

RADIATION SAFETY TRAINING FOR THE FLUOROSCOPIST

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Like all medical imaging procedures, fluoroscopy procedures present both benefits and risks. Fluoroscopy imaging procedures have led to improvements in the diagnosis and treatment of numerous medical conditions. At the same time, they expose patients to ionizing radiation, which may elevate a person's lifetime risk of developing cancer. A balanced approach to the use of fluoroscopy seeks to support the benefits of the imaging procedures while minimizing the risks.

This facility is committed to provide the best quality of care for its patients, as well as comply with all the regulations of the Pennsylvania Dept. of Environmental Protection. In keeping with these commitments, physicians who utilize fluoroscopy devices at this facility are required to be familiar with the radiation physics and safety principles necessary for safe operation.

The use of X-ray fluoroscopy has increased dramatically in recent years and is spreading beyond the radiology department. Advances in medical technology have resulted in the development of more powerful X-ray machines used during complex procedures requiring extensive use of fluoroscopy. The use of such equipment by personnel who have not received specialized training in the proper use of radiation creates the potential for excessive radiation exposure to personnel and patients. Inadequate training combined with increased radiation outputs, higher X-ray tube heat capacities, and real-time digital image acquisition and storage can produce patient doses that induce serious skin damage.

Procedures Involving Extended Fluoroscopy Exposures

(FDA 1994)

Radiofrequency cardiac catheter ablation
Percutaneous transluminal angioplasty (PTCA, PTA)
Vascular embolization
Stent and filter placement
Thrombolytic and fibrinolytic procedures
Percutaneous transhepatic cholangiography
Endoscopic retrograde cholangiopancreatography (ERCP)
Transjugular intrahepatic portosystemic shunt (TIPS)
Percutaneous nephrostomy, biliary drainage, or stone removal

Numerous instances of serious injuries have been documented, and they have spurred efforts to make specialized training available for fluoroscopists. The Pennsylvania Department of Environmental Protection (DEP) has gone one step further. It has mandated that all individuals involved in fluoroscopy must undergo at least eight hours of initial training for high risk procedures or 4 hours of initial training for low risk procedures along with one hour of refresher training annually. The training requirements can be found in Title 25 Pennsylvania Code, Section 221.11 Appendix A:

The registrant shall ensure that training on the subjects listed in Appendix A has been conducted. The individual shall be trained and competent in the general operation of the x-ray equipment and in the following subject areas, as applicable to the procedures performed and the specific equipment utilized:

- (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

The risk of adverse radiation effects originating from a medically necessary procedure is almost always offset by the benefit received by the patient. However, in order to improve the benefit-risk tradeoff for these procedures, it is incumbent on the operator to explore the reasons behind radiation effects that have occurred and to seek means by which to avoid them or reduce their severity for future cases.

This manual is intended to provide physicians and other users of fluoroscopic equipment one means of achieving compliance with the DEP rule. It covers some basic principles of radiation physics, biology, and radiation safety in order to provide an understanding of the optimal utilization of fluoroscopy, while minimizing exposures to the patient, operators, and their colleagues.

Chapter 1: Basic Properties of Radiation

General principles

Radiation is energy in the form of electromagnetic waves and particles and can be broken down into two general categories: ionizing and non-ionizing. Ionizing radiation is, typically, what we think of when we use the word “radiation”. It incorporates, gamma and X-rays, beta particles, charged particles, alpha particles and neutrons. For most hospitals and imaging centers, we primarily find gamma particles and X-rays. It is characterized by the ability to “ionize” matter by which we mean there’s enough energy available to strip orbital electrons off of atoms. The absolute minimum energy needed to ionize an atom is 13.6 eV for an atom of Hydrogen. The ability to ionize matter, as we will see, is what makes radiology possible. It is also responsible for the harmful effects on living tissue.

Non-ionizing radiation includes lasers, microwaves, ultrasound, visible and infrared. In all cases, the energy of the radiation is less than 13.6 eV.

Ionizing radiation affects matter (such as human tissue) by physically changing the atomic structure of the matter. Non-ionizing can affect matter by locally increasing the temperature from absorbed energy but it doesn’t affect the underlying atomic structure of the matter.

For radiation safety in the hospital or imaging center we are interested in ionizing radiation.

Production of Radiation

There are two ways to produce radiation in the hospital or imaging center: 1) in nuclear medicine where naturally decaying radioisotopes produce radiation during the process of decay and 2) radiology using X-rays. X-rays occur when fast moving electrons are suddenly decelerated by an interaction with matter. During the interaction, the kinetic energy of the high speed electrons are converted into X-rays (about 1%) and heat (about 99%). The energy of the X-ray produced is proportional to the energy of the incident electrons.

Production of X-rays takes place through two types of electron interactions:

1. Bremsstrahlung radiation where the electron passes near the nucleus of the atom, is deflected around the nucleus and loses energy in the form of X-rays and heat and;
2. Characteristic X-rays where the incoming electron strikes an inner shell orbital electron causing it to eject from the atom. Outer shell electrons fill in the suddenly vacant lower orbits. The amount of energy released as X-rays is proportional to the difference in energy levels between the different orbits.

Interactions of X-rays with matter (i.e. what to do with the X-rays once you have them).

There are 5 ways that X-rays interact with matter and they are dependent on the energy of the X-rays.

1. Coherent Scattering: the X-ray interacts with the whole atom, the energy of the x-ray is transferred to the atom, the excess energy is given up by the atom as an X-ray travelling in an altered direction. This is a low energy interaction.
2. Compton Effect: The X-ray interacts with an outer shell electron, the electron is ejected from the orbit of the atom, the X-ray is deflected from it’s original path and continues with decreased energy. This is a moderate energy interaction generally becoming dominant from 80 keV to above 140 keV in the clinical setting. Almost all of diagnostic X-ray scattering is from Compton Effect X-rays. Lead foil is

placed in the backs of cassettes to prevent backscattering (Compton Effect X-rays scattering at 180 degrees) from fogging film (if you still use film). I

3. Photoelectric Effect: first described by Albert Einstein in one of his five amazing papers from 1905, the X-ray interacts with an inner shell orbital electron, ejecting the electron and absorbing the X-ray. An outer shell electron rushes in to fill in the hole producing Characteristic X-rays. It's a low to moderate energy interaction, dominant in the mammography range (25-35 keV), it gradually cedes dominance to Compton Effect above about 80 keV. Photoelectric Effect produces very little scatter radiation (one reason that mammography suites needs little or no shielding in the walls). It is very dependent on the atomic mass of the receiving atom so it is very affected by the density of material it is trying to penetrate. By comparison, the Compton Effect is minimally affected by density of the material. This means that denser materials will show up with greater subject contrast using lower energy X-rays which interact predominantly photo-electrically. This makes mammography possible as small differences in density are relatively easy to differentiate. As you increase kVp to the range of energies dominated by the Compton Effect, density is less determinant of interaction. Compton Effect is the reason you can blur ribs out of a chest X-ray using a high kVp (such as 120 kVp). The probability of interaction between the dense bone and less dense soft tissue is almost the same in the range of energies dominated by the Compton Effect.
4. Pair Production: High energy X-rays (greater than 1.02 MeV) interact with the nucleus. The X-ray is converted into an 511 keV electron and a 511 keV positron. The positron quickly interacts with an electron and annihilates producing annihilation radiation. This is the basis of PET imaging but is otherwise of no consequence of diagnostic radiology.
5. Photodisintegration: Very high energy X-ray (7-15 MeV) interacts with a nucleus and ejects part of the nucleus. No consequence in diagnostic radiology.

Chapter 2: Units of Measurement

There is a myriad of terms describing radiation and radiation exposure. This is often confusing even to those quite familiar with radiation physics. Terms which the physician should be aware of include those that:

- Describe X-ray machine radiation output;
- Describe patient radiation exposure; and
- Describe personal radiation risk

There are three units that are used: Roentgen (R), Rad and Rem. Those are the English units. The S.I. units for Rad and Rem are the Gray and Sievert respectively. The conversion is 100 Rad = 1 Gray and 100 Rem = 1 Sievert. Throughout most of the world and in all academic publications, the S.I. units are used. The U.S. still uses the English units for most day to day operations. The use of the English units are codified in the U.S. Code of Federal Regulations (10 CFR 20).

Roentgen (R)

Technically, the Roentgen is a measure of the exposure in air and can be used to describe the intensity of the X-ray beam and also as a measure of scatter around a source. The State limit for exposure is 10 R/min at 30 cm from the image intensifier. C-arms with a boost mode are allowed 20 R/min while in boost mode. X-ray machine output can be described in terms of Entrance Skin Exposure (ESE) which is the amount of radiation delivered to the patient's skin at the beam's entrance point. ESE may also be described as "table-top dose." **Most X-ray machine regulations are defined in ESE.** The units of ESE are Roentgens per minute (R/min).

Rad

Patient radiation exposure is described in terms of radiation dose. Radiation dose is the energy imparted per unit mass of tissue and has the units of Rad.

Rem

The Rem is a Rad that takes into account the biological effect of the radiation or the Rad times a weighting factor. For gamma radiation and X-ray radiation, the weighting factor is very close to 1 and we can, for our purposes, assume they are equivalent. Occupational radiation exposure is also described in terms of radiation dose. We measure personnel radiation exposure in units of mrem (millirem or 1/1000 of a Rem). The annual allowable limit for occupational workers is 5,000 mrem. For pregnant workers, it is 500 mrem from declaration of pregnancy until birth or ultimate outcome.

Chapter 3: Sources of Radiation Exposure

Sources of radiation exposure in the typical hospital include: Computed Tomography units, X-ray and fluoroscopy units and radioisotopes used nuclear medicine. MRI and ultrasound are two imaging modalities that do not use ionizing radiation.

Chapter 4: Methods of Radiation Protection (ALARA)

Radiation protection for the worker and the patient

There are three basic methods of reducing radiation exposure to the worker: Time, Distance and Shielding. These are collectively known as ALARA concepts. ALARA is an acronym for As Low As Reasonably Achievable and is a philosophy for radiation safety that is applied to every situation involving radiation. We want to reduce radiation exposure as much as possible given certain economic and technological constraints. Note that it isn't just to get the lowest exposure possible. We wouldn't spend 10 million dollars to build an elaborate shielding system to save 10 mrem per year. Even though the exposure is lower, the cost is not reasonable and is therefore not "ALARA". We always strive to make situations ALARA. It is evaluated on a case-by-case basis and one of the purposes of this manual is assist the operator in evaluating what constitutes ALARA for his or her practice.

1. **Time:** Spend as little time near the source of radiation as possible. In the case of a fluoroscopy patient, the source of scatter is the patient. The point where the X-ray beam enters the patient is the primary sources of a scatter radiation. Reduce as much as possible the time spent near the point where the X-ray beam enters the patient.
2. **Distance:** Stay as far from the sources as possible while the beam is engaged. In most cases, the scatter is significantly reduced 3-6 feet from the point of scatter.
3. **Shielding:** anything between you and the beam. Examples of shielding include lead aprons, portable shields, and permanent shielding in the walls of the room.

Inverse Square Law: The inverse square law mathematically describes the strength of an X-ray beam or its scatter as a function of distance from the source. The strength of an X-ray beam or its scatter decreases with the inverse square of the distance from the source. This is a very powerful concept. If you are standing 2 feet from the source of X-rays and the exposure rate is 20 mrem/min; if you step back 2 feet, thereby doubling your distance from the source, the exposure rate will drop by a factor of 4. It will be 1/4 of the exposure rate it was at your original position or 5 mrem/min. Double your distance again and the dose rate will drop by another factor

of 4 to 1.25 mrem/min or 1/16 of your original exposure rate. It also works the other way. If you halve your distance to the source, your exposure rate will quadruple so it is very important to know where you are in relation to the source of the radiation. Choosing an operator position is very important. In percutaneous transluminal techniques, using the femoral approach rather than the brachial approach yields tremendous distance benefits to the operator. All of this boils down to a simple rule: **Taking one step back from the patient can reduce the operator's exposure by a factor of approximately 4.**

There are many other supplemental methods (or ALARA concepts) of radiation protection:

1. Collimation: Always collimate the beam to the smallest size adequate for performing the study. The tighter the collimator, the lower the scatter radiation produced. A good rule of thumb is that fluoroscopy images should display the edges of the collimators .
2. Reduced Use: Don't fluoro while not viewing the TV image. If you aren't looking at the image, keep your foot off of the pedal. Any fluoro produced when not looking at the image is unnecessary radiation exposure for the staff and the patient.
3. Pre-planning images: plan ahead to avoid unnecessary panning
4. Operator awareness of the 5 minute time notification
5. Use of last image hold allows the operator to the viewing of static images without continuously exposing the patient and staff to radiation
6. Delaying fluoro while staff interact with the patient or alerting staff when fluoroing.
7. Reducing the "air gap" between the image intensifier and the patient. The further the image intensifier from the patient, the greater the automatic brightness system needs to work to get an appropriate image. The harder the ABS works, the higher the beam is driven increasing the dose to the patient as well as the scatter to the staff. In the case of C-arms, minimizing the air gap ensures that the X-ray tube is as far as possible from the patient's skin thereby minimizing the skin dose to the patient and reducing the probability of skin burns.
8. Minimize the use of magnification: magnification drives the beam up causing greater exposure to the patient and staff. Magnification should be employed only when the increased resolution of fine detail is necessary.
9. Use alternate projections. Avoid steeply angled oblique images whenever possible. X-rays must pass through more tissue before reaching the image intensifier. The ABS compensates by driving the X-ray beam up causing significantly higher patient and staff exposure.
10. Stand on the image intensifier side during lateral projections. The dose rate to the physician can be reduced by a factor of 5 when the physician stands on the II side of the table versus the X-ray tube side.
11. Use of portable shields (this is technically part of the "shielding" above but is worth repeating). Shields are more effective when placed close to the scatter source (i.e. the patient).
12. Use lead aprons, thyroid shields and leaded glasses when doing high level fluoroscopy procedures like cardiac cath and/or angioplasty.
13. Avoid placing hands in the primary beam at all times. Never places hands under the patient during fluoro.
14. The majority of the scatter received by the operator is due to scattering off of the patient. The intensity of the scatter decreases with increasing distance due to the inverse-square effect. Scatter is highest near its source and since radiation scattered into the patient is subject to further tissue attenuation, radiation levels are significantly lower if the X-ray tube is positioned below the patient (PA position). Scatter levels to the operator increase when the X-ray tube is tilted towards the operator and decrease when tilted away and is at a maximum when the X-ray tube is in an AP position.

Chapter 5: Radiobiology

Biological effects of radiation

There are three basic categories of effects to humans from radiation exposure:

1. Somatic Effects
2. Genetic Effects
3. Teratogenic Effects

Somatic effects are effects that occur to you from exposure to you and can be further broken down into short term and long term effects.

Short term effects (or acute effects) are generally seen within days to months after exposure. They usually result from necrosis of the rapidly proliferative cell lines particularly intestine, bone marrow, germinal cells, small lymphocytes and embryonal tissues. Necrosis may be accompanied by transient vascular dilation at the capillary level. We can further break down acute effects into Acute Radiation Syndrome and skin erythema (or skin burns).

Short term effects are also characterized by a **threshold** below which the effect does not occur. The threshold for Acute Radiation Syndrome varies from person to person but is approximately 200,000 mrad whole body exposure. Skin erythema is a broad term for a series of progressive effects that have increasing thresholds. Transient Erythema is the most common and has a threshold of about 200,000 mrad skin dose, Epilation has a threshold of about 300,000 mrad skin dose, Erythema has an approximate threshold of 600,000 mrad and Dermal Necrosis has a threshold of approximately, 1,800,000 mrad.

While Transient Erythema and possibly Epilation are occasionally seen in a non-radiation therapy medical setting, the higher dose acute effects are almost never seen.

Cataract induction is of special interest to fluoroscopy operators since the lens of eye often receives the most significant levels of radiation (provided lead aprons are used). Radiation is known to induce cataracts in humans from single doses of 200 rad. Higher exposures can be tolerated when accumulated over time. **Cumulative exposures of up to 750 rads have resulted in no evidence of cataracts. Personnel exposed to the maximum levels each year would accumulate only 450 rems over 30 years.** As such, the risk for cataracts is likely to be small.

Long Term effects or delayed effects are effects that are seen after years. There are no deterministic effects seen long term. The effects are stochastic that is, there is a probability after exposure of an effect occurring. At higher doses, the correlation between exposure and probability of effect is reasonably understood and quantified. At lower doses, this effect is less well understood and, as of this writing, there is no concrete evidence that doses below 10,000 mrem have any effect on humans although there is a suspicion that there is a weak correlation. We assume for radiation safety purposes that the risk is linearly related to the dose. At higher doses, this relationship has been experimentally observed. At lower doses (i.e. below 10,000 mrem), this relationship has only been extrapolated. The validity of this extrapolation is constantly under study but, to date, has never been proven.

Long term effects include various cancers and leukemia. The higher the radiation dose, the higher the probability of developing a secondary cancer. Long term effects are also characterized by a long latency period. This latency period is the period from the exposure to the onset of the effect and can be as short as 7 years and as long as 40 years but it typically longer for lower doses. One of the difficulties in finding evidence for human effects below doses of 10,000 mrad is the extremely low probability of an effect occurring coupled with the long latency period and the fact that cancers risk in unexposed populations increases with age. If an effect is occurring at low doses, it is being obscured in the statistical noise. Clearly, one conclusion we can draw is the risk is concentrated in younger patients. If an effect is going to show up 40 years after the exposure, patients

who are 15 at the time of the exposure are more at risk than a 70 year old patient simply because they have a significantly greater probability of living long enough to get a radiation induced cancer.

For radiation workers, it is prudent to assume a conservative model of risk. As such, small savings in radiation exposure realized by utilizing the ALARA principles outlined in Chapter 3 can, theoretically, result in significant reductions in personal risk when integrated over a working lifetime. The same holds for patients. By reducing patient exposure to the minimum necessary for an acceptable study, you will also reduce the exposure to all of the workers in the room with the patient.

Genetic Effects are effects that occur to an unconceived child from exposure to you.

Radiation exposure can cause chromosomal damage that may be repaired with an incorrect sequence and theoretically be passed on to the next generation. Various mutations and other genetic effects have been observed within controlled animal studies however no genetic effects have been seen among the offspring of Hiroshima survivors so it is unclear if genetic effects are of real concern to humans.

Teratogenic Effects are effects that occur to a child that was exposed in utero.

Animal studies have shown that the embryo and fetus are more sensitive to the effects of radiation than the adult. **There are three general prenatal effects observed that are dependent upon the dose and stage of fetal development:**

- **Lethality.**
- **Congenital abnormalities at birth.**
- **Delayed effects, not visible at birth, but manifested later in life.**

A dose of 250 rads or more delivered to a human embryo before 2 to 3 weeks of gestation will likely result in prenatal death. Those infants, who survive to term, generally do not exhibit congenital abnormalities.

Irradiation of the human fetus between 8 to 15 weeks of gestation may potentially cause multiple severe abnormalities of many organs.

Irradiation during the 11th to 15th week of gestation may result in mental retardation and microcephaly. After the 20th week, the human fetus is more radioresistant, however, functional defects may be observed. In addition, a low incidence (one in 2000) of leukemia has been observed in individuals who received prenatal radiation.

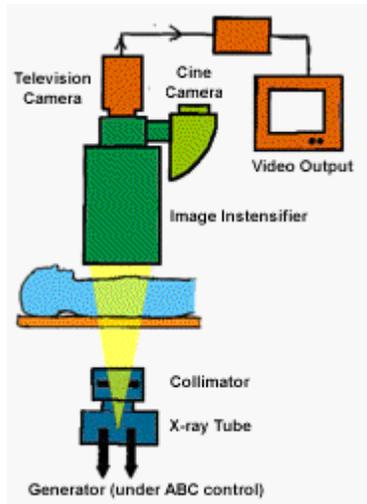
Fetal doses of less than 10,000 mrem are unlikely to cause any of the above effects and most diagnostic uses of medical X-rays including CT scans will produce fetal doses significantly lower than 10,000 mrem. This means that medically indicated procedures involving radiation can be appropriate for pregnant women. However, such procedures should be avoided if alternate procedures are available or are appropriate (MRI or Ultrasound for example or lower dose procedures such as plain film or its digital equivalent in lieu of CT or fluoroscopy). It is suggested that physicians consult with a radiologist and/or the medical physicist prior to performing fluoroscopy procedures on pregnant or potentially pregnant patients to evaluate the imaging options available.

Chapters 6 and 7: X-ray Equipment and Imaging Recording

FLUOROSCOPY SYSTEM DESCRIPTION

Modern fluoroscopy imaging systems consist of an X-ray tube which produces X-rays, and an **Image Intensifier (II), which converts the X-ray energy into light**. The light output is then distributed to a closed-circuit video system ultimately producing a "live" image on a video monitor. The light output can also be distributed to a spot film or cinematography recording systems, though the output must be greater for these imaging modalities.

The figure on the left shows the basic components of a fluoroscopy system in schematic form. Actual systems will vary in detail and take different shapes. The apparatus for GI studies may have a device at the bottom of the image intensifier for taking "spot films". It can hold x-ray film and record snapshots of the image appearing on the TV monitor. The cine camera will be present only where cineangiography must be done.



The photo images depict a mobile fluoroscope, often referred to as a "C-arm", its control panel, and various components. Activation of fluoroscopic x-rays is usually with a foot-switch, although a switch may be present at a control panel or even on a hand-held module.

Radiation exposure during fluoroscopy is directly proportional to the length of time the unit is activated by the foot switch. Unlike regular X-ray units, fluoroscopic units do not have an automatic timer to terminate the exposure after it is activated. Instead, depression of the foot switch determines the length of the exposure, which ceases only after the foot switch is released.

Fluoroscopy machines are equipped with a timer and an alarm that sounds at the end of 5 minutes. The alarm serves as a reminder of the elapsed time and can then be reset for another 5 minutes.

Automatic Brightness Control

Modern fluoroscopy machines produce images with an II that captures the radiation exiting the patient. The II brightens the image level sufficiently so that the TV tube can display the image on a video screen. The machine can be operated in either a manual mode or in an **automatic brightness control (ABC)** mode.

The radiation exposure rate is independent of the patient size, body part imaged and tissue type when manual mode is used. However, the image quality and brightness are greatly affected (often adversely) by these factors when the

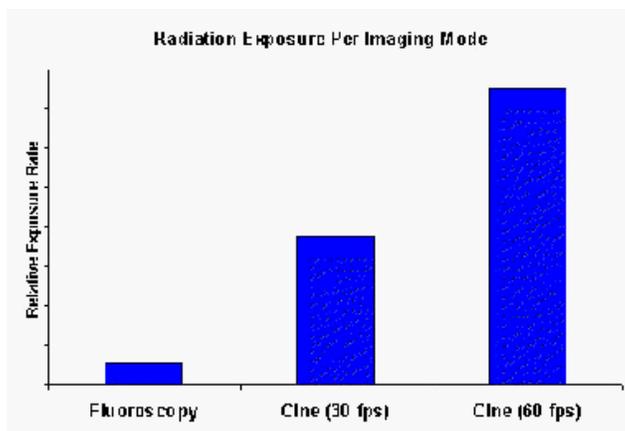
operator "pans" across tissues with different thickness and composition. For this reason, most fluoroscopic examinations are performed using ABC.

ABC mode was developed to provide a consistent image quality during dynamic imaging. When using ABC, the II output is constantly monitored. Machine factors are then adjusted automatically to bring the brightness to a constant, proper level. When there is inadequate brightness (or too much), the ABC increases (or decreases) the mA, kVp, or both, depending on the device manufacturer.

Both patient and operator factors influence the number of X-rays reaching the II. **If less radiation is received by the II, the ABC compensates for the loss in brightness of the video image by generating more x-rays (which increases radiation exposure) and/or making them more penetrating (which reduces image contrast).**

IMAGING MODES

Normal mode is used in the majority of fluoroscopy procedures. The radiation output is sufficient to provide video images for guiding procedures or observing dynamic functions. **The typical exposure rate at the X-ray beam entrance into the patient (ESE, or Entrance Skin Exposure) is 2 R/min.**



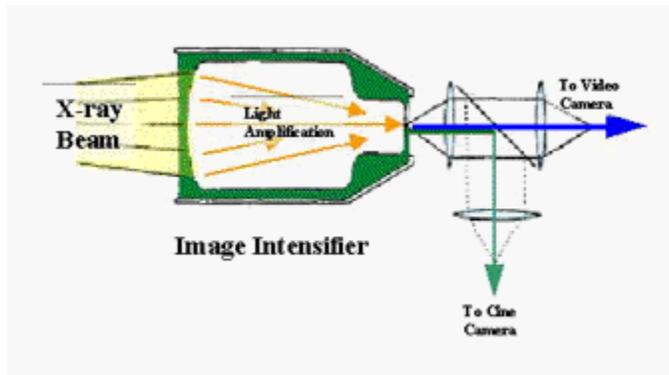
The Food and Drug Administration (FDA) regulates the construction of all fluoroscopy systems. For routine fluoroscopy applications, the FDA limits the maximum ESE to 10 R/min. **The Pennsylvania Dept. of Environmental Protection also limits the ESE to 10R/min for general fluoroscopy use. For C-arm fluoroscopes, the limit applies to a special point (30 cm from the input screen of the II).**

The use of higher radiation rates or "boost" modes are useful in situations requiring high video image resolution. ESE of up to 20 R/min is permitted for short duration. **Special operator reminders, such as audible alarms, are activated during "boost" modes.**

All new fluoroscopic devices include a pulse mode of operation, in addition to a continuous one. In this mode, depressing the foot pedal induces electrons to flow in spurts through the x-ray tube, rather than steadily, so that x-rays are generated in pulses. Sometimes the pulse rate can be varied (30, 15, 7.5 per second). Radiation exposure can be reduced significantly at lower pulse rates.

Cineangiography involves exposing cinematic film to the II output, providing a permanent record of the imaged sequence. The II output required to expose cinematic film is much higher

than the level needed for video imaging. As such, X-ray production must be increased to adequately expose the cinematic film. Consequently, **dose rates during cine recording are usually 10 to 20 times higher than normal fluoroscopy** (i.e., ESE of 90 R/min or greater). For this reason, judicious use of cineangiography is required.



In modern cineangiography, film has given way to digital recording on magnetic media. The newer modality permits a reduction in patient dose as well as operator dose, when performed correctly.

FIELD SIZE AND COLLIMATORS

The maximum useful area of the X-ray beam, or field size, is machine specific. **Most fluoroscopy systems allow the operator to reduce the field size through the use of lead shutters or collimators.**

Irradiating larger field sizes increases the probability of scatter radiation production. A portion of the increased scatter will enter the II, degrading the resulting video image. Prudent use of collimators can also improve image quality by blocking-out video "bright areas," such as lung regions, allowing better resolution of other tissues.

Collimator use also reduces the total volume of tissue irradiated. The subsequent benefit-risk ratio is improved when irradiation of tissue with little diagnostic value is avoided.

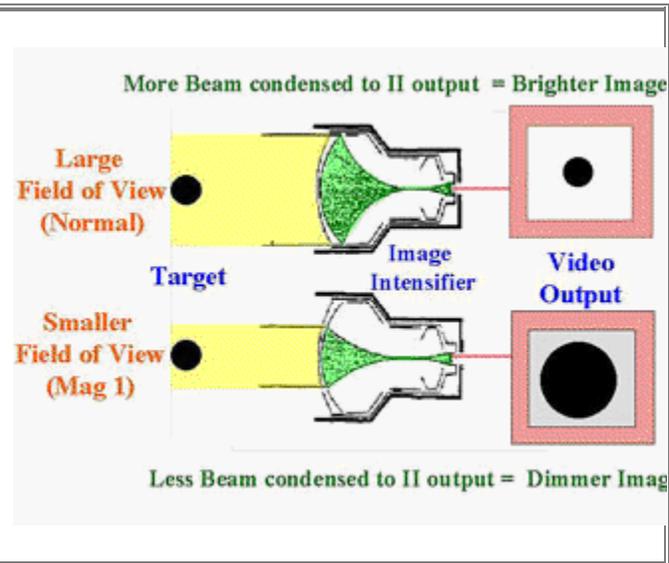
MAGNIFICATION MODES

Many fluoroscopy systems have one or several magnification modes. Magnification is achieved by electronically manipulating a smaller radiation II input area over the same II output area. A reduction in radiation input subsequently results, lowering image brightness. The ABC system, in turn, compensates for the lower output brightness by increasing radiation production and subsequent exposure to patient and staff.

Under Normal mode, there is little magnification with the whole beam used to generate a bright image.

Under Mag 1 mode, a smaller beam area is projected to the same II output. The resulting object size is larger, but the image is dimmer due to the less beam input.

The ABC system senses the brightness loss and either boosts machine X-ray output, increases tube voltage, or a combination of both.



The following Table illustrates the effect of changing Field-Of-View, or magnification modes, for a fluoroscopy system used at this facility: in which both the tube voltage (kvp) and the tube current (mA) change:

Mag Mode (Field-Of-View)	ESE (R/min)	Increase Factor
Normal (9 inch)	1.7	1.0
Mag 1 (6 inch)	2.3	1.4
Mag 2 (4.5 inch)	3.3	1.9

LAST IMAGE HOLD

Newer fluoroscopy units are often equipped with a last-view freeze-frame feature and/or video recording. Use of these modes allows the operator to view a static image at leisure, avoiding continuous patient and staff radiation exposure caused by constant fluoroscopy use.

Chapter 8: Patient Exposure and Positioning

The following is an expansion on some of the concepts found in Chapter 4.

During normal mode fluoroscopy, the average patient Entrance Skin Exposure (ESE) is approximately 2-3 R/min for most fluoroscopy systems. The level of radiation exposure falls off exponentially with increasing tissue depth due to attenuation and inverse-square effects. Only approximately 1% of the original radiation beam reaches the image intensifier for image generation. The ESE exposure rate can be as high as 30 R/min under certain conditions using a high dose rate or boost mode if the patient's skin is close to the X-ray tube.

Case Studies of Radiation Injury

Non-Symptomatic Skin Reactions

Patients may not be aware of skin changes that take place as a result of lengthy fluoroscopic procedures (Wagner 1999):

- Physical examination one year following coronary angioplasty identified a 1 x 2.5 cm-depigmented area with telangiectasia on the patient's left shoulder. Total fluoroscopy time: 34 minutes.
- One year after PTCA involving 66 minutes of fluoroscopy, a 10-cm diameter hyperpigmented area with telangiectasia was evident on the patient's right shoulder.

These skin changes were in areas not visible to the patients and were only identified upon physical examination.

Symptomatic Skin Reactions

The circumstances leading to symptomatic radiation induced changes are varied. Case reports are grouped according to common factors in order to identify the reasons for radiation-induced effects.

PA Fluoroscopy

The posteroanterior (PA) orientation of the fluoroscope, when properly configured with the image intensifier down close to the patient, is probably the least problematic with regard to ESE rate. However, extended fluoroscopy usage has resulted in reports of skin damage. The following case study illustrates this effect (Shope 1995).

Additional reported cases of radiation-induced injury (Wagner 1999):

- Following a transjugular intrahepatic portosystemic shunt (TIPS) procedure involving 90 minutes of fluoroscopy, a discharged patient developed erythema and discoloration on his back. One year after the TIPS procedure an ulcer developed, which did not heal, and two years later it was 4-cm in size. A split thickness skin graft from the right buttock was performed.
- Following a TIPS procedure lasting 6 hours and 30 minutes (no indication of total fluoroscopy time), a 16- x 18-cm hyperpigmented area developed on the patient's back and progressed over a period of several months into a central area with ulceration. After 14 months a split thickness skin graft was performed leaving a depressed scar at the surgical sight.

These case studies indicate that **extensive use of fluoroscopy can induce severe skin damage**, even under the most favorable geometries.

Steep Fluoroscopic Angles

When the fluoroscope is oriented at a lateral or an oblique angle, two factors combine to increase the patient's ESE rate. The first is that a thicker mass of body tissue must be penetrated. The second is that the skin of the patient is closer to the source because of the wider span of anatomy (Wagner 1999).

- A PA oblique angle using a C-arm involved 57 minutes of fluoroscopy. Twenty-four hours later the patient reported a stabbing pain in his right thorax. Three days later an erythema developed which evolved into a superficial ulcer. At two and half months after the procedure the area was approximately 12-cm x 6.5-cm and described as a brownish pigmented area with telangiectasia, central infiltration and hyperkeratosis.
- A PA oblique angle was employed during a catheter ablation procedure involving 190 minutes of fluoroscopy. A symptomatic discoloration was noted several days after the procedure on the patient's left upper back. In the next few weeks the area had become painful and was draining. At seven weeks

the area was approximately 7- x14-cm in size and described as a rectangular erythema with ulcers. After treatment, there was a gradual lessening of tenderness with reepithelialization, leaving a mottled slightly depressed plaque.

- A steep PA oblique angle through the right shoulder was employed involving 51 minutes of fluoroscopy. Fourteen days after the procedure, an erythema appeared on the right shoulder that progressed into moist superficial ulcer with poor healing. This degenerated into a deep muscular ulcer requiring a myocutaneous skin graft approximately 14 months after the procedure.

The temporal progressions of these effects are consistent with high levels of acute exposure to x-ray radiation. **The temporal differences in the responses are due in part to the levels of radiation received, but are also likely due to variations in radiation sensitivity amongst the patients.**

Steep angled views, especially in large patients, often require penetration of large masses of tissue and dense bone, creating situations in which x-ray output rates are driven near or at the maximum (10 R/min)

Multiple Procedures

Although intervals between procedures should permit the skin to recover, healing might not be complete. This may lower the tolerance of the skin for further procedures (**Wagner 1999**):

- A patient underwent two PTCA procedures about one year apart. Skin changes appeared approximately three weeks after the second procedure. At seven weeks a cutaneous ulcer had developed over the right scapula and healed without grafting.
- A patient underwent two unsuccessful cardiac ablations involving approximately 100 minutes of fluoroscopy in a lateral oblique orientation. Approximately 12 hours after the second attempt, an erythema developed in the right axilla. At one month the area was red and blistering. At two years the area was described as a 10 x 5cm atrophic indurated plaque with lineal edges, hyper- and hypopigmentation, and telangiectasia. The patient was described as having difficulty raising her right arm.
- Three PTCAs were performed on the patient, the last two completed on the same day approximately 6 months after the first procedure. The total fluoroscopy time was approximately 51 minutes. Erythema was noted immediately after the last procedure. This progressed from a prolonged erythema with poor healing into a deep dermal necrosis. The patient underwent a successful split thickness skin graft two years after the last procedure.
- Past treatment of pulmonary tuberculosis often resulted in many patients undergoing extensive exposure to fluoroscopy. These patients had a demonstrated high incidence of breast cancer.

Previous procedures can lower the skin's tolerance for future irradiation. Prior to commencing any lengthy fluoroscopic procedure, the patient's medical history should be reviewed. The skin of the patient should be examined to ascertain if any skin damage is apparent should the patient have a history of lengthy fluoroscopic examinations. **Direct irradiation of damaged areas should be avoided when possible.**

Positions of arms

Keeping arms out of the x-ray beam during some procedures can be a difficult objective. Careful attention must be given to providing the arms with a resting position that will not restrict circulation but will at the same time maintain the arms in an area that is outside the radiation field (**Archer 2000**).

The separator cone ensures that a minimal distance between the X-ray source and the patient is maintained (inverse square law effects). For some X-ray machines, the separator cone is designed to be removable in order to provide more flexibility in positioning for some special surgical procedures (e.g., portable C-arms). **There is a risk of very high dose rates to the skin surface when it is removed.**

Skin sensitivity

Some patients may be hypersensitive to radiation due to pre-existing health conditions (**Wagner 1999**).

- Erythema developed after diagnostic angiography and liver biopsy. Skin necrosis requiring rib resection evolved in the same patient after a TIPS procedure. The wound remained open for five years before a successful cover was put in place. Investigation into the events revealed that the patient suffered from multiple problems, including Sjögren's syndrome and mixed connective tissue disease.

Injuries to personnel

The following are modern-day examples of how improper use of the fluoroscope can lead to injuries in personnel (**Wagner 1999**).

- Hands of physicians have incurred physiologic changes indicative of high cumulative doses of chronic low-dose-rate irradiation. Brown finger nails and epidermal degeneration are typical signs. These changes were the result of years of inserting hands into the x-ray field with the x-ray tube above the patient.
- Four cases of radiation-induced cataract have been reported in personnel from procedures utilizing the x-ray tube above the patient orientation.

Doses accumulated to hands and eyes from frequently using the fluoroscope with the tube above the patient can be extremely high. Only routine application of proper radiation management techniques will be effective at avoiding such high doses.

Chapter 9: Procedures

The procedures that typically produce the highest exposure to patients and staff are:

Procedures Involving Extended Fluoroscopy Exposures

(FDA 1994)

Radiofrequency cardiac catheter ablation
Percutaneous transluminal angioplasty (PTCA, PTA)
Vascular embolization
Stent and filter placement
Thrombolytic and fibrinolytic procedures
Percutaneous transhepatic cholangiography
Endoscopic retrograde cholangiopancreatography (ERCP)
Transjugular intrahepatic portosystemic shunt (TIPS)
Percutaneous nephrostomy, biliary drainage, or stone removal

Chapter 10: Quality Assurance Program

The following are the elements of the facility QA Program and their frequencies:

1. Image Quality Evaluation	Monthly
2. Visual Checklist	Quarterly
3. Medical Physics survey	Annually
4. Preventive Maintenance	At least annually
5. Lead apron/glove/thyroid check	Annually
6. Review of QC program	Annually

Chapter 11: Regulations

MEDICAL DOSE LIMITS

There are no dose limits for patients. It is the responsibility of medical professionals to prescribe the appropriate studies and to reduce the doses to the patient during those studies to the lowest level possible to get an adequate study.

OCCUPATIONAL DOSE LIMITS

The **Pennsylvania Department of Environmental Protection (DEP)** has established upper limits on the amount of radiation that occupationally exposed personnel can receive. Below are the legal limits of exposure in PA:

Part of body	Maximum allowable dose
Whole body	5,000 mrem/yr
Extremities	50,000 mrem/yr
Lens of Eye	15,000 mrem/yr

PERSONNEL RADIATION MONITORING

The following personnel will be issued radiation monitoring devices:

-Adults likely to receive, in one year, a dose in excess of 500 mrem to the whole body, 1,500 mrem to the lens of the eye or 5,000 mrem to an extremity. Note that these values are 10% of the annual allowable dose listed above.

-Declared pregnant workers who are likely to receive in excess of 100 mrem during the pregnancy.

The following methods will be used to demonstrate that doses are expected to be less than 10% of regulatory limits:

-Prior experience: Reviews of radiation dose histories for workers in specific work areas show that they are not likely to receive a dose in excess of 10% of the limits

-Area surveys: Demonstrate through the conduct of appropriate radiation level surveys (e.g. using a survey meter or area thermoluminescent dosimeters (TLDs)) in the work area, combined with estimates of occupancy

rates and calculations, that doses to workers are not likely to exceed 10% of the limits (exposures associated with reasonable “accident” scenarios should also be evaluated);

-Performance of a reasonable calculation based upon source strength, distance, shielding and time spent in the work area, that shows that workers are not likely to receive a dose in excess of 10% of the limits.

We reserve the right to issue individual monitoring to any worker even if they are unlikely to exceed 10% of the occupational dose limits in 10 CFR 20.1201(a).

Investigation levels

Throughout the calendar year, annual cumulated exposure is evaluated quarterly by the RSO or his designee, and action is taken at the following levels:

*From Reg Guide 1556 Volume 9 revision 2 Appendix M Table M.1. Investigation Levels

Table M.1

Part of body	ALARA I	ALARA II
	Investigational Level I (mrem per year)	Investigational Level II (mrem per year)
Whole body, trunk including Male gonads, arms above the Elbow, or legs above the knee	500 (5 mSv)	1,500 (15 mSv)
Hands, elbows, arms below the Elbow, feet, knees, legs below the Knee, or skin	5,000 (50 mSv)	15,000 (150 mSv)
Lens of eye	1,500 (15 mSv)	4,500 (45 mSv)

Personnel dose less than Investigational Level I (ALARA I)

Except when deemed appropriate by the RSO, no further action will be taken if an individual’s dose is less than Table M.1 values for Investigational Level I (ALARA I).

Personnel dose equal to or greater than Investigational Level I but less than Investigational Level II

When the dose of an individual equals or exceeds Investigational Level I (ALARA I), the RSO or his designee will conduct a timely investigation and review the actions that might be taken to reduce the probability of recurrence, following the period when the dose was recorded. If the dose does not equal or exceed Investigational Level II, no action related specifically to the exposure is required unless deemed appropriate by the RSO. The employee will be notified.

Personnel dose equal to or greater than Investigational Level II (ALARA II)

The RSO or his designee will investigate in a timely manner the causes of all personnel dose equaling or exceeding Investigational Level II. The RSO will consider actions to reduce the probability of occurrence, and a report of the actions will be reviewed with management at the first radiation safety committee meeting following the investigation. The report will be documented in the Committee meeting minutes.

A summary of all individuals exceeding these levels will be presented at the quarterly Radiation Safety Committee Meeting.

Declared Pregnancy and Dose to Embryo/Fetus

We will ensure that the dose to an embryo/fetus, from the moment of declaration, due to occupational exposure of a declared pregnant woman, does not exceed 0.5 rem. We will make efforts to avoid substantial variation above a uniform monthly exposure rate to a declared pregnant woman.

Notifications

-An annual report will be provided to each monitored individual if:

- a) the individual's occupational dose exceeds 100 mrem
- b) the individual requests his or her annual report
- c) we utilize Webster's equation for all personnel solely exposed to X-rays; personnel exposed solely to X-rays will be issued an annual report only if their exposure exceeds 100 mrem utilizing Webster's equation.

-At the request of a monitored worker formerly employed at this facility, we shall furnish to the worker a report of the worker's exposure to radiation year-to-date of the current year. If records are not available, we reserve the right to estimate the exposure.

-We will request radiation exposure records for all new employees and for employees who work at multiple facilities with a special emphasis on the year to date exposures of the current year to ensure that no employee exceeds 5,000 mrem during any calendar year.

Radiation badges are to be worn outside the apron on the collar. If two badges are utilized, the outer badge goes on the collar outside the apron and the inner badge goes on the waist inside the apron. It is vitally important that the badge do not get mixed up. Swapping the badges will invalidate all of the readings for the reporting period. The badges are to be worn at all times when working with radiation. They are not to be worn for personal medical exposure. Do not take it to the dentist with you or wear it while getting a chest X-ray.

The Radiation Safety Officer (RSO) reviews dosimetry records when they are received from the dosimetry vendor. Investigations of any exposure exceeding the established standards are performed to determine whether corrective action can eliminate or reduce exposures for all concerned. The circumstances surrounding most cases of excessive radiation exposures are often readily mitigated. The results of these reviews are presented quarterly to the Radiation Safety Committee.

Radiation Safety Program

The facility's administration is committed to ensuring that radiation exposure to its medical staff and employees is ALARA, as low as reasonably achievable. **Full attainment of this goal is not possible without the cooperation of all medical users of radiation devices.**

The hospital administration has authorized the Radiation Safety Committee to oversee all uses of radiation. The Radiation Safety Committee is composed of members chosen from various departments in the hospital. Day-to-day activities are conducted by the Radiation Safety Officer (RSO). Meetings of the Radiation Safety Committee are conducted quarterly.

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I have received and read the material presented. I acknowledge understanding of the material and its importance. I will incorporate this information and knowledge into my role as a member of the medical staff.

The material included:

Radiation Safety Training for the FLUOROSCOPIST

Printed name

Date

Signature