Commonwealth of Pennsylvania
Bureau of Radiation Protection

X-ray Refresher Training Notes

pennsylvania
DEPARTMENT OF ENVIRONMENTAL PROTECTION

2910-BK-DEP4452 6/2014

Introduction

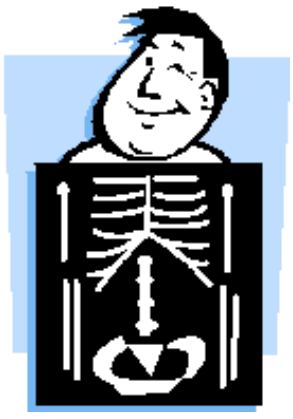
Background

X-rays have been a key component of diagnostic medicine for over a hundred years and with the development of the computer, the applications of X-rays in the medical and dental fields continue to expand rapidly. Modern X-ray systems provide detailed images of patients that can greatly assist in the diagnosis and treatment of disease. However, medical X-rays also expose the patient and attending staff to radiation; therefore, care must be taken by the staff to ensure the benefit of the procedure to the patient outweighs the risk of the radiation exposure.

The Food and Drug Administration (FDA) recommends that imaging professionals follow two principles of radiation protection of patients developed by the International Commission on Radiological Protection (Ref. ICRP Publications 103 and 105). These two principles are:

Justification: The imaging procedure should be judged to do more good than harm; therefore, all such exams should be performed only when necessary to answer a medical question, treat a disease, or guide a procedure.

Optimization: X-ray exams should use techniques that are adjusted to administer the lowest radiation dose that yields an image quality adequate for diagnosis or intervention (i.e., radiation doses should be "As Low As Reasonably Achievable," commonly referred to as the ALARA principle).



The medical team (technologist, imaging physician, etc.) has the primary responsibility for exam optimization and for ensuring that the patient receives an appropriate exam at a radiation dose that is ALARA. Training of medical personnel, with an emphasis on radiation safety, is a key component of this responsibility. For this reason Pennsylvania Department of Environmental Protection (DEP) regulations require individuals who operate X-ray systems to receive initial instructions in the safe operating procedures and to be competent in the safe use of equipment. They are also required to have continuing education in radiation safety, biological effects of radiation, quality assurance and quality control (25 Pa. Code § 221.11 and Chapter 221, Appendix A).

Purpose

According to the National Council on Radiation Protection and Measurements (NCRP) Report No. 134, *Operational Radiation Safety Training*, there are at least four important reasons for conducting such training:

First, the development of worker skills through training enables the individual to perform tasks efficiently and with confidence;

Second, when individuals are aware that there is some risk associated with the exposure (both to themselves and their patients), they can become active participants in the decision to accept and, where possible, reduce such risk;

Third, the number and seriousness of accidents can be reduced through training;

and

Fourth, workers who are properly trained will be aware of the regulatory requirements associated with their activities that involve radiation exposure.

Based on those reasons, the primary goal of this document is to provide the generic portions of the continuous education requirements for operators performing low-risk X-ray medical procedures as defined in the DEP Bureau of Radiation Protection (BRP) Technical Guidance Document No. 291-4200-001, entitled Medical X-ray Procedures Operator Training Guide. This requirement states that "all operators performing Low-Risk Procedures must demonstrate two contact hours or four units of continuing education every four years in topics covered in Appendix A." The list of topics in Appendix A follows:

(1) Basic Properties of Radiation

(2) Units of Measurement

(3) Sources of Radiation Exposure

(4) Methods of Radiation Protection

(5) Biological Effects of Radiation Exposure

(6) X-ray Equipment

(7) Imaging Recording and Processing

(8) Patient Exposure and Positioning

(9) Procedures

(10) Quality Assurance Program

(11) Regulations

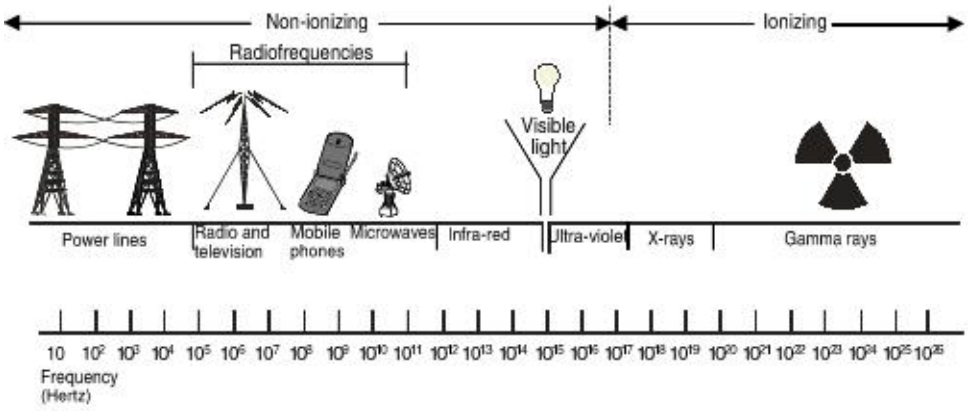
Fundamentals

Properties of Radiation

Radiation is a generic term that simply means energy emitted and transferred through matter. However, in the medical community and especially in radiology, radiation refers to ionizing radiation; defined as high energy particles or high energy electromagnetic (EM) energy that is capable of removing orbital electrons from atoms. The electron, along with the atom that it was stripped from, is referred to as an ion pair and the process is called ionization. The potential damage to the human body from ionizing radiation is the basis for radiation protection requirements.

High energy particles, such as alpha radiation and beta radiation, directly produce ionization due to both their high energy and their electrical charge. Other high energy particles such as neutrons, produced in nuclear reactors, can produce ionization as well, as they collide with or are absorbed by atoms in the materials they are passing through. These types of radiation are referred to as particulate radiation. Generally particulate radiation is easier to shield than EM radiation as the particles lose energy with every collision.

Another method of producing ionization is by the interaction of high energy EM energy with atoms. EM energy can have a wide range of energies, which is related to their frequency and wavelength. The diagram below shows the range of frequencies and the common names for EM energies.



Source: "Research and Regulatory Efforts on Mobile Phone Health Issues," www.gao.gov, May 2001

Most forms of EM energy, such as radio waves, microwaves, and visible light, are non-ionizing. However, at higher energies such as the ultraviolet range, greater and greater biological damage may happen and at the highest frequencies, corresponding to X-rays and gamma rays, ionization occurs. X-rays and gamma rays are fundamentally the same thing – high frequency EM energy; but they differ in how they are produced and in their typical energy range. Gamma rays often follow alpha or beta decay, and generally have higher energies. X-rays are most commonly

produced by the interaction of high energy electrons with a target material and their energy is dependent on the energy of the accelerated electrons and the type of material they strike. Therefore, X-rays are usually associated with a machine that can accelerate electrons into a target—in other words, an X-ray machine.

One distinct advantage of an X-ray machine is that it can be turned off, immediately stopping the production of ionizing radiation. Alpha, beta, and gamma radiation are all associated with radioactive material that is emitting the ionizing radiation. These radioactive materials can be shielded but cannot be turned off like a machine. They can also be crushed into a powder, spilled as a liquid or released as a gas, frequently becoming an unwanted source of radiation, referred to as contamination. Contamination on an individual may seem to make the person radioactive, though in fact, they simply have radioactive materials on or in them. Contamination is not a problem with X-ray machines and, despite what patients sometimes believe, people cannot become radioactive by exposure to X-rays, just as they cannot glow in the dark from being exposed to sunlight.

Units of Measurement

Units of measurement for radiation dose are sometimes confusing because of the different endpoints they are trying to measure. In addition the International community has converted to a new set of units (the International System, or SI) that are still being considered for use in the USA, so equipment and publications from other countries often do not use the units that most individuals in the States are familiar with.

In the medical X-ray field there are three basic quantities, each with its own set of units. The first of these is also the oldest, first defined in 1928 and known as exposure. Exposure measures the amount of charge produced in air by X-ray or gamma radiation. The traditional unit of exposure is the roentgen (R), named for the discoverer of X-rays, Wilhelm Roentgen, and defined as 2.58×10^{-4} C/kg, where C stands for coulombs, a measure of electrical charge, and kg is the mass of air in which the charge is produced. The SI unit for exposure is known as air kerma and is measured in units of gray (Gy), which is defined as 1 joule/kg. Because the gray can be used for other materials besides air, when it is used for exposure it is often subscripted with a letter "a" to indicate it applies only to air: Gy_a. To a close approximation, 1R = 0.01 Gy_a. Though exposure seems to have a very narrow definition, it is widely used in the X-ray field because it is easy to measure and can readily be related to the other quantities used.

The second quantity, known as absorbed dose, is more broadly defined as the amount of energy deposited by any form of ionizing radiation in any type of material. In the medical field this is typically the quantity used to define the radiation dose to a patient. The traditional unit for absorbed dose is the rad, which is equal to 100 erg/g. The SI unit is the gray (Gy) and the relationship is 1 rad = 0.01 Gy. Absorbed dose is a good measure of the damage caused by radiation to various materials, including human tissue, but can be very difficult to measure directly.

The third quantity is called equivalent dose. The various types of radiation do not all cause the same level of biological damage, even for equal amounts of energy deposited. Equivalent dose has been defined as equal to absorbed dose times a quality factor that accounts for these differences in biological damage. For X-rays and gammas, this is a very simple calculation since these radiations were used as the relative standard for the quality factor and are equal to one. The traditional unit for equivalent dose is the rem and the SI unit is the seivert (Sv). The relationship is 1 rem = 0.01 Sv. The following table summarizes the quantities and units used with radiation:

Quantity	Traditional Units		SI Units	
	Name	Symbol	Name	Symbol
Exposure	roentgen	R (= 0.01 Gy_a)	air kerma	Gy_a (= 100 R)
Absorbed Dose	rad	rad (= 0.01 Gy)	gray	Gy (= 100 Gy)
Dose Equivalent	rem	rem (= 0.01 Sv)	seivert	Sv (= 100 rem)

Because of the way that exposure was originally defined and the fact that the quality factor is 1 for gammas and X-rays, the relationships of these three quantities (to a close approximation) are very simple in X-ray radiology. In the traditional units:

1 R = 1 rad = 1 rem

Similarly, in SI units:

1 Gy_a = 1 Gy = 1 Sv

Often when discussing relatively large or small numbers, numeric prefixes are used. While these prefixes greatly simplify the recording of numbers, they must be used carefully as significant overexposures have resulted from the misinterpretation of these prefixes. A table of the key prefixes follows:

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-	□
10^{-9}	nano-	n

Finally, radiation levels are frequently measured as dose rates or dose per time, which may be converted into dose by multiplying by time. In equation form this is:

Dose Received = Dose Rate Measured X Time exposed.

As an example, suppose that the average exposure rate in an area was measured as 2 mR/hr and the question is whether the yearly occupational limit of 5 rem would be exceeded by a radiation worker occupying the area full time. Assume that the worker is in the area 40 hours per week for a total of 50 weeks per year. The total exposure would then be:

Exposure = 2 mR/hr X 40 hr/wk X 50 wks/yr = 4000 mR in the year.

Assuming the exposure is due to X-ray radiation, this value can easily be converted to dose equivalent:

Dose equivalent = absorbed dose = exposure = 4000 mrem.

Finally, converting to rem in order to compare with the 5 rem limit:

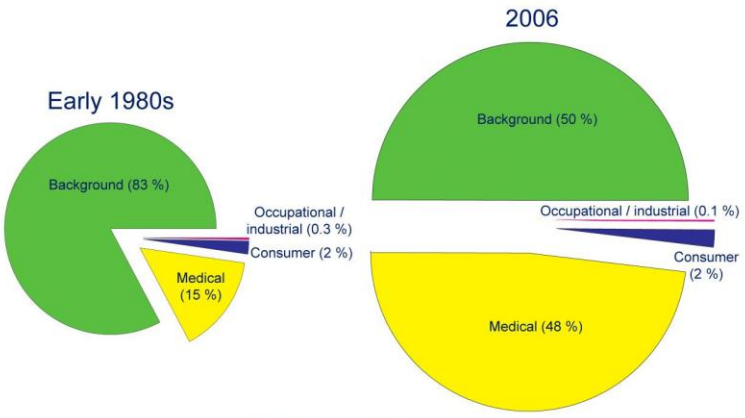
Dose equivalent = 4000 mrem X (1rem/1000 mrem) = 4 rem.

While technically below the limit, this value represents a significant portion of the annual permissible dose and may need to be reduced as much as possible, based on the ALARA principle.

Sources of Radiation

Most members of the public do not realize the extent of radiation exposure in their lives or understand which sources are the most significant. In fact, even within the Radiation Protection community, there have been some surprises at changes in the levels of average radiation exposure from advancing medical techniques. This was made evident in a recent study by the NCRP (NCRP Report No. 160*, Ionizing Radiation Exposure of the Population of the United States*). The pie chart below shows the changes in the sources and magnitude of dose to the population from the early 1980's to 2006.

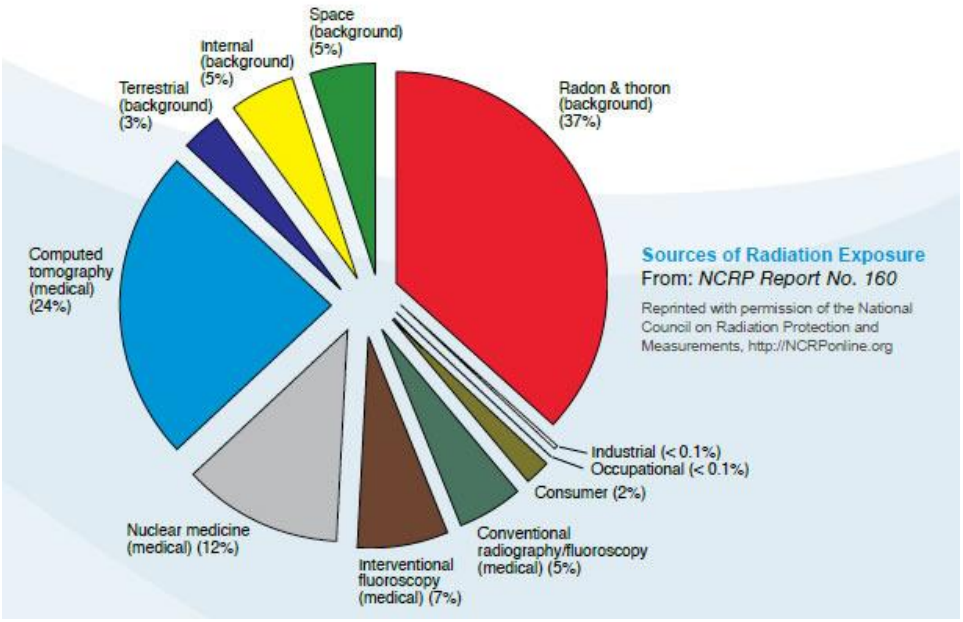
NCRP Report No. 160, *Ionizing Radiation Exposure of the Population of the United States*



	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

Two things stand out in this chart. First, on the average, the dose per individual has increased by over 70%, going from 3.6 mSv to 6.2 mSv. Second, this increase has been almost exclusively due to medical procedures.

Another chart from NCRP 160 helps explain how this increase came about:



In this pie chart, details of the two most significant categories from the previous chart are broken down into more detailed components. For example, the largest single category is natural background. It is broken down into radon and thoron, primarily from air in homes, terrestrial radiation from uranium and other radioactive materials in the soil, internal radiation from radioactive materials naturally occurring in our bodies (i.e. potassium-40), and space radiation from cosmic rays and their interactions in the atmosphere. The only one of these components that an individual may be able to significantly reduce is radon, which can be tested for in homes and mitigated as necessary. Pennsylvania has a history of high radon levels in homes due to uranium and radium levels in the ground in several regions of the State.

The medical breakdown clearly shows where most of the increase in the last 20 years has occurred. The use of computed tomography (CT) scans, nuclear medicine and interventional fluoroscopy have all significantly increased with a resulting increase in the average radiation dose to an individual. From a medical standpoint, the latest technology in these diagnostic modalities has resulted in great benefits to the patients with relatively low risk.

Conventional radiography, while representing a relatively small fraction of the medical exposure, still remains a significant source of radiation exposure to the general population. Also, conventional X-ray scans such as dental exams and injuries to extremities are more likely to be given to a younger population that would be at greater risk from radiation, so the levels of exposure still must be carefully monitored.

The newer X-ray medical procedures also frequently involve higher doses to the individual patient during the procedure. For this reason, Pennsylvania has divided X-ray medical procedures into two risk classes, namely:

High-Risk Procedures – defined as any radiologic procedure that utilizes energies of less than 1 million electron volts (MeV), that could exceed skin doses of 200 rads (2 Gy), and

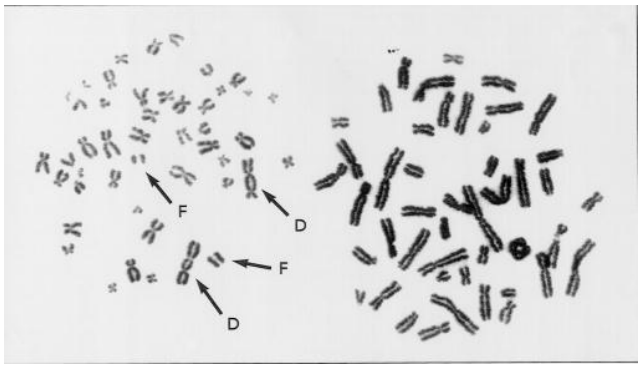
Low-Risk Procedures – defined as any radiologic procedure that is not a "High-Risk Procedure."

Examples of High-Risk Procedures include CT scans and interventional radiography. Low-risk procedures include conventional X-ray scans, dental X-rays, and the use of X-rays in Podiatry, Chiropractic, and Veterinary procedures.

Biological Effects of Radiation

Just as the uses of X-rays in the medical field rapidly expanded after their discovery, so did the reports of injuries. For example, Thomas Edison ceased his research on X-rays following the serious injury and subsequent death of his friend and assistant, Charles Daly, in 1904. Research in France in 1906 led to a series of radiobiology "laws" by Bergonie and Tribondeau that can be summarized as "the more rapidly a cell is dividing, the greater the sensitivity to radiation." While this generalization does not always apply, it still is very useful in understanding many of our concerns with radiation exposure. It also helps explain the radiobiological effects within certain organs of the body such as the skin, blood-forming organs, gonads and also to the unborn child.

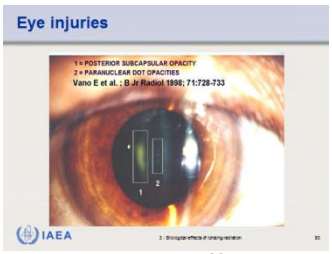
Later research helped reveal the underlying reason for the sensitivity of these dividing cells, namely that one of the most significant biological effects of ionizing radiation is damage to the DNA within the nucleus of cells. Dividing cells use the DNA structure as a template for the new cell, and when the DNA is damaged, the dividing cell either fails to divide and dies, or reproduces a new strand of DNA with errors that may result in long-term problems with the function of the cell. In the picture below, chromosomes formed during DNA replication show some of the effects of radiation including chromosome fragments (labeled F) and dicentrics (two centromeres) (labeled D). Correctly dividing strands have a single centromere.



Effects of radiation to the human can be divided into those effects that occur to the

exposed individual, known as somatic effects and those that occur in future generations, known as genetic effects. Research from survivors of the bombings of Hiroshima and Nagasaki and other radiation exposures have shown that somatic effects occur at lower radiation levels than genetic effects, so all current radiation regulations are based on limiting radiation doses to prevent somatic effects, which by default will prevent genetic effects.

Somatic effects to the individual can be divided into two categories: acute and delayed effects. Acute effects, also commonly referred to as early effects or deterministic effects, typically occur at high levels of radiation and appear within a short period of time after exposure, i.e. in days or weeks. Acute effects usually have a dose threshold below which they do not appear and the severity of the effect varies directly with the radiation exposure. Common examples of acute effects include radiation skin burns, sterility, and depression of white blood cells.



In addition, some organs are more sensitive to radiation than others and require special attention to reduce radiation exposure. For example, the thyroid is relatively sensitive and should generally be shielded in dental procedures; the lens of the eye is sensitive to the production of cataracts from radiation, so exposures to the eye should be avoided to the extent possible. Acute effects should never occur following low-risk X-ray procedures and only very rarely following high-risk procedures.

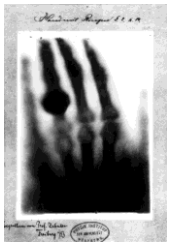
Delayed effects, also referred to as late effects or stochastic effects, are very difficult to directly observe in an individual as they do not occur until long after the exposure and most often are manifested as a disease that has a natural occurrence rate. Delayed effects are governed by the laws of chance (hence, the term stochastic – or statistical), so there is no lower threshold below which the risk is zero. Also, even if the initiating dose is very small, the resulting effect can be extremely serious. An analogy is to think of the risk of a delayed effect as winning a large State lottery. The chances of winning may be very small but can never be said to be zero, as long as you buy a ticket. Likewise, the chance of getting cancer from a small exposure to radiation is also very small. The chance of winning the lottery increases linearly as you purchase more tickets, along with the chance of getting cancer with increased radiation exposures, but in both cases, the odds remain low. On the other hand the impact of winning the lottery (or being diagnosed with cancer) would be very significant though opposite of each other.

In summary, radiobiology plays a significant role in our efforts to reduce patient dose, both in order to keep overall dose low, as well as making special efforts to keep dose low to sensitive organs, expectant mothers and young children. Low-risk imaging procedures should be conducted in a manner that always prevents acute effects. In addition, radiation doses from low-risk procedures should still be minimized as possible using the ALARA principle to reduce the risk of delayed effects.

Review of X-ray Imaging

X-ray Design and Terminology

X-rays, named for the symbol that mathematicians still use for an unknown quantity, were accidently discovered by Wilhelm Roentgen in 1895. While studying the properties of a partially evacuated glass tube when electricity was passed through it, Roentgen noticed a fluorescent plate several feet away was glowing. Within just a few months, Roentgen and others were exploring the use of X-rays in medicine. The first recorded image of the human body was made by Roentgen of his wife's hand.



The basic components of the X-ray tube remain the same as those used by Roentgen, though a number of refinements have been made to improve the quality and safety of X-ray imaging. These components consist of:

(1) The cathode – a wire heated by electricity and producing a large source of free electrons, along with a focusing cup which helps narrow the beam of electrons produced.

(2) The anode – a target of high atomic number material which is imbedded in copper or other material to prevent melting. Cooling fins or a cooling fluid may also be a part of the anode to help in heat dissipation.

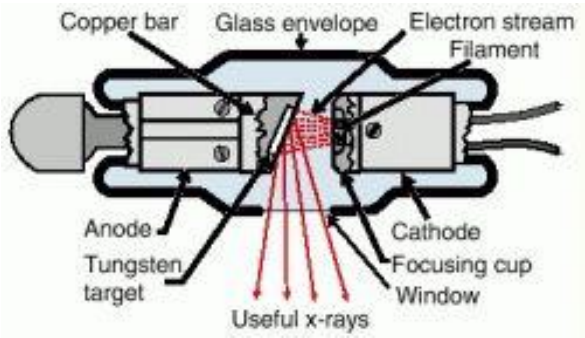
(3) A voltage supply – including a transformer, rectifier, and other components to create a very high voltage potential between the cathode and anode.

(4) An envelope – consisting of a glass or metal vacuum tube containing the anode and cathode.

(5) The tube housing – designed to protect the envelope, shield stray X-rays, and provide a means for safely mounting the X-ray tube.

In addition, other components are added to the X-ray machine to improve the safety and quality of the image, such as a collimator that can narrow the X-ray beam to only the area of interest and filtration that removes unwanted low-energy X-rays.

The following drawing shows most of these components in a fixed anode X-ray tube.



The primary settings for an X-ray machine are a control for the current supplied to the cathode, typically measured in units of milliamperes (mA), a timer measuring the length of time the current is applied, usually measured in seconds (s), and a voltage control measuring the peak voltage between the anode and cathode, normally in units of kiloVolts (kVp). The timer and current setting may be combined giving a unit of milliamp-seconds (mAs), which is equivalent to the total number of electrons that flow between the cathode and anode producing X-rays.

Medical X-rays are characterized by the quantity of X-rays and the quality (or penetrability) of the X-rays. The quantity of X-rays reaching the patient is directly proportional to the radiation dose and is determined by the following four factors and what effect occurs when they are changed:

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.

X-ray quality is a measure of the penetrability or ability of the X-ray beam to pass through tissue. High quality X-rays have high penetrability while low quality X-rays have low penetrability. Beam quality is an important factor in the radiation dose to the patient. Low quality X-rays have little or no chance of penetrating the patient and reaching the image receptor; therefore, they provide no medical information while delivering radiation dose to the patient. For this reason, some minimum filtration (typically the equivalent of 1-5 mm of aluminum) is needed for medical X-ray imaging to reduce the low energy X-rays. X-ray tubes always have some amount of inherent filtration due to the envelope, but added filtration is normally needed for proper imaging and dose reduction. This filtration is sometimes designed to correspond to the varying thickness of the body part imaged, such as the arch of a foot, and is then referred to as a compensating filter.

Another important factor in X-ray quality is the kVp. Increasing the kVp by even a relatively small amount can often reduce the radiation dose to the patient and improve the quality of the image. Quality is normally specified by the half-value layer (HVL) of the beam, which is the thickness of absorbing material placed in the beam that is necessary to reduce the X-ray intensity to half its original value.

Looking at the same four factors from above, quality is affected as follows:

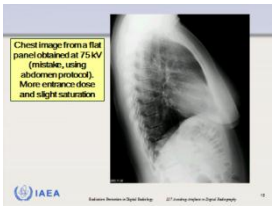
mAs	when changed	does not change quality
kVp	when increased	improves quality
distance	when changed	does not change quality
filtration	when increased	increases quality.

In summary, radiation dose to the patient can be reduced by ensuring that proper filtration is used, and kVp settings are as high as reasonable and mAs settings are as low as reasonable for medically useful images.

Impact of Digital Imaging

Digital radiography has in many cases replaced conventional imaging systems for many of the same reasons that digital cameras have replaced film. Images are immediately available, can be transmitted and stored electronically, and can be post-processed to obtain even more information, correct mistakes, or enhance contrast. The wide range of contrast resolution in digital images allows the recovery of information from images that would have previously been discarded as over or under exposed.

For these reasons, radiation dose to patients should be reduced as the number of retakes declines due to improper settings for film. However, this has not always been the case. It was discovered a few years ago that doses were actually increasing in some cases. This effect, sometimes referred to as dose creep, was happening because technicians were getting good images without changing factors between different views and did not recognize that radiation doses were sometimes higher as a result. Also, since one of the most common problems with digital imaging is signal noise, technologists tended to increase technique in order to reduce signal noise without realizing the effect on patient dose.



Most digital X-ray systems now come with a standard set of imaging options designed to minimize dose. In addition, manufacturers provide training in optimizing image processing while maintaining image quality and reducing dose. These methods should be reviewed to ensure continued compliance with best practices.

Reducing Patient (and Employee) Dose From Radiation

In medical X-ray imaging, there are three sources of radiation in the room. The primary beam (or radiation), also called the useful beam, is the most intense source and is the X-ray beam coming from the X-ray tube, through the patient to the image receptor. The next most intense source is usually scatter radiation, which results from the primary beam interacting with material it is intercepting. In most cases, the largest source of scatter radiation is the patient. Finally, there is leakage radiation from the X-ray tube housing. This value is regulated to 100 mR/hr (1 mGy/hr) at 1 meter and in practice is normally much lower. Scatter and leakage radiation are sometimes combined and referred to as secondary or stray radiation since they represent a lower level of risk, but they also can be anywhere in the room. Outside the medical X-ray room, radiation levels are maintained within limits by the use of shielding, often including lead or other materials built into the walls. This shielding is based on assumptions on the use of adjacent areas, the direction(s) of the primary beam and the number of scans performed. Any changes in these assumptions or remodeling of the facility may necessitate a re-evaluation of the adequacy of the shielding.

The most significant risk of radiation exposure is to the patient and any other individuals within the room. While the risk may be low for low-risk procedures, every effort should still be made to keep these doses ALARA. The three basic principles for reducing radiation dose around any radiation source can be summed up as follows:

(1) **Reduce TIME,**
(2) **Increase DISTANCE, and**
(3) **Use SHIELDING.**

In medical radiography, there will always need to be some compromise in these factors in order to obtain good images, but with appropriate use of the "as low as reasonably achievable" (ALARA) principle, radiation dose to patients can be optimized and dose to staff can be minimized.

25 Pa. Code § 221.11 contains a list of responsibilities for registrants to assist in ensuring radiation doses are ALARA. A brief summary of this section is provided in the following table. See the referenced sections for complete details.

Table 1. Summary of Requirements in 25 Pa. Code § 221.11

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 shall be instructed in safe operating procedures and competent to use equipment.	Instructions shall include items in Appendix A.
221.11(c)	Chart specifying techniques for examinations performed with system shall be provided in vicinity of control panel.	Chart should contain pertinent information to particular exams.
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 useful beam unless protected by 0.5 mm lead equivalent material.	Lead equivalent of material determined at 60 kV.
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.	2-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, 2-meter distance is based on nearest portion of body from both the tube head and nearest edge of image receptor.

Table 1 (cont.)

Section Number	Summary of Requirement	Additional Comments and Clarifications
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 arts 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.	
221.11(j)	Screen and film systems used shall be spectrally compatible.	Defective screens may not be used for diagnostic imaging.
211.11(k)	Film may not be used without intensifying screens for routine diagnostic imaging.	An exception to this is for intraoral dental radiography.
211.11(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) Image recording, processing and viewing. (3) Maintenance and modifications to QA program.	Records shall be maintained for inspection by DEP for 3 yrs. DEP's guidelines and list of recognized organizations are available on DEP's website and on request.
211.11(m)	Neither X-ray tube housing nor collimating device may be hand-held during exposure.	

Besides these requirements, there are a variety of other recommendations that can improve image quality while reducing dose to the patient and staff. Several of these recommendations are discussed on the next two pages.

kVp and mAs settings

As a general rule and within the limits of obtaining a good image, the lowest dose to patients is achieved when kVp settings are increased and mAs settings are decreased. For example, Bushong's text on *Radiologic Science for Technologists* recommends that when using digital imaging, avoid dose creep by using technique creep, i.e., for a specific type of imaging technique, gradually increase the kVp over successive examinations as long as image quality remains satisfactory until an optimum quality is reached.

Use of grids

Grids are devices placed between the patient and image receptor to reduce the scatter radiation and can greatly increase image quality. However, they also increase patient dose and should only be used as necessary, especially on younger patients.

Reducing personnel dose from scatter radiation

The main source of scatter radiation is the patient, especially the side of the patient towards the X-ray tube. Individuals in the room should always be aware of this and use proper procedures to reduce their dose. Shielding requirements for staff are given in § 221.11(e), but users must maintain awareness of the primary beam and also sources of scatter radiation.

Distance also plays a critical role in reducing dose from scatter radiation to staff members. The inverse square law states that the radiation dose drops inversely as the square of the distance increases. In other words, double the distance and the dose can be reduced by a factor of four.

The use of carbon fiber and other low atomic number materials for cassettes, grids, and tables can also greatly reduce scatter radiation, reducing dose to the patient and staff.

Collimation and Beam Size

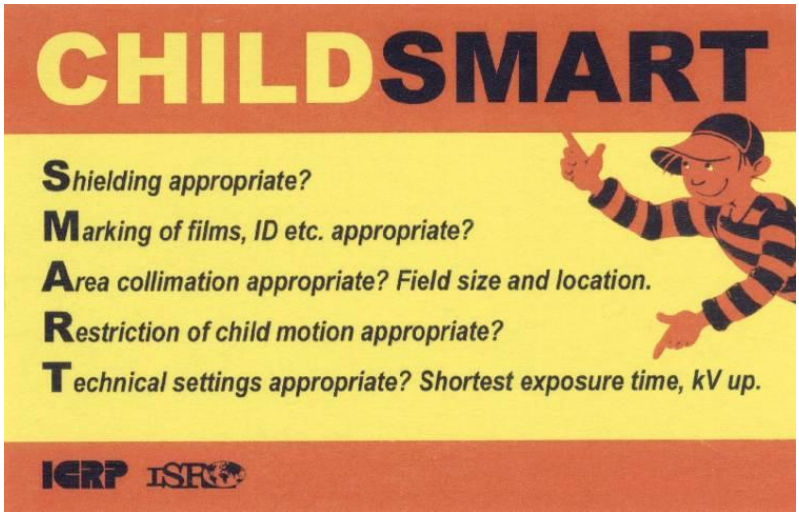
The primary beam should be sized to cover the area of interest but not overly exceed it. Reducing the area of tissue irradiated reduces scatter radiation and minimizes dose to the patient.

Special Cases – Children

Because of their greater expected lifetimes and higher sensitivities to radiation, children need to receive extra care in X-ray exams. First, special consideration for the justification of the exam should be made because of this greater risk. This topic has become an even greater concern as the number of radiation procedures continues to climb and the number of younger patients increases. A special program referred to as "Image Gently" has been developed to assist medical practitioners in improved methods for imaging children. The website is *www.pedrad.org/associations/5364/ig/* , and is a great resource for information regarding imaging children. The International Atomic Energy Agency has developed a number of PowerPoint lectures in collaboration with the Image Gently program

that deal with reducing childhood exposure from a wide variety of imaging techniques. These presentations are available for free downloading at https://rpop.iaea.org/RPOP/RPoP/Content/AdditionalResources/Training/1_TrainingMaterial/PaediatricRadiology.htm.

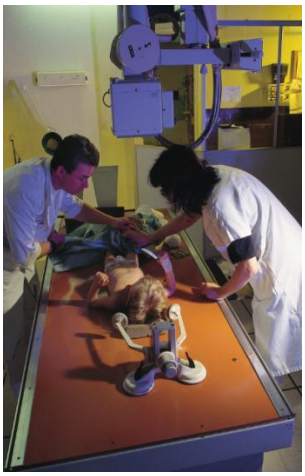
The poster below, copied from this site, summarizes the factors that should be considered when imaging children:



Motion tends to be a major problem in imaging children and may require special techniques to ensure that a quality image is obtained without the need for extra scans.

Special restraints; properly sized gonadal shielding; and patient, caring staff members can all contribute in obtaining good images while minimizing the stress on the child.

The following images show examples of young patients being prepared for imaging and demonstrate some of these techniques.



Special Cases – Patient Size

While children present unique challenges due to their small size, larger adults also present unusual challenges. Larger patients may require adjustments of the kVp and mAs settings to get good quality imaging and, because of their size, they are often a higher source of scatter radiation. For example, one study estimates that an increase of body thickness from 16 to 24 cm (6.3 to 9.5 inches) increases the scatter dose by a factor of five. Staff should be aware of this and make what changes they can, such as increasing distance to reduce their exposure.

Special Cases – Pregnancy

When the possibility of pregnancy exists, either with the patient or a staff member, special care must be taken to minimize radiation dose to the fetus. Female patients of child-bearing age should be asked about the possibility of being pregnant before any imaging that might result in dose to the abdomen. Warning signs requesting that the patient inform the technologist before the exam that they are or might be pregnant should be posted at the X-ray room entrance, waiting room, and patient changing area. If the patient is or may be pregnant, efforts should be made to reduce dose to the fetus through the use of patient positioning and shielding. Other techniques such as using PA abdominal projections instead of AP can also reduce dose to the fetus when the procedure is necessary.

Female medical staff persons exposed to occupational sources of radiation and who may become pregnant are required by Federal and State regulations to be instructed on the risks of exposure. If the woman chooses to "declare" her pregnancy in writing to her employer, then she must be made aware of the special limits that apply to exposure of the embryo/fetus. The U. S. Nuclear Regulatory Commission (USNRC) has written a Regulatory Guide entitled *Instruction Concerning Prenatal Radiation Exposure* that provides details on the risks of radiation exposure to the embryo/fetus, instructions for formally declaring the pregnancy if the woman chooses to, and the lower limits that apply during the pregnancy as a result of this declaration. This regulatory guide is available on the USNRC website at www.nrc.gov.

Radiation Safety Plan, Documentation, and QA

Radiation Safety Plan

A Radiation Safety Plan is the mechanism that ensures that the registrant properly directs the X-ray systems under their control. According to the recently published Federal Guidance Report No. 14 "Radiation Protection Guidance for Diagnostic and Interventional X-ray Procedures," this plan should ensure that:

(1) The use of radiation is performed in accordance with existing laws and regulations;

(2) Individual health professionals and technologists are equipped with knowledge of the options available to them as they make benefit v. risk determinations and prescribe the appropriate examination for each individual patient; and

(3) X-ray equipment users and the surrounding public receive adequate protection from this radiation.

The following outlines the key components of a Radiation Safety Plan.

Documentation

Essential to a good Radiation Safety Plan are the charts, records, procedures, and other documentation that support the plan. In many cases, Pennsylvania regulations mandate certain items that are essential to the program. For example, 25 Pa. Code § 221.11(d) requires that written safety procedures and rules shall be available at a facility including restrictions of the operating technique required for the safe operation of the particular X-ray system. This section also requires that operators of the system shall be able to demonstrate familiarity with the rules. These procedures and rules should not simply be generic rules for safety, but should be written for the particular application(s) planned at the facility.

25 Pa. Code § 221.11(c) requires that a chart shall be provided in the vicinity of each diagnostic X-ray system's control panel which specifies the techniques for examinations performed with the system (see previous section and referenced regulation for additional details).

25 Pa. Code § 221.12 states that the registrant shall maintain records of surveys, calibrations, maintenance and modifications performed on the X-ray systems including the names of persons who performed the services. This section also requires that all such inspection records be kept by the DEP for 5 years.

Quality Assurance

Another important part of the Radiation Safety Plan is the Quality Assurance Program. In the US Food and Drug Administration regulations (Code of Regulations, 21 CFR 1000), Quality Assurance is defined as follows:

> "Quality assurance means 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."

The FDA states that quality assurance actions include both "quality control" techniques and "quality administration" procedures. These techniques and procedures are defined as follows:

> "Quality control techniques are those techniques used in monitoring (or testing) and maintenance of the components of x-ray system. The quality control techniques are concerned directly with the equipment."
>
> "Quality administration procedures are those management actions intended to guarantee that monitoring techniques are properly performed and evaluated and that necessary corrective actions are taken in response to monitoring results. These procedures provide the organizational framework for the quality assurance program."

25 Pa. Code § 221.11(l) states that "the registrant shall have a quality assurance program. This quality assurance program shall be documented and in accordance with guidelines established by the Department or another appropriate organization recognized by the Department. At a minimum, the quality assurance program shall address repeat rate; image recording, processing and viewing; and maintenance and modifications to the quality assurance program. Records shall be maintained by the registrant for inspection by the Department for 3 years. The Department's guidelines and a list of recognized organizations will be maintained and made available on the Department's website and on request."

This website is available at http://www.dep.state.pa.us/brp/Radiation_Control_Division/X-Ray/QARequHealing.htm.

A Fact Sheet at this site, entitled "Minimum Quality Assurance Requirements for Healing Arts Radiography," provides additional information on the State regulatory requirements. Another Fact Sheet, entitled "Model Quality Assurance Guidelines for Dental, Diagnostic Radiology and Mammography," discusses sources of guidelines for quality assurance programs and cites the Conference of Radiation Control Program Directors' (CRCPD) *Quality Control Recommendations for Diagnostic Radiography Volumes 1, 2, and 3* as acceptable reference documents for QA programs and that these three guides provide a model program and instruction for establishing and maintaining a QA program in dental, podiatry, and radiographic/fluoroscopic facilities other than mammography, respectively.

In addition to these fact sheets, this site also has the list of recognized organizations providing acceptable quality assurance program guidelines as mentioned in the regulations. This list includes sources that provide general guidelines applicable to a variety of imaging techniques as well as sources for specific QA/QC guidelines for dental, computed tomography, mammography, podiatry, and chiropractic facilities. The list as of fall 2013 is provided below.

General QA/QC Guidelines

American Association of Physicists in Medicine (AAPM) Report No. 74, *Quality Control in Diagnostic Radiology, July 2002*. http://www.aapm.org/pubs/reports/

Conference of Radiation Control Program Directors, Inc. (CRCPD), *Quality Control Recommendations for Diagnostic Radiology, Radiographic or Fluoroscopic Machines (Volume 3), Publication 01-6****** http://www.crcpd.org/Pubs/QC-Docs/QC-Vol3-Web.pdf

National Council on Radiation Protection and Measurements (NCRP) Report No. 99, *Quality Assurance for Diagnostic Imaging Equipment 1988 http://www.ncrponline.org/pubs.html*

Gray, J. E., Winkler, N. T., Stears, J., Frank, E. D., *Quality Control in Diagnostic Imaging*; Rockville, MD: Aspen Publishers; 1983

New Jersey Department of Environmental Protection – BRH *Compliance Guidance for Quality Assurance Manual****** http://www.nj.gov/dep/rpp/brh/brhdown.htm

New Jersey Department of Environmental Protection – BRH *Compliance Guidance for Radiographic Quality Control****** http://www.nj.gov/dep/rpp/brh/brhdown.htm

New Jersey Department of Environmental Protection – BRH *Compliance Guidance for Fluoroscopic Quality Control****** http://www.nj.gov/dep/rpp/brh/brhdown.htm

U.S. Food and Drug Administration, HHS 21CFR1000.55 *Recommendation for Quality Assurance Programs in diagnostic Radiology Facilities******
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm

Specialty QA/QC – Dental

Conference of Radiation Control Program Directors, Inc. (CRCPD), *Quality Control Recommendations for Diagnostic Radiology, Dental Facilities (Volume 1), Publication 01-4****** http://www.crcpd.org/Pubs/QC-Docs/QC-Vol1-Web.pdf

National Council on Radiation Protection and Measurements (NCRP) Report No. 145 *Radiation Protection in Dentistry http://www.ncrponline.org/publications/145press.html*

Specialty QA/QC – Computed Tomography

American Association of Physicists in Medicine (AAPM) Report No. 83, *Quality Assurance for Computed Tomography Simulators, July 2002*. Medical Physics, Volume 30, Issue 10 (2003)
http://www.aapm.org/pubs/reports/

New Jersey Department of Environmental Protection – BRH *Compliance Guidance for Computed Tomography Quality Control* ***** http://www.nj.gov/dep/rpp/brh/brhdown.htm

Specialty QA/QC – Mammography

U.S. Food and Drug Administration, HHS 21 CFR 900.12 *Mammography Quality Standards******
http://www.accessdata/fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=900

Specialty QA/QC – Podiatry **Conference of Radiation Control Program Directors, Inc. (CRCPD),** *Quality Control Recommendations for Diagnostic Radiology, Podiatric Facilities (Volume 2), Publication 01-5****** http://www.crcpd.org/Pubs/QC-Docs/QC-Vol2-Web.pdf

Specialty QA/QC – Chiropractic

Wilson, Russell L., *Chiropractic radiography and quality assurance handbook*; Boca Raton, FL: CRC Press LLC; 2000

American Chiropractic College of Radiology; http://www.accr.org

*Denotes electronic documents available for download at no cost

Regulations

Overview

To someone outside the radiation field (and even to many within it), radiation regulations can sometimes seem confusing, conflicting, and difficult to determine applicability to a particular situation. The key is to determine which regulations apply to your application.

Historically, regulation of the use of x-ray machines and other devices that produce radiation has been assigned to the States. However, control of most radioactive materials, especially those derived from nuclear reactors, was originally assigned to the Federal government under the Atomic Energy Commission (AEC) whose regulatory function was later assigned to a newly created agency, the Nuclear Regulatory Commission (NRC). As the use of radioactive materials rapidly expanded outside the fields of weapons and reactors, the AEC (and later the NRC) began to reach agreements with individual States that allowed for State regulatory oversight of most radioactive sources. The NRC maintained regulatory control over nuclear reactors and certain other uses of radioactive materials primarily dealing with weapons and defense. The States that reached these agreements with the NRC are referred to as Agreement States, and in 2008 Pennsylvania became an NRC Agreement State.

The State regulations regarding radiological health are found in the Pennsylvania Code, Title 25 Environmental Protection Chapters 215-240. These regulations include those for X-ray devices as well as use of radioactive materials. In some cases regulations from the Code of Federal Regulations, Title 10 Chapter I (Nuclear Regulatory Commission), are incorporated into the Pennsylvania regulations by reference. For this reason, all individuals that are responsible for the use of radioactive materials and/or radiation-producing devices need to be aware of both applicable State regulations as well as the incorporated Federal regulations.

Another Federal agency involved with ensuring the safe use of diagnostic medical X-rays is the Food and Drug Administration (FDA). The mission of the FDA's radiological health program is to protect the public from hazardous or unnecessary radiation exposure from radiation-emitting electronic products. They do this by overseeing product manufacture compliance with all applicable requirements, providing direction and guidance to the general public and users of radiation-emitting products, assessing radiation emission levels from products, and studying the biological effects from these products and their potential risks to health.

In addition the FDA is tasked with regulating facilities that perform mammography under the authority of the Mammography Quality Standards Act (MQSA). The FDA requires that all facilities performing mammography attain accreditation and they (along with the DEP) maintain a list of certified mammography facilities. In Pennsylvania, the DEP Bureau of Radiation Protection (BRP) contracts with the FDA to perform annual inspections of mammography facilities in the State.

Regulations issued by the FDA are found in Title 21 of the Code of Federal Regulations (21 CFR).

Review of Regulations Related to the Use of Diagnostic X-rays

The following is an overview of the principle regulations that deal with the safe use of diagnostic X-rays in medicine and is directed towards registrants and operators in medical diagnostic settings. Note that other regulations may apply and the reader should refer directly to the appropriate chapters of Title 25 for specific issues.

Chapter 216. Registration of Radiation-Producing Machines and Radiation-Producing Machine Service Providers

For the medical practitioner, this chapter provides requirements for registering the radiation-producing machine (§216.2), renewing the certificate of registration (§216.4), expiration or termination of the certificate of registration (§216.4a), and transfer and disposal obligations of the radiation-producing machine (§216.6).

Briefly, registration of the radiation-producing machine shall be completed within 30 days after acquisition by submitting the necessary forms and fee to DEP. Changes such as owner, address, number of machines, etc., must be submitted to DEP and a certificate may not be transferred, assigned or in any manner disposed without a written request to DEP. (§216.4)

Applications for renewal of the certificate of registration shall be sent by DEP to registrants at least 2 months prior to the expiration date, and the applicant shall submit a request for renewal and the fee required to DEP prior to the expiration date. (§216.4)

When a registrant terminates all activities involving radiation-producing machines, the registrant shall:

(1) Terminate the use of all radiation-producing machines subject to this registration.

(2) Transfer or dispose of all radiation-producing machines subject to this registration.

(3) Remit any outstanding fees related to the registration.

(4) Request termination of the certificate of registration in writing to DEP. (§216.4a)

The DEP shall be notified of any transfer or disposal of any X-ray producing device, including name and address of the person receiving the device, identifying information for the device and date of transfer. (§§ 216.6 and 216.2b)

Chapter 219. Standards for Protection Against Radiation

This chapter closely parallels the NRC Federal regulations in 10 CFR Part 20, which according to § 219.5 are incorporated by reference except as provided in Chapter 219. For the diagnostic X-ray user, many sections of 10 CFR Part 20 (and

therefore Chapter 219) do not apply since they refer to users of radioactive materials; however, certain sections do apply and registrants of medical X-ray devices need to be aware of them. These sections are reviewed below.

Occupational Dose Limits (10 CFR Part 20 Subchapter B, 25 Pa. Code §§ 219.21-22)

Occupational dose limits apply only to occupational workers – defined by the NRC as an individual who in the course of their work are exposed to radiation or to radioactive material from licensed and unlicensed sources of radiation, whether in the possession of the licensee or other person. Occupational dose does not include doses received from background radiation, from any medical administration the individual has received, from exposure to individuals who were administered medical radioactive material and released, from voluntary participation in medical research programs, or as a member of the public. Note that this definition also means that patient radiation dose from medical treatments does not fall under these regulations. Good medical practice should ensure that patient dose is justified, taking into account the objectives of the exposure, but no specific values for diagnosis or treatment are given as regulatory limits.

Annual occupational dose limits for diagnostic X-ray workers who have no other occupational exposure to radioactive materials are:

Effective dose equivalent to whole body (defined as head, trunk (including male gonads), arms above the elbow, or legs above the knee)	5 rem (0.05 Sv)
Lens of the eye dose equivalent	15 rem (0.15 Sv)
Shallow-dose equivalent to the skin of the whole body or to the skin of any extremity	50 rem
Dose limits for minors (<18 yrs)	10% of adult limits above
Dose equivalent to embryo/fetus of declared pregnant female (see NRC Regulatory Guide 8.13 for additional information)	0.5 rem (5 mSv) during entire pregnancy (see 10 CFR 20.1208 for additional information)

Dose limits for individual members of the public (10 CFR Part 20 Subchapter D, 25 Pa. Code § 219.51)

According to 10 CFR 20.1301 the dose equivalent limit to individual members of the public shall not exceed 0.1 rem (1 mSv) in a year. Like the limits for occupational exposure, this limit excludes background radiation or medical administration of radiation. In other words, this limit does not apply to the radiation a patient receives at your facility, but does apply to their time in the waiting room, people accompanying them, or any other member of the public visiting your facility.

This limit was changed in the NRC regulations from 0.5 rem (5 mSv) in one year to the current value in the mid-1990s. Shielding in facilities designed before the change was made was designed to meet the higher limit and may not meet the current level. However, Pennsylvania regulations (§ 219.51) have an exception that states that “locations having existing radiation-producing machines or equipment

or other registered sources will not be required to retrofit installations existing before November 18, 1995." The DEP also does not require retrofitting of shielding for replacement in those facilities as long as the equipment is replaced with similar equipment.

This exception brings up the issue that at X-ray facilities, shielding in the walls, ceiling and floor is designed based on the use of the adjoining rooms. In the original planning of the facility, the shielding should be conservatively designed to ensure that workers or members of the public in those other rooms will not exceed limits. However, if the facility undergoes a major renovation and especially if adjacent rooms go from low occupancy to high occupancy use, a technical expert qualified in X-ray shielding design should review the changes and the shielding that is in place to ensure that limits are still being met.

Storage and control of licensed or registered sources of radiation (25 Pa. Code §§ 219.131-132, 10 CFR 20.1801 and 1802)

This section of the regulations requires that sources of radiation be secured from unauthorized removal or access while in storage or available for use. 25 Pa. Code §§ 219.131-132 expand the NRC regulations to include security from unauthorized removal or access to radiation sources in storage and control of radiation-producing machines that are not in storage. This imposes the same requirements for security and control on X-ray machines as the NRC requires for radioactive materials.

Posting of radiation-producing machines and exceptions to NRC posting requirements (25 Pa. Code §§ 219.159 and 219.160)

Radiation-producing machines are required to be labeled in a conspicuous manner to indicate that radiation is produced when energized. For example:

"CAUTION – RADIATION
THIS EQUIPMENT PRODUCES RADIATION
WHEN ENERGIZED"

In NRC 10 CFR Part 20 a number of other posting requirements are given based on radiation level; however, 25 Pa. Code § 219.160 provides an exception for posting caution signs for a room or area that contains radiation machines used solely for diagnosis in the healing arts.

Reports of stolen, lost, or missing licensed or registered sources of radiation; Notification of incidents and reportable events; and Other medical reports (25 Pa. Code §§ 219.221, 219.222, and 219.229)

25 Pa. Code §§ 219.221 and 219.222 expand the NRC 10 CFR Part 20 regulations on notification of incidents and events; and reports of such events to include radiation producing machines. If such an incident or event occurs, the registrant should consult these sections of the State regulations to ensure that the required reports are complete and timely.

In addition, § 219.229 (other medical reports) requires that a report be submitted within 30 days of the determination by a physician of either actual or suspected acute or long-term functional damage to an organ or a physiological system of a

patient exposed to therapeutic or diagnostic radiation from a radiation-producing machine. Such an injury is very unlikely for low-risk procedures, but the registrant should be aware of this responsibility in the event of such a severe incident.

Chapter 220. Notices, Instructions, and Reports to Workers; Inspections and Investigations

Registrants of radiation-producing machines are required to post the following notices to workers:

1. 25 Pa. Code Chapters 219 and 220
2. Certificate of Registration
3. Operating procedures applicable to activities under the registration
4. Notice of violation involving radiological working conditions, proposed imposition of civil penalty or order issued under Chapter 215 and response of the registrant

If posting of these documents is not practicable, the registrant may post a notice which describes the documents and states where they may be examined.

In addition, Department Form 2900-FM-BRP0003 “Notice to Employees” shall be posted. This form is available on the Department’s website and appears on the following page.

2900-FM-BRP0003 6/2014

pennsylvania
DEPARTMENT OF ENVIRONMENTAL PROTECTION

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 their 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) 787-3720
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.

25 Pa. Code § 220.9 incorporates a number of sections of NRC 10 CFR Part 19 including notices, instructions to workers, notifications and reports to workers of their radiation exposure, inspections and investigations. These sections include when a worker is required to be monitored for radiation exposure, information that must be reported to workers such as monitoring results, as well as the requirements for registrants to make staff and facilities available for inspections by the State as required.

Chapter 221. X-rays in the Healing Arts

Chapter 221 provides detailed information on the requirements for operation of medical X-rays. **General Provisions** of this chapter include purpose, scope and an extensive list of definitions in §§ 221.1 and 221.2. **Administrative Controls**, many of which have been discussed in earlier sections, are provided in §§ 221.11 – 221.15. The sections concerning low-risk procedures are primarily those found in the **Diagnostic Installations General Requirements**, §§ 221.21 – 221.49.

The following table briefly summarizes the key points of these chapters; however, the medical staff should consult the regulations directly when examining their systems for compliance.

Section Number and Title	Abbreviated Summary of Chapter Requirements (See Regulations for Additional Details)
221.21 – Diagnostic equipment requirements	Certified components shall comply with relevant regulations of the Food and Drug Administration (21 CFR 1020.30 – 1020.33).
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.
221.21 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.
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.
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	Fluoro-systems shall use image intensifier and comply with prior regulations in this chapter.
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.
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.

The remaining sections of Chapter 221 deal with radiation therapy simulation systems, therapeutic X-ray systems with energies less than 1 Mev and computed tomography X-ray system.

Definitions

Agreement State

A State that has signed an agreement with the NRC authorizing the State to regulate certain uses of radioactive materials within the State. Pennsylvania became an Agreement State in 2008. Pennsylvania also has authority to regulate radiation-producing machines, such as medical X-ray equipment.

Alpha particle

A positively charged particle ejected spontaneously from the nuclei of some radioactive elements. It is identical to a helium nucleus that has a mass number of 4 and an electrostatic charge of +2. It has low penetrating power and a short range (a few centimeters in air). The most energetic alpha particle will generally fail to penetrate the dead layers of cells covering the skin, and can be easily stopped by a sheet of paper. Alpha particles are hazardous when an alpha-emitting isotope is inside the body.

Background radiation

The natural radiation that is always present in the environment. It includes cosmic radiation which comes from the sun and stars, terrestrial radiation which comes from the Earth, and internal radiation which exists in all living things. The typical average individual exposure in the United States from natural background sources is about 300 millirems per year.

Beta particle

A charged particle (with a mass equal to 1/1837 that of a proton) that is emitted from the nucleus of a radioactive element during radioactive decay (or disintegration) of an unstable atom. A negatively charged beta particle is identical to an electron, while a positively charged beta particle is called a positron. Large amounts of beta radiation may cause skin burns, and beta emitters are harmful if they enter the body. Beta particles may be stopped by thin sheets of metal or plastic.

Declared pregnant woman

A woman who is an occupational radiation worker and has voluntarily informed her employer, in writing, of her pregnancy and the estimated date of conception (see 10 CFR 20.1003 and 20.1208).

Deterministic effect

The health effects of radiation, the severity of which varies with the dose and for which a threshold is believed to exist. Radiation-induced cataract formation is an example of a deterministic effect (also called a non-stochastic effect) (see 10 CFR 20.1003).

Dose

A general term, which may be used to refer to the amount of energy absorbed by an object or person per unit mass. Known as the "absorbed dose," this reflects the amount of energy that ionizing radiation sources deposit in materials through which they pass, and is measured in units of radiation-absorbed dose (rad). The related international system unit is the gray (Gy), where 1 Gy is equivalent to 100 rad. By contrast, the biological dose or dose equivalent, given in rems or sieverts (Sv), is a measure of the

biological damage to living tissue as a result of radiation exposure. For additional information, see Doses in Our Daily Lives and Measuring Radiation.

Dose equivalent

A measure of the biological damage to living tissue as a result of radiation exposure. Also known as the "biological dose," the dose equivalent is calculated as the product of absorbed dose in tissue multiplied by a quality factor and then sometimes multiplied by other necessary modifying factors at the location of interest. The dose equivalent is expressed numerically in rems or sieverts (Sv) (see 10 CFR 20.1003). For additional information, see Doses in Our Daily Lives and Measuring Radiation.

Dose, absorbed

The amount of energy absorbed by an object or person per unit mass. Known as the "absorbed dose," this reflects the amount of energy that ionizing radiation sources deposit in materials through which they pass, and is measured in units of radiation-absorbed dose (rad). The related international system unit is the gray (Gy), where 1 Gy is equivalent to 100 rad. For additional information, see Doses in Our Daily Lives and Measuring Radiation.

Dose rate

The dose of ionizing radiation delivered per unit time. For example, rems or sieverts (Sv) per hour.

Dosimeter

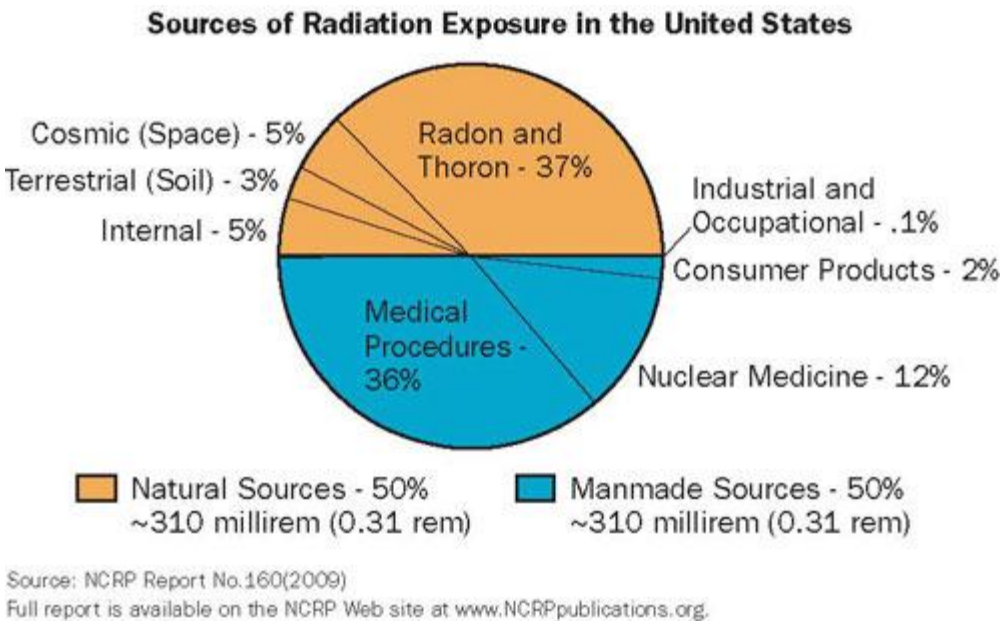
A small portable instrument (such as a film badge, thermoluminescent dosimeter, or pocket dosimeter) used to measure and record the total accumulated personal dose of ionizing radiation.

Electromagnetic radiation

A traveling wave motion resulting from changing electric or magnetic fields. Familiar electromagnetic radiation range from X-rays (and gamma rays) of short wavelength, through the ultraviolet, visible, and infrared regions, to radar and radio waves of relatively long wavelength.

Exposure

Absorption of ionizing radiation or ingestion of a radioisotope. Acute exposure is a large exposure received over a short period of time. Chronic exposure is exposure received over a long period of time, such as during a lifetime. The National Council on Radiation Protection and Measurements (NCRP) estimates that an average person in the United States receives a total annual dose of about 0.62 rem (620 millirem) from all radiations sources, a level that has not been shown to cause humans any harm. Of this total, natural background sources of radiation—including radon and thoron gas, natural radiation from soil and rocks, radiation from space and radiation sources that are found naturally within the human body—account for approximately 50 percent. Medical procedures such as computed tomography (CT scans) and nuclear medicine account approximately for another 48 percent. Other small contributors of exposure to the U.S. population include consumer products and activities, industrial and research uses, and occupational tasks. The maximum permissible yearly dose for a person working with or around nuclear material is 5 rem. For additional detail, see Doses in Our Daily Lives and Measuring Radiation.



Extremities

The hands, forearms, elbows, feet, knees, leg below the knees, and ankles. Permissible radiation exposures in these regions are generally greater than those for whole body exposure because the extremities contain fewer blood-forming organs and have smaller volumes for energy absorption. (See 10 CFR 20.1003.)

Film badge

Photographic film used to measure exposure to ionizing radiation for purposes of personnel monitoring. The film badge may contain two or three films of differing sensitivities, and it may also contain a filter that shields part of the film from certain types of radiation.

Gamma radiation

High-energy, short-wavelength, electromagnetic radiation emitted from the nucleus of an atom. Gamma radiation frequently accompanies emissions of alpha particles and beta particles, and always accompanies fission. Gamma rays are similar to X-rays, but are very penetrating and are best stopped or shielded by dense materials, such as lead or depleted uranium.

Ionization

The process of adding one or more electrons to, or removing one or more electrons from, atoms or molecules, thereby creating ions. High temperatures, electrical discharges, or nuclear radiation can cause ionization.

Ionizing radiation

A form of radiation, which includes alpha particles, beta particles, gamma rays, x-rays, neutrons, high-speed electrons, high-speed protons, and other particles capable of producing ions. Compared to non-ionizing radiation, such as radio- or microwaves, or visible, infrared, or ultraviolet light, ionizing

radiation is considerably more energetic. When ionizing radiation passes through material such as air, water, or living tissue, it deposits enough energy to produce ions by breaking molecular bonds and displace (or remove) electrons from atoms or molecules. This electron displacement may lead to changes in living cells. Given this ability, ionizing radiation has a number of beneficial uses, including treating cancer or sterilizing medical equipment. However, ionizing radiation is potentially harmful if not used correctly, and high doses may result in severe skin or tissue damage. It is for this reason that the NRC strictly regulates commercial and institutional uses of the various types of ionizing radiation. Radiation, as used in 10 CFR 20.1003, does not include non-ionizing radiation (see also10 CFR 20.1003).

kilovolts peak (kVp)

The maximum value of the potential difference across the X-ray tube during an exposure is the kVp.

milliAmp seconds (mAs)

The product of the X-ray tube current (mA) and exposure time (s) is mAs. The quantity of X-rays produced is directly proportional to the mAs.

Occupational dose

The internal and external dose of ionizing radiation received by workers in the course of employment in such areas as fuel cycle facilities, industrial radiography, nuclear medicine, and nuclear power plants. These workers are exposed to varying amounts of radiation, depending on their jobs and the sources with which they work. The NRC requires its licensees to limit occupational exposure to 5,000 mrem (50 mSv) per year. Occupational dose does not include the dose received from natural background sources, doses received as a medical patient or participant in medical research programs, or "second-hand doses" received through exposure to individuals treated with radioactive materials.

Photon

A quantum (or packet) of energy emitted in the form of electromagnetic radiation. Gamma rays and X-rays are examples of photons.

Rad (radiation-absorbed dose)

One of the two units used to measure the amount of radiation absorbed by an object or person, known as the "absorbed dose," which reflects the amount of energy that radioactive sources deposit in materials through which they pass. The radiation-absorbed dose (rad) is the amount of energy (from any type of ionizing radiation) deposited in any medium (e.g., water, tissue, air). An absorbed dose of 1 rad means that 1 gram of material absorbed 100 ergs of energy (a small but measurable amount) as a result of exposure to radiation. The related international system unit is the gray (Gy), where 1 Gy is equivalent to 100 rad.

Radiation (ionizing radiation)

Alpha particles, beta particles, gamma rays, x-rays, neutrons, high-speed electrons, high-speed protons, and other particles capable of producing ions. Radiation, as used in 10 CFR Part 20, does not include non-ionizing radiation, such as radio- or microwaves, or visible, infrared, or ultraviolet light.

Radiology

That branch of medicine dealing with the diagnostic and therapeutic applications of radiant energy, including X-rays and radioisotopes.

REM (Roentgen equivalent man)

One of the two standard units used to measure the dose equivalent (or effective dose), which combines the amount of energy (from any type of ionizing radiation that is deposited in human tissue), along with the medical effects of the given type of radiation. For beta and gamma radiation, the dose equivalent is the same as the absorbed dose. By contrast, the dose equivalent is larger than the absorbed dose for alpha and neutron radiation, because these types of radiation are more damaging to the human body. Thus, the dose equivalent (in rems) is equal to the absorbed dose (in rads) multiplied by the quality factor of the type of radiation [see Title 10, Section 20.1004, of the *Code of Federal Regulations* (10 CFR 20.1004), "Units of Radiation Dose"]. The related international system unit is the sievert (Sv), where 100 rem is equivalent to 1 Sv.

Roentgen (R)

A unit of exposure to ionizing radiation. It is the amount of gamma or X-rays required to produce ions resulting in a charge of 0.000258 coulombs/kilogram of air under standard conditions. Named after Wilhelm Roentgen, the German scientist who discovered X-rays in 1895.

Scatter radiation

Radiation that, during its passage through a substance, has been changed in direction. It may also have been modified by a decrease in energy. It is one form of secondary radiation.

Sievert (Sv)

The international system (SI) unit for dose equivalent equal to 1 Joule/kilogram. 1 sievert = 100 rem. Named for physicist Rolf Sievert.

Somatic effects of radiation

Effects of radiation limited to the exposed individual, as distinguished from genetic effects, that may also affect subsequent unexposed generations.

Stochastic effects

Effects that occur by chance, generally occurring without a threshold level of dose, whose probability is proportional to the dose and whose severity is independent of the dose. In the context of radiation protection, the main stochastic effects are cancer and genetic effects.

X-rays

Penetrating electromagnetic radiation (photon) having a wavelength that is much shorter than that of visible light. These rays are usually produced by excitation of the electron field around certain nuclei. In nuclear reactions, it is customary to refer to photons originating in the electron shell as X-rays.