Medical Fluoroscopy:

A Guide for Safe Usage

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I. INTRODUCTION

The State of Wisconsin, Department of Health Services (DHS), publishes and enforces Radiation Protection regulations for the use of ionizing radiation. These regulations may be found in the Wisconsin Administrative Code, Chapter DHS 157. With regard to the human use of fluoroscopic x-rays, the following is stated:

> **DHS 157.76 Fluoroscopic Equipment.** (11) EQUIPMENT OPERATIONS.
> (a) The facility shall ensure that only a licensed practitioner or a radiologic technologist who is trained in the safe use of fluoroscopic x-ray systems is allowed to operate these systems. All fluoroscopic x-ray images shall be viewed, directly or indirectly, and interpreted by a licensed practitioner.
> (b) The use of fluoroscopic x-ray systems by radiologic technologists shall be performed under the supervision of a licensed practitioner for the purpose of localization to obtain images for diagnostic purposes.
> (c) Radiologic technology students may not operate fluoroscopic x-ray systems except under the direct supervision of a licensed practitioner or radiologic technologist.
> (d) Fluoroscopic x-ray systems may not be used as a positioning tool for general purpose radiographic examinations.
> (e) The registrant shall require the operator of a fluoroscopic x-ray system to meet either of the following requirements:
>
> 1. Is certified by the American Board of Radiology or board eligible.
> 2. Has completed training to include the following:
>
> a. Principles and operation of the fluoroscopic x-ray system.
> b. Biological effects of x-ray.
> c. Principles of radiation protection.
> d. Fluoroscopic outputs.
> e. High level control options.
> f. Dose reduction techniques for fluoroscopic x-ray systems.
> g. Applicable state and federal regulations.

The regulation above applies to any facility that registers medical x-ray equipment with DHS, such as hospitals and medical clinics. Any individual who performs fluoroscopy on human patients or research subjects must be able to provide documentation of compliance with the training requirements listed above. This includes licensed practitioners and certified radiologic technologists. Licensed practitioners include chiropractors, dentists, physicians, podiatrists, physician assistants, nurse practitioners or radiologist's assistants licensed in the state of Wisconsin (DHS 157.03[191]).

II. BASIC RADIATION PHYSICS

<u>X-Ray Production</u>

X-rays are produced when electrons are accelerated through a high voltage in the range of 50,000 to 150,000 volts, (50 to 150 kVp) and allowed to crash into a target composed of a high atomic number material, such as the tungsten target in an x-ray tube. Electrons are released from an

electrically heated filament in an x-ray tube and accelerated to the target by the high voltage. The flow of electrons from the filament to the target is referred to as the tube current and is given in milliamperes (mA). Fluoroscopy is usually performed using 2 to 6 milliamperes (mA) and an accelerating voltage of 75 to 125 kVp.

The amount of x-rays produced by an x-ray tube is determined by the tube current (mA) and the high voltage (kVp). X-ray production is directly proportional to the tube current and doubling the tube current doubles the number of x-rays produced at a particular kVp. However, x-ray production increases more rapidly with kVp than mA and increasing the kVp by 15% is equivalent to doubling the mA. Higher kVp values also provide a more penetrating x-ray beam.

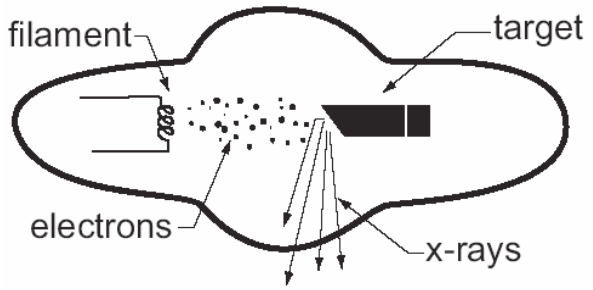

Figure 1. A Simple X-Ray Tube Configuration.

III. UNITS OF RADIATION EXPOSURE AND ABSORBED DOSE

Three quantities and their units and are important to the following concepts and will be defined here. These are *exposure*, *absorbed dose*, and *effective dose equivalent*:

Exposure

Exposure is defined as the quantity of x-rays or gamma radiation required to produce an amount of ionization (electric charge) in air at standard temperature and pressure. The traditional unit of exposure is the *Roentgen (R)* and is defined as 1 R = 2.58×10^{-4} C/kg. The SI unit of exposure is defined in units of coulombs/kilogram (C/kg). Frequently, ionization measurements are made of exposure rate, i.e., the amount of exposure per unit of time. Radiation safety survey meters generally read ~~out~~ in units of Roentgen per hour (R/hr) or milliRoentgen per hour (mR/hr). A medical physicist making measurements of fluoroscopic x-ray machines would most often measure the "fluoro output" in R per minute (R/min).

Absorbed Dose

Absorbed dose is defined as the amount of ionizing radiation energy absorbed per unit mass. The traditional unit of absorbed dose is the *rad (Radiation Absorbed Dose)*, 1 rad = 100 ergs/gram. The SI unit of absorbed dose is the *Gray (Gy)*, 1 Gy = 100 rad. For x-rays used in fluoroscopy an exposure of 1 R results in an absorbed dose of approximately 1 rad.

Dose Equivalent and Effective Dose Equivalent

Dose equivalent is used in radiation safety to account for differences in the biological effectiveness of different types ionizing radiation. Dose equivalent is defined as the absorbed dose times a radiation quality factor specific the type of radiation to which an individual is exposed. The traditional unit for dose equivalent is the *rem (Roentgen Equivalent in Man)*; the SI unit is the *Sievert (Sv)*, 1 Sv = 100 rem. For diagnostic medical x-rays, the quality factor is one, so an absorbed dose of 1 rad is equal to a dose equivalent of 1 rem.

The risk of potential health effects when only part of the body is irradiated is smaller than when the whole body is exposed. For example, if a single organ receives a dose equivalent of 300 rem (3 Sv), the resulting health effect to the individual will not be the same as what would be caused by a 300 rem (3 Sv) dose equivalent to the whole body. To account for these differences, the quantity effective dose equivalent (EDE) is used. EDE is defined as the sum of the absorbed dose to tissue(s) or an organ(s) times a weighting factor, and is also expressed in the units of rem or Sieverts. The EDE is a calculation of risk to an individual posed by partial body irradiation as compared to total body irradiation. The EDE is used estimate the equivalent whole body exposure for fluoroscopy staff wearing protective aprons for comparison to annual personnel dose limits for radiation exposure.

IV. FLUOROSCOPY EXPOSURE, FACTORS INFLUENCING EXPOSURE RATE

Modern fluoroscopy machines produce images with an image intensifier (II) which brightens the image level sufficiently so that the image can be displayed on a TV screen. Fluoroscopy units are usually operated in an automatic brightness control (ABC) mode.

In the automatic brightness control mode, or automatic exposure control (AEC) mode, a sensor in the image intensifier monitors the image brightness. Machine factors are then automatically adjusted to bring the brightness to a proper level. When there is inadequate brightness, the ABC generally increases the kVp first, to increase x-ray penetration through the patient, and then adjusts the mA to increase the brightness. Exposure to a thick patient will be greater than to a thin patient, and abdominal fluoro will require a greater exposure than fluoro in the chest because of the increased thickness and tissue density in the abdomen. The following are recommendations to optimize image quality while reducing patient and operator exposure.

Recommendation #1: The image intensifier input should be positioned as close to the patient as practicable. This results in a lower patient dose and sharper image.

With the II input located far from the patient, the ABC automatically increases the mA to provide the required brightness and increases the patient radiation dose. Keeping the II input, also produces another benefit: a sharper image due to less blurring due to of the x-ray tube focal spot.

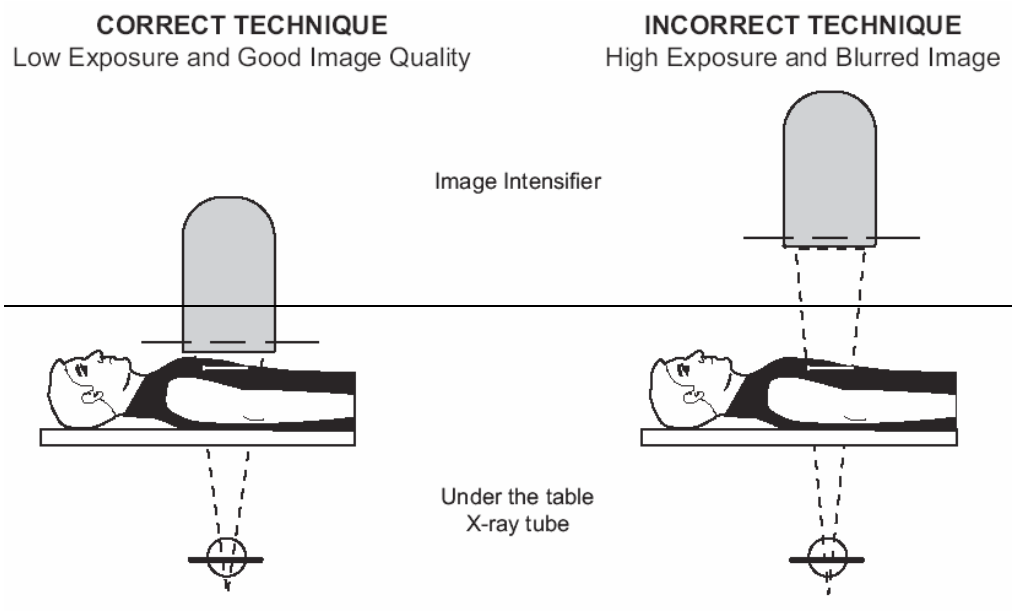

Figure 2.

Recommendation #2: Use the exposure pedal as sparingly as possible.

Radiation exposure during fluoroscopy is also directly proportional to the length of time the unit is activated by the foot pedal switch. The fluoro time is an important determinant of patient and staff radiation dose. Depression of the foot switch determines the length of the exposure. Fluoroscopy machines are usually 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.

Recommendation #3: Use last-image-hold and pulsed fluoro whenever possible.

Most modern fluoro units are also equipped with "last-image-hold", which stores the last fluoro image and allows viewing of the image without having to again expose the patient. Many fluoro units also offer a "pulsed fluoro mode", in which the x-ray beam is pulsed rapidly on/off, resulting in a lower radiation dose without significantly degrading the appearance of the image on the TV display.

Recommendation #4: Use the smallest field of view practicable.

Radiation exposure also depends on x-ray field size and keeping the x-ray field as small as possible (by using the collimators) will decrease the dose to BOTH the patient and the staff in the fluoro room. Restricting the field size offers a double bonus of not only decreasing radiation dose, but it also produces a better image! The contrast in the image between various tissue types will be greater for the smallest field of view that encompasses the desired anatomy.

Recommendation #5: High dose or detail modes should be used only when necessary.

Many fluoro units will have various dose modes, perhaps a low dose, medium dose, and high dose mode. For example, the modes may be identified as:

It is important to recognize that fluoroscopic image quality can be adversely affected by too few x-rays in the image; images are sometimes noisy for low dose. More tissue contrast is produced by the high dose modes, thus improving image quality at the expense of increased patient dose. Sometimes the high dose mode is labeled as "detail mode".

Recommendation # 6: Magnification should be used only when necessary.

Most fluoroscopy units are capable of using different magnification modes. Image resolution is improved with magnification but field size is reduced and patient radiation dose is increased. Patient dose is minimized by using the lowest magnification (largest field size) appropriate for the imaging procedure being performed.

Recommendation # 7: For C-arm type fluoroscopy units the patient should be position as far from the x-ray tube as practicable to minimize patient entrance dose. To reduce personnel exposure the x-ray tube should be position beneath the patient cart.

In conventional under-table x-ray tube fluoroscopic units (Figure 2), the x-ray tube is located at fixed distance from the patient's skin. In C-arm fluoroscopy (in which the distance between the x-ray tube and the image intensifier is fixed) the patient can be positioned in close proximity to the x-ray tube thereby increasing the entrance dose and reducing image sharpness.

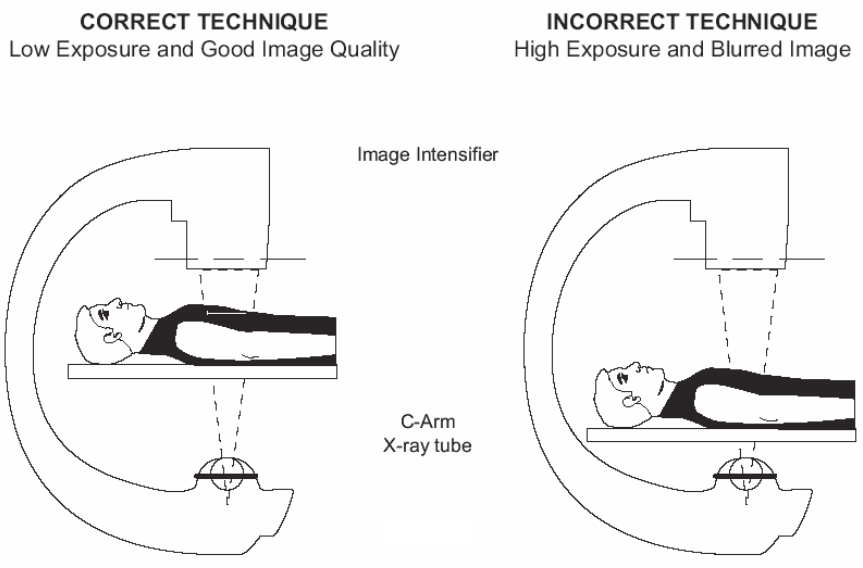

Figure 3.

It is preferable to locate the C-arm x-ray tube underneath the patient. Since the radiation transmitted through the patient is typically only 5-10% of the entrance dose, inadvertent exposure to the operator hand on the exit side of the patient will results in a smaller dose compared to the dose to the hand on the entrance side of the patient. Also the amount of scatter radiation the operator is exposed to on the beam exit side of the patient is significantly less than on the beam entrance side.

V. SOURCES OF RADIATION EXPOSURE

Direct Exposure

Entrance skin exposure (ESE) rates in fluoroscopy (meaning exposure in the x-ray beam where it enters the patient) are limited to less than 10 R/minute. At the maximum allowed ESE rate, 30 minutes of fluoroscopy can therefore deliver 300 R in skin exposure. ESE rates for typical fluoroscopy procedures are usually less that 5 R/minute.

Fluoroscopy ESE rates can be higher than 10 R/minute under certain circumstances. The regulatory limits for fluoro exposure rates are listed below (adapted from DHS 157.76[4]):

> Fluoroscopic equipment may not be operable at any tube potential (kVp) and current (mA) that will result in an exposure rate in excess of 10 R/min at the point where the center of the useful beam enters the patient, except under either of the following conditions:
>
> > (a) During the recording of images from an x–ray image intensifier tube using photographic film or a video camera when an x–ray source is operated in pulse mode.

(b) When an optional high–level control is activated, the equipment may not be operable at any combination of tube potential (kVp) and current (mA) that will result in an exposure rate in excess of 20 R/min at the point where the center of the useful beam enters the patient. Special means of activation of the high-level controls shall be required. The high-level control shall only be operable when the operator provides continuous manual activation. A continuous signal, audible to the fluoroscopist, shall indicate that the high-level control is being employed.

The output of each fluoroscope must be checked annually or after any maintenance that may affect x-ray dose parameters. Note that the dose to the patient is not regulated; only the maximum dose rate of the fluoroscopy unit is regulated.

Scatter Exposure to Personnel

The majority of the radiation exposure received by the operator or other personnel in the fluoroscopy suite during a procedure is due to scattered radiation from the patient. In general, the operator will be exposed at dose rate of approximately one one-thousandth (1/1000) of the ESE rate at a distance of 1 meter from the center of the fluoroscopy field. Several factors can increase the dose from scattered radiation, including:

1. Large patients cause the ABC to adjust the kVp and mA to higher values, which therefore generate a greater amount of scattered radiation.
2. A large x-ray field, a result of not restricting the field size will also increase scatter radiation.
3. The length of time during with the fluoroscope is on. Complex interventional cases require greater procedure time, increasing the dose to both the patient and the fluoroscopist.

A small percentage of the radiation received by the operator during fluoroscopy is due to leakage radiation through the x-ray tube housing. Radiation exposure to the operators from an under-the-table x-ray tube is negligible. C-arm operators, however, should be aware that the shielding built in to a “fixed” fluoroscope is not available for protection against backscatter under the table. This is of greater concern if the C-arm is rotated out of the normal vertical plane.

VI. RADIATION PROTECTION

The three most productive means of reducing radiation dose to fluoroscope operators and other staff in the room during fluoroscopy are listed below:

Time

Minimization of time spent in a radiation field is one of the first principles of radiation safety and exposure reduction. In the case of fluoroscopy, this corresponds to how much time the fluoroscope is producing x-rays. An important balance must be reached between the productive clinical use of x-rays and minimizing fluoroscopy time. The operator needs to produce an image with the necessary information to treat the patient, yet not linger needlessly. The use of last-image-hold and

pulsed fluoro features are technical advantages in reducing the total amount of time during which x-rays are produced.

Distance

Radiation dose rates increase or decrease according to the inverse square of the distance from the source. As mentioned previously, the main source of radiation exposure to fluoroscopic staff is scattered radiation from the patient, not from the x-ray tube. An example demonstrates the use of the inverse square law and dose rates at varying distances from the patient:

The intensity (I_1) of the radiation at one meter (d_1) from the patient is approximately 1/1000th of the patient entrance skin exposure. If the patient dose rate is 5 R/minute, then I_1 = 5 mR/minute. According to the inverse square law, the dose rate (I_2) at some new distance (d_2) is calculated as follows:

$$I_1 d_1^{\,2} = I_2 d_2^{\,2} \quad \text{or} \quad I_2 = I_1 \frac{d_1^{\,2}}{d_2^{\,2}}$$

Using two different distances for d_2, the change in dose rate is dramatically demonstrated. In the first case, the fluoroscopist (or other staff member) moves from 1 meter from the patient to 2 meters away, doubling the distance.

$$I_2 = (5)\frac{1^2}{2^2} = 1.25 \text{ mR/minute}$$

Notice that by increasing the distance from the source by a factor of 2, the dose rate decreases by a factor of 2^2, or 4. But when the distance from the source is decreased, such as when the fluoroscopist moves closer to the patient, the dose increases by the same exponential function:

$$I_2 = (5)\frac{1^2}{0.5^2} = 20 \text{ mR/minute}$$

In this second example, the distance was decreased to one-half meter, and the dose increased by a factor of 2^2, or 4.

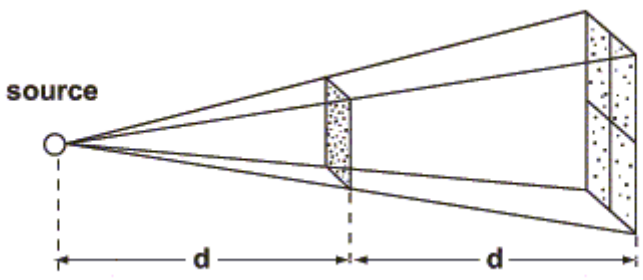

Figure 4. Graphical Representation of the Inverse Square Law.

The positioning of staff during fluoroscopy is critical to radiation protection. In many cases, the physician must be in close proximity to the patient during a fluoro exam. All non-essential personnel should be removed from the room, or at least be placed outside of a six-foot radius during x-ray use. Any personnel within six feet of an operating medical fluoroscope must wear lead (or lead equivalent) protective aprons, according to the regulations. This brings us to the next major dose reduction method, shielding.

Shielding

Lead garments, lead gloves, thyroid shields, leaded eyeglasses, lead drapes and clear leaded glass barriers between the patient and the operator all reduce exposure to medical personnel from scattered radiation. State regulations require that all persons, including staff or other patients, must be at least 2 meters from the tube head, direct beam, or the exposed area of the patient's body, or protected by shielding of thickness equivalent to 0.25 mm of lead (Pb). Furthermore, gonadal shielding of at least 0.5 mm Pb-equivalent shielding must be used for patients who have not passed reproductive age for radiographic procedures. Since staff aprons are frequently utilized for this function, it is recommended that all lead or lead-equivalent aprons be of 0.5 mm Pb-equivalence.

Dose Monitoring

Even when radiation protection techniques and engineering controls are in place to reduce personnel exposure, dose monitoring of individuals is required. Dosimeters come in several shapes, sizes and types:

Film Badges – As the name implies, these dosimeters employ film, similar to 35 mm camera film, that is sensitive to radiation. The film is contained in a paper/foil wrapper that must not be allowed to be damaged by heat or moisture. The film is loaded into a plastic holder that contains a system of filters (strips of copper, aluminum, lead, etc.) that allow the dosimeter reader to correctly identify the type of radiation the badge was exposed to. As such, the film and holder are an integral system, and must be loaded correctly.

Thermoluminescent Dosimeters (TLDs) – This dosimeter material is composed of small chips of LiF or CaF crystals that can be used to measure radiation dose. The small size of the TLD chips make them ideal for extremity monitoring, loaded into plastic rings that may be worn on fingers. TLD rings may be cold sterilized using a liquid sterilizing solution, but are extremely heat-sensitive, and may not be sterilized by heat sterilization.

Optically-Stimulated Luminescent (OSL) Dosimeters – Some dosimeter badges use a technology that records radiation exposure and is read by laser light. These badges can be used in place of film badges. Generally, the OSL badge comes as a packaged unit that attaches to a plastic holder. Unlike film badges, OSL badges holders do not incorporate filters, which are contained within the badge package itself.

Wisconsin Administrative Coded DHS 157.25 requires that any individual (other than the patient) working within 6 feet of an operating medical fluoroscope must be monitored for radiation exposure. General requirements for dosimeters are as follows:

- When a dosimeter is assigned, it is assigned to a single individual, and must not be shared.
- Dosimeters designed to measure dose to the whole body (torso, including head) must be worn at the collar, OUTSIDE any shielded apron.
- Ring badges should be worn inside gloves.
- Dosimeters may be assigned to monitor a period of up to one quarter year (3 months), but if exposures reach 10% of any of the limits (see Section VIII, Regulatory Exposure Limits), they must be exchanged on a monthly basis.

Dosimeters (unless otherwise authorized) are to be worn at the collar level, OUTSIDE of the protective apron.

In some cases, where daily fluoroscopic use is anticipated, two dosimeters will be assigned. When two dosimeters are in use, one badge is to be worn at the collar outside the apron in the standard position; the second is to be worn at the waist level UNDER the apron. Dosimeters assigned in this manner will be color-coded, to prevent the user from inadvertently wearing a badge in the wrong position. This two-badge method of dose monitoring is used to calculate the individual's effective dose equivalent (EDE), taking into account the protective factor of the lead apron. When two dosimeters are assigned, they must not be confused and worn in the incorrect position.

Dosimeters, when assigned, are to be worn when performing fluoroscopy procedures. A dosimeter assigned to a fluoroscopy user will be expected to show some radiation exposure above zero, or minimal readings. Abnormally low dosimeter results will be investigated by the Radiation Safety Officer (RSO) for compliance with the requirements listed above. ***Failure to properly wear a dosimeter could result in disciplinary action, including the revocation or suspension of the user's fluoroscopy privileges***.

Dosimeters wearers must promptly turn in and exchange badges each month or quarter, whatever the monitoring period. Chronically late badge users will be referred to the RSO for action.

The State of Wisconsin occupational radiation dose limits apply to an individual, even when radiation dose is received at more than one facility. To comply with the dose monitoring requirements, all monitored radiation doses must be added together. Fluoroscopy users who are monitored at more than one facility must make arrangements for the sharing of dose information with all facilities where they have been monitored during the current calendar year, or where they are still currently monitored. The dosimeter application contains a section authorizing the release of personal dosimetry records to the facility.

If a dosimeter is damaged, lost or exposed in error (such as being left inside the fluoroscopy suite), a report must be made immediately to the RSO. Dosimeters are susceptible to heat and moisture

damage; store them in a cool, dry place, away from any sources of radiation. Do not take a dosimeter home, or travel on an airplane with a dosimeter.

VII. BASIC RADIATION BIOLOGY

Direct Cellular Effects: Skin Injury

X-rays from fluoroscopy interact with biological material by transferring their energy to an electron, which subsequently interacts with the target molecule (DNA, RNA, or protein) to produce an ion or free radical. Radiosensitivity is a function of the cell cycle, with late S phase being the most radio-resistant, and the G1, G2 phases and mitosis being more radiosensitive. According to the law of Bergonie-Tribondeau, radiosensitivity is highest in undifferentiated and actively proliferating cells, proportionate to the amount of mitotic and developmental activity which they must undergo. Cells can sustain a variable amount of radiation and still repair themselves from sub-lethal damage. Continuous high intensity radiation, however, produces greater damage than an equivalent, fractionated (multiple smaller) dose, since fractionation allows time for cellular repair.

The total dose, dose rate, fractionation scheme, volume of irradiated tissue and inherent tissue radiation sensitivity all affect a given organ's response to radiation. Generally, a large total dose (as possible in fluoroscopy), a high dose rate (as in fluoroscopy), small fractionation schedule (as in fluoroscopy), and large irradiated volumes (hopefully not in fluoroscopy) cause a greater degree of damage.

A major concern from fluoroscopy is the possibility of acute, direct or deterministic, radiation damage which manifests as skin injury. The severity of the skin injury is dose-dependent; more dose means more severe symptoms. The FDA guidelines list the following skin injury effects from radiation exposure. *Remember that typical fluoro unit output may be as high as 10 R/min in normal mode and 20 R/min in high dose or detail mode. Note that the time to expression of symptoms is long enough that the patient may very likely no longer be in the hospital when symptoms appear. The physician performing the fluoroscopy cannot discern the damage by observing the patient immediately after fluoroscopy.*

FDA Specification of Radiation-Induced Skin Injuries					
Skin Effect	Threshold Dose		Typical Fluoro-On Time in Minutes		Time to Onset
	rem	Sv	Normal Mode @ 10 R/min	High Dose Mode @ 20 R/min	
Early Transient Erythema	200	2	20 minutes	10 minutes	Hours
Temporary Epilation	300	3	30 minutes	15 minutes	20 days
Basal Cell Erythema	600	6	60 minutes	30 minutes	10 days
Permanent Epilation	700	7	70 minutes	35 minutes	20 days
Dry Desquamation	1000	10	100 minutes	50 minutes	30 days

These threshold doses to cause an effect cannot be considered exact since there are many variables involved, including individual biological response, age and characteristics of the person exposed, and the area of skin exposed. Often, a patient may exceed the threshold dose or typical threshold fluoro-on times in the table above without showing any symptoms, owing to at least two reasons: the fluoro x-ray beam is often not necessarily concentrated on a single area of skin for the entire time, and secondly because 10 R/minute or 20 R/minute are maximum outputs for very thick patients. Nevertheless, users of fluoro units should be aware of the thresholds listed above and should attempt to maintain exposures below these symptomatic levels. Thirty minutes of fluoro time is often suggested as a target time for a “safe” or “benign” fluoro procedure. Thirty minutes of fluoroscopy is often suggested for a threshold to counsel patients concerning probable radiation induced skin injury effects. Of course, the medical need for any procedure must always take precedence over other concerns, and a “safe” fluoro time clearly depends on the x-ray machine operating parameters.

It should also be noted that the skin injury dose thresholds above, generally in the hundreds of rem, are for exposure to only a localized area of the body. Exposure of the entire body to such levels of radiation would cause severe radiation damage known as acute radiation syndrome. The $LD_{50/30}$ (Lethal Dose that would kill 50% of the exposed persons within 30 days) for an acute radiation dose without medical care is about 400 rem. Exposure of the gonads should be avoided since this

tissue is very radiosensitive. Just a few minutes of gonadal fluoroscopy could induce temporary sterility in males; with permanent sterility in either males or females is likely for doses the range of a few hundreds of rem.

Stochastic Effects: Cancer

Late effects due to low doses of radiation, specifically radiation-induced cancer, may remain dormant and then become evident 10-50 years after the original exposure. It is often difficult, if not impossible, to establish a direct connection with the earlier radiation event. Furthermore, radiation does not often produce specific "radiation-induced" cancer types, but simply increases the incidence of other already naturally-occurring cancers. This type of radiation effect is called a stochastic effect. The incidence of cancer induction is dose dependent (more dose means more cancers), but the severity of the induced effect is not dose dependent. There is considerable scientific controversy in specifying stochastic radiation risk estimates, but the prevailing scientific opinion is that there is no dose threshold for cancer induction, and that the cancer risk is linear with the absorbed dose. According to the Linear No-Threshold (LNT) dose-response model, no level of radiation is too small to produce some risk, and doubling the absorbed dose will double the cancer risk. This is unlike deterministic skin injury effects, where there is generally no risk below some dose threshold.

A group from the National Council on Radiation Protection and Measurements (NCRP) issued a report that specifies the latest risk estimates (NCRP Report #115, see references). The total detriment (excess cancer deaths and severe hereditary disorders) from low-level, low dose-rate exposure to radiation is between 4 and 8×10^{-2} Sv^{-1}. This applies to whole body irradiation, and these risk estimates are: based on human populations that were generally exposed to high doses of radiation delivered at very high dose rates, such as Japanese atomic bomb survivors. These risk estimates therefore have wide error bars, and must be interpreted accordingly. A typical calculation with such risk estimates might involve a scenario in which 10,000 persons are exposed to 1 rem of whole body radiation. This would lead to an estimate of between 4 and 8 radiation-induced cancer deaths in this group of 10,000 people. The natural incidence of cancer death is about 22%, so about 2,200 people would die naturally of cancer, and the radiation-induced additional 4-8 cancer deaths would not be easily detectable. This type of analysis is fraught with assumptions, perhaps akin to using the risk estimates for jumping off a very high building to calculate the risk for jumping off a one foot high log. In diagnostic radiology, the patients are not exposed to whole body radiation (to which these cancer estimates apply), but there is also considerable data in NCRP #115 for particular organ cancer types. Also, as occupationally exposed radiation workers, our dose rate is quite low (presuming we utilize appropriate protective techniques), and using the above cancer risk estimates may be akin to comparing the risk from consuming 100 aspirin all at once to the risk of consuming one aspirin per day for 100 days. These risks are different, and radiation effects exhibit similar dependencies on dose and dose rate. Nevertheless, based on the very large volume of scientific data available to us today, we can fairly confidently conclude that: these potentially late cancer responses to "low dose radiation" are a prime reason for judicious use of fluoroscopy during medical procedures. We cannot very exactly specify the number of cancers caused by use of fluoroscopy in our patients or in ourselves as health care workers. The number of cancers is scientifically likely to be small, but not zero, and the number of cancers we cause is increased as we give more absorbed dose to our patients.

Genetic Effects

Low dose radiation can cause chromosomal damage which may be "repaired" with an incorrect sequence and subsequently be passed on to the next generation. Radiation does not cause new types of mutations *per se*, but simply increases the incidence of certain mutations above their natural rate of occurrence. A gonadal dose of 250 cGy (250 rad) will cause temporary sterility, while 500 cGy (500 rad) will induce permanent sterility in males. Sterilizing doses in females may require greater than 625 cGy (625 rad), particularly in younger individuals. Controlled studies of genetic effects are only available from animal models and must therefore be interpreted with considerable caution for implications in humans. The 7 million mice, "Megamouse" project revealed the following five conclusions:

1. Different mutations differ significantly in the rate at which they are produced by a given radiation dose.
2. There is a substantial dose-rate effect with no threshold for mutation production.
3. The male was more radiosensitive than the female. Most of the radiation-included genetic burden was carried by the males.
4. The genetic consequences of a radiation dose can be greatly reduced by extending the time interval between irradiation and conception. Six months to a year is recommended.
5. The amount of radiation required to double the natural and spontaneous mutation rate is between 20 to 200 cGy.

NCRP #115 suggests that the quantitative risk of severe hereditary risks is 4-8 times lower than the cancer risks specified above. While these late effect genetic risks appear less frequent than cancer risks, they nevertheless suggest prudence in irradiating our patients and ourselves.

Embryo and Fetus

There are three general effects from irradiation *in utero* which 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.

250 cGy (250 rad) or more delivered to a human embryo before 2 to 3 weeks of gestation will likely result in prenatal death. Those infants with irradiation in the 1st 2-3 weeks who survive to term generally do not exhibit congenital abnormalities. Irradiation of the human fetus somewhat later, between 4 to 11 weeks of gestation, may cause multiple severe abnormalities of many organs. Irradiation during the 8th to 15th week of gestation may result in mental retardation and microcephaly. NCRP #115 suggests that the quantitative risk of mental retardation from irradiation during the 8th-15th week is similar in magnitude to the cancer risks mentioned above. The fetus is therefore considered more radiosensitive in its early stages. After the 20th week, the human fetus is more radio-resistant but functional defects may be observed. In addition, a low incidence (one in 2000) of leukemia induction has been observed in individuals who received prenatal radiation.

It seems clear that irradiation of the fetus should be avoided without clear medical justification relating to the medical condition of fetus or mother.

VIII. REGULATORY EXPOSURE LIMITS

The occupational exposure limits concept utilizes an assumption that radiation doses below the stated levels are an acceptable risk for occupationally exposed personnel and the general population within the lifetime of the exposed individual. These acceptable risk levels have been set based on comparisons to other risks in our society: other occupational hazards in other safe industries, environmental hazards, etc. There are no regulatory limits for patient exposures, but FDA guidelines and our professional understanding of radiation effects dictate minimizing patient exposures. And, of course, minimizing patient exposure also minimizes hospital personnel exposures.

Occupational	**Annual Dose Limit (mrem)**
Whole Body, Effective Dose Equivalent	5,000
Skin, Individual Organs, Extremities	50,000
Lens of the Eye	15,000
Members of the Public	**100**
Embryo/Fetus*	**500**

* The embryo/fetus of an occupationally exposed *declared pregnant woman.*

ALARA, As Low As Reasonably Achievable

The facility Radiation Safety Program has as a core principle the ALARA concept. ALARA means that every reasonable effort, whether through procedural or engineering controls, will be made to reduce radiation exposures.

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