Fluoroscopic Radiation Safety

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CONTENTS:

1. Purpose
2. Goals
3. Introduction
4. Ionizing Radiation
5. Generation of X-Rays
6. Fluoroscopy
7. Geometry
8. Other factors affecting radiation dose
9. Radiation Dose
10. Biological Effects of Radiation
11. Radiation Dose from Fluoroscopy
PURPOSE:

This training course is designed to provide non-radiologist physicians the necessary training in radiation safety specifically aimed at radiographic fluoroscopic equipment.

The UAMS Radiation Safety Committee requires proof of radiation safety training to qualify as a user of any radiation-producing equipment. The policy of the UAMS Radiation Safety Committee requires the following:

All physicians who operate or supervise the operation of x-ray producing equipment should be prepared to show documentation that they meet one of the following requirements for safety training:

A. Board certified, or Board eligible in Radiology or Radiation Oncology.

B. Board certified in a specialty, which includes radiation safety training associated with the operation of radiation producing equipment.

C. Successful completion of this in-house radiation safety training course.

To document your participation in this self-study, we have provided a short multiple-choice test. A score of 90% or better must be achieved to receive credit for this safety training. Click on Post-test to take the test.
GOALS:

1. Minimize the likelihood of radiation–induced injuries to patients treated with fluoroscopically guided medical procedures.

2. Reduce the radiation dose of physicians and ancillary personnel who work around fluoroscopic equipment.
INTRODUCTION:

The Food and Drug Administration (FDA) published the advisory notice: *Avoidance of Serious X-Ray-Induced Skin Injuries to Patients During Fluoroscopically-Guided Procedures* on September 9, 1994. The following information is taken from that report. The entire notice can be reviewed at the website: http://www.fda.gov/cdrh/fluoro.html.

The Food and Drug Administration (FDA) Center for Devices and Radiological Health (CDRH) has received reports of occasional, but at times severe, radiation-induced skin injuries to patients resulting from prolonged, fluoroscopically guided, invasive procedures. Procedures typically involving extended fluoroscopic time are:

Percutaneous transluminal angioplasty (coronary and other vessels),
Radiofrequency cardiac catheter ablation,
Vascular embolization,
Stent and filter placement,
Thrombolytic and fibrinolytic procedures,
Percutaneous transhepatic cholangiography,
Endoscopic retrograde cholangiopancreatography,
Transjugular intrahepatic portosystemic shunt,
Percutaneous nephrostomy, Biliary drainage or
Urinary/biliary stone removal.

Physicians performing these procedures should be aware of the potential for serious, radiation-induced skin injury caused by long periods of fluoroscopy during these procedures. It is important to note that the onset of these injuries is usually delayed, so that the physician cannot discern the damage by observing the patient immediately after the treatment.

The absorbed dose in the skin required to cause skin injury depends on a number of factors, but typical threshold doses for various effects are about 2 Gy (200 rad) for early erythema, 3 Gy (300 rad) for epilation, and 15 to 20 Gy (1,500 to 2,000 rad) for moist desquamation, dermal necrosis and secondary ulceration. The absorbed dose rate in the skin from the direct beam of a fluoroscopic x-ray system is typically between 0.02 Gy/min and 0.05 Gy/min (2 to 5 rad/min), but may be higher, depending on the mode in which the equipment is operated and the size of the patient. Even typical dose rates can result in skin injury after less than one hour of fluoroscopy.

FDA suggests that facilities performing fluoroscopically guided procedures observe the following principles:

1. Establish standard operating procedures and clinical protocols for each specific type of procedure performed. The protocols should address all aspects of the procedure, such as patient selection, normal conduct of the procedure, actions in response to complications and consideration of limits on fluoroscopy exposure time.
2. Know the radiation dose rates for the specific fluoroscopic system and for each mode of operation used during the clinical protocol. These dose rates should be derived from measurements performed at the facility.

3. Assess the impact of each procedure's protocol on the potential for radiation injury to the patient.

4. Modify the protocol, as appropriate, to limit the cumulative absorbed dose to any irradiated area of the skin to the minimum necessary for the clinical tasks, and particularly to avoid approaching cumulative doses that would induce unacceptable adverse effects. Use equipment that aids in minimizing absorbed dose.

5. Enlist a qualified medical physicist to assist in implementing these principles in such a manner so as not to adversely affect the clinical objectives of the procedure.

Physicians should know that radiation-induced injuries from fluoroscopy are not immediately apparent. Other than the mildest symptoms, such as transient erythema, the effects of the radiation may not appear until weeks following the exposure. Physicians performing these procedures may not be in direct contact with the patients following the procedure and may not observe the symptoms when they occur. Missing the milder symptoms in some patients can lead to surprise at the magnitude of the absorbed doses delivered to the skin of other patients when more serious symptoms appear. For this reason, we recommend that information be recorded in the patient's record that permits estimation of the absorbed dose to the skin. Patients should also be advised to report signs and/or symptoms of radiation induced injury to their attending physician.

The Safe Medical Devices Act of 1990 (SMDA) requires hospitals and other user facilities to report deaths, serious illnesses and injuries associated with the use of medical devices. Follow the procedures established by your facility for such mandatory reporting. Practitioners who become aware of any medical device related adverse event or product problem/malfunction should report to their Medical Device User Facility Reporting person.
IONIZING RADIATION

X-rays are a form of electromagnetic radiation or energy. You will find other types of electromagnetic radiation, such as radio waves, ultraviolet, infrared, and white light in this general category. X-rays have very high frequencies and very short wavelengths, which gives the x-rays the ability to penetrate human tissue to produce images. X-rays also have the ability to interact with other atoms to remove electrons producing ion pairs (ionization).

We can also think of the x-ray as a defined quantity of energy called a photon. Photons can interact with tissue by giving up a small portion of their energy to an electron and the remaining lower energy photon bounces (scatters) off in a new direction (Compton scattering). Scatter radiation cause unsharp images and can cause radiation exposure to objects not in the direct beam.
Interactions with high atomic number materials, like lead, are primarily an absorption process (Photoelectric effect). For energies used in Radiography, lead is an effective shield and can stop most radiation. The use of lead aprons, drapes and thyroid collars are an effective method to reduce the radiation dose to physician and ancillary personnel.
GENERATING X-RAYS

X-rays are generated by causing high-speed electrons to slam into a target at one end of an x-ray tube. The electrons are generated at the filament (cathode) end of the x-ray tube by boiling them off of a heated wire. They are then given kinetic energy by applying a high voltage between the filament and the target (anode). If a voltage of 100,000 volts (100kVp) is applied to the x-ray tube, then the electrons strike the tungsten target with energy of 100 keV and produce x-rays from 0 to 100 keV. Note: kVp is the voltage applied to the x-ray tube and keV is the energy of the x-ray. The low energy x-rays cannot get out of the x-ray tube so the actual spectrum of x-rays range from about 10 keV to 100keV.

The higher the x-ray energy, more radiation penetrates the tissue. As the kVp increases so does the intensity of the x-ray beam, i.e. more x-rays of all energies are generated. For a given tube voltage, the quantity of x-rays produced by the machine is determined by the milliamps (mA) of current flowing in the x-ray tube. The larger the mA, the larger will be the radiation dose to the patient. Image quality depends on the number of x-rays reaching various parts of the body being imaged. Image contrast is the difference of the number of photons that get through the various parts of the body being imaged. The higher the kVp, the more photons get through, but there is less differentiation between tissues (contrast).

The goal is to keep the mA as low as possible and the kVp as high as possible to achieve a compromise between the image quality (contrast) and the minimum radiation dose to the patient.
FLUOROSCOPY

Fluoroscopy differs from conventional x-ray imaging in that the x-ray image can be viewed in real time. Instead of film, the detector is an image intensifier fluorescent screen coupled to a video camera. The x-ray image can be viewed directly on the TV screen or can be captured in digital format and viewed/manipulated later. To maintain a constant image quality, an automatic brightness system (ABS) detects the x-ray intensity that is reaching the detector and adjusts the mA and/or kVp. So, if the fluoroscope moves from a thick part of the body to a thin part of the body, the x-ray intensity is reduced to avoid flooding the detector and to reduce the radiation dose to the patient.

Fluoroscopy System Components

In some equipment there is an x-ray grid between the patient and detector. This is a flat plate with a series of lead strips that allow the primary radiation beam to pass through but stops the radiation scatter and improving the contrast in the image. Some primary photons are absorbed by the grid, which means that fewer photons reach the detector. So more photons have to be generated (increase mA or kVp) and the patient receives a higher radiation dose when using the grid.

GEOMETRY

Several factors that can affect radiation dose to the patient and the quality of the image are geometrical in nature. The size of the patient, the size of the viewing field
collimation), the distance from the x-ray tube to the patient, the distance of the detector (image intensifier) from the patient and the use of a grid.

1. The size of the patient is an uncontrollable variable. For a large patient or dense region, to obtain enough x-rays that get to the detector, a more intense x-ray beam is required. Hence an increase in mA or kVp is needed. This also increases the radiation dose to the patient.

   - **Radiation dose is greater for larger patients.**
   - **Use the lowest mA possible and as high a kVp as possible to obtain image quality and lowest dose.**

2. Collimators are used to determine the size of the x-ray field. The larger the field size, the larger the amount of scatter radiation. Scatter radiation degrades the image quality. By tightly collimating the x-ray beam to the area of interest reduces the amount of scatter, reduces the volume of tissue exposed and improves the quality of the image.

   - **Use the tightest collimation possible**

3. In the x-ray tube the x-rays emanate from the focal spot of the x-ray tube, typically 1mm diameter. The intensity of the x-ray beam decreases as the square of the distance from this focal spot. Thus, the further away from the x-ray tube the patient is located, the less radiation per square meter and the less likely a radiation skin burn will occur. This is especially important in lateral or oblique views since the x-ray tube is usually much closer to the patient than in AP or PA views.

   - **The x-ray tube should be as far from the patient as possible.**
4. For the same reasons that we want the x-ray tube as far away from the patient as possible, we want the image intensifier (detector) as close to the patient as possible. The closer the detector is to the patient (x-ray tube) the more x-rays will be recorded by the detector. Also, magnification and the accompanying distortion of the anatomy and image blur are reduced. Thus, better image quality and less radiation dose to the patient is achieved. In some procedures an air gap is needed for working space and the image intensifier is placed at some distance from the patient. In these circumstances other means of reducing dose such as removing the grid, keeping exposure times short and using tight collimation become even more important.

- **The image intensifier should be as close to the patient as possible.**


5. The grid is a device that has parallel strips of lead so that when placed in the x-ray beam in front of the image intensifier tends to filter out the scattered radiation. The grid also stops many non-scattered photons resulting in the need to increase the x-ray intensity. This also increases the radiation dose to the patient. If highest resolution images are critical to the procedure, then grids should be used, but if image quality is adequate without the grid, the grid should be removed to keep the radiation dose at a minimum. In general for pediatric cases and when the image intensifier cannot be moved closer than 25 cm to the patient, grids should not be used.

- **The use of a grid increases radiation dose.**
OTHER FACTORS THAT AFFECT RADIATION DOSE ARE:

1. Image tube magnification – the smaller the field size, the more magnified an image appears on the viewing screen. The radiation dose at the entrance to the patient generally increases with magnification.

2. Shielding – The x-ray tube is pointed through the patient toward the image intensifier and typically the operator is standing outside the beam, but parallel to the x-ray beam. Scatter radiation from the patient is the major source of radiation exposure to personnel. Shielding can be used to reduce the radiation dose. Examples are the use of lead aprons. Some machines have lead drapes hanging from the image intensifier that shield the operator. Other systems use mobile shields that can be placed in appropriate places to shield personnel.

3. Distance – The radiation dose decreases by the inverse square of the distance from the x-ray source (in this case the patient). Thus, the dose rate decreases by a factor of 4 if you double the distance (example move from one foot from the patient to two feet from the patient).

4. Beam-On time – The single major control over the amount of radiation dose given to patient or personnel is the amount of time the x-ray machine is generating x-rays. Long durations of On Time, absentmindedly leaving the beam on, being distracted by doing other things while the beam is on, all contribute to unnecessary radiation dose and in fact it adds up very quickly.
All fluoroscopic machines have a 5-minute timer. This timer is to aid the physician to keep track of the amount of time that the unit has been on. Cumulative time should be recorded and reviewed as a quality control measure.

High dose rate fluoroscopy

Some units have a capability of being operated in the high dose rate mode. This mode allows a higher than normal level of dose rate. The FDA has placed restrictions on the maximum dose rate (May 1995). For an average adult, the dose rate at the tabletop is typically 2 to 5 R/min. Regulations limit the maximum dose rate at tabletop to 10 R/min in normal mode. However, some equipment provides a high-level mode, which allows the dose rate to go as high as 20 R/min, but must be accompanied by an audible alarm signal. High-level mode should be used sparingly and with caution. Fifteen minutes of fluoroscopy at the maximum level can produce skin erythema.
RADIATION DOSE

When x-rays interact with matter, energy is transferred to the matter in the form of kinetic energy of moving electrons. This kinetic energy can result in ionization, excitation and changes in molecular motion. In tissue, the deposition of the energy results in biological and chemical changes, breaking molecules, generation of free radicals, etc. A quantitative measure of radiation can be made from three different aspects, a) the exposure which is a measure of electrons produced in a defined quantity of air, b) the absorbed dose which is a measure of the amount of energy deposited in a defined quantity of matter, and c) the effective dose (or effective dose equivalent) which takes into consideration the sensitivity of the organ irradiated and the relative importance of that organ to the well being of the human.

Exposure is measured by collecting the number of electrons generated in a quantity of air. The classical unit is the Roentgen (R) and the international unit is the coulomb/kg (1 C/kg = 3876 R). The radiation dose rate at the table top of a fluoroscopy unit is typically measured in units of R/min.

Absorbed dose is the energy deposited in the tissue. The classical unit is the rad (radiation absorbed dose) and 1 rad is 100 ergs of energy deposited/gram of tissue. The international unit is the gray (GY). 1 Gy = 100 rads.

Absorbed dose can be calculated from the measurement made in units of roentgens. By taking into consideration the different energy absorption factors between air and tissue for the specific radiation energy, a conversion factor (f) can be calculated and multiplied by the measured exposure dose to determine the absorbed dose. Typically for the x-ray energy used in fluoroscopy this factor is 1.

Effective dose makes judgments about what effect radiation will have on the human, we need to take into consideration which organs were exposed to the radiation, how much energy was deposited (rads) in each organ, what the sensitivity of that organ is to radiation, and what the overall effect would be to the whole person. The classical unit of measurement for effective dose is the rem (radiation equivalent man). The international unit is the Sievert (1SV = 100 rem).

For example: for chest fluoroscopy assume that the table top exposure dose rate is 1.8 R/min at 76 kVp and 0.7 mA. Assume f = 1 so the skin absorbed dose is 1.8 rad/min. Other organs exposed are: breast, red bone marrow, lungs esophagus, bone surfaces, stomach and liver. Using International Commission on Radiation Protection (ICRP) weighting factors for each of these organs, the weighting factor is about 0.5 to give an effective dose to the patient of 0.9 rem/min. In this example a 66 second fluoro time would cause a skin dose of 2 rads (0.02 Gy where 2 Gy is the threshold for skin erythema) and an effective dose of about 1 rem (0.01 Sv).
BIOLOGICAL EFFECTS OF RADIATION

Ionization of biological materials, the production of free radicals, the direct breaking of chemical bonds are all possible biological effects of radiation. Often, damage can be repaired before the end of a cell’s cycle if not, the cell may die or may survive but with modifications. Some of these modifications result in malignancy. Repair enzymes and the immune system reduce the chances of radiation causing cancer or genetic changes, but take time. If the radiation is received at low doses over long periods of time, it is less likely to have a biological effect than if the radiation is received in large doses in a short period of time.

The following table is a summary of radiation dose and the biological effect

<table>
<thead>
<tr>
<th>Exposure (R)</th>
<th>Biological Effect</th>
<th>Time to Onset of Effect*</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 to 25</td>
<td>No effect detected</td>
<td></td>
</tr>
<tr>
<td>25 to 50</td>
<td>Some blood changes</td>
<td>3 weeks</td>
</tr>
<tr>
<td>50 to 100</td>
<td>Blood changes and nausea</td>
<td>3 weeks</td>
</tr>
<tr>
<td>100 to 200</td>
<td>Nausea, diarrhea, life shortening</td>
<td>3 weeks</td>
</tr>
<tr>
<td>200 to 300</td>
<td>Skin erythema threshold, temporary epilation</td>
<td>3 weeks</td>
</tr>
<tr>
<td>350 to 400</td>
<td>Death in 50% of the population in 30 days</td>
<td>1-2 weeks</td>
</tr>
<tr>
<td>600</td>
<td>100% death in 30 days</td>
<td>1-2 hours</td>
</tr>
<tr>
<td>1000</td>
<td>Death in 2 weeks</td>
<td>1-2 hours</td>
</tr>
<tr>
<td>3000</td>
<td>Death in 2 days</td>
<td>0-1 hours</td>
</tr>
</tbody>
</table>

The table represents the biological effect from total body exposure to radiation.

Various models are used to predict the increased incidence of cancer from exposure to radiation, but in general the statistics indicate that if 10,000 people received 1 rem of radiation, there would be an increase of 8 cancers above the natural incidence. Another way to consider the cancer risk is that if an individual receives 100 rem (we could assume 100 R exposure would be about the same radiation) then that individual has 8% increase chance of getting cancer caused by the radiation. To put this into perspective, however, one must compare this to the natural incidence of getting cancer, about 1 out of 3.

Because of the well established facts that exposure to radiation causes biological effects, there have been established regulations for radiation dose. The following table shows what levels of radiation are allowable by the Arkansas Department of Health, Radiation Control and Emergency Management Programs.

Maximum Permissible Radiation Dose

<table>
<thead>
<tr>
<th>Category</th>
<th>Allowable Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Occupational</td>
<td>5000 mrem/yr (50 mSv/yr)</td>
</tr>
<tr>
<td>General Public</td>
<td>100 mrem/yr (1 mSv/yr)</td>
</tr>
<tr>
<td>Fetus</td>
<td>500 mrem/9months</td>
</tr>
<tr>
<td>Extremities</td>
<td>50 rems/yr (0.5 Sv/yr)</td>
</tr>
<tr>
<td>Patients</td>
<td>No regulatory limit</td>
</tr>
</tbody>
</table>
RADIATION DOSE FROM FLUOROSCOPY

Fluoroscopy is particularly high dose rate procedure. The fluoroscopist should be concerned about radiation dose to the patient and to themselves and co-workers in the vicinity of the fluoroscopic machine.

Click **CASE STUDIES** to view radiation–induced injuries.

Radiation to the patient can be reduced by considering the following factors:

- Short periods of screening exposure.
- Digital image storage.
- Temporary removal of anti-scatter grid (less radiation needed for film exposure with sacrifice in image quality).
- Automatic brightness control compensates for different anatomy.
- 90 kV at 0.5 mA should be exposure level to deliver 1R/min (10 mGy) at the table top.
- X-ray tube a maximal distance from patient.
- Image intensifier as close to patient as possible.
- Appropriate use of the magnification mode of operation consistent with the procedure.
- Collimate the beam to the smallest field.
- Keep beam-on time to a minimum.

Radiation to personnel can be reduced by the following:

- Use local shielding around equipment (ceiling mounted lead-glass shields, mobile standup shields).
- Wear protective clothing (lead aprons, thyroid shields, leaded eyewear).
- Exposure timing devices with audible warning.

Personnel monitoring

Personnel monitoring does not reduce radiation exposure, but it is important to wear the monitors (badges) to be able to know what the radiation dose you receive. Individuals who operate diagnostic x-ray equipment should wear radiation dosimeters. It is a requirement of state and federal regulations that individuals who are likely to receive 10% of the annual occupational limit (500 mrem/yr) wear dosimeters. If assigned one badge, it should be worn on the outside of the “apron” at the collar level. If assigned two badges, one badge should be worn on the outside of the “apron” at the collar level and the other badge worn under the apron at the waist level. Badges should be worn for one month and returned at the end of the monitoring period.