

Fluoroscopy: Regulation and Radiation Protection



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Fluoroscopy: Regulation and Radiation Protection

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Fluoroscopy is used in a variety of different settings, including operating rooms, interventional departments, cardiac catheterization suites, pain management clinics and orthopedic centers. Fluoroscopic procedures can expose patients and personnel to high levels of radiation, an area of public and regulatory concern. Radiologic technologists, radiologist assistants and other professionals operating fluoroscopic units or assisting in fluoroscopic procedures are legally and ethically responsible for operating equipment safely and taking proper radiation protection measures. One way of fulfilling this responsibility is to understand the federal and state regulations regarding fluoroscopy and to be conscious of public awareness initiatives concerning radiation exposure during medical imaging procedures.

After completing this article, readers should be able to:

- Describe international advisory groups that have studied and created radiation protection standards.
- Summarize the function of the various federal and state agencies that standardize radiation protection practices.
- Discuss the federal laws and regulations that govern fluoroscopy and radiation protection of patients and personnel.
- Explain the significance of the CARE (Consistency, Accuracy, Responsibility and Excellence in Medical Imaging and Radiation Therapy) bill in relation to radiation safety practices.
- Describe various radiation dose reduction practices in fluoroscopy.
- Discuss the regulation and education of fluoroscopy operators.
- Discuss various radiation safety awareness campaigns and their audiences.

International, federal and state agencies have been involved in establishing radiation protection practices since the early 1900s.¹ Over time, excessive radiation from appliances such as televisions and microwave ovens has become a thing of the past, and regulatory agencies have turned their focus on equipment that produces ionizing radiation and reducing the radiation dose from that equipment.¹ The United States works in conjunction with numerous international organizations to protect the public and radiation workers from the effects of ionizing radiation.²⁻⁵ Statutory rules have been established for nuclear power plants, radionuclide management, the manufacture of electronic products and the handling of nuclear contamination.^{2,6} With respect to medical imaging equipment, design standards have been established at the national level, but medical imaging personnel are licensed primarily by the individual

states.^{4,7,8} Today, medical imaging equipment is capable of emitting higher levels of radiation for longer periods of time and is used by a variety of practitioners on more patients for different types of procedures.¹ For the most part, fluoroscopy operators can be assured that their equipment meets federal and state regulations if there is an inspection sticker on the radiographic unit. Medical imaging personnel who operate fluoroscopy units are ethically and legally responsible for using equipment safely and for minimizing radiation exposure. In addition, fluoroscopy operators and other staff involved in fluoroscopic procedures should be qualified under the national and state regulations.

Organizations and Agencies

Congressional acts or state mandates have established radiation exposure limits and equipment specifications based on international recommendations,^{7,9-11} and

federal and state agencies are responsible for enforcing those regulations and standards established by law.⁹ Because numerous international and national agencies have played a role in developing radiation protection guidelines and recommendations, the vast amount of documents and regulations can be overwhelming to read and understand.⁹ In addition, the various advisory groups and regulatory agencies usually are referred to by an array of abbreviations and acronyms. However, to adequately understand radiation protection and safety, imaging professionals must be familiar with various agencies and organizations and be aware of recent concerns regarding radiation exposure. Increased use of fluoroscopy-guided procedures — and the resulting radiation dose — is an example of current national concern.¹

International Organizations

International advisory groups that have studied and created radiation protection standards include the:

- International Commission on Radiological Protection (ICRP).
- International Commission on Radiation Units and Measurements (ICRU).
- United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR).
- World Health Organization (WHO).
- International Atomic Energy Agency (IAEA).^{2,9-11}

The International Commission on Radiological Protection (ICRP) is considered the international authority regarding the safe use of ionizing radiation.⁹ The ICRP is an independent registered group that provides recommendations and guidance on all aspects of ionizing radiation protection.³ Functioning as an advisory body, it consists of a main commission and 4 standing committees. The committees focus on radiation effects, radiation exposure, radiation protection in medicine and the application of ICRP recommendations.^{3,9}

The ICRP has published reports since 1928, and in 1959 the committee began to develop its own series of publications. From 1977 onward, the commission published *Annals of the ICRP*, which contains information about ICRP activities.⁹ Although the ICRP has no formal enforcement power, most countries adhere closely to ICRP recommendations when developing and enforcing their own regulations.³ Two ICRP reports, Publication 26 (1977) and Publication 60 (1990) provide the basis for

regulations and recommendations not only in the United States and Canada but also in other countries.¹¹

Established in 1925, the International Commission on Radiation Units and Measurements (ICRU) ensures consistent reporting of data and information on radiation risks and protection. The ICRU primarily deals with radiation quantities, units and measurement techniques, and is responsible for the development of radiation units such as the sievert, gray and roentgen per kilogram.¹¹

The United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) provides information to the ICRP for evaluation. UNSCEAR develops radiation risk assessments from epidemiological data and research, and issues reports concerning the risks associated with radiation.^{9,11}

The World Health Organization (WHO) is a specialized agency of the United Nations. WHO acts as a coordinating authority for health concerns within the United Nations system, providing leadership on global health issues.¹²

The International Atomic Energy Agency (IAEA) is an international organization that seeks to promote the peaceful use of nuclear energy and to inhibit its use for military purposes.¹³

Federal Organizations

In the United States, a number of organizations function as advisory groups or regulatory agencies for radiation protection standards, including the:

- Nuclear Regulatory Commission (NRC).
- National Council on Radiation Protection and Measurements (NCRP).
- U.S. Food and Drug Administration (FDA).
- Environmental Protection Agency (EPA).
- Occupational Safety and Health Administration (OSHA).
- National Research Council, Committee on the Biological Effects of Ionizing Radiation (NRC-BEIR).
- National Institutes of Health (NIH).⁹⁻¹¹

The ICRP and NCRP recommend effective dose limits for radiation workers based on reports from UNSCEAR and NRC-BEIR.^{9,11} Legal dose limits have been set for the radiation dose received per year or accumulated over a working lifetime by occupationally exposed individuals. There are no dose limits for medical exposure of patients.¹¹

Levels of ionizing radiation formerly considered acceptable by the ICRP have been revised downward.⁹ In 1991 the ICRP recommended reducing the annual effective dose limit for occupationally exposed individuals from 50 mSv to 20 mSv as a result of new information from studies of Japanese bomb survivors.⁹ The NCRP is still considering reducing exposure standards but currently recommends an annual effective dose limit of 50 mSv for radiation workers.^{9,11} National and state agencies are responsible for enforcing radiation protection standards established by the NCRP through legislative mandates.^{9,10}

NRC and NCRP

The NRC was charged by Congress with protecting people and the environment from unnecessary exposure to radiation as a result of civilian uses of nuclear materials. The NRC focuses on regulations pertaining to nuclear power plants, research reactors and the storage of radioactive materials. With respect to nuclear medicine, the NRC establishes dose limit guidelines, licensing requirements and rules for the safe use of radioactive materials. The NRC does not regulate or inspect x-ray imaging facilities.⁴

A group of American scientists, the National Advisory Committee on X-Ray and Radium Protection, established the first dose-limiting recommendations 46 years after Roentgen discovered x-rays.⁵ In 1964 the group was chartered by Congress (Public Law 88-376) as the National Council on Radiation Protection and Measurements. The role of the nonprofit NCRP is to advise federal and state regulators on issues concerning radiation protection.¹¹ To fulfill its mission, the council collects, analyzes and distributes information and regulations about radiation protection, quantities and measurements.^{5,10} The group also enters into written agreements with state governments permitting the state to license and regulate the use of radioisotopes and certain other materials within that state.⁹

The NCRP has developed more than 150 scientific reports, and its rules and regulations are published in Title 10 of the U.S. Code of Federal Regulations.^{5,9} In 2009 the NCRP completed a draft report, "Radiation Safety Issues for Image-Guided Interventional Medical Procedures." The purpose of the report was to review the existing literature on image-guided medical procedures and evaluate the most common high-dose procedures

with regard to radiation dose and safety issues. The final report will provide recommendations for imaging protocols, managing procedure time, radiation protection equipment including dose-reduction features, tracking patient and staff dose, and credentialing criteria for equipment operators.¹⁴ The NCRP also is concerned with computed tomography (CT) dose. Imaging professionals are responsible for being familiar with the most current NCRP reports and recommendations.

FDA

The FDA is generally considered an agency that regulates food and drugs. However, in 1968 the Radiation Control for Health and Safety Act (Public Law 90-602) created the Center for Devices and Radiological Health (CDRH) and extended the FDA's role to include issues related to radiation protection.^{1,10} Under this law, the FDA regulates the design and manufacture of electronic products and medical devices including diagnostic x-ray equipment.⁹ Public Law 90-602 ensures that the public is protected from the hazards of unnecessary radiation exposure.⁹

The CDRH oversees consumer, industrial and medical products that emit electromagnetic radiation. In the early years, the CDRH focused on standards related to electronic products such as televisions and microwave ovens. However, with the standardization of equipment manufacturing, concerns about consumer products have decreased. The FDA now regulates radiopharmaceuticals and the performance and radiation safety of commercial x-ray equipment.¹⁰ The agency has the authority to deny the sale of equipment, inspect facilities, issue fines and revoke radiation use authorizations.¹⁰

The FDA has focused on areas in which the risk of radiation exposure is greatest and which have the greatest potential to improve public health and safety, such as dose-intensive procedures associated with CT and fluoroscopy.¹ Skin burns caused by fluoroscopic radiation exposure are uncommon but can cause considerable distress to the patient. The injuries often lead to deep ulcers requiring skin grafts.¹⁵

Some degree of radiation-induced trauma is to be expected during radiation therapy because of high levels of radiation exposure; however, the frequency and seriousness of these injuries may be surprising. In addition,

radiation therapy patients often undergo image-guided procedures that require long fluoroscopic exposure times. A recent article in *The New York Times* regarding radiation injuries noted that in 2009 the nation's largest wound care company treated 3,000 radiation injuries. Jeff Nelson, president and chief executive of Diversified Clinical Services, said that "most of the radiation injuries were serious enough to require treatment in hyperbaric oxygen chambers, which utilize pure pressurized oxygen to promote healing."¹⁶ However, even though radiation-induced trauma occurs during radiation therapy, the fluoroscopy equipment used for treatment planning is exempt from most FDA performance standards.¹⁷

The number of CT examinations performed in this country is a major concern for the FDA, especially if many of these procedures are repetitious or unwarranted. A 2009 *New England Journal of Medicine* article reported that imaging procedures are a major and growing source of ionizing radiation exposure in the United States and can result in high cumulative radiation doses.¹⁸ According to the article, CT and nuclear imaging procedures accounted for 75.4% of the cumulative effective dose to the 952,240 patients studied; interventional procedures were the third greatest source of medical radiation exposure.¹⁸ The report created a certain amount of public anxiety by predicting that 2,500 cancer deaths a year could result from the high number of CT procedures.¹⁹ No scientific evidence is available to support this prediction, but there appears to be a justifiable concern about radiation exposure from CT exams and fluoroscopy-guided procedures.²¹

EPA and OSHA

The EPA was established in 1970 by President Richard M Nixon. The agency facilitates the development and enforcement of regulations pertaining to the control of radiation in the environment. It has the authority for specific areas such as determining the action level for radon.¹⁰

OSHA is a monitoring agency with regard to hazards in the workplace. Part 1910 of Title 29 of the U.S. Code of Federal Regulations (29 CFR 1910) regulates occupational exposure to radiation and mandates an employee's "right to know" about possible workplace dangers. The act covers hazardous substances, infectious agents, and ionizing and nonionizing radiation.¹¹

NRC-BEIR

The National Research Council Committee on the Biological Effects of Ionizing Radiation (NRC-BEIR) is an advisory group that reviews studies concerning the biological effects of ionizing radiation and risk assessment.¹⁰ The committee has published 7 reports concerning radiation health effects known as the BEIR reports. BEIR V, "Health Effects of Exposure to Low Levels of Ionizing Radiation," was published in 1990. The report was significant in that it stated the risks of radiation are 3 to 4 times greater than had been previously estimated.²¹ After publication of BEIR V, the ICRP revised its recommendations, reducing the annual allowable dose for radiation workers.¹¹ The BEIR VII report was completed in 2006 and is the most up-to-date and comprehensive risk estimate for cancer and other health effects from exposure to low-level ionizing radiation.²¹ The report is one of the first scientific publications to include detailed estimates for cancer incidence in addition to cancer mortality. The data in the report supports the linear nonthreshold risk model. This model presumes that the risk of cancer is directly proportional to the dose and that there is no threshold for exposure. In other words, the smallest radiation exposure has the potential to cause a small increase in risk to humans.²¹

NIH

The National Institutes of Health, (NIH) is a part of the U.S. Department of Health and Human Services, and is the primary federal agency responsible for conducting and supporting medical research in the United States. Composed of 27 institutes and centers, NIH invests more than \$28 billion annually to fund research at hospitals, universities and medical schools. Current NIH efforts include medical research related to Alzheimer disease, potential agents of bioterrorism, improved imaging techniques, vaccines, precise ways to treat cancer and the causes of outbreaks of infectious diseases such as severe acute respiratory syndrome.²²

The NIH can influence regulations and practices related to imaging equipment. For example, when NCRP statistics showed that Americans received 7 times more medical radiation in 2006 than in the 1980s, the NIH established a series of steps to improve the tracking of patients' exposures. The Radiology and Imaging Sciences Department of the NIH Clinical Center

Table 1

States With Licensure, Certification or Recognition Standards by Discipline or Practitioner⁸

Discipline or Practitioner	Number of States
Radiography	39
Radiation therapy	33
Limited x-ray machine operator	31
Nuclear medicine	27
Radiologist assistant	26
Fusion imaging	11
Cardiovascular	6
Mammography	5
Magnetic resonance	3
Computed tomography	3
Sonography	2
Fluoroscopy only	1

requires vendors to include radiation dose-tracking technology as part of the equipment it purchases. The new technology is the first step toward developing a standard that can be used by health care facilities nationwide.²³

The new dose-tracking policy began with CT and positron emission tomography (PET)-CT scanners. Standard reporting algorithms allow data to be entered and stored in a radiology information system or hospital-based electronic medical record.²³

Agreement States

Individual states can enter into an agreement with the NRC to assume responsibility for enforcing radiation protection regulations through their health departments. Agreement states also can formulate their own regulations regarding radiation safety, including the licensing criteria for radiography and fluoroscopy operators.¹⁰ Currently, 5 states (Alabama, Idaho, Missouri, North Carolina and South Dakota) and the District of Columbia have no formal licensing standards.⁸ Table 1 shows the state professional licensing categories and number of states that specify standards for various radiologic technology disciplines and practitioners.

Imaging professionals are responsible for obtaining the appropriate license to practice radiography or other modalities in an agreement state.

Federal Laws and Regulations

Imaging professionals must be familiar with various federal regulations that pertain to protecting patients, personnel and the public from ionizing radiation exposure. Radiologic technologists also should have an active interest in events occurring on Capitol Hill that relate to the profession.

Numerous federal guidelines and recommendations for dose management have been formulated over the years and relate directly to fluoroscopy. At this time, the Radiation Control for Health and Safety Act of 1968 and the Consumer-Patient Radiation Health and Safety Act of 1981 are the most significant.¹¹ The Consistency, Accuracy, Responsibility and Excellence in Medical Imaging and Radiation Therapy (CARE) bill could potentially have the most effect on who is authorized to operate medical imaging and radiation therapy equipment.²⁴

Radiation Control for Health and Safety Act

In 1968 the U.S. Congress passed Public Law 90-602, the Radiation Control for Health and Safety Act. The law was enacted to protect the public from the hazards of unnecessary radiation exposure from electronic products such as color televisions, microwave ovens, electronic equipment used in high school and college science classes and diagnostic x-ray equipment.^{9,25} Before 1968 state and local governments regulated radiation-emitting electronic devices. However, in 1967 the voluntary recall of 90,000 General Electric television sets believed to emit dangerous levels of radiation raised awareness at the national level.²⁵ As a result, the CDRH was established to evaluate radiation emissions from electronic products.^{9,25} The CDRH sets more than 60 performance standards for the manufacture, installation, assembly and maintenance of radiological equipment used for diagnostic x-ray procedures.⁹ Public Law 90-602 is strictly a performance standard for equipment and does not specify standards for equipment operators.

Code of Federal Regulations Title 21 – Part 1020

The Code of Federal Regulations Title 21 contains more than 1,300 sections of regulations pertaining to nutrition labels, pharmaceuticals, animal feed, animal medications, cosmetics, cell phones, lasers, controlled substances and medical devices.²⁶ Part 1020 specifically deals with performance standards for ionizing

Box 1

Selected Provisions of CFR Title 21, §1020.32^{7,9,10,17}

Primary protective barrier – limitation of the useful beam. The fluoroscopic imaging assembly should have a primary protective barrier that intercepts the entire cross section of the useful beam at any source-to-image distance (SID). The fluoroscopic tube cannot produce x-rays unless this barrier is in position.

Measuring compliance. Describes how the output from the x-ray tube should be calculated.

Field limitation for image-intensified fluoroscopy. The x-ray field in the plane of the image receptor should not exceed that of the visible area of the image receptor by more than 3% of the SID. On systems that automatically adjust field sizes, an override capability may be provided in case of system failure, but must be clearly labeled.

Activation of the tube. X-ray production must be controlled by a device that requires continuous pressure (formerly known as the “dead man’s switch”). When recording serial images, the operator should be able to terminate the exposure at any time.

Entrance exposure rates. Limits fluoroscopic exposure rates. Equipment with an automatic exposure rate control (AERC) is limited to 10 roentgen per minute (R/min) or 2.58×10^{-3} coulomb per kilogram (C/kg) per minute. Equipment without AERC (ie, manual mode) is limited to 5 R/minute or not to exceed 1.29×10^{-3} C/kg per minute. Equipment with both devices is limited to 10 R/minute or 2.58×10^{-3} C/kg per minute. Optional high-level controls can be provided on fluoroscopic equipment, both with and without AERC, but should not exceed 5 R/min or in excess of 1.29×10^{-3} C/kg per minute. The equipment must provide a special means of activating high-level control and a continuous signal audible to the operator should indicate when high-level control is used. The limitations do not pertain to the recording of fluoroscopic images.

Automatic exposure rate control requirement. Fluoroscopic equipment that can operate in excess of 5 R/minute or 1.29×10^{-3} C/kg per minute should be equipped with AERC. The tube limits are exempt when recording images from an x-ray image intensifier tube using photographic film or a video camera when the x-ray source is operated in pulse mode.

Indications of potential and current. During fluoroscopy and cine fluorography, x-ray tube potential and current should be continuously indicated.

Source-to-skin distance. Equipment should have a way to limit the source-to-skin distance to not less than 38 cm on stationary fluoroscopes and to not less than 30 cm on mobile and portable fluoroscopes. Image-intensified fluoroscopes intended for specific surgical applications can operate at shorter source-to-skin distances but never less than 20 cm.

Fluoroscopic timer. Equipment must have a means to track the cumulative on-time of the fluoroscopic tube, and the maximum cumulative time should not exceed 5 minutes without resetting. An audible signal must occur when the 5 minutes are reached and continue until the timing device is reset.

Mobile and portable fluoroscopes. Mobile and portable fluoroscopes should provide intensified imaging.

Fluoroscopic radiation therapy simulation systems. Fluoroscopic units used for radiation therapy simulation are exempt from the regulations in the section.

radiation-emitting products. The provisions of section 1020.32 apply to fluoroscopic imaging equipment or recording images from the fluoroscopic image receptor, except CT x-ray systems manufactured on or after November 29, 1984.²⁷ The most current amended version is dated July 2, 1999. Box 1 contains a sample of Title 21 regulations that pertain to fluoroscopic equipment.

The CDRH is continuously advocating for equipment features to reduce fluoroscopic radiation exposure. A recently published amendment to the x-ray standard for

fluoroscopy systems requires manufacturers to provide a display that indicates exposure rate and the cumulative exposure to the patient.⁷

The role of the CDRH in regulating imaging equipment standards is important to reducing radiation exposure to the patient. However, equipment regulations are not the primary CDRH concern. The new radiation health focus of the CDRH is to promote the philosophy of the American College of Radiology (ACR) that “the right exam is performed for the right reason

Table 2

Consumer-Patient Radiation Health and Safety Act of 1981²⁸

Section	Focus of Section
10001	Statement of findings
10002	Purpose
10003	Definitions of terminology
10004	Promulgation of standards
10005	Model statute for radiologic procedure safety
10006	Compliance
10007	Federal radiation guidelines
10008	Applicability to federal agencies

at the right time.” The CDRH recommends the use of exam-appropriateness criteria, such as the ACR criteria, both for screening patients for exams and for educating referring providers about what exam is appropriate in what circumstance. For example, in some cases, it may be more appropriate to use an alternative examination, such as magnetic resonance (MR) imaging or sonography, to avoid the risks of ionizing radiation. The CDRH also advocates adjusting techniques and protocols not only for the patient’s age and body size, but also for the clinical image quality necessary for the condition being evaluated. Lastly, the CDRH encourages radiologists to educate nonradiologist colleagues performing fluoroscopy about methods to reduce dose and injuries.¹

Consumer-Patient Radiation Health And Safety Act of 1981

The American Society of Radiologic Technologists (ASRT) spearheaded passage of the Consumer-Patient Radiation Health and Safety Act (CPRHSA) of 1981, Title IX of Public Law 97-35.²⁸ Within the framework of the 1981 Act, the federal government set minimum standards for the accreditation of education programs for practitioners who administer radiologic procedures and the certification of these practitioners.^{9,11,28}

The CPRHSA is divided into 8 sections — 42 USC §10001-10008. Table 2 shows the focus of each section.²⁸ The model statute described in section 10005 provides that:

- “It shall be unlawful in a State for individuals to perform radiologic procedures unless such

individuals are certified by the State to perform such procedures; and

- Any educational requirements for certification of individuals to perform radiologic procedures shall be limited to educational programs accredited by the State.”²⁸

In addition to establishing education and certification standards, the CPRHSA was developed to ensure that medical and dental radiologic procedures adhere to safety precautions and standards.⁹ Individual states were encouraged to develop similar statutes and administer certification programs based on the established standards.

Despite the congressional mandate set forth in 1981, not all states have developed licensing laws.¹⁶ There currently is no penalty for noncompliance with the CPRHSA, resulting in a tremendous amount of variation in established laws.^{9,24}

Code of Federal Regulations Title 42 — Part 75

The standards for accrediting educational programs and credentialing radiologic personnel were established in 1985 and are described in Title 42 of the Code of Federal Regulations, Standards for the Accreditation of Educational Programs for the Credentialing of Radiologic Personnel.²⁹ The standards cover the following occupational groups:

- Radiographers.
- Dental hygienists.
- Dental assistants.
- Nuclear medicine technologists.
- Radiation therapists.

An understanding of terminology is important to interpreting the regulations. When applied to an educational program, the term “accreditation” means that a state government, nongovernmental agency or association recognizes a specialized program of study as meeting or exceeding certain established qualifications and educational standards.^{9,29} “Credentialing” indicates any process whereby a state government, nongovernmental agency or association recognizes an individual who meets certain predetermined qualifications. “Licensed practitioner” denotes a licensed doctor of medicine, osteopathy, dentistry, podiatry or chiropractic. The term “licensure” signifies the process by which an agency of the state government grants permission to practitioners meeting predetermined qualifications to engage in an occupation.²⁹

Radiologic science educational programs are accredited by either regional or programmatic accreditation agencies. Programmatic agencies accredit only the specific programs they are authorized to evaluate. The Joint Review Committee on Education in Radiologic Technology (JRCERT), a programmatic agency, accredits radiography, radiation therapy and medical dosimetry programs. Regional agencies, such as the Middle States Association of Colleges and Schools, accredit degree-granting colleges and universities rather than specific educational programs within an institution. Therefore, some educational programs in the radiological sciences are accredited by virtue of their association with the college or university.³⁰

Appendices A through E of Part 75 outline the minimum standards required for the accreditation of educational programs for the occupational groups covered by the regulations.²⁹ The standards include the following areas:

- Description of the profession.
- Sponsorship of the program.
- Instructional facility requirements.
- Clinical education requirements.
- Curriculum structure and length, including designated courses.
- Identifiable financial resources.
- Faculty credentials.²⁹

Accreditation agencies such as the JRCERT further distill the standards to guide the evaluation process, and professional societies such as the ASRT develop the educational curricula.

To be credentialed to practice, graduates of accredited radiologic science educational programs must successfully pass a standardized examination administered by a certification body such as the American Registry of Radiologic Technologists (ARRT). Once an individual passes the certification examination, he or she may be identified by the applicable credentials, such as R.T.(R) for radiographers, R.R.A. for radiologist assistants (RAs) or R.T.(T) for radiation therapists.³⁰

The licensing of medical imaging professionals occurs at the state level. Each state has developed its own set of requirements and allowances for the specific tasks a medical imaging practitioner can perform.⁸ For example, the 2007 Radiography Scope of Practice adopted by the ASRT allows radiographers to assist a licensed independent practitioner with fluoroscopic and specialized interventional radiography procedures and perform

noninterpretive fluoroscopic procedures. However, the ASRT clearly indicates that the professional must have appropriate clinical and didactic education and conform to applicable state statutes and institutional policies.³¹ The Radiologist Assistant Scope of Practice includes operating a fluoroscopic unit and performing studies the radiologist deems appropriate in accordance with supervision guidelines jointly established by the ACR, ASRT and ARRT.³²

CARE Bill

Since 1997 the ASRT and an alliance of more than 25 organizations and 500,000 professionals have pursued educational and certification standards for health care workers who administer radiologic procedures. The most recent version of the CARE bill was introduced in the House of Representatives (HR 3652) on September 25, 2009, and the Senate (S 3737) on August 5, 2010.³³ The purpose of the bill is to amend and enforce the Consumer-Patient Radiation Health and Safety Act of 1981.

During the final vote on CPRHSA, a political bargain was made to ensure the bill's passage and the enforcement mechanism was removed.³⁴ As a result, there are currently no legal enforceable penalties for states that do not comply with education and certification requirements of CPRHSA. The regulations are considered to be "federally recommended guidelines," which has resulted in the lack of comprehensive licensure laws in some states.³⁴

If enacted, the CARE bill would amend CPRHSA and charge the Secretary of Health and Human Services to promulgate updated regulations specifying certification requirements for individuals who perform medical imaging exams and deliver radiation therapy treatments.³⁴ Revised educational standards and credentials are necessary because technology and the medical imaging field have changed substantially since CPRHSA was passed. The CARE bill addresses only nonphysician technical personnel qualifications and does not include physicians, nurse practitioners and physician assistants. Box 2 lists the disciplines that would be included in minimum federal standards under the CARE bill.

In effect, the CARE bill makes the federal education and credentialing standards of CPRHSA enforceable because it sets those standards as a condition for Medicare reimbursement.²⁶ A comparison can be made

Box 2

Practitioners Included in the CARE Bill Standards³⁴

Radiographer
Radiation therapist
Nuclear medicine technologist
Medical dosimetrist
Medical physicist
Magnetic resonance imaging technologist
Sonographer
Radiologist assistant
Cardiovascular-interventional, cardiac-interventional, vascular-interventional technologist
Cardiovascular invasive specialist
Bone density equipment operator
Limited x-ray machine operator

to the Mammography Quality Standards Act (MQSA) of 1992 that established federal standards for mammography. However, the CARE bill differs from MQSA in that it only addresses nonphysician imaging personnel qualifications, whereas MQSA includes facility inspection, quality assurance measures and physician assessment.³⁴

CARE bill advocates argue that the legislation would:

- Decrease medical errors, including misdiagnoses and the misadministration of radiation therapy.
- Ensure the quality of diagnostic images and radiation therapy treatments.
- Decrease health care costs.
- Improve the safety of radiologic procedures.³³

Radiation Dose Reduction in Fluoroscopy

In 1989 the NCRP reported that fluoroscopic examinations result in higher doses to patients than most radiographic procedures. In addition to ensuring fluoroscopy equipment meets current regulations, fluoroscopy operators can use a number of practices to reduce the amount of radiation exposure to the patient and medical personnel. Many of the practices are based on recommendations of various organizations that focus on radiation protection.³⁵ Imaging professionals have the ethical responsibility to ensure they are knowledgeable about fluoroscopic equipment features that increase or decrease dose and to actively educate others who operate fluoroscopy equipment.

High-Level Control Fluoroscopy

During interventional procedures, operators often use the high-level control feature of the fluoroscopy unit. This feature helps to demonstrate small and lower-contrast objects, such as fine catheters, that are not readily seen during standard fluoroscopy.⁹ FDA equipment standards limit the tabletop exposure rate of fluoroscopic equipment to 10 R per minute unless the system has a high-level control feature. In this case, routine fluoroscopy is limited to 5 R per minute when the high-level control is not in use, but has no limit when the high-level control is on.⁹

Patient exposure rates have been estimated to range from 20 to 120 R per minute when using the high-level control.⁹ The higher dose rate improves image quality by reducing quantum noise.²⁴ However, fluoroscopy-guided interventional procedures can potentially deliver a substantial patient dose because the use of the high-level control can increase patient exposure 3 to 4 times that of a standard fluoroscopic procedure. Doses of 40 to 50 R per minute are similar to those delivered by radiation therapy equipment and can potentially cause grave damage.³⁵

On September 30, 1974, the FDA issued a public health advisory alerting health care workers to the dangers of overexposing patients while using the high-level control. Data indicate that 30 minutes of total beam-on time at one location on the patient's skin is sufficient to produce erythema. This effect is not readily apparent and requires up to 10 days to appear.⁹

Reports of radiation-induced skin injuries as a result of interventional procedures include temporary epilation, dry and moist desquamation, dermal necrosis and secondary ulcerations.^{9,23} Patient monitoring, radiation dosimetry and accurate record keeping are important to manage adverse reactions to high levels of radiation exposure during interventional procedures. The FDA recommends documenting any skin dose of 1 to 2 Gy (100-200 rad) and noting the location on the skin with a diagram, annotated photograph or narrative description.⁹

Pulsed Progressive Fluoroscopy

Pulsed fluoroscopy allows the radiation to be distributed in short bursts, or pulses. During pulsed fluoroscopy, the x-ray beam is turned off and on while scanning,

which decreases patient dose.^{9,10} Systems that can pulse the beam at less than 10 pulses per second can result in up to 90% less exposure compared with nonpulsed systems.³⁵ If a fluoroscopic unit is not equipped with automatic pulsing, this technique can be employed manually.

Last-Image Hold Feature

The last-image hold feature of digital fluoroscopy systems is another way of reducing dose.^{9,10} With last-image hold, an image is stored from the last time that the foot switch was depressed and radiation was emitted. This image generally is composed of several frames of information that have been added together to reduce the effect of quantum mottle.⁹

Magnification

Multifield, or magnification, image intensifiers are found in the majority of image intensifiers today.⁹ Image magnification is sometimes needed to view small structures, although image clarity can be compromised. The image clarity is degraded on the television monitor because of a decrease in the magnification gain when fewer photoelectrons strike the output phosphor on the image intensifier.^{9,10}

To maintain brightness on the television monitor, the fluoroscopic milliamperage (mA) is automatically increased, and therefore, the patient dose subsequently increases. The most common commercial tube in fluoroscopic units is the 30- to 15-cm (12- to 6-inch) diameter model.⁹ In this system, the normal viewing mode uses a 30-cm focal point; the 15-cm mode magnifies the image. The change in the focal point of the electrons decreases the field of view, with a corresponding increase in magnification.¹⁰ The change in mA using the magnification mode can double patient dose.³⁵

It is important that fluoroscopy operators understand magnification mode is associated with a significant increase in dose. Magnification mode should only be used when necessary and should not be used as the normal viewing mode. Using collimation in conjunction with the magnification mode can decrease patient dose. Some image intensifiers have interlock devices that automatically collimate when magnifying the image, although this feature is not required by regulation.¹⁰

Image Recording Techniques

The two most common methods for recording fluoroscopic images are cine fluorography and spot-film recording.³⁵ Both techniques capture the image from the output screen of the image intensifier. The photospot camera uses 100-mm cut film or 105-mm roll film. Exposures occur at 6 and 12 frames per second. Cine cameras use 35- or 16-mm film, with film rates of 7.5, 15, 30 and 60 frames per second.^{9,35} Patient dose is higher when using 16-mm film; therefore, the 35-mm format is the most frequently used film in the United States.⁹ With regard to frame rate, as the frequency of the frames increases, the radiation dose increases. Thus, using the 35-mm film with a filming rate of 7.5 frames per second should deliver the lowest dose to the patient. Swallow function studies and cardiac imaging procedures require higher frame rates because they are dynamic functional studies.⁷

Photospot techniques reduce dose by a factor of 5 to 10 compared with cassette-loaded spot films and large-format cassette films.³⁵ Spot films and large-format films require using radiographic exposure technique factors, whereas photospot images are taken from the output screen. Spot image recorders vary in the dose delivered to the patient. Cassettes may require 30 mR per exposure compared with an average of about 10 mR per exposure associated with 105-mm film.¹⁰ Therefore, using photospot images rather than cassette-loaded images decreases patient dose. It has been estimated that each spot image may be equal to more than a minute of fluoroscopy time.¹⁰

Patient dose for cine is significant, and dose reduction techniques are especially important.^{9,10} The high dose for cine is caused by a relatively high inherent dose rate and the length of the imaging procedure.⁹ The minimum exposure required at the entrance to the image intensifier is 20 mR per frame.¹⁰

The radiologist or cardiologist can reduce radiation exposure during cine procedures by decreasing the time of the cine run and using fluoroscopy when possible to locate catheters.³⁵ Intermittent or pulsed fluoroscopy can be used to locate catheters, and the last-image hold feature also can help reduce dose.³⁵

Radiologic technologists are responsible for ensuring that anyone present in the fluoroscopy room during an examination wears a lead apron. The fluoroscopy procedure should not begin until all individuals comply with this requirement.¹⁰

Fluoroscopy Operators

Historically, fluoroscopy has primarily been the responsibility of the radiologist or physician; the role of the radiographer was to conduct postfluoroscopic radiography and assist during the procedure.¹⁰ Interventional fluoroscopy procedures, such as cerebral angiography, often require active diagnosis during the examination and possible therapeutic intervention.³⁶ However, not all fluoroscopic examinations require real-time diagnosis. In recent years, these procedures have become a part of the radiologic technologist's responsibility. For example, it is accepted practice for radiographers to use fluoroscopy for static images of the terminal ilium.¹⁰

In addition, fluoroscopy procedures today are performed in many locations, including surgery suites, orthopedic centers, heart institutes, pain clinics and freestanding outpatient facilities. These sites are not always associated with a radiology or imaging department and may not have medical imaging professionals available to perform fluoroscopic procedures. As a result, many non-radiologists, physician extenders and other professionals perform fluoroscopy on a routine basis.³⁷ The perplexing question of who is authorized to perform fluoroscopic procedures is not always easy to solve because the answer depends on a variety of factors, such as applicable federal and state regulations, reimbursement standards and the positions of professional societies such as the ACR and ASRT. Often, the answer becomes a matter of circumstance, depending on what fluoroscopic procedure is performed, for which reason, at what facility and in which state.

In 2003 the ACR and the ASRT passed a joint statement delineating the role of radiologist assistants, a new professional category of physician extenders who assist with imaging studies.³⁸ The ASRT, ARRT, ACR, the National Society of Radiology Practitioner Assistants and some state regulatory agencies agreed that the RA could assume responsibility for patient assessment, patient education, patient management and perform fluoroscopy and other radiology procedures.^{39,40} It was determined from the beginning that RAs would not perform interpretations (preliminary or final) of any radiologic examination.³⁹

The RA role delineation defines 3 levels of supervision for radiologic procedures including fluoroscopy.⁴⁰ Personal supervision means the radiologist must be

in the room during the procedure; direct supervision requires the radiologist to be in the office suite and immediately available to provide assistance and direction; general supervision means the procedure is conducted under the radiologist's overall direction and control.⁴⁰ Medicare has established supervision rules for RAs who serve at freestanding clinics and independent diagnostic testing facilities. The rules require that radiologists or their physician designees must supervise radiology extenders who perform diagnostic studies.³⁹

The ARRT cautions that the RA role delineation should not be interpreted as authorizing the RA to perform certain activities, nor does the ARRT suggest that RAs can legally perform fluoroscopy in all states.⁴⁰ The ACR has a long-standing policy on the performance of interventional or radiotherapeutic procedures. The organization believes strongly that radiologists or their physician designees "be involved on a personal level" with patients, family members or guardians depending on the clinical situation.³⁹ Fluoroscopy procedures performed by RAs may not be eligible for reimbursement under current Centers for Medicare & Medicaid Services (CMS) or private insurance payment schedules. Providers should consult state and institutional regulations and the insurer's reimbursement requirements on a case-by-case basis to determine payment eligibility.⁴⁰

In 2007 the ASRT House of Delegates adopted a revised position statement "Fluoroscopy by Radiologic Technologists," which stated, "The American Society of Radiologic Technologists (ASRT) advocates that fluoroscopy is within the scope of practice of radiologic technologists with the appropriate clinical and didactic education and where federal or state law and/or institutional policy permits."⁴¹ Although a professional organization can define the profession's scope of practice, the authority to perform procedures such as fluoroscopy rests with the states, rather than certification boards or academic programs.³⁹ Thus, radiographers who perform fluoroscopy studies must ensure that they are under appropriate supervision and adhere to all state laws and regulations. The ASRT website has a complete list of applicable state agencies, with a summary page that outlines state regulations concerning contrast media, venipuncture and fluoroscopy.⁸

Table 3

State Licensing and Requirements for Performing Fluoroscopy⁸

State	Fluoroscopy Regulation	State	Fluoroscopy Regulation
Alabama	No licensure	Montana	Does not identify practitioners
Alaska	No licensure	Nebraska	Identifies practitioners
Arizona	Does not identify practitioners	Nevada	Does not identify practitioners
Arkansas	Does not identify practitioners	New Hampshire	Does not identify practitioners
California	Specific criteria	New Jersey	Identifies practitioners
Colorado	Does not identify practitioners	New Mexico	Identifies practitioners
Connecticut	Does not identify practitioners	New York	Identifies practitioners
Delaware	Identifies practitioners	North Carolina	No licensure
Florida	Identifies practitioners	North Dakota	Does not identify practitioners
Georgia	No licensure	Ohio	Identifies practitioners
Hawaii	Does not identify practitioners	Oklahoma	Does not identify practitioners
Idaho	No licensure	Oregon	Identifies practitioners
Illinois	Does not identify practitioners	Pennsylvania	Does not identify practitioners
Indiana	Does not identify practitioners	Rhode Island	Does not identify practitioners
Iowa	Identifies practitioners	South Carolina	Does not identify practitioners
Kansas	Does not identify practitioners	South Dakota	No licensure
Kentucky	Specific criteria	Tennessee	Does not identify practitioners
Louisiana	Does not identify practitioners	Texas	Identifies practitioners
Maine	Does not identify practitioners	Utah	Does not identify practitioners
Maryland	Specific criteria	Vermont	Specific criteria
Massachusetts	Identifies practitioners	Virginia	Does not identify practitioners
Michigan	Does not identify practitioners	Washington	Does not identify practitioners
Minnesota	Specific criteria	West Virginia	Specific criteria
Mississippi	Does not identify practitioners	Wisconsin	Does not identify practitioners
Missouri	No licensure	Wyoming	Does not identify practitioners

No licensure = no licensing laws; does not identify practitioners = state has licensing, but regulations do not specify who can and cannot perform fluoroscopy; identifies practitioners = state has licensing and specifies who can and cannot perform fluoroscopy; specific criteria = state has licensing and specific criteria and/or language regarding who can perform fluoroscopy.

State Regulation of Fluoroscopy Operators

State regulation of nonphysician fluoroscopy practitioners encompasses licensing, the scope of professional practice, supervision requirements, medical liability and radiation safety.³⁹ Each individual state has developed licensure laws that establish what type of credentials and education an individual must have to perform radiographic procedures.⁸ Of the states with licensing laws, 17 states specify who can and cannot perform

fluoroscopy, 25 have nothing written in their regulations pertaining to who can operate fluoroscopic equipment and 6 states identify special permits, examinations or demonstration of competency that must be completed to perform fluoroscopy.³⁹ For example, in Vermont a fluoroscopy operator must complete a course of instruction and demonstrate to a qualified expert the appropriate use of fluoroscopic equipment.⁴² West Virginia regulations state that individuals can

perform noninterpretive fluoroscopy procedures according to institutional policy,⁴³ and Iowa requires operators to pass an exam on fluoroscopy techniques.⁴⁴

Kentucky law permits technologists to perform fluoroscopy under the direction of a radiologist and allows fluoroscopy to be used for localization when obtaining images.⁴⁵ Minnesota regulations state that documented fluoroscopy training is required for those operators not licensed.⁸ States that allow limited x-ray machine operators (LXMOs) to perform radiologic procedures strictly prohibit them from performing fluoroscopy.⁴⁶ Because of the large variation in state regulations, fluoroscopy operators should contact their appropriate state licensing division to determine the pertinent regulations.⁸ Table 3 summarizes state licensing of fluoroscopy practitioners.

Education and Training

C-arm fluoroscopy units and fluoroscopy equipment with high-level control mode are used increasingly by nonradiologist physicians.³⁵ There is a need for ongoing education of fluoroscopy operators who perform interventional procedures and other lengthy studies, because such procedures can expose the patient, equipment operator and other personnel to substantial doses of ionizing radiation.¹⁰ Many fluoroscopy operators are not trained in radiation protection and safety, and are unaware of the risk of radiation injury and radiation-induced cancers for personnel as well as patients.³⁷

Several organizations involved in radiation and patient safety have joined the call when it comes to the issue of fluoroscopy operator education.^{1,35,37,46} In 1994 the CDRH issued an advisory warning, stating that fluoroscopy training for physicians was for the most part insufficient and needed to be expanded.^{37,46} The American Heart Association and the American College of Cardiology have published strongly worded position papers recognizing an urgent need for fluoroscopy and radiation safety training.⁴⁶ Hospitals and administrators are being encouraged to require radiation management credentials as a prerequisite for obtaining fluoroscopy privileges.³⁷ The Joint Commission is considering implementing standards regarding privileges for practitioners to use fluoroscopy equipment. One way of meeting these requirements would be the successful completion of an approved educational program. Ensuring that a fluoroscopy operator has

the appropriate training may fall to the radiology administrator and radiation safety staff.⁴⁶

In a recent report, the CDRH gave the following reasons for high radiation exposures during interventional procedures, all of which are related to lack of training:

- Fluoroscopic tubes operated for long periods of time in continuous rather than pulsed mode.
- Failure to use the protective curtain or floating shields on the stationary equipment's image intensifier as a means of protection.
- Extensive use of cine as a recording medium.³⁵

The FDA continues to encourage fluoroscopy operators who perform dose-intensive radiologic procedures to be aware of radiation exposures, to be educated in radiation biology, physics and safety, and to use techniques and protocols that decrease dose.^{1,37,46} Radiologic technologists and other personnel assisting in fluoroscopy procedures can contribute to safety efforts by alerting the physician who loses track of how long a procedure is taking and how much exposure is being delivered to a localized area.³⁵ In the event of excessive fluoroscopic time, the radiographer should notify the appropriate supervisor, who should then follow the imaging facility's protocol.³⁵

Public Awareness of Radiation Risks

The public is becoming aware of the risks associated with medical radiation exposure through media coverage of radiation accidents, alarmist warnings and easy access to articles posted on the Internet. The public's perception of risk is usually quite different from the actual measured or estimated risk for many hazards and activities.⁴⁷ According to health physics professor Kenneth Mossman, "the leading issue in health physics today is the perception of radiation risk by the general public," not the risk itself.⁴⁷

The general public's estimate of risk may be seriously distorted by media coverage and misleading experiences and feedback. For example, in a survey conducted by the Office of Cancer Communication and Education of the National Cancer Institute (NCI), 64% of the population surveyed thought radiation was a significant cause of cancer in the United States, when, in fact, only about 1% of all cancer deaths can be attributed to radiation exposure.⁴⁷ The most recent example of widespread coverage in the media involved 206 patients undergoing CT perfusion studies

at Cedars-Sinai Medical Center in Los Angeles. According to a current FDA investigation, the patients received up to 8 times the recommended radiation dose because inappropriate CT protocols were used.⁴⁸

Media outlets often reinterpret research reports^{49,50} published in major medical journals such as the *New England Journal of Medicine*, leaving the public frightened of radiological procedures and lacking a thorough understanding of radiation and risk. For example, the journal's study "Exposure to Low-Dose Ionizing Radiation from Medical Procedures" concluded that imaging procedures are an important source of ionizing radiation exposure and can result in high cumulative effective doses.⁴⁹ However, the article did not explain that the increased number of the procedures is partially because of technological advances and that many of these procedures are replacing surgery and saving lives.²⁰

Margulis cited an article by Brenner and Hall, "Computed Tomography — An Increasing Source of Radiation Exposure," as creating a great deal of fear among patients who have undergone or are scheduled to undergo CT exams.²⁰ In analyzing the article, Margulis acknowledged the potential danger in the increasing use of CT exams and agreed that nonionizing imaging procedures could be substituted for some CT studies. However, Margulis also pointed out several flaws in the article that could have an unwarranted effect on whether a patient decides to have a CT procedure. He argued that the authors predicted an increase in cancers as a result of the increasing number of CT studies based on theory rather than fact. Margulis pointed out that radiation doses and CT techniques quoted in the article were not those recommended by the ACR or the Society of Pediatric Radiology. In addition, the paper overlooked many dose-reduction techniques manufacturers have developed for children. Margulis concluded that many critics don't understand or consider the risk-benefit ratio of CT, particularly with respect to life-threatening conditions.²⁰

News coverage of events related to radiation exposure contributes to misunderstanding and public concern about radiation, and the general public does not always have the necessary background to place these events in an appropriate context. For example, a mother read a scientific article posted on the Internet concerning CT dose and cancer; she concluded that her son had developed leukemia as a result of CT scans performed

after a motor vehicle accident. This mother and other concerned parents have formed an alliance group called the Mothers Against Silence About CT Radiation Risks (MASACRR).⁵¹

Misconceptions about radiation may prevent people from getting appropriate diagnostic tests or therapy and ultimately compromise their medical care.⁴⁷ In the past, the use of certain diagnostic studies has come under attack because of potential risk vs benefit.²⁰ For example, breast cancer screening was questioned at one time because of the fear that mammography caused more cancers than it detected. Today breast cancer screening and early treatment are generally credited for the significant reduction in breast cancer deaths among U.S. women.²⁰ Thus, it would be unfortunate if individuals refused or postponed critically needed radiologic examinations because of misinformation.^{20,47}

Public Awareness Campaigns and Patient Education

Health physicists have concluded that the public needs understandable information concerning radiation. Knowledgeable health care professionals are in an ideal position to help patients develop a realistic perspective concerning radiation risk. Radiation risk should be defined in lay terms, using a simple vocabulary that describes radiation, its benefits and possible dangers. The use of comparative approaches, such as contrasting the risk associated with a specific radiologic procedure to the risk of common, everyday activities, frequently can place radiation risk in its proper perspective.⁴⁷

To address the need for accurate information about radiation exposure, radiation safety and medical imaging procedures, a number of organizations, including the NCI, the Society for Pediatric Radiology, the Society for Pediatric Interventional Radiology, the Society of Interventional Radiology, the ACR and ASRT, are actively involved in public awareness campaigns.^{36,52-54}

Today, one of the most notable campaigns is Image Gently, created by the Alliance for Radiation Safety in Pediatric Imaging, a coalition of health care organizations dedicated to providing safe, high-quality pediatric imaging (see Figure 1). Formed in 2007, the Alliance includes more than 55 national and international organizations, representing more than 600,000 health care professionals in radiology, pediatric imaging, medical physics and radiation safety.⁵³ The goal of the campaign



Fig. 1. The Image Gently campaign was created by the Alliance for Radiation Safety in Pediatric Imaging, a coalition of health care organizations dedicated to providing safe, high-quality pediatric imaging.

is to ensure that every facility uses appropriate dose reduction techniques when performing pediatric imaging and interventional procedures.⁵⁴ Originally focused on pediatric CT dose, the Image Gently campaign has expanded to include interventional radiology exams.⁵⁵ Under the theme of “step lightly,” the interventional phase of the campaign reminds medical imaging professionals to use a light touch on the fluoroscopy pedal and child-size technique, and to consider ultrasound and MR guidance when appropriate.^{54,55}

The Image Gently website, www.imagegently.org, provides parents, radiologists, pediatricians, medical physicists, the media and imaging personnel a range of resources explaining radiation concepts in understandable terms. The site offers detailed information on CT and interventional exams and provides information related to radiation dose.^{56,57} The site also includes downloadable presentations, patient brochures, a log for recording radiation dose received during an exam, checklists for reducing dose and an outline of dose reduction and quality maintenance steps to take in the department.^{53,54}

An example of the downloadable resources on the Image Gently website, the Step Lightly checklist (see Box 3) is a comprehensive inventory of protection measures that can be taken to ensure overall safety during an interventional exam. The campaign also has developed a table that provides estimated radiation doses for 6 common interventional exams and compares the dose to its equivalent amount of background radiation.^{53,55}

The NCI and ACR also have information about radiation protection and imaging procedures on their websites.^{36,52} NCI provides a guide on interventional

fluoroscopy and focuses on ways to reduce radiation risks.⁵² The guide discusses the value of interventional procedures, the associated radiation risks and the importance of optimizing radiation dose. NCI advocates auditing the radiation exposure levels for each operator.⁵² The ACR and the Radiological Society of North America jointly developed a patient-focused website, www.radiologyinfo.org, which is designed to answer questions about today’s radiologic procedures and therapies.⁵² Box 4 lists additional websites that offer information to patients on imaging procedures and radiation exposure.

Conclusion

The concern with radiation protection and safety has a long history, beginning in 1928 with the creation of the International Commission on Radiological Protection and the development of the first recognized unit of radiation exposure, the skin erythema dose. Today, numerous scientific advisory groups conduct research on radiation exposure and make recommendations to minimize the potential harmful effects of radiation to patients and operators. The U.S. Congress has passed noteworthy legislation concerning radiation protection, including the Radiation Control for Health and Safety Act of 1968 and the Consumer-Patient Radiation Health and Safety Act of 1981. Regulations now are in place covering equipment, educational programs and credentialing of ionizing equipment operators. State agencies are generally responsible for enforcing the standards.

With the increased use of advanced imaging modalities, however, there has been a shift in legislative emphasis from equipment standards to the education and training of equipment operators and the use of proper radiation protection techniques. The CARE bill is an excellent example of where the focus of radiation protection lies today. Public awareness of the potential dangers of ionizing radiation also has influenced the regulatory environment. Several recent well-publicized incidents have raised the concern that patients will refuse needed imaging procedures because of misguided fears.

The public, physicians and health care providers need accurate information concerning radiation exposure and the associated risks. They must be able to adequately evaluate the benefit of a specific

Box 3

Step Lightly Checklist⁵³

Review steps below before starting the procedure:

- Ask patient or family about previous radiation exposures. Answer questions about radiation safety.
- Use ultrasound when possible.
- Position hanging table shields and overhead shields before the procedure.
- Operators and personnel should wear lead aprons, thyroid shield and leaded eyewear.
- Use pulse rather than continuous fluoroscopy when possible, with as low a pulse as possible.
- Position and collimate with fluoroscopy off, tapping on the pedal to check position.
- Collimate tightly. Exclude eyes, thyroid, breast and gonads when possible.
- Keep operator and personnel hands out of beam.
- Step lightly: tap on pedal and review anatomy on last image rather than with live fluoroscopy when possible; minimize live fluoroscopy time.
- Minimize use of electronic magnification; use digital zoom whenever possible.
- Acknowledge fluoroscopy timing alerts during the procedure.
- Use last-image hold whenever possible instead of exposures.
- Adjust acquisition parameters to achieve lowest dose necessary to accomplish procedure; use lowest dose protocol for patient size and lower frame rate, minimize magnification, reduce length of run.
- Plan and communicate number and timing of acquisitions, contrast parameters, patient positioning and suspension of respiration with radiology and sedation team in advance to minimize improper or unneeded runs.
- Move table away from x-ray tube in both planes; move patient as close as possible to detector in both planes.
- Use a power injector, or extension tubing if injecting by hand.
- Move personnel away from the table or behind protective shields during acquisitions.
- Minimize overlap of fields on subsequent acquisitions.
- After the procedure, record and review dose.

procedure vs that procedure's risks. Imaging facilities can contribute to this effort by maintaining a list of credible websites for patients and their families so that they receive accurate and reliable information. Health

care professionals can keep up to date on the latest issues concerning radiation safety by maintaining membership and involvement in professional societies such as the ASRT and the ACR.

Box 4

Additional Resources for Patient Information⁵³

Society for Pediatric Radiology

www.pedrad.org

Society for Pediatric Interventional Radiology

www.spirweb.org

Society of Interventional Radiology

www.sirweb.org

National Cancer Institute

www.cancer.gov/cancertopics/interventionalf fluoroscopy

References

1. Barr HJ, Ohlhaber T, Finder C. Focusing in on dose reduction: the FDA perspective. *AJR Am J Roentgenol.* 2006;186(6):1716-1717.
2. Dimond BC. *Legal Aspects of Radiography and Radiology.* Malden, MA: Blackwell Science Inc; 2002:224-225.
3. International Commission on Radiological Protection. www.icrp.org/index.asp. Accessed January 18, 2010.
4. How the NRC protects you. Nuclear Regulatory Commission website. www.nrc.gov/about-nrc/radiation/protects-you.html. Accessed December 28, 2009.

5. National Council on Radiation Protection and Measurements. <http://ncrponline.org>. Accessed December 28, 2009.
6. SEC.532. [21 USC §360ii] Electronic product radiation control program. www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAct/FDCActChapterVDrugsandDevices/ucm110337.htm. Accessed January 25, 2010.
7. Performance standards for ionizing radiation-emitting products. 21 CFR §1020. www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=1020&showFR=1. Accessed June 17, 2010.
8. Individual state licensure information. American Society of Radiologic Technologists website. www.asrt.org/content/GovernmentRelations/LegislativeGuidebook/IndividualStateLicensureInfo.aspx. Accessed February 11, 2010.
9. Statkiewicz-Sherer M, Visconti P, Ritenour E. *Radiation Protection in Medical Radiography*. 5th ed. St Louis, MO: Mosby Elsevier; 2006:141-162, 300-303.
10. Carlton RR, Adler AM. *Principles of Radiographic Imaging: An Art and a Science*. 4th ed. Clifton NY: Thomson Delmar Learning; 2006: 149-163.
11. Seeram E. *Rad Tech's Guide to Radiation Protection*. Malden, MA: Blackwell Science Inc; 2001:3-9; 51-55; 67-85; 94-98.
12. About WHO. World Health Organization website. www.who.int/about/en. Accessed January 28, 2010.
13. About IAEA. International Atomic Energy Agency website. www.iaea.org/About/index.html. Accessed January 28, 2010.
14. SC 2-3: radiation safety issues for image-guided interventional medical procedures. National Council on Radiation Protection and Measurements website. www.ncrponline.org/Current_Prog/SC_2-3.html. Accessed January 24, 2010.
15. Vlietstra RE, Wagner LK, Koenig T, Mettler F. Radiation burns as a severe complication of fluoroscopically guided cardiological interventions. *J Interv Cardiol*. 2004;17(3):131-142.
16. Bogdanich W. The radiation boom. Radiation offers new cures, and ways to do harm. *The New York Times* website. www.nytimes.com/2010/01/24/health/24radiation.html?th&emc=th. Published January 23, 2010. Accessed January 31, 2010.
17. Food and Drug Administration. 21 CFR §1020.31. http://edocket.access.gpo.gov/cfr_2001/aprqr/pdf/21cfr1020.32.pdf. Accessed January 18, 2010.
18. Barnes E. NEJM study: Imaging procedures, radiation growing. AuntMinnie.com website. www.auntminnie.com/index.asp?Sec=sup&Sub=imc&Pag=dis&ItemId=87053. Posted August 26, 2009. Accessed February 10, 2010.
19. Brenner D, Elliston CD, Hall E, Berdon W. Estimated risks of radiation-induced fatal cancer from pediatric CT. *AJR Am J Roentgenol*. 2001;176(2):289-296.
20. Margulis AR. An alarmist warning. *Imaging Economics*. January 2008. www.imagingeconomics.com/issues/articles/2008-01_13.asp. Accessed January 26, 2010.
21. BEIR VII: Health risks from exposure to low levels of ionizing radiation. The National Academies. http://dels.nas.edu/resources/static-assets/materials-based-on-reports/reports-in-brief/beir_vii_final.pdf. Accessed June 17, 2010.
22. About NIH. National Institutes of Health website. www.nih.gov/about/NIHoverview.html. Accessed February 7, 2010.
23. Barnes E. NIH tells scanner suppliers to include radiation monitoring. AuntMinnie.com website. www.auntminnie.com/index.asp?Sec=sup&Sub=cto&Pag=dis&ItemId=89289. Posted February 1, 2010. Accessed February 10, 2010.
24. May L. ASRT seeks to ensure patient safety through proper education of radiologic technologists. American Society of Radiologic Technologists website. www.asrt.org/content/GovernmentRelations/CAREBill/Patient_Safety.aspx. Accessed January 30, 2010.
25. Tran V. The Radiation Control for Health and Safety Act of 1968: history, accomplishments, and future. May 2006. <http://leda.law.harvard.edu/leda/data/792/Tran06.pdf>. Accessed January 30, 2010.
26. Lung C, Shams-Avari P. Legal and practice standards implications. *Radiol Technol*. 2006;77:173-178.
27. Title 21 of the code of federal regulations. Wikipedia website. http://en.wikipedia.org/wiki/Title_21_of_the_Code_of_Federal_Regulations. Accessed January 18, 2010.
28. Consumer-Patient Radiation Health and Safety Act of 1981. American Society of Radiologic Technologists website. www.asrt.org/content/GovernmentRelations/LegislativeGuidebook/ConsumerPatientRadHealthandSafety1981.aspx. Accessed January 30, 2010.
29. Standards for the accreditation of educational programs for and the credentialing of radiologic personnel. 42 USC §10004. American Society of Radiologic Technologists website. www.asrt.org/content/GovernmentRelations/LegislativeGuidebook/StandardsforAccreditation.aspx. Accessed January 30, 2010.
30. *Alphabet Soup: A Guide to Organizations in Radiologic Technology*. American Society of Radiologic Technologists website. www.asrt.org/media/pdf/abouttheprofession/alphabet_soup.pdf. Accessed June 9, 2010.
31. *The Practice Standards for Medical Imaging and Radiation Therapy. Radiography Practice Standards*. American Society of Radiologic Technologists website. www.asrt.org/media/pdf/practicestds/GR06_OPI_Strds_Rad_Adpd.pdf. Accessed June 9, 2010.
32. *The Practice Standards for Medical Imaging and Radiation Therapy. Radiologist Assistant Practice Standards*. American Society of Radiologic Technologists website. https://www.asrt.org/media/pdf/practicestds/GR06_OPI_Strds_Rad_Adpd.pdf. Accessed June 9, 2010.

- asrt.org/media/pdf/practicestds/GR06_OPI_RA_Stnds_Adpd.pdf. Accessed June 9, 2010.
33. Consistency, Accuracy, Responsibility and Excellence in Medical Imaging and Radiation Therapy bill. HR 3652. American Society of Radiologic Technologists website. www.asrt.org/media/pdf/GovRel/HR3652_CAREAct_111thCongress.pdf. Accessed January 31, 2010.
 34. CARE bill FAQs. American Society of Radiologic Technologists website. www.asrt.org/content/GovernmentRelations/CAREBill/faq_legislative.aspx. Accessed January 31, 2010.
 35. Seeram E, Travis EL. *Radiation Protection*. Philadelphia, PA: Lippincott Williams & Wilkins; 1997:171-176.
 36. Patient safety. RadiologyInfo.org website. www.radiologyinfo.org/en/safety/. Accessed February 11, 2010.
 37. Archer BR. Radiation management and credentialing of fluoroscopy users. *Pediatr Radiol*. 2006;36(suppl 2):182-184.
 38. Advanced Practice Advisory Panel. The radiologist assistant: improving patient care while providing work force solutions. March 2002. American Society of Radiologic Technologists website. www.asrt.org/media/pdf/ra_consensuspaper.pdf. Accessed February 7, 2010.
 39. Ellenbogen PH, Hoffman TR, Short BW, Gonzalez. The radiologist assistant: what radiologists need to know now. *J Am Coll Radiol*. 2007;4(7):461-470.
 40. Registered radiologist assistant role delineation. January 2005. American Registry of Radiologic Technologists website. www.arrt.org/radasst/finalrarolelineation.pdf. Accessed February 7, 2010.
 41. ASRT House of Delegates adopts 30 resolutions. Delegates advocate educational levels, adopt practice standards for profession. American Society of Radiologic Technologists website. www.asrt.org/content/News/PressRoom/PR2007/asrthouse070607.aspx. Posted June 5, 2007. Accessed February 10, 2010.
 42. Vermont state licensure information. American Society of Radiologic Technologists website. www.asrt.org/Content/GovernmentRelations/IndStateInfo/LicensureVT.aspx. Accessed February 13, 2010.
 43. West Virginia state licensure information. American Society of Radiologic Technologists website. www.asrt.org/content/governmentrelations/IndStateInfo/licensureWV.aspx. Accessed February 13, 2010.
 44. Iowa state licensure information. American Society of Radiologic Technologists website. www.asrt.org/content/governmentrelations/IndStateInfo/licensureIA.aspx. Accessed February 13, 2010.
 45. Kentucky state licensure information. American Society of Radiologic Technologists website. www.asrt.org/Content/GovernmentRelations/IndStateInfo/LicensureKY.aspx. Accessed February 13, 2010.
 46. Archer BR. High-dose fluoroscopy: the administrator's responsibilities. *Radiol Manage*. 2002;24(2):26-32.
 47. Mossman K. Public perception of radiation: the leading issue in health physics today. *Radiation Protection Management*. 2003;20(4):34-37.
 48. Casey B. FDA finds new cases of CT radiation overexposure. AuntMinnie.com website. www.auntminnie.com/index.asp?Sec=sup&Sub=cto&Pag=dis&ItemId=88721. Posted December 7, 2009. Accessed February 15, 2010.
 49. Fazel R, Krumholz HM, Wang Y, et al. Exposure to low-dose ionizing radiation from medical imaging procedures. *N Engl J Med*. 2009;361(9):849-857.
 50. Brenner D, Hall E. Computed tomography — an increasing source of radiation exposure. *N Eng J Med*. 2007;357:2277-84.
 51. Chevrier R. June 2006: mothers against silence about CT radiation risks (MASACRR). Medscape Today website. www.medscape.com/viewarticle/536132. Posted June 21, 2006. Accessed February 14, 2010.
 52. Interventional fluoroscopy: reducing radiation risks for patients and staff. National Cancer Institute website. www.cancer.gov/cancertopics/interventionalfluoroscopy. Posted April 18, 2005. Accessed February 11, 2010.
 53. Image Gently campaign. Alliance for Radiation Safety in Pediatric Imaging website. www.imagegently.org. Accessed February 10, 2010.
 54. Image gently campaign launches interventional phase. September 3, 2009. American Society of Radiologic Technologists website. www.asrt.org/Content/News/PressRoom/PR2009/imagegentl090903.aspx. Accessed February 12, 2010.
 55. Kollmer J. Image gently. A new campaign seeks to reduce radiation dosage in children. *RT Image* website. www.rt-image.com/Image_Gently_A_new_campaign_seeks_to_reduce_radiation_dosage_in_children/content=8004f05C4856A084407698764460A0441. Accessed June 17, 2010.
 56. ARRT on board with image gently alliance. American Registry of Radiologic Technologists website. www.arrt.org/new/ImageGentlyNewsRelease.html. Posted January 23, 2008. Accessed February 14, 2010.
 57. Image gently campaign expands to include interventional radiology. American College of Radiology website. www.acr.org/MainMenuCategories/media_room/FeaturedCategories/PressReleases/ImageGentlyCampaignIRPhase.aspx. Accessed February 14, 2010.

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