

# 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 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 fluoroscopy units or assisting with fluoroscopy 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 studying the information presented, the reader 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.
- 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.<sup>1</sup> 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 reducing the radiation dose from equipment that produces ionizing radiation.<sup>1</sup>

The United States works in conjunction with numerous international organizations to protect the public and radiation workers from the effects of ionizing radiation.<sup>2-5</sup> Statutory rules have been established for nuclear power plants, radionuclide management, the manufacture of electronic products and the handling of nuclear contamination.<sup>2,6</sup> 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.<sup>4,7,8</sup> 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 for different types of procedures.<sup>1</sup>

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,<sup>7,9-11</sup> and federal and state agencies are responsible for enforcing the regulations and standards established by law.<sup>9</sup> Because several 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.<sup>9</sup> In addition, the 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.<sup>1</sup>

### 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).<sup>2,9-11</sup>

The International Commission on Radiological Protection (ICRP) is considered the international authority regarding the safe use of ionizing radiation.<sup>9</sup> The ICRP is an independent registered group that provides recommendations and guidance on all aspects of ionizing radiation protection.<sup>3</sup> Functioning as an advisory body, it consists of a main commission and 5 standing committees. The committees focus on radiation effects, radiation exposure, radiation protection in medicine, the application of ICRP recommendations and environmental protection.<sup>3,9</sup>

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.<sup>9</sup> Although the ICRP has no formal enforcement power, most countries adhere closely to

ICRP recommendations when developing and enforcing their own regulations.<sup>3</sup> Two ICRP reports, Publication 26 (1977) and Publication 60 (1990) are the basis for regulations and recommendations not only in the United States and Canada but also in other countries.<sup>11</sup>

Established in 1928, 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.<sup>11</sup>

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.<sup>9,11</sup>

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.<sup>12</sup>

The International Atomic Energy Agency (IAEA) is an international organization that promotes the safe and peaceful use of nuclear science and technology and works to inhibit its use for military purposes.<sup>13</sup>

### 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 Academy of Sciences, National Research Council, Committee on the Biological Effects of Ionizing Radiation (NAS/NRC-BEIR).
- National Institutes of Health (NIH).<sup>9-11</sup>

The ICRP and NCRP recommend effective dose limits for radiation workers based on reports from

UNSCEAR and NAS/NRC-BEIR.<sup>9,11</sup> 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.<sup>11</sup> Levels of ionizing radiation formerly considered acceptable by the ICRP have been revised downward.<sup>9</sup> 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.<sup>9</sup> The NCRP is still considering reducing exposure standards but currently recommends an annual effective dose limit of 50 mSv for radiation workers.<sup>9,11</sup> National and state agencies are responsible for enforcing radiation protection standards established by the NCRP through legislative mandates.<sup>9,10</sup>

#### NRC and NCRP

The NRC was charged by Congress with protecting people and the environment from unnecessary radiation 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.<sup>4</sup>

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.<sup>5</sup> 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.<sup>11</sup> To fulfill its mission, the council collects, analyzes and distributes information and regulations about radiation protection, quantities and measurements.<sup>5,10</sup> 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.<sup>9</sup>

The NCRP has developed more than 175 scientific reports, and its rules and regulations are published

in Title 10 of the U.S. Code of Federal Regulations.<sup>5,9</sup> In 2010 the NCRP released Report 168, "Radiation Dose Management for Fluoroscopically-Guided Interventional Medical Procedures." The report focuses on the use of fluoroscopic systems as a tool for guiding diagnostic and therapeutic procedures and provides recommendations concerning reducing radiation exposure to patients and medical staff.<sup>14</sup> 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.<sup>1,10</sup> Under this law, the FDA regulates the design and manufacture of electronic products and medical devices including diagnostic x-ray equipment.<sup>9</sup> Public Law 90-602 ensures that the public is protected from the hazards of unnecessary radiation exposure.<sup>9</sup>

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.<sup>10</sup> The agency has the authority to deny the sale of equipment, inspect facilities, issue fines and revoke radiation use authorizations.<sup>10</sup>

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.<sup>1</sup> 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.<sup>15</sup>

Some degree of radiation-induced trauma is to be expected during radiation therapy because of the high

levels of radiation administered; 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."<sup>16</sup> However, even though radiation-induced trauma occurs during radiation therapy, the fluoroscopy equipment used for treatment planning is exempt from most FDA performance standards.<sup>17</sup>

The number of CT examinations performed in this country is a major concern for the FDA, especially if many of these procedures are redundant 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.<sup>18</sup> 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. 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.<sup>19</sup> 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.<sup>21</sup>

#### 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.<sup>10</sup>

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.<sup>11</sup>

#### NAS/NRC-BEIR

The National Academy of Sciences, National Research Council Committee on the Biological Effects of Ionizing Radiation (NAS/NRC-BEIR) is an advisory group that reviews studies concerning the biological effects of ionizing radiation and risk assessment.<sup>10</sup> 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.<sup>21</sup> After publication of BEIR V, the ICRP revised its recommendations, reducing the annual allowable dose for radiation workers.<sup>11</sup> 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.<sup>21</sup> 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.<sup>21</sup>

#### 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 \$32 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.<sup>22</sup>

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 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.<sup>23</sup>

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 system.<sup>23</sup>

### 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.<sup>10</sup> Currently, 5 states (Alabama, Idaho, Missouri, Nevada, and North Carolina) and the District of Columbia have no formal licensing standards for any discipline or specialty.<sup>8</sup> **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 pieces of legislation.<sup>11</sup>

Table 1

#### States With Licensure, Certification or Recognition Standards by Discipline or Practitioner<sup>8</sup>

Discipline or Practitioner	Number of States
Radiography	42
Radiation therapy	38
Limited x-ray machine operator	34
Nuclear medicine	37
Radiologist assistant	31
Cardiovascular	7
Magnetic resonance	6
Computed tomography	10
Sonography	4
Fluoroscopy only	2

### 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.<sup>9,24</sup> 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.<sup>24</sup> As a result, the CDRH was established to evaluate radiation emissions from electronic products.<sup>9,24</sup> The CDRH sets more than 60 performance standards for the manufacture, installation, assembly and maintenance of radiological equipment used for diagnostic x-ray procedures.<sup>9</sup> 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.<sup>25</sup>

## Box 1

**Selected Provisions of CFR Title 21, §1020.32<sup>7</sup>**

**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  $2.58 \times 10^{-3}$  coulomb per kilogram (C/kg) per minute. Equipment without AERC (ie, manual mode) is limited to 5 R/minute or not to exceed  $1.29 \times 10^{-3}$  C/kg per minute. Equipment with both devices is limited to 10 R/minute or  $2.58 \times 10^{-3}$  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  $1.29 \times 10^{-3}$  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  $1.29 \times 10^{-3}$  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.

Part 1020 specifically deals with performance standards for ionizing 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.<sup>7</sup> 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.<sup>7</sup>

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 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 might be more appropriate to use another modality, 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.<sup>1</sup>

### **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.<sup>27</sup> 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.<sup>9,11,27,28</sup>

The CPRHSA is divided into 8 sections — 42 USC §10001-10008. **Table 2** shows the focus of each section.<sup>27</sup> 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.”<sup>27</sup>

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.<sup>9</sup> Individual states were encouraged to develop similar statutes and

Table 2

#### **Consumer-Patient Radiation Health and Safety Act of 1981<sup>27</sup>**

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

administer certification programs based on the established standards. Despite the congressional mandate set forth in 1981, not all states have developed licensing laws.<sup>16</sup> There currently is no penalty for noncompliance with the CPRHSA, resulting in tremendous variation in established laws.<sup>9</sup>

### **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.<sup>28</sup> 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.<sup>9,28</sup> “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.<sup>28</sup>

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 radio-graphy, 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.<sup>29</sup>

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.<sup>28</sup> 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.<sup>28</sup>

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.<sup>29</sup>

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.<sup>8</sup> According to the Radiographer Scope of Practice developed by the ASRT, the radiographer can assist a licensed independent practitioner with fluoroscopic and specialized radiologic 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.<sup>30</sup> The Radiologist Assistant Scope of Practice includes assisting with or performing studies with radiologist supervision or delegation according to state laws and institutional policies.<sup>31</sup>

### **Legislative Efforts**

In 1998 the ASRT began pursuing federal minimum standards for the education and certification of health care workers who administer radiologic procedures. As part of this effort, ASRT formed a Government Relations Department and built an extensive grassroots lobbying network. The ASRT also backed federal legislation to amend the 1981 Consumer-Patient Radiation Health and Safety Act.<sup>32</sup>

During the final vote on CPRHSA, a political bargain was made to ensure the bill’s passage and the enforcement mechanism was removed. As a result, there are currently no legal enforceable penalties for states that do not comply with education and certification requirements of CPRHSA. To make state compliance with CPRHSA mandatory, the ASRT and an alliance of other radiologic science organizations worked on the Consumer Assurance of Radiologic Excellence bill (CARE bill). The bill was introduced several times in the House and Senate between 2000 and 2013, but has failed to pass both houses of Congress. In 2014, ASRT shifted its pursuit of minimum education and certification standards from the federal to the state level.<sup>32</sup>

At the federal level, the ASRT supports legislation to protect radiologic technologists, improve patient safety and ensure appropriate reimbursement for medical imaging services. Today, the ASRT and other professional organizations are pursuing federal legislation to amend Medicare reimbursement policy and supervision

levels for radiologist assistants. The legislation seeks to align Medicare policies with state RA licensure laws. In this way, radiologist assistants would be able to work more independently and efficiently.<sup>33</sup>

## 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 radiation exposure to the patient and medical personnel. Many of the practices are based on recommendations of various organizations that focus on radiation protection.<sup>34</sup> 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.<sup>9</sup> According to FDA standards, all fluoroscopic equipment manufactured after May 19, 1995 must be equipped with an automatic exposure rate control (AERC) system if the unit could potentially generate a dose greater than 5 R per minute. These regulations further stipulate that the equipment cannot exceed an exposure rate of 10 R per minute unless the high-level control feature is activated. If this feature is activated, the maximum exposure rate cannot exceed 20 R per minute. However, it is important to note that the FDA currently has no dose-limiting standards when recording fluoroscopic images.<sup>7</sup>

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.<sup>9</sup>

Radiation-induced skin injuries as a result of interventional procedures include temporary epilation, dry and moist desquamation, dermal necrosis and secondary ulcerations.<sup>9,23</sup> 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.<sup>9</sup>

### 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.<sup>9,10</sup> 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.<sup>34</sup> 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.<sup>9,10</sup> With last-image hold, an image is displayed from the last time the foot switch was depressed and radiation was emitted. This image generally is composed of several frames of information that are combined to reduce the effect of quantum mottle.<sup>9</sup>

### Magnification

Multifield, or magnification, image intensifiers are found in the majority of image intensifiers today.<sup>9</sup> Image magnification is sometimes needed to demonstrate small structures, although image clarity can be compromised. Image clarity is degraded on the display monitor because of a decrease in the minification gain when fewer photoelectrons strike the output phosphor on the image intensifier.<sup>9,10</sup>

To maintain brightness on the monitor, the fluoroscopy unit automatically adjusts the exposure factors, and therefore, the patient dose subsequently increases. For example, in some systems the magnification setting can be changed from a 30- to 15-cm diameter

field of view. 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.<sup>10</sup> The change in mA using the magnification mode can double patient dose.<sup>34</sup>

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.<sup>10</sup>

### **Image Recording Techniques**

Like MR and CT imaging, most contemporary fluoroscopy units have digital recording capabilities. Digital technology has replaced older recording methods such as cine fluorography and spot-film recording that were used in conventional fluoroscopy. These older techniques captured the image from the output screen of the image intensifier, and they were associated with significant radiation exposure.<sup>10</sup>

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.<sup>10</sup>

### **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.<sup>10</sup> Interventional fluoroscopy procedures, such as cerebral angiography, often require active diagnosis during the examination and possible therapeutic intervention.<sup>35</sup> 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.<sup>10</sup>

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 might not have medical imaging professionals available to perform fluoroscopic procedures. As a result, many nonradiologists, physician extenders and other professionals perform fluoroscopy on a routine basis.<sup>36</sup> 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. 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 2002, representatives from the ASRT, ACR, ARRT, state agencies that license radiologic technologists and radiologic science educational programs met to explore key issues surrounding advanced-level practice for radiologic technologists. The advisory panel issued 12 consensus statements concerning the educational preparation, experience, roles and responsibilities, level of supervision and level of regulatory oversight of practitioners that would become known as radiologist assistants. Participants agreed that the RA could assume responsibility for patient assessment, patient education, patient management and perform fluoroscopy and other radiology procedures.<sup>37-39</sup> It was determined from the beginning that RAs would not perform interpretations (preliminary or final) of any radiologic examination.<sup>37</sup> The ARRT issued the first role delineation for RAs in 2005 and updated certification requirements for registered radiologist assistants in 2014 after a job analysis update.<sup>39</sup>

The initial RA role delineation defined three levels of supervision for radiologic procedures including fluoroscopy.<sup>40</sup> 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.<sup>40</sup> 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.<sup>38</sup>

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.<sup>40</sup> 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.<sup>38</sup> 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.<sup>40</sup>

According to the practice standards developed by the ASRT, fluoroscopy is within the scope of practice of radiologic technologists with the appropriate clinical and didactic education and where federal or state law and institutional policy permits.<sup>30</sup> 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.<sup>38</sup> Thus, radiographers who perform fluoroscopy studies must ensure that they are under appropriate supervision and adhere to all state laws and regulations.

### **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.<sup>38</sup> More than three-quarters of states have licensing laws covering the practice of radiologic technology, and some of these states also have specific laws governing fluoroscopy.<sup>41</sup> The ARRT currently administers a fluoroscopy examination for state licensing purposes.<sup>42</sup> Because of the large

variation in state regulations, fluoroscopy operators should contact their appropriate state licensing division to determine the pertinent regulations.<sup>8</sup>

### **Education and Training**

C-arm fluoroscopy units and fluoroscopy equipment with high-level control mode are used increasingly by nonradiologist physicians.<sup>34</sup> 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.<sup>10</sup> 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.<sup>36</sup>

Several organizations involved in radiation exposure issues and patient safety have joined the call when it comes to the issue of fluoroscopy operator education.<sup>1,34,36,43</sup> 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.<sup>36,43</sup> 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.<sup>43</sup> Hospitals and administrators are encouraged to require radiation management credentials as a prerequisite for obtaining fluoroscopy privileges.<sup>36</sup> 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 might fall to the radiology administrator and radiation safety staff.<sup>43</sup>

In February 2010 the FDA published a white paper introducing an initiative to reduce unnecessary radiation exposure from medical imaging. The document identified two broad categories that could account for unwarranted radiation exposure: inappropriate equipment use and a lack of awareness in clinical decision making. With respect to education and training, the FDA suggested that fluoroscopy operators might not have an adequate understanding of current methods to optimize radiation dose. The agency also maintained

that ordering physicians might be unaware of referral criteria for certain medical imaging examinations.<sup>44</sup>

The FDA continues to encourage fluoroscopy operators who perform dose-intensive radiologic procedures to be aware of radiation exposure; to be educated in radiation biology, physics and safety; and to use techniques and protocols that decrease dose.<sup>1,35,43</sup> Radiologic technologists and other personnel assisting with 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. In the event of excessive fluoroscopic time, the radiographer should notify the appropriate supervisor, who should then follow the imaging facility's protocol.<sup>34</sup>

### 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. People's perception of risk is usually quite different from the actual measured or estimated risk for many hazards and activities. 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.<sup>45</sup>

The general public's estimate of risk can 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 2% of all cancer deaths can be attributed to radiation exposure.<sup>45,46</sup> One 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.<sup>47</sup>

Media outlets often reinterpret research reports<sup>48,49</sup> 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.<sup>48</sup> 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.<sup>20</sup>

Margulis cited an article by Brenner and Hall, "Computed Tomography — An Increasing Source of Radiation Exposure,"<sup>49</sup> as creating a great deal of fear among patients who have undergone or are scheduled to undergo CT exams.<sup>20</sup> In analyzing the article, Margulis acknowledged the potential danger in the increasing use of CT exams and agreed that nonionizing imaging procedures should 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.<sup>20</sup>

News coverage of events related to radiation exposure contributes to misunderstanding and public concern about radiation, and the community at large 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 formed an alliance group called the Mothers Against Silence About CT Radiation Risks (MASACRR).<sup>50</sup>

Misconceptions about radiation could prevent people from getting appropriate diagnostic tests or therapy

and ultimately compromise their medical care.<sup>45</sup> In the past, the use of certain diagnostic studies came under attack because of potential risk vs benefit. 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.<sup>20</sup> Thus, it would be unfortunate if individuals refused or postponed critically needed radiologic examinations because of misinformation.<sup>20,45</sup>

### 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.<sup>45</sup>

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.<sup>35,52-54</sup> 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**). Formed in 2007, the Alliance includes more than 100 national and international organizations, representing thousands of health care professionals in radiology, pediatric imaging, medical physics and radiation safety.

The goal of the campaign is to ensure that every facility uses appropriate dose reduction techniques when performing pediatric imaging and interventional procedures.<sup>52</sup> Originally focused on pediatric CT dose, the Image Gently campaign has expanded to include



**Figure.** 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.

fluoroscopy, interventional radiology, nuclear medicine and digital radiography. The campaign also will include information concerning dental imaging in the future.<sup>52,53,55</sup> 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.<sup>52,54</sup>

The Image Gently website, [www.imagegently.org](http://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 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.<sup>52</sup> The Step Lightly checklist (see **Box 2**) is an example of a resource for fluoroscopy operators. This comprehensive inventory of protection measures outlines steps that can be taken to ensure overall safety during an interventional exam.<sup>52,54</sup>

Following the success of Image Gently, several professional organizations including the ACR, ASRT and the American Association of Physicists in Medicine (AAPM) created the Image Wisely campaign to address radiation safety concerns in adult medical imaging. The goal of the campaign is to limit radiation exposure delivered by medically necessary imaging studies and eliminate unwarranted procedures. In addition to information on CT and nuclear medicine procedures, the Image Wisely website ([imagewisely.org](http://imagewisely.org))

## Box 2

**Step Lightly Checklist<sup>52</sup>**
**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.

provides resources on fluoroscopy topics, including recommended protocols and techniques, how to develop a safety culture, patient education materials and specific equipment information.<sup>56</sup>

The NCI and ACR also have information about radiation protection and imaging procedures on their websites.<sup>35,51</sup> NCI provides a guide on interventional fluoroscopy and focuses on ways to reduce radiation risks. 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.<sup>51</sup> The ACR and the Radiological Society of

North America jointly developed a patient-focused website, [www.radiologyinfo.org](http://www.radiologyinfo.org), which is designed to answer questions about today's radiologic procedures and therapies.<sup>35</sup> **Box 3** 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,

## Box 3

**Additional Resources for Patient Information**<sup>52</sup>
**Society for Pediatric Radiology**
[www.pedrad.org](http://www.pedrad.org)
**Society for Pediatric Interventional Radiology**
[www.spirweb.org](http://www.spirweb.org)
**Society of Interventional Radiology**
[www.sirweb.org](http://www.sirweb.org)
**National Cancer Institute**
[www.cancer.gov/cancertopics/interventionalfluoroscopy](http://www.cancer.gov/cancertopics/interventionalfluoroscopy)

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. 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 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.

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