patients the physician, radiologist and/or medical physicist should be consulted to decide whether the radiation dose to the patient and embryo or fetus is justified. The decision to proceed for a high risk pregnant patient should be made by the patient and the authorizing physician. A physician may expose a high risk patient to radiation, in the best interest of the patient.

General Public Protection

Protection of Persons Other Than the Subject

No individual shall be exposed to the useful beam for training, demonstration or non-healing arts purposes. Implementing the three basic radiation safety principles; time, distance, & shielding; will reduce exposure to ancillary personnel and the general public.

All individuals within 2 meters of the X-ray unit must be shielded or wear protective garments. This is including and not limited to any individual whom may be passing by. If an X-ray is being performed in a common area, it is the responsibility of the technologist to secure an area at least 2 meters around the unit to ensure no inadvertent exposure to the general public.

All X-ray units are evaluated to ensure proper wall shielding is installed. In some cases EHRS may post a limit for the beam on time of a given room. If this limit is ever exceeded, EHRS must be notified. Additionally, if the occupancy of an adjacent area to an X-ray unit changes, EHRS shall be notified immediately to reassess the exposure potential.

General Operating Procedures & System Requirements

All staff supervising or operating X-ray producing equipment must complete the annual Temple X-ray training for each modality used. Prior to the first use, the individual must be trained and display competency on each model used, in good standing by a PA DEP recognized organization (ARRT, Medical Board, etc.) and/or under the appropriate level of supervision by an authorized individual for human use. Specific requirements for operators can be found in 49 PA Code Part I, Subpart A. Written safety procedures and policies must be available to all staff regarding techniques and safe operation of each particular X-ray system.

No individuals other than the operator and/or ancillary employees should be in the room while an X-ray producing machine is in use. Under rare circumstances other patients or individuals may

remain. For these rare occurrences, under no circumstance may another person be within the useful beam or within 2 meters without interposed shielding or protective garment(s). Every attempt to use a device (i.e. Pigg-O-Stat, etc.) to correctly position the patient shall be performed prior to manually manipulating a patient physically with another individual. If another individual is required, proper protective garments must be utilized. As required by law, under no circumstances may any individual be exposed to the useful beam for training, demonstration, non-healing arts practice or unauthorized healing art practice (PA CODE § 221.11 (g) (1)).

The dose to the patient or human research subjects must be kept ALARA and consistent with clinical objectives. The useful beam must be collimated to the area of clinical interest. Too low of an exposure may compromise the examination and diagnosis. Any inadvertent damage to the patient's organs or physiological systems must be documented and reported to EHRS. Other notification requirements to EHRS are described later in the document.

Departmental management must maintain a current inventory of all X-ray producing machines which must include at a minimum the manufacturer, model, serial number, location and registration due date. Ensure all staff are properly trained, competent and knowledgeable of all safety and operational procedures.

Protocol information for each examination must be retrievable and include: the patient's body part and anatomical size, or body part thickness, or age, versus technique factors to be utilized; the type and size of the image receptor; if used, the type of grid; the type and location of placement of patient shielding (i.e. gonads); source to image receptor distance to be used, except for dental intraoral radiography; for mammography, indication of kVp/target/filter combination.

As required by law, a quality assurance program must be in place. The quality assurance program will ensure that doses to patients or human research subjects are in accordance with the standards of good practice. As described in the PA DEP regulations, this program must include: repeat rate; diagnostic reference levels; image recording; processing and viewing; image quality and artifacts; and maintenance and modifications to the quality assurance program.

Additionally a quality control program will assess the operation of equipment at frequencies (monthly, quarterly, annual, etc.) described in the PA DEP regulations for a given modality using calibrated phantoms and exposure monitoring equipment. Typically beam quality, beam limitation, exposure control, kV accuracy, technique indicators, reproducibility, timers, audible visual alerts/signals, position locks, etc. will be evaluated by either a qualified expert (QE) or qualified medical physicist (QMP) as required to meet the regulations, institutional program objectives, and accrediting agencies.

All records must be maintained for at least 5 years and available for inspection.

Inspection of Protective Garments

An annual inspection of the protective garments, such as lead aprons, thyroid shield and leaded gloves must be performed. This test must be performed by a trained technologist and if possible by use of fluoroscopy. Garments with holes larger than 3 mm or tears larger than 30 mm in location that cover the sensitive organs must not be used. All inspections must be documented and are subject to audits.

If garments fail inspection or need to be replaced, please contact the manufacturer as they may provide a free of charge replacement program (one-for-one). Otherwise please contact EHRS and request a hazardous/chemical waste disposal. Garments containing lead are hazardous and must be disposed of properly.

Posting & Signage

The Commonwealth of Pennsylvania Department of Environmental Protection (PA DEP) *Notice to Employees* Form (both English and Spanish), PA Code Title 25 Chapter 219 and 220, license, certificate of registration, operating procedures, and notice of violations must be posted or have a posting informing the employees where the documents are located for review. The room shall be posted to identify the hazards as required. Additionally, most of the modalities require the exposure index to be posted at the control panel, see individual sections below for more details.

The X-ray producing machine must have a permanent tag/label affixed as described in 21 CFR 1010.2 and indicators to caution individuals that radiation is emitted when the machine is being operated.

Mammography Units

Technical/Specification Requirements

- The unit must have a protective barrier for the operator to stand behind to make an exposure and be able to observe the patient/subject during the exposure.

- There must be a visual indication at the control panel whenever X-rays are produced. An audible signal must indicate the termination of exposure.

- The X-ray tube must have a visible exterior mark to indicate the focal spot location.

- The tube image receptor assembly must be capable of being fixed in any position where it is designed to operate. The locking system must not fail when power is lost.

- Systems with a light beam that passes through the X-ray beam-limiting device, must have an average illumination greater than or equal to 160 lux (15 foot candles) at 100 cm or the maximum SID, whichever is less.

- Systems used to perform non-interventional procedures must have radiographic magnification capability. When used at least one magnification value must be within the range of 1.4 to 2.0.

- All mammography systems shall incorporate a compression device. There must be different sized compression paddles that match the sizes of all full-field image receptors provided for the system. The compression paddle must be flat and parallel to the breast support table when compression is applied, with less than 1 cm of deflection, unless specifically designed by the manufacturer not to be flat and parallel. This exception must meet the manufacturer's specification and maintenance requirements.

- The Automatic Exposure Control (AEC) System must be capable of compensating adequately for variation in clinically used kVp and breast thickness. Density control setting must operate in such a manner that an increase in density setting results in an increase in mAs and optical density.

- Each unit must have a mechanism or button to terminate the exposure, should the AEC fail.

Operational/Procedural Requirements

- All radiographic equipment used for mammography shall be specifically designed for mammography and must be certified.

- The operator must be specifically trained, competent and stand behind the shield wall prior to initiating an exposure.

- The X-ray tube potential (kVp), filtration and source to skin distance (SSD) should be as large as practical, consistent with the objective of the study.

- The technique chart must be posted at the control panel. The technique factors for radiographic systems shall be indicated before exposure except for units utilizing automatic exposure controls, in which case the maximum mAs and kVp shall be indicated.

- X-ray systems utilizing automatic exposure control, in which the back-up mAs values are preset and cannot be selected by the operator, shall prominently indicate the preset mAs value on the console, along with an appropriate warning notice to the operator.

- Sufficient breast tissue must be imaged to ensure adequacy of the examination.

- Compression must be applied to minimize overlying breast tissue and motion artifact.

- Artifacts external to the breast must not obscure breast structures or suggest the appearance of structures not actually present. If they are present in the image the technologist must note the presence during the examination.

- Each image shall have the following information indicated on it in a permanent, legible, and unambiguous manner and placed so as not to obscure anatomic structures:
  - Name of the patient and an additional patient identifier.
  - Date of examination.
  - View and laterality. This information shall be placed on the image in a position near the axilla. Standardized codes specified by the accreditation body and approved by FDA.
  - Facility name and location. At a minimum, the location shall include the city, state, and zip code of the facility.
  - Technologist identification.
  - Mammography unit identification, if there is more than one unit in the facility.

QC/QA

Follow departmental policy and procedure which meet applicable regulations (FDA, ACR, PA DEP, MQSA, etc.) an appropriate QC/QA program must be implemented. Mammography equipment must be tested by a qualified medical physicist (QMP) initially, annually and whenever a major repair has been performed. The test must either be provided by the manufacturer or ACR Digital Mammography QC Manual and meet the Mammography Quality Standard Act (MQSA) and PA DEP regulations. In addition to the annual test performed by the QMP, the following QC tests are performed and documented by mammography QC technologists:

- *Weekly:*
  - DICOM Printer QC
  - Viewboxes and Viewing Conditions
  - Artifact Evaluation
  - SNR & CNR Measurements
  - Phantom Image
  - Detector Flat-Field Calibration

- Diagnostic Review Workstations QC
- Compression Thickness Indicator (bi-weekly)

- *Monthly, Quarterly and Semi-Annually:*
  - Visual Checklist
  - Repeat/Reject Analysis (quarterly)
  - Compression (semi-annually)
  - Geometry Calibration for Tomo (semiannually)
  - Diagnostic Review Workstation Calibration (semi-annually)

Reject-Repeat Analysis

The analysis of rejected radiographs provides information about the different aspects of radiological imaging. Analysis of data will help identify ways to improve efficiency, reduce cost, and reduce patient exposure by eliminating repeated exposure. Routine analysis of reject-repeat analysis must be documented and are subject to audits by the regulator.

Dental & Podiatry Units

Technical/Specification Requirements

- The unit must have a protective barrier for the operator to stand behind to make an exposure and be able to observe the patient/subject during the exposure.

- There must be a visual indication at the control panel whenever X-rays are produced. An audible signal must indicate the termination of exposure.

- The Automatic Exposure Control (AEC) System must be capable of compensating adequately for variation in clinically used kVp. Density control setting must operate in such a manner that an increase in density setting results in an increase in mAs and optical density.

- Each unit must have a mechanism or button to terminate the exposure, should the AEC fail.

Operational/Procedural Requirements

- The operator must be specifically trained, competent and stand behind the shield wall prior to initiating an exposure.

- The technique chart must be posted at the control panel.

- Collimation must be used to limit the X-ray beam to the smallest area practical and consistent with the objectives of the radiological examination.

- The X-ray unit must be maintained and operated following manufacturer recommendations.

- The minimum SSD cannot be less than 18 cm for units that operate above 50 kVp and not less than 10 cm for units that operate below 50 kVp.

- The maximum diameter of the X-ray field at minimum SSD cannot be larger than 7 cm for units that operate above 50 kVp and not larger than 6 cm for units that operate below 50 kVp.

QC/QA

The dental and podiatry equipment must be tested by a qualified medical physicist (QMP) or qualified expert (QE) initially, annually and whenever a major repair has been performed. The results are recorded and compared to the National Evaluation of X-ray Trends (NEXT) data or manufacturer recommendations. The radiation safety characteristics of the machine must meet the PA DEP regulations.

Radiographic Units

Technical/Specification Requirements

- The unit must have a protective barrier for the operator to stand behind to make an exposure and be able to observe the patient/subject during the exposure.

- There must be a visual indication at the control panel whenever X-rays are produced. An audible signal must indicate the termination of exposure.

- The X-ray tube must have a visible exterior mark to indicate the focal spot location.

- For X-ray systems with two or more tubes or focal spots that are controlled by one exposure switch the selected tube must be clearly indicated on the X-ray control panel and at or near the tube housing assembly prior to initiation of an exposure.

- The Automatic Exposure Control (AEC) System must be capable of compensating adequately for variation in clinically used kVp. Density control setting must operate in such a manner that an increase in density setting results in an increase in mAs and optical density.

- Each unit must have a mechanism or button to terminate the exposure, should the AEC fail.

Operational/Procedural Requirements

- The operator must be specifically trained, competent and stand behind the shield wall prior to initiating an exposure.

- The X-ray tube potential (kVp), filtration and source to skin distance (SSD) should be as large as practical, consistent with the objective of the study.

- Collimation must be used to limit the X-ray beam to the smallest area practical and consistent with the objectives of the radiological examination. The radiation beam cannot be larger than the linear dimensions of the image receptor (digital plate) being used. The positive beam limitation (PBL) systems must allow further reduction in the X-ray field size.

- The technique chart must be posted at the control panel. The technique factors for radiographic systems shall be indicated before exposure except for units utilizing automatic exposure controls, in which case the maximum mAs shall be indicated.

- For X-ray systems operating in automatic exposure control mode, and which lack engineered safeguards that prevent exposure in the event of either a malfunction or a misaligned X-ray beam with respect to film cassette sensors, the back-up or default mAs shall be set by the operator to an appropriate maximum value for the projection.

- X-ray systems utilizing automatic exposure control, in which the back-up mAs values are preset and cannot be selected by the operator, shall prominently indicate the preset mAs value on the console, along with an appropriate warning notice to the operator.

- All CR and DR units must have a posted exposure index range (EI, EXI, S Value, DEI, UDExp, CDExp, etc.) at the control panel. This vendor and sometimes model specific range indicates the exposure to the image receptor. This information along with analysis by the physicians, QE & QMP regarding image quality with a commitment to maintaining patient doses ALARA, may result modification of the manufacturers published range. Individual departments may not modify these ranges without consultation and approval from the individuals aforementioned.

- Every image captured must be compared against the appropriate exposure index range. Any image exceeding the range must be documented appropriately and analyzed such that trends can be identified. All trends must be investigated and documented. Any subsequent corrective actions must also be documented.

- If you have a CR or DR imaging unit which does not indicate an exposure value for a captured image, please contact the manufacturer and EHRS.

QC/QA

Radiographic equipment must be tested by a qualified medical physicist (QMP) or qualified expert (QE) initially, annually and whenever a major repair has been performed. The results are recorded and compared to the National Evaluation of X-ray Trends (NEXT) data or manufacturer recommendations. The radiation safety characteristics of the machine must meet the PA DEP regulations.

All CR cassettes must be erased at least weekly and should be documented.

Reject-Repeat Analysis

The analysis of rejected radiographs provides information about the different aspects of radiological imaging. Analysis of data will help identify ways to improve efficiency, reduce cost, and reduce patient exposure by eliminating repeated exposure.

Mobile Radiographic Units

Technical/Specification Requirements

Mobile radiographic units are those which meet all the requirements described above in the section for Radiographic Units and are battery-powered units on wheels or casters. While on battery-power, the control panel must have means to indicate visually whether the battery is adequately charged for proper operation.

Operational/Procedural Requirements

In addition to those procedural requirements mentioned previously for radiographic units, mobile radiographic units must:

- Prior to the operation of the X-ray unit, be sure its use is authorized.

- Ensure no person is within the useful beam or within 2 meters without interposed shielding or protective garment(s). It is the mobile X-ray operator's responsibility to ensure this is met prior to operation.

- The operator and any other individuals, other than the patient, within 2 meters must wear protective garments; except for individuals, such as adjacent patients, whose health may be jeopardized by applying such a garment. EHRS recommends that protective garments be placed on the bed rails of adjacent patients.

- The source to skin distance cannot be less than 30 centimeters.

QC/QA

Radiographic equipment must be tested by a qualified medical physicist (QMP) or qualified expert (QE) initially, annually and whenever a major repair has been performed. The results are recorded and compared to the National Evaluation of X-ray Trends (NEXT) data or manufacturer recommendations. The radiation safety characteristics of the machine must meet the PA DEP regulations.

Reject-Repeat Analysis

The analysis of rejected radiographs provides information about the different aspects of radiological imaging. Analysis of data will help identify ways to improve efficiency, reduce cost, and reduce patient exposure by eliminating repeated exposure.

Exposure Index Range

All CR and DR units must have a posted exposure index range (EI, EXI, S Value, DEI, UDExp, CDExp, etc.) for a particular technique. Every image captured must be compared against the appropriate exposure index range. Any image exceeding the range must be documented appropriately such that trends can be identified. All trends must be investigated and documented. Any subsequent corrective actions must also be documented.

If you have a CR or DR imaging unit which does not indicate an exposure value for a captured image, please contact the manufacturer and EHRS.

Fluoroscopic Units

Technical/Specification Requirements

- The fluoroscopic exposure switch must be deadman type switch.

- The unit must be interlocked such that X-rays cannot be produced if the barrier is not in place to intercept the entire cross section of the beam and if the imaging device is not in place or operational.
    - The unit must be interlocked such that X-rays cannot be produced if the SSD is less than 30 cm.

- During the procedure the kVp and mA/mAs must be continuously indicated.

Operational/Procedural Requirements

Individuals allowed to operate fluoroscopic units on humans are limited to qualified licensed practitioners of the healing arts; PA DEP recognized radiologist assistants under direct supervision (located on site and available for immediate assistance) of a qualified licensed practitioner; Board certified radiologic technologists, medical residents, radiologist assistants or radiologic technology students, provided a supervising licensed practitioner is in the room or control room during the performance of the procedure, specifically the critical portions of the procedure. Operators should be familiar with and understand the following:

- Operators should use the timing device to indicate a preset time (5 minutes), which will serve as a reminder to keep it as short as possible.
    - Entrance exposure cannot exceed 10 R/min except when in high level control mode which cannot exceed 20 R/min.

- The image receptor and X-ray tube must be aligned with the patient prior to the initiation of a fluoroscopy procedure.

- Except for mini-C arms, the source to skin distance (SSD) must be at least 30 cm, increasing image clarity. The greater the SSD, the lower the entrance exposure to patient for the same procedure.

- The distance from the X-ray tube to the image receptor (SID) should be minimized. This will reduce entrance radiation exposure to the patient, scatter radiation, and images will be sharper.

- If possible, pulsed fluoroscopy should be used instead of continuous fluoroscopy.

- Use of the freeze frame (last image hold) can reduce radiation exposure to the patient and the operator.

- Collimation must be used to limit the X-ray beam to the smallest area practical and consistent with the objectives of the radiological examination. Appropriate collimation will reduce the exposure to the patient, scatter radiation, and improve image quality.

- Minimize the use of CINE (Digital Acquisition). The dose to both the patient and adjacent personnel is significantly higher when cine is utilized.

- Minimize fluoroscopic exposure by reducing the beam ON time, pulsed and low dose modes. Fluoroscopic time, of course, varies with different patients, the type of the examination, and the complexity of the clinical study.

- Personnel must wear issued dosimetry and protective garments and thyroid shields during the fluoroscopic procedure. Use of additional shielding barriers should be used when available.

- Record of the patient dose from an examination must be stored in retrievable format.

- Develop and implement a method to review each patient's exposure history for the last 6 months. The results should be taken into consideration prior to the performance of a particular examination.

The patient dose record from an examination must be retrievable for further analysis. This record can be set up electronically and can be performed either automatically or manually. This record must include: patient identification; date and type of exam; specific fluoroscopic unit used; peak skin dose, cumulative air kerma or dose area product used if available. If no exposure data is available, other information must be provided to estimate the patient skin dose. At a minimum the total beam on time and total number of images must be recorded. Any additional information, such as mode or magnification is preferred. EHRS further recommends the electronic medical records to contain the total fluoroscopic time and numerical dose received to help facilitate the review of the patient's cumulative exposure within the last 6 months.

Additionally, interventional fluoroscopy must have written procedures that include: a current list of all individuals authorized to use the unit with a distinction of those who perform interventional procedures, a method used to monitor patient dose during the procedure, dose notification levels to alert the physician (the operator 5 min beam on time, etc), substantial radiation dose level

(SDRL) values (2 Gy cumulative dose, 60 min total beam time), actions taken when SDRL is exceeded (dose minimization during procedure as practical & post procedure patient follow-up), a method to review the procedure(s) not to exceed 12 months.

QC/QA

Fluoroscopic equipment must be tested by a qualified medical physicist (QMP) or qualified expert (QE) initially, annually and whenever a major repair has been performed. The radiation safety characteristics of the machine must meet the PA DEP regulations.

Computed Tomography Units

Technical/Specification Requirements

- All diagnostic CT X-ray systems must be accredited by an accrediting organization within 1 year from first patient use.
- The CT conditions of operation must be indicated prior to the initiation of a scan.
- The operator shall be capable of terminating the X-ray exposure at any time during a scan which is greater than 0.5 seconds. Any premature termination of the X-ray exposure by the operator must require the operator to reset the CT conditions of operation prior to the initiating another scan.
- A tomogram system must be able to permit visual determination of the tomographic plane or a reference plane offset from the tomographic plane.
- The emergency buttons or switches must be clearly labeled.
- All scans or series shall require initiation by the operator.
- The CT system must be normalized to water.
- The noise may not exceed the manufacturer's published specifications.
- There must be means of oral communication between the operator and patient.
- The operator must be capable of viewing the patient during the examination. If electronic, an alternate viewing system must be available.

- The CT system must be capable of alerting the operator prior to initiation of the scan that the dose index ($CTDI_{VOL}$ or DLP) will be exceeded. Careful consideration and review must be taken prior to initiating a scan that exceeds this value.

- Only individuals whose presence is necessary should be in the CT X-ray room during exposures. All such individuals should be protected with protective garments and/or portable shields.

- The CT X-ray control and gantry must provide a visual indication when the X-ray beam is produced and the status of the shutter (opened or closed).

Operational/Procedural Requirements

The following must be posted or readily available to the operator with posted instructions where to locate:

- The technical and safety information relating to the conditions of operation, dose information and imaging performance provided by the CT manufacturer.

- Protocols based on current standards and practices which address the following key criteria: clinical indications, contrast administration, patient age, patient size and body habitus, expected radiation dose index range.

- The result of the most recent performance evaluation and the information related to the dates and frequency of this test.

- The date of the latest radiation measurement.

- The information on the use of CT phantoms.

- Procedure for reporting deviations in protocols and routine QC.

- Allowable variations in routine QC.

- QC schedule.

- The technique chart detailing the operating conditions and exposure index range must be posted at the control panel.

Each CT study must be checked for scan dose and image quality parameters, such as equipment related artifacts and dose index limits ($CTDI_{VOL}$ or DLP). If equipment related artifacts are present, appropriate corrective action must be taken and documented. If the dose index is exceeded, the cause should be reviewed to assess whether any trends are identified. The review process, conclusion and corrective actions, if applicable, must be documented.

QC/QA

A written routine QC procedure must be established by a QMP detailing the allowable variations and procedure for reporting and restricting the use for conditions exceeding the allowable variation. The routine QC must be performed by staff not to exceed 1 week and assess the following:

- Noise
- Mean CT number for water
- Artifact evaluation

CT equipment must be tested by a qualified medical physicist (QMP) initially, annually and whenever a major repair has been performed. The results are recorded and compared to the National Evaluation of X-ray Trends (NEXT) data or manufacturer recommendations. The radiation safety characteristics of the machine must meet the PA DEP regulations and maintain accreditation requirements.

Cone Beam Computed Tomography Units

Technical/Specification Requirements

Cone-beam computed tomography (CBCT) units function as a cone-shaped CT beam which is married with computer software to create 3-dimensional imagery. These units are typically found in dental and oncology departments. Other than dental units, CBCT used in a therapeutic or diagnostic manner must meet all the CT regulations and guidance provided above for CT units. Otherwise the unit is exempt from the CT regulations.

Operational/Procedural Requirements

- A written procedure must be in place and a policy addressing deviations from established protocols.

- The CBCT operator shall have instructions on all of the following: performing routine QC; use of the phantom(s); routine QC schedule; acceptable range or variations when performing the QC; results of most recent QC.

QC/QA

CBCT equipment must be tested by a qualified medical physicist (QMP) or qualified expert (QE) initially, annually and whenever a major repair has been performed. The results are recorded and compared to National Evaluation of X-ray Trends (NEXT) data or manufacturer recommendations. The radiation safety characteristics of the machine must meet the PA DEP regulations outlined in §221.64.

Notification to EHRS

Report all conspicuous problems with X-ray equipment, postings, permits, shielding, as well as any other safety problems observed to EHRS at 2-2520 or 215-707-2520 immediately. EHRS must be notified of:

- The wrong patient or wrong site being radiographed.
- Consistent deviations from posted exposure index ranges.
- A procedure which exceeds 2 Gy cumulative dose.
- A procedure which exceeds 60 min of beam on time.
- An unintended peak skin dose to the patient exceeding 50 rads (0.5 Sv).
- Patients that receive an unintended dose which would exceed 5 rem EDE or 50 rem (0.5 Sv) to any organ.
- A therapy dose that exceeds 20% to the target or ancillary organs stated in the written directive.
- A physician determining actual or suspected acute or long-term functional damage to an organ or a physiological system of a patient from a diagnostic or interventional procedure which were not intended.

- Advanced notification of intent to acquire or install a new X-ray generating device.
- Advanced notification of intent to dispose an X-ray generating device or protective garment.
- Advanced notification of intent to relocate existing X-ray equipment.
- Advanced notification of intent to transfer an X-ray device to another institution.

Response to Reported Problems

All reported issues with X-ray machines must be documented. Subsequent investigations and corrective actions must be documented and completed by competent personnel. All repairs on the units should be made as soon as possible. Repair documentation should be sent to the authorizing personnel upon completion of the repairs. Once repaired a QE or QMP must validate the instrument meets institutional program guidelines and policies.

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