American Society for Gastrointestinal Endoscopy radiation and fluoroscopy safety in GI endoscopy

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A fundamental tool of interventional endoscopy is the "x-ray," named in 1895 for the mathematic symbol of "the unknown" by Professor Wilhelm Röntgen in an accidental, Nobel-Prize winning discovery. In the subsequent 125 years, multiple commercial, industrial, and medical applications of x-rays have been developed. Yet, perhaps because of its widespread availability and great utility, the proper and safe use of medical radiation is often taken for granted. For example, nearly 70 million CTs were performed in the United States in 2007, with 1 study demonstrating up to a 13-fold variation in CT radiation dose for identical study types.[1-3] This and other data highlight an alarming inattentiveness to radiation safety protocols, which may place both patients and practitioners at risk. Similarly, fluoroscopy usage during ERCP has been shown to be affected by endoscopist experience/trainee involvement,[4,5] procedure difficulty,[6] and endoscopist self-awareness of fluoroscopy usage.[7] However, formal education in radiation safety during interventional endoscopy training remains limited and sparse.[8]

There are several aims of this document. First, this article will provide the reader a working understanding of fluoroscopy (ie, how a fluoroscopic picture is generated, how to balance image quality with radiation dose). This understanding is crucial not only for the safe deployment of this modality, but also to the long-term protection of nurses, physicians, and support staff in the procedure room based on the "ALARA" principle (as low as reasonably achievable). Second, the core concepts of radiation protection, both to the patient and staff, are discussed. Finally, the article outlines how to promote radiation safety in daily clinical practice, now and in the future.

KEY FLUOROSCOPY CONCEPTS

X-ray (radiation) is a type of energy that is part of the electromagnetic spectrum, which covers a wide range of electromagnetic energy—from radio waves and television signals, to visible light and ionizing radiation. Thus, radiation exposure is part of daily living, and humans are constantly exposed to natural radiation (eg, ground radiation in the form of radon and cosmic radiation when flying).[9]

Ionizing radiation such as fluoroscopy is used in medical imaging because of its ability to penetrate tissues and be captured by a detector device (ie, by an image intensifier or flat panel detector). The detector device then converts the information into a visible image for the endoscopist.

A typical fluoroscopy setup uses a C-arm or fluoro table, and electricity via the power line enters the x-ray generator and becomes upregulated to 25 to 150 kV peak. This electricity is delivered to the x-ray tube, which converts the energy into a stream of electrons fired against a tungsten target. The subsequent collision stops the stream of electrons and releases x-rays, directed toward the body part of interest.[10,11] Various body parts have varying degrees of absorption, which generates contrast and therefore an image. The x-ray is then captured by an image intensifier (or flat panel detector), which brightens the image and transmits the image to a television monitor or liquid crystal display screen. Although many factors affect fluoroscopic image quality, in general higher frame rates and higher magnification typically produce higher image quality, but at the cost of higher radiation dose to both the patient and the staff.

Last, some endoscopy units use a fluoroscopy technician, rather than the performing physician, for fluoroscopic pedal control. Although there are plausible arguments that one (or the other) may yield optimized fluoroscopy application, the question of whether single- or dual-operator fluoroscopy is preferable remains subject to debate.[11-13] Although 1 randomized control trial of pediatric urologists found no difference between the 2,[12] 2 similar gastroenterology studies each concluded that ERCP fluoroscopy time and/or dose was significantly lower when the fluoroscopy pedal was endoscopist rather than technologist controlled.[13,14]

UNDERSTANDING FLUOROSCOPY EQUIPMENT

Unlike a typical automobile in which the position of key pedals (accelerator pedal, brake pedal, gear shift order)

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Figure 1. Representative control panels from 4 different fluoroscopy manufacturers. Note the lack of standardization of key controls. Clockwise from upper left: Philips (Amsterdam, Netherlands), Siemens Healthineers (Erlangen, Germany), GE Healthcare (Chicago, Illinois), Omega Medical Imaging (Sanford, Fla, USA).

evolved into an industry standard, there is no equivalent uniformity across various fluoroscopy machines. Federal regulations, which establish standards for safety in ionizing radiation-emitting products manufactured after 2006 (21 Code of Federal Regulations [CFR] 1020.32), is principally focused on various safety features such as source-to-skin distance, radiation output values, and a mandatory 5-minute alarm on all fluoroscopic control systems.[15] However, there is no federal guidance, and therefore no industry uniformity, regarding control button position or even standardized icon graphics on fluoroscopic equipment (Fig. 1). This issue is compounded by varying ages of fluoroscopic equipment in clinical use.

Therefore, it is important for all physicians to consult with their local radiation safety officer to understand each machine that may be used in their specific practice. This may be particularly important if an endoscopist performs procedures in multiple locations. For instance, although most modern fluoroscopy systems are "under couch" (meaning the x-ray source is underneath the fluoroscopy table), some practice environments may still have an "over-couch" setup—for instance, C-arms used by urologists. This setup has important implications for physician and staff safety because radiation scatter is always highest on the side of the x-ray tube.[16]

Digital fluoroscopy is a recent advancement in which the image intensifier is replaced by a flat panel detector. Digital fluoroscopy may hold several advantages over analog fluoroscopy, including the ability for "last image hold" and pulsed fluoroscopy and filtration of "soft" radiation, or photons, which only increases radiation exposure but does not contribute to a useful fluoroscopic image. In an article comparing analog versus digital radiography, for the same field of view (magnification), digital fluoroscopy reduced fluoroscopy dose up to 27% ± 5% compared with analog fluoroscopy ($P < .1$).[17] However, digital fluoroscopy acquisition costs are typically several-fold more than analog systems. Additionally, it is critical to note that digital fluoroscopy is not inherently safer than analog fluoroscopy; indeed, some digital systems output images at a higher radiation dose compared with analog fluoroscopy for equivalent examination types.[18] For example, if the endoscopist is not situationally aware, digital fluoroscopy may paradoxically increase delivered radiation because of inherent properties of all digital systems; that is, physicians may be inclined to take more fluoroscopic pictures to select the "best" image (without realizing radiation delivery with each photograph).

PRINCIPLES OF RADIATION SAFETY

Deterministic versus stochastic effects of radiation

Radiation injury to humans can either be nondose-dependent (stochastic) or dose-dependent (deterministic). The injury in both situations is mediated by ionizing radiation, which causes either direct DNA damage or indirect DNA damage from free radicals that are released from ionizing radiation colliding with nearby water.[19,20] Stochastic effects can occur at any radiation dose.

Increasing the radiation dose increases the probability that an effect will occur but does not increase the severity of the effect.[21-25] Cancer is an example of a stochastic effect; although increasing radiation dose can increase cancer probability, cancer can still occur at low radiation doses. In contrast, deterministic effects occur at a threshold dose, and their severity increases with the amount of radiation received.[21,22] These effects will only occur if a threshold dose of radiation is received. Examples of deterministic effects include hair loss, skin burns, cataracts, and desquamation.

Units of measurement

Beyond the fact that humans cannot use their normal senses to detect radiation exposure, the practicing physician may find the concepts of radiation safety abstract and inaccessible because of often confusing units of measurement. Two radiation measurements are of interest with which all endoscopists should be familiar: absorbed dose (D) and dose equivalent (H). The absorbed dose (D) typically measures deterministic effects, whereas the dose equivalent (H) typically measures stochastic effects. Furthermore, all comprehensive radiation safety programs should aim to record 2 sets of measurements, 1 for the physicians and nurses (via effective dose in mSv) and 1 for the patient (via absorbed dose in the form of fluoroscopy time, entrance skin dose [mGy], and ideally Kerma air product [Gy cm^2]). These principles are summarized in Table 1.

As low as reasonably achievable

The use of fluoroscopy should be guided by the principle of ALARA, which is to use doses "as low as reasonably achievable."[21,26-28] ALARA aims to prevent overexposure to patients and occupational workers and to minimize the risk of stochastic and deterministic effects.[24,29] The ALARA principle is primarily based on radiation time, distance from the radiation source, and shielding from both the radiation beam and scatter but also includes other factors such as beam modification (ie, magnification and collimation), education, and radiation awareness.[25,29]

Automatic brightness control

The automatic brightness control (ABC) feature of fluoroscopic systems keeps the overall image brightness constant. Image brightness is determined by the radiation input received at the image intensifier. If the image is not bright enough, the ABC system compensates by generating more x-rays or more penetrating x-rays (ie, increasing the fluoroscopic milliamperage or the kV peak), either of which increases dose.[21] In contrast, if the image is too bright, the ABC system produces less x-rays or less penetrating x-rays (ie, decreases the fluoroscopic milliamperage or the kV peak), which decreases dose.

TABLE 1. Absorbed dose (D) vs dose equivalent (H)

	SI	Non-SI (USA)
Absorbed dose (D)	1 Gray (Gy)	100 rad
Equivalent dose (H)	1 Sievert (Sv)	100 rem
	1 milliSievert (mSv)	100 mrem

SI, Système international.

Magnification

Most fluoroscopy systems have an average of 3 to 5 available magnification modes. Magnification is achieved when a smaller input area is focused over the same output area on the image intensifier. This results in a decrease in photoelectrons reaching the image intensifier, which results in a degraded image with lowered image brightness. ABC systems compensate for this decrease in brightness by increasing the fluoroscopic milliamperage, which increases the radiation dose.[21] In fact, when the field of view is decreased by 2 (in colloquial terminology, "mag up 1 level"), the dose rate increases by a factor of 4.[30] Therefore, magnification mode is associated with a significant increase in dose, and, in general, the radiation dose increases with greater magnification.[22,31,32] Therefore, for radiation dose reduction, the magnification should be set at the lowest possible setting.

Collimation

Collimation shapes the x-ray beam using round and rectangular radiopaque shutters.[10] The operator should collimate the x-ray beam to include only the area of interest. For instance, by collimating out the gastric bubble, the image of the biliary system is typically enhanced with crisper contrast of anatomic features. Although collimation reduces image brightness and the ABC system responds by increasing the entrance skin exposure dose, the net result is that less tissue is irradiated, less scatter is generated, and therefore the overall dose to patients and staff is still greatly reduced.[33] In general, collimation decreases patient and operator dose in proportion to the image field area.[10]

Gantry angle

Radiation exposure also varies according to the angle at which the x-ray beam is projected. Oblique views and steep angulations increase the length of the radiation path through the body, resulting in a compensatory increase in radiation output, sometimes by a factor of 10 or more.[22] Angulations of 60 degrees result in 3 times the radiation dose compared with 30-degree angulations.[21]

LICENSURE AND DOCUMENTATION REQUIREMENTS AND OCCUPATIONAL DOSE LIMITS

In the United States there is no uniform federal requirement for radiation safety training in the healing arts. Thus, each of the 50 states and the District of Columbia has

TABLE 2. Annual occupational dose limits

	Dose limit	Notes
International Atomic Energy Agency[98]		
Total body	20 mSv	Per year averaged over 5 y
	50 mSv	In 1 y
Lens of eye	20 mSv	Per year averaged over 5 y
	50 mSv	In 1 single year
Extremity (hands, feet, or skin)	500 mSv/y	
NCRP[99]		
Total body effective dose	50 mSv	Per year
Lens of eye	50 mGy	Lowered limits based on NCRP Commentary No. 26
Extremity (hands, feet, or skin)	500 mSv/y	

NCRP, National Council of Radiation Protection.

developed their own radiation certification requirements. For instance, 9 states require documented proof of fluoroscopic safety training, whereas 8 states have no requirements for any x-ray operators. Only 1 state (California) has a dedicated state licensure examination for physician fluoroscopy operators (Fluoroscopy Supervisor and Operator Permit) (Supplementary Table 1, available online at www.giejournal.org). Nevertheless, it is important for physicians to be aware of published radiation dose limits from international and national authorities (International Atomic Energy Agency and National Council of Radiation Protection) (Table 2).

The most common method of acquiring occupational dose limits is through the use of a dosimeter. Three types of dosimeters exist in routine clinical practice. The first type is the film-based dosimeter. Film-based dosimeters are very sensitive to x-rays; the darker the exposed film, the higher the radiation dose received. Although film-based dosimeters are quite affordable, because of their physical properties, the film badges cannot be left in enclosed cars and need to be returned every month to prevent fogging caused by environmental factors (eg, temperature and humidity). A more modern type of dosimeter is the thermoluminescent dosimeter, which is a badge containing a radiosensitive material chip (lithium fluoride). In the process of absorbing x-rays, the electrons in this material become charged/excited electrons. On return to the lab for processing, the electrons return to their normal state and emit light. The emitted light is proportional to the absorbed dose.[34] The third type of dosimeter is the optically stimulated luminescence dosimeter, which is a detector with 3 different filters—aluminum, tin, and copper. When the badge is returned for processing, various lasers of different energies are used to "read" each detector; the brightness of the resulting light is proportional to the radiation each detector receives. This dosimeter design is advantageous because it allows for the determination of various proportions of low-, medium-, and high-energy radiation to which the wearer is exposed, which corresponds to "shallow," "eye," and "deep" radiation, respectively.[35] The primary disadvantage of such dosimeters is the need for postprocessing, and therefore the user cannot obtain real-time information. Electronic personal dosimeters (metal oxide semiconductor field-effect transistor) are now commercially available. These devices are primarily used for patients receiving total body radiation in radiation oncology settings. Such devices have several advantages over postprocessing types of dosimeters, such as giving real-time dose exposures, warning the user instantly if dose limits are exceeded, and supporting near-field communications that allow automatic reading and resetting.

Regardless of the type of dosimeter used, proper positioning of the detector is critical to ensure accurate data reports. A dosimeter should be worn at collar level, outside the apron. This most closely approximates the thyroid and lens equivalent dose. However, during intense fluoroscopy procedures or for pregnant personnel, a second dosimeter should be worn at waist level below the lead apron; these data most closely approximate the penetrating dose to the lower trunk. In this situation, it is critical that the 2 dosimeters are color-coded to prevent misinterpretation of results (eg, if the collar dosimeter is accidentally mistaken for the "under apron" dosimeter, this could lead to a misinterpretation of the results as an unsafe/cracked lead).

PROTECTING THE PATIENT, PHYSICIAN, AND STAFF

Radiation-induced organ injury is a complex interplay of radiation dose, exposure time, a specific organ's radiosensitivity, and a person's genetic susceptibility. To provide context, it is useful to stratify events into early deterministic effects (days to weeks after exposure) and late deterministic/stochastic effects (months to years after exposure). Examples of early deterministic effects include skin erythema, temporary sterility (each occurring after an average of 2-Gy exposure), and blood dyscrasias such as leukopenia (which can occur after a little as .1-Gy exposure).[36] Late deterministic and stochastic events, meanwhile, are harder to ascribe a dose–response relationship in part because of the extremely long lead time between exposure and effect. Much of what is known is through observational studies from occupational (uranium miners and radium watch dial painters) and mass casualty incidents (Nagasaki and Chernobyl). Examples of late deterministic effects include cataract formation and decreased fertility, whereas late stochastic effects include cancer and hereditary effects (birth defects).[37] As mentioned previously, although stochastic effects can still occur at low doses, the likelihood of stochastic effects may increase with increasing dose, which is important because radiation exposure is cumulative over a person's lifetime.

Thus, keeping in mind the principles of ALARA, the International Commission on Radiological Protection has stratified occupational radiation exposure as follows:

1. Low: <3 mSv (300 mrem) per year, equivalent to the natural background level of radiation,
2. Moderate: 3 to 20 mSv (300-2000 mrem) per year, upper annual limit for occupational exposure for at-risk workers averaged over 5 years,
3. High: >20 to 50 mSv (2000-5000 mrem) per year, upper annual limit for occupational exposure for at-risk workers in any given year.[38]

Similarly, the National Council for Radiation Protection has established the annual deep dose equivalent limit for occupational exposure to be 5000 mrem (50 mSv). Most states have adopted these dose limits in their regional regulations and guidelines.

Effective radiation protection of the patient and medical team should be the goal of every fluoroscopic procedure, especially because the highest dose to the physicians and nurses comes from the patient (in the form of scatter).[33] Some believed leaders in gastroenterology have strongly embraced the fundamental principles of ALARA, such as advocating for documenting fluoroscopy times in ERCP reports,[7] the use of alternative/adjunctive modalities such as EUS and digital cholangioscopy,[39] and even ERCP without fluoroscopy.[40] However, in most clinical situations ERCP still relies heavily on fluoroscopy for diagnostic and therapeutic purposes.

In the remaining section we review the 3 variables of radiation safety: time, distance, and shielding. We also focus particular attention on 4 special situations: the obese patient, the pediatric patient, the pregnant patient and the patient of childbearing age, and pregnant members of the fluoroscopic team.

TABLE 3. Time-reducing "best practices" to reduce effective radiation dose

Only activate fluoroscopy when images are required for clinical care
Predetermine desired field of image before activating fluoroscopy (to avoid unnecessary panning)
Use intermittent taps of the fluoroscopy pedal
Avoid redundant views
Use pulsed, not continuous, fluoroscopy
Use last image hold
Avoid unnecessary spot films
Pay attention to audible alarms (federally mandated 5-min fluoroscopy time for machines manufactured after 2006)

Time

The most important factor influencing radiation dose is fluoroscopy time.[25] Radiation dose is directly proportional to the time of exposure; therefore, it is critical to understand ways in which fluoroscopy time can be reduced.[21,29] Several time-reduction "best practices" reduce effective radiation dose (Table 3).[29,41] The use of pulsed fluoroscopy with the pulse and frame rate set as low as possible results in a significant radiation dose reduction.[28,33,42,43] In pulsed fluoroscopy, the x-ray beam turns on and off at a lower frame rate (ie, 7.5 or 15 pulses per second) when the pedal is depressed, delivering a lower total radiation dose than in conventional continuous fluoroscopy (30 pulses per second).[31,44] The operator selects the pulse rate frequency, and the total radiation dose is proportional to the pulse rate frequency. Systems set to <10 pulses per second can result in up to 90% less exposure compared with nonpulsed systems.[45] Another way to reduce fluoroscopy time, and therefore the dose, is the last image hold feature of fluoroscopy systems.[31,32,42,46] This feature keeps the last fluoroscopic image on the monitor without the need for continuous fluoroscopy (ie, the image from the last time the foot pedal was depressed is displayed on the monitor). This can decrease the total fluoroscopy time by 50% to 80%.[29]

Distance

The amount of radiation an individual receives depends on his or her distance from the radiation source. Although the main source of radiation to the patient is from the x-ray tube, the main source of radiation to endoscopy personnel is actually from the patient because of radiation scatter.[21,25,41] Moreover, radiation exposure is dictated by the inverse square law; specifically, exposure is inversely proportional to the square of the distance from the source.[25,47] Therefore, tripling the distance between the radiation source and an individual decreases exposure by a factor of 9. Therefore, endoscopists and staff should stay as far away from the radiation beam as possible to reduce their radiation dose.

TABLE 4. Radiation attenuation based on kV peak and lead thickness[44,100,101]

Lead thickness	Approximate weight (kg)	60 kV peak	80 kV peak	100 kV peak	120 kV peak
.25 mm	2.7-2.9	95.72	88.05	83.27	79.84
.5 mm	2.9-5.8	99.58	97.45	95.04	93.69
1 mm	5-12	99.99	99.73	99.14	98.91
2 mm	26*	100	99.99	99.95	99.94

Adapted from References 44, 102, and 103.
*This value is extrapolated. There is no known commercially available, wearable apron in 2-mm lead thickness.

Shielding: personal protective equipment and structural shielding

Lead aprons are the primary radiation protective garment used by personnel during fluoroscopy and commercially available in various thickness options, including .25 mm, .35 mm, .5 mm, and 1 mm. In addition to thickness, the particular matrix of composite materials, which can differ by the manufacturer, can also alter attenuation rates. In routine clinical practice, .5 mm of lead can attenuate over 90% of scattered radiation.[48] Thereafter, the incremental gain in attenuation is typically offset by a notable increase in weight (Table 4).

Several different designs are available, including aprons with front coverage only, double-sided wraparound, or 2-piece aprons. Two-piece lead aprons, which consist of a vest and a skirt, are preferred to 1-piece options because they distribute weight more evenly to the hips and shoulders and afford consistent protection when the endoscopist must stand tangential to the radiation source to view video and fluoroscopy monitors.[25,41] A wraparound lead apron with .25-mm lead-equivalent thickness also provides a .5-mm lead equivalence in the front portion of the body.

The long-term use of traditional lead aprons has been associated with musculoskeletal problems and fatigue in interventional physicians.[49,50] Lightweight lead, composed of lead composite or lead-free material (such as barium, tin, and antimony), can often provide similar protection to pure lead at approximately 30% of the weight,[51] although at a higher cost. Given a standard .5-mm lead apron can weigh up to 15 pounds, the impact of lightweight lead can be significant. Regardless of the material and design, it is crucial the protective apron fits properly at the neckline and armhole. Large gaps could result in increased exposure of breast tissue, which is particularly important for female staff because increased risk of breast cancer has previously been described in female fluoroscopy operators.[52,53]

Furthermore, the shielding materials inside protective garments may suffer damage after long-term use, such as microscopic cracks or holes that may not be visible. Therefore, lead aprons require an annual inspection (eg, via radiographic surveillance) to evaluate for defects. Proper care of the lead apron prolongs lifespan of the garment; specifically, the apron should always be handled carefully and hung vertically to prevent cracks. Tossing the apron into a folded, crumpled pile should be avoided.

Although lead aprons effectively reduce most scatter radiation to the trunk and pelvis, other vulnerable regions of the body remain exposed and require dedicated shielding. Radiation exposure of the thyroid gland and eyes can be significant during fluoroscopy-guided endoscopy (median of .3 mGy, or .03 Rad, per ERCP), particularly with unshielded over-couch systems.[54] The annual maximum permissible dose recommended to the thyroid is 300 mSv (30,000 mrem). Thyroid guards have been shown to reduce the total body effective dose by 46% per year.[55] Although prior studies likely underestimated the risk of thyroid cancer (because of the several-decade arc between exposure time and development of thyroid cancer), professional awareness of this concern is increasing.[56] For example, there has been a self-reported 44% increase in thyroid shield use among interventional endoscopists from 2000 and 2019.[8,25] Similar to the adage that "the best camera is the one that is with you," the best thyroid shield is the one that is with you at all times—ideally, a shield that is $\geq$.5-mm lead equivalent, permanently attached to your lead apron, and worn snugly.[57,58]

Cataract formation from radiation exposure is often an underappreciated occupational hazard. Because of the eye's radiosensitivity, a yearly limit of 15 mSv (1500 mrem) has been recommended to prevent cataract formation,[59] as was confirmed in a study of interventional cardiologists that demonstrated a 3-fold increased risk of cataract formation compared with the general population (38% vs 12%; $P = .005$).[60] Despite this risk, self-reported leaded glass usage is poor. For instance, in a survey of over 150 attending and trainee interventional endoscopists, consistent usage was seen in as few as 31% of attendings and 14% of interventional fellows.[8] Similar to lead aprons, the most protection comes from .5-mm lead thickness (95%).[56] Although lightweight lenses exist, they have significant limitations, including up to 50% reduction in radiation protection if the endoscopist stands tangentially to the radiation source.[61]

Typically, arms and legs are unprotected from scatter radiation during fluoroscopic procedures, with 1 study demonstrating operator leg doses as high as 2.6 mSv (260 mrem) per procedure.[62] Additional lead shielding

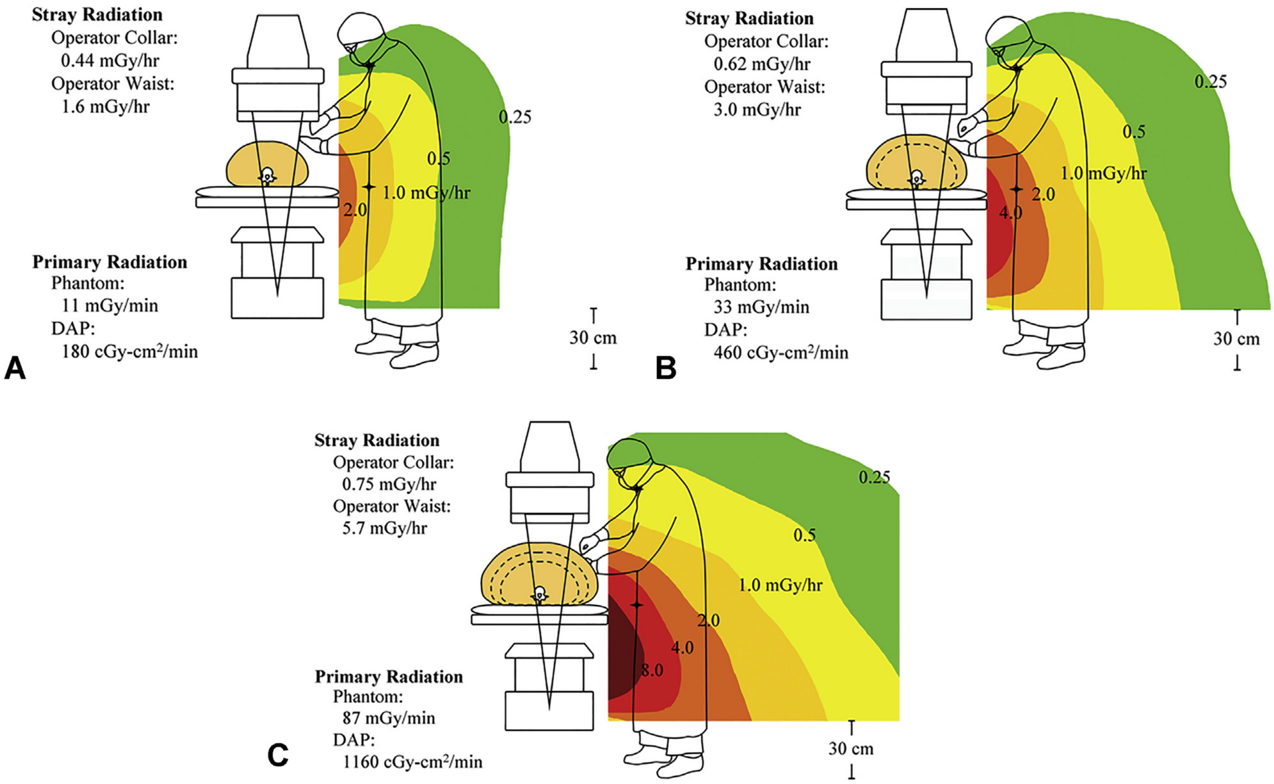

Figure 2. The effect of increasing patient abdominal thickness on operator exposure, at abdominal thicknesses of 24 cm (**A**), 29 cm (**B**), and 34 cm (**C**). (Reproduced with permission from Schueler BA, Vireze TJ, Bjarnason H, et al. An investigation of operator exposure in interventional radiology. RadioGraphics 2006;26:1533-41.)

on the shoulders ("gauntlet" style shoulder pads) or hands (leaded gloves) may negatively impact an endoscopist's ability to perform fine motor movements. Thus, properly placed structural (ceiling-mounted), mobile (lead shield on wheels), and equipment-based (lead drape) shielding can reduce up to 90% of scatter radiation.[56,63] In a randomized, double-blind, sham-controlled trial, a lead-equivalent drape around the image intensifier resulted in ≥90% reduction in scatter to both the endoscopist's and the nurse's eyes and neck.[64]

Special patient populations: obese patients, pediatric patients, and women of childbearing age

Other factors being constant, radiation doses are higher for patients with obesity than a patient with a normal body mass index (Fig. 2A-C). A larger body habitus significantly attenuates radiation beams and results in a darker image. The ABC will compensate by increasing the kV peak or mA, which generates more scatter. In a study of coronary angiography procedures, patients with morbid obesity were shown to be associated with a doubling of patient radiation doses compared with patients with a normal body mass index and a 7-fold increase in physician radiation dose because of increased scatter.[65] Optimal collimation to only the region of interest can reduce both the volume of patient tissue irradiated and the amount of scatter to nurses and physicians. In patients with obesity, additional external shielding may also help to decrease the higher levels of scatter radiation.

Pediatric patients, particularly at younger ages, have a stochastic risk (sensitivity to cancer induction by radiation) 3 to 5 times higher than adults.[66] Best practices include exhausting all radiation-sparing options first and then aggressively using inverse-square law, pulsed fluoroscopy, and collimiation and consider using methods of reducing a child's movements (up to and including general endotracheal anesthesia if clinically indicated) to minimize the need for multiple retakes of fluoroscopy images.

For female patients of childbearing age, a pregnancy test should be considered before fluoroscopic procedures to assess the level of risk and to assist with a shared decision, patient-centered model in making a decision of proceeding with ERCP. Shields should be placed above the patient for over-couch systems and below the patient for under-couch systems. Therapeutic ERCP is relatively safe and effective during pregnancy when performed by an experienced endoscopist and optimal during the second trimester of pregnancy. Several case series have reported no increase in birth defects, preterm deliveries, or abortion in pregnant women who undergo ERCP.[67-70] The fetus should be shielded with a radiation protection apron between the x-ray tube and the patient's abdomen. In addition, biliary cannulation with a wire-guided technique and biliary access confirmation by bile aspiration can further reduce radiation exposure.

Pregnancy and the performance of fluoroscopic procedures

Despite data supporting the safety of fluoroscopic procedures, even when pregnant, multiple survey-based studies across other fluoroscopic-based interventional subspecialties (eg, interventional cardiology, interventional radiology, vascular surgery) have repeatedly shown a fear of teratogenic risks of radiation.[71-73] Such concerns may negatively influence otherwise qualified female physicians from pursuing careers in these specialties, whereas fertility risks of radiation exposure may be underappreciated by male physicians.

Although some international countries prohibit the use of fluoroscopy during pregnancy,[74] in the United States, federal law protects the right for pregnant workers to continue performing fluoroscopic procedures and deems the declaration of pregnancy as strictly voluntary.[75] At the time of declaration, the pregnant worker is issued a fetal dosimeter that is worn at the level of the abdomen under the lead apron. A radiation safety officer monitors the monthly dose reading to ensure regulatory fetal dose limits are not exceeded. Report No. 174 by the National Council for Radiation Protection recommends limiting occupational exposure of the fetus to less than 5 mSv (500 mrem) throughout the pregnancy or .5 mSv (50 mrem) per month.

Reproductive and fetal risks of radiation: preconception risks

Occupational radiation exposure can impact both male and female reproductive health. Preconception risks of radiation are defined as potential genetic mutations that can lead to sterility and hereditary effects. Most of what is known of preconception risks is based on animal models and epidemiologic data from survivors of the atomic bombings at Hiroshima and Nagasaki.[76]

Although legitimate concerns exist about occupational fluoroscopy exposure leading to radiation-induced sterility and hereditary effects, this is tempered by our current understanding of radiobiology. Specifically, sterility is a deterministic effect with threshold doses for risks. Thus, in male subjects, annual unshielded occupational exposures below 15 mSv/y (1500 mrem/y) are unlikely to result in testicular effects of radiation.[77] Similarly, for female subjects, epidemiologic studies suggest that cumulative absorbed doses of 12,000 mGy (1200 Rad) before puberty to 2000 mGy (200 Rad) in women of childbearing age are unlikely to result in sterility.[78] These doses are well above the typical lifetime exposure for interventionalists practicing standard shielding.

Hereditary risk (defined as potential genetic disease in offspring resulting from germ cell mutations) is technically a deterministic effect. The UN Scientific Commission on Effects of Atomic Radiation 2001 report estimates the total risk of hereditary effects in humans increases by .41% to .46% per 1000 mGY (100 Rad) of exposure. However, preconception irradiation of either parent's gonads has not been shown to increase cancer or malformations in children.[79] Thus, the 2001 UN Scientific Commission on Effects of Atomic Radiation report has declared that "radiation exposure has never been demonstrated to cause hereditary effects in human populations."[80] Thus, the risks of sterility or hereditary effects appear to be minimal for interventional endoscopists, especially with protective gonadal shields, which reduce gonadal doses up to 98%.[81]

Reproductive and fetal risks of radiation: perinatal risks

The overall perinatal risk to the fetus is determined by the trimester of pregnancy, dose exposure, and actual absorbed dose. Deterministic risks, those associated with a threshold dose, are the primary drivers of perinatal risks and are strongly dependent on the stage of gestation (Table 5).

There is a known risk of embryonic demise because of radiation exposure before implantation; however, this is not well quantified. The underlying rates of miscarriage during this time period are difficult to measure, given women are often not aware of the pregnancy at this stage. At doses under 100 mGy (10 Rad), embryonic demise 0 to 8 days before implantation is believed to be very rare.[80] After implantation, the risk of malformation because of radiation exposure is greatest during organogenesis (weeks 2-8) with a threshold of approximately 100 mGy (10 Rad). Between 8 and 15 weeks, the risks include growth retardation, severe mental disability, and microcephaly. After 16 weeks, the primary risk is decreased intelligence quotient.

The stochastic risk associated with perinatal radiation exposure, which does not have a threshold dose, increases childhood cancer risk. The estimated excess absolute risk for childhood cancer is approximately 6% per 1000 mGy (100 Rad) of fetal radiation exposure. These risks are in the context of direct exposure to the radiation beam for a continuous length of time without wearing personal protective equipment. As described earlier, the endoscopist is not exposed to the direct beam but exposed to scatter radiation, most of which is attenuated by a lead apron. Based on exposure data for interventional radiologists, the average exposure to a pregnant interventional radiologist during a 40-week pregnancy wearing double lead is approximately 30 mrem (.3 mSv), well below the occupational fetal dose limit of 500 mrem (5 mSv).[75] According to a conservative model from the National Council of Radiation Protection, for a fetus exposed to 50 mrem (.5

TABLE 5. Deterministic effects at each gestation with threshold doses[83]

Radiation effect	Gestation (wk)	Threshold dose (mGy)	Threshold dose (Rad)
Embryonic death	3-4	100-200	10-20
Major malformations	4-8	250-500	25-50
Growth retardation	4-8	200-500	20-50
Irreversible whole body growth retardation	8-15	250-500	25-50
Severe mental disability	8-15 >16	60-500 >1500	6-50 >150
Microcephaly	8-15	>20,000	>2000
Decrease in intelligence quotient	>16	>100	>10

mSv) in utero, the probability of live birth without malformation or cancer is reduced from 95.93% to 95.928%.[82]

PROMOTING RADIATION SAFETY AND QUALITY IN GI: NOW AND IN THE FUTURE

Medical radiation exposure in the United States has increased dramatically over the past 3 decades because of increased use of radiologic studies and radiation-based therapies.[83,84] Additionally, depending on case complexity, some interventional fluoroscopy procedures generate radiation levels even greater than that from abdominal CTs.[85] Thus, formal radiation safety training and ongoing quality audits are 2 cornerstones of radiation protection of both patients and staff. Although the diagnostic radiology and interventional cardiology communities have implemented radiation safety programs and guidelines to the training curriculum,[86-90] no such equivalent is currently in place for the interventional endoscopy community. In 1 recent survey among therapeutic endoscopy fellows, 91.7% of respondents believed that formal education to operate their hospital's fluoroscopy system and to reduce radiation exposure would have been beneficial, yet 78.6% reported they had received no such formal training and did not know how to modulate settings to reduce radiation doses.[8] Consequently, therapeutic endoscopy fellows are generally unaware of their state's fluoroscopy licensing requirements (57.1%).[8] This is not simply an American problem: A recent survey of 107 British ERCP physicians (58 trainees and 49 attendings) revealed that less than half of respondents routinely wore protective eye shields, and almost one-fourth of trainee respondents did not routinely wear thyroid shields.[91]

Despite the rudimentary state of radiation safety training for interventional endoscopists in the United States, there is a path forward. In addition to this document, the European Society of Gastrointestinal Endoscopy has released guidelines for the use of fluoroscopy during endoscopic procedures.[33] One study also demonstrated that even a brief 20-minute educational program on minimizing radiation by optimizing the fluoroscopy settings (image frame rate, magnification, and collimation) resulted in a marked decrease in ERCP-associated radiation exposure.[92] Furthermore, participation in a formal registry such as the American College of Radiology's Dose Index Registry (which collects radiation dose data from various institutions, allowing them to compare a facility's radiation utilization with the national averages) may help encourage the practicing endoscopist to exercise ALARA in flurosocopy procedures.[86,89,93,94] As the field of endoscopy continues to expand, it is conceivable that interventional gastroenterology will emulate other medical specialties (ie, interventional cardiology) in requiring formal training and certification in radiation safety.[95]

The widespread availability of EUS and MRCP has largely eliminated the role of diagnostic ERCP. Excitingly, new technology that uses artificial intelligence (AI) may help further reduce exposure to the patient and personnel in the room. At the time of writing, there is currently one AI-incorporated fluoroscopy (AIF) system on the market (FluoroShield; Omega Medical Imaging, Sanford, Fla, USA). The AIF system minimizes radiation exposure through a secondary collimator by constantly adjusting the shutter's leak blade orientation to block radiation to the area outside of the region of interest. The secondary collimator reduces radiation exposure to the patient by further reducing radiation that passes through the aperture of the primary collimator. The secondary collimator shutter's blades are controlled by an automatic region of interest processor that includes AI technology. The first study to evaluate this technology showed that radiation exposure to patients was significantly lower for the AIF system compared with the conventional fluoroscopy system. The radiation scatter was 59.4% less for the AIF system as compared with the conventional fluoroscopy system.[96] This is an important incremental development in the field, and it is anticipated that other fluoroscopy manufacturers will release their version of AIF-based systems in the future.

TABLE 6. Top 10 “best practices” in radiation protection of patients and staff

Distance	• Inverse-square law: standing 3 times away from the source lowers the amount of scatter 9 times. Raising the patient table AWAY from the x-ray source and TOWARD the image intensifier has the same effect.
Time	• Pulsed fluoroscopy (eg, 7.5 frames per second) and short taps of the fluoroscopy pedal are cornerstones of reducing unnecessary radiation to the patient and staff. For instance, standard choledocholithiasis cases can be completed in as little as .2 min of fluoroscopy time.
Shielding	• .5-mm lead equivalent aprons attenuate over 95% of radiation scatter in most clinical situations. • Two-piece apron designs shift 50% of the weight to the hip, thereby reducing low back pain. • Collimation improves image quality and reduces entrance skin dose to the patient, which in turn reduces scatter to the physicians and staff.
Gantry angle	• Perpendicular positioning of the x-ray beam relative to a prone or supine patient (ie, up or down) always results in the lowest radiation dose to the patient and staff. Excessive angulation may result in up to 10× more radiation exposure.
Magnification	• For each level of magnification, dose rates are increased by up to a factor of 4.
Other considerations	• Document in procedure reports the dosimetry metrics that important to staff (mGy, fluoroscopy time) and patients (Kerma Area Product or dose area product). Periodic quality control audits are advised. • Scatter is ALWAYS highest on the side of the x-ray tube. This is an important consideration for over-couch systems (eg, off-site procedures using urology service C-arms). • Take proper care of your lead. To prevent microscopic cracks, do not throw the lead into a crumpled/folded pile after use. Ensure your lead undergoes annual safety inspection (eg, radiographic inspection by the radiation safety officer).

CONCLUSION

All endoscopists should be familiar with basic principles of radiation safety, including its 3 pillars of distance, time, and shielding. To ensure that all interventional endoscopists are fully educated in the importance of these factors, a formalized curriculum should be developed to maximize safety and image quality while minimizing risks of exposure to x-rays. Because of a lack of standardization at a regulatory and equipment level, the implementation of best safety practices is especially critical for individual interventional endoscopy teams who must understand their local factors at play (ie, fluoroscopy machines, room setups, etc) to reduce radiation scatter and cumulative dose. Endoscopists today must also recognize that 99% of scatter can be attenuated with cutting-edge, lightweight lead-equivalent aprons and help to advocate for updated and adequate protective wear for all personnel involved in procedures. At this time, it has been determined that with proper protection (including 2-piece aprons) and techniques, female physicians can safely perform ERCP throughout pregnancy, with no evidence of genetic malformations or cancer risks to the fetus.

As the interventional endoscopy field continues to advance, the science and knowledge of radiation protection will continue to evolve, as evidenced by AI-enhanced collimation and other scientific advances. Additionally, radiation-sparing modalities are evolving, such as those in endovascular catheterization procedures, where magnetically assisted remote control catheters under real-time magnetic resonance imaging are being studied as a superior navigational aid that does not require fluoroscopy.[97] Thus, it is conceivable that fluoroscopy usage may be severely curtailed at some point in the future, even for complex interventional endoscopy. Until then, a compendium of current “best practices” in radiation safety is listed in Table 6. The goal of this article is to demystify radiation safety for the interventional endoscopy community, for the protection of everyone performing and receiving these lifesaving procedures.

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Abbreviations: ABC, automatic brightness control; AI, artificial intelligence; AIF, artificial intelligence–incorporated fluoroscopy; ALARA, as low as reasonably achievable.

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SUPPLEMENTARY TABLE 1. State by state requirements for fluoroscopy licensure, as of December 19, 2020

State	Physician education requirements	Examination requirement for physicians*	Physician fluoroscopy licensure requirements	State regulation†	Website
Alabama	Fluoroscopy-specific training in ACGME training programs (at least 4-8 h)	No	No licensure of x ray equipment operators	AAC 420-3-26-.06	http://www.alabamaadministrativecode.state.al.us/JCARR/JCARR-AUG-14/HLTH%20420-3-26-.06.pdf
Alaska	Fluoroscopy-specific training (minimum 10 hours)	No		7 AAC 18.420	https://casetext.com/regulation/alaska-administrative-code/title-7-health-and-social-services/part-2-public-health/chapter-18-radiation-sources-and-radiation-protection/article-4-use-of-radiation-sources-in-the-healing-arts/section-7-aac-18420-instruction-of-medical-radiation-device-operators
"	"	"	"	House Bill 29, Chapter 89, article 1, Sec 08.89.100(b)(1)	https://www.akleg.gov/basis/Bill/Text/29?Hsid=HB0029A
Arizona	.	No	.	9 AAC 7 R9-7-603	https://apps.azsos.gov/public_services/Title_09/9-07.pdf
Arkansas	6 h continuing education per year	No	.	ACA §17-106-111	https://www.sos.arkansas.gov/uploads/rulesRegs/Arkansas%20Register/2004/jun_2004/007.14.04-001.pdf
"	"	"	"	"	https://www.healthy.arkansas.gov/programs-services/topics/frequently-asked-questions-radiologic-tech
California	10 CE credits every 2 y; 4 of 10 credits in radiation safety for clinical uses of fluoroscopy	Yes	Yes; California supervisor and operator permit	17 CCR 30403(b)	https://www.cdph.ca.gov/Programs/CEH/DRSEM/Pages/RHB.aspx
Colorado	Written documentation of adequate training	No	.	CCR 1007-1, part 2, part 6	https://www.colorado.gov/pacific/sites/default/files/HM_xray-interp-operation-of-fluoroscopy-equipment.pdf
Connecticut	.	No	.	.	https://www.cga.ct.gov/current/pub/chap_370.htm
Delaware	.	No	.	Delaware Administrative Code Title 16, 4465 5.13.1.1	https://regulations.delaware.gov/AdminCode/title16/Department%20of%20Health%20and%20Social%20Services/Division%20of%20Public%20Health/Health%20Systems%20Protection%20(HSP)/4465.shtml
District of Columbia	.	No	No licensure of x ray equipment operators	.	https://dchealth.dc.gov/service/physician-licensing
Florida	.	No	.	Title XXXII 468.301-302	http://www.floridahealth.gov/environmental-health/radiation-control/radtech/radtech-faq.html
Georgia	.	No	No licensure of x ray equipment operators	.	https://medicalboard.georgia.gov/initial-physician-licensure
Hawaii	.	No	.	.	https://cca.hawaii.gov/pvl/boards/medical/application_publication/

(*continued on the next page*)

SUPPLEMENTARY TABLE 1. Continued

State	Physician education requirements	Examination requirement for physicians*	Physician fluoroscopy licensure requirements	State regulation†	Website
Idaho	.	No	No licensure requirements for any x-ray professionals	.	https://bom.idaho.gov/BOMPortal/BoardAdditional.aspx?Board=BOM&BureauLinkID=930
Illinois	.	No	.	420 ILCS 40/5	https://www.ilga.gov/legislation/ilcs/fulltext.asp?DocName=042000400K5
Indiana	.	No	.	410 IAC 5.2-2-1	http://ai.org/isdh/files/radiology_rule.pdf
Iowa	n/a	No	.	IAC Ch 41 appendix C	https://idph.iowa.gov/radiological-health/healing-arts
Kansas	.	No	.	.	https://www.kdheks.gov/radiation/10cfrpart36.html
Kentucky	.	No	.	.	https://kbml.ky.gov/physician/Pages/Apply-For-License.aspx
Louisiana	.	No	.	LA Rev Stat § 37:3213b	https://www.lsrtbe.org/wp-content/uploads/CHAPTER-45-LRS-37-3200-3221-8-1-20142.pdf
Maine	.	No	.	MRS Title 32, Ch 103 §9854.2	https://www.mainelegislature.org/legis/statutes/32/title32ch103.pdf
Maryland	4 h of initial training; 1 h continuing education every 24 mo	No	.	COMAR F.5(n)(2)	https://mde.maryland.gov/programs/Air/RadiologicalHealth/Documents/www.mde.state.md.us/assets/document/air/RH_comar/regs_final_new.pdf
Massachusetts	Trained in fluoroscopy safety	No	.	105 CMR 120.405	https://casetext.com/regulation/code-of-massachusetts-regulations/department-105-cmr-department-of-public-health/title-105-cmr-120000-the-control-of-radiation/recordkeeping-requirements/section-120405-fluoroscopic-x-ray-systems
Michigan	.	No	.	.	https://www.michigan.gov/leo/0,5863,7-336-94422_11407_35791-46761–,00.html
Minnesota	.	No	.	Minnesota Administrative Rule 4732.0825	https://www.revisor.mn.gov/rules/4732.0825/
"	"	"	"	"	https://www.health.state.mn.us/communities/environment/radiation/docs/xray/4732info/influoroop.pdf
Mississippi	.	No	.	.	https://www.msbml.ms.gov/sites/default/files/07-2017Administrative%20Code.pdf
Missouri	.	No	No licensure of x ray equipment operators	.	https://health.mo.gov/safety/radprotection/pdf/xray-operator-requirements.pdf
Montana	.	No	.	.	http://boards.bsd.dli.mt.gov/Portals/133/Documents/med/CHECKLISTS/MED-PHYS-APP_License-App-Checklist.pdf?ver=2018-06-21-094617-420
Nebraska	.	No	.	Nebraska Revised Statute 38-1915	https://nebraskalegislature.gov/laws/statutes.php?statute=38-1915

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SUPPLEMENTARY TABLE 1. Continued

State	Physician education requirements	Examination requirement for physicians*	Physician fluoroscopy licensure requirements	State regulation†	Website
Nevada	.	No	.	NRS 653.640	https://www.leg.state.nv.us/NRS/NRS-653.html
New Hampshire	.	No	.	Title XXX Chapter 328-J:25	http://www.gencourt.state.nh.us/rsa/html/XXX/328-J/328-J-mrg.htm
New Jersey	.	No	.	.	https://www.state.nj.us/dep/rpp/tec/index.htm
New Mexico	.	No	.	NM Code R § 20.3.20.100	http://164.64.110.134/parts/title20/20.003.0020.html
New York	.	No	.	.	https://www.health.ny.gov/environmental/radiological/faqs/radhlthtech.htm
North Carolina	.	No	No licensure of x ray equipment operators	.	https://www.ncleg.gov/BillLookup/2013/S390 (no update after first read)
"	"	"	"	"	https://webservices.ncleg.gov/ViewBillDocument/2013/3435/0/DRH30339-LUfqq-68 (no update after first read)
North Dakota	.	No	.	ND Cent Code § 43-62-03	https://www.legis.nd.gov/cencode/t43c62.pdf
Ohio	.	No	.	Ohio Revised Code § 4773.02	https://codes.ohio.gov/orc/4773.02
Oklahoma	.	No	No licensure of x ray equipment operators	.	https://pay.apps.ok.gov/medlic/licensing/app/menu.php
Oregon	All operators need proper training in fluoroscopy; nonradiologists need collaboration with medical physicist or radiologist for education program and annual quality audits	No	.	OAR 333-106-0205(2)-(4)	https://secure.sos.state.or.us/oard/viewSingleRule.action?ruleVrsnRsn=273498
Pennsylvania	Fluoroscopy training; continuing education every 2 y (high-risk procedures); every 4 y (low-risk procedures)‡	No	.	25 PA Code § 221.16	http://www.pacodeandbulletin.gov/Display/pacode?file=/secure/pacode/data/025/chapter221/s221.16.html&d=reduce
Rhode Island	.	No	.	.	https://health.ri.gov/licenses/detail.php?id=200
South Carolina	.	No	.	South Carolina Code 44-74-40	https://www.scstatehouse.gov/code/t44c074.php
South Dakota	.	No	No licensure of x ray equipment operators	.	http://www.sdbmoe.gov/
Tennessee	.	No	.	Tennessee Public Chapter 1029 (Senate Bill 899), Section 1, (d)(1)	https://www.tn.gov/content/dam/tn/health/documents/pc1029.pdf

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SUPPLEMENTARY TABLE 1. Continued

State	Physician education requirements	Examination requirement for physicians*	Physician fluoroscopy licensure requirements	State regulation†	Website
Texas	Mandatory requirements for radiation safety awareness training indefinitely suspended (as of 1/13/2015)	No	.	TAC 289.227	https://www.dshs.texas.gov/radiation/laws-rules.aspx
Utah	.	No	.	UT Code § 58-54-102	https://le.utah.gov/xcode/Title58/Chapter54/C58-54_1800010118000101.pdf
Vermont	.	No	.	.	https://www.healthvermont.gov/sites/default/files/documents/pdf/BMP_Board%20Rules%20Effective%202017.pdf
Virginia	.	No	.	.	https://www.dhp.virginia.gov/medicine/medicine_forms.htm#MedicineandSurgery
Washington	.	No	.	.	https://wmc.wa.gov/licensing/applications-and-forms/physician-md-application
West Virginia	.	No	.	.	https://wvbom.wv.gov/practitioners/MD/index.asp
Wisconsin	.	No	.	Wis. Stat. § 462.02(2)(a)	https://docs.legis.wisconsin.gov/statutes/statutes/462
Wyoming	.	No	.	.	https://radiology.wyo.gov/

CE, Continuing education; h, hour(s); n/a, not applicable; y, year(s).
Same as above line (Alaska, Arkansas, Minnesota, North Carolina)
*Some states may accept ARRT (American Registry of Radiologic Technologists) exams.
†It is important for the reader to confirm the medical board of a respective state for updated information. Also, the 110th session of the U.S. Congress passed a House resolution "Medicare Improvements for Patients and Providers Act of 2008" (H.R. 6331), which establishes an accreditation requirement for advanced diagnostic imaging services. https://www.congress.gov/bill/110th-congress/house-bill/6331.
‡High-risk procedure = any procedure that may result in skin dose exceeding 200 rad (2 Gy); low-risk = any radiographic procedure that does not result in such doses.
. = No data.