Fluoroscopic Safety

14

Kenneth D. Candido and Tennison Malcolm

Introduction

Fluoroscopy use is a practical necessity for many procedures performed by interventional clinicians; however, when used inappropriately or indiscriminately, it can prove hazardous for both patients and providers. Following a series of rare but serious radiation-induced skin burns, the United States Food and Drug Administration (FDA) issued an advisory statement in 1994 describing the need for sufficient training among caregivers utilizing fluoroscopy [1, 2]. Cancer is the second leading cause of death in the United States and is among the top five causes for middle- and high-income nations worldwide [3, 4]. Prior to significant reductions in occupational risk associated with a greater appreciation of prophylactic measures used to reduce radiation exposure, medical providers with high exposure to ionizing radiation were among the most affected by breast cancer, leukemia, and skin cancer [5–8].

Terminology

An understanding of fluoroscopic safety demands a familiarity with basic radiation principles and nomenclature.

Radiation is the process by which energy is emitted or transmitted either as a wave (e.g., electromagnetic, acoustic, and gravitational radiation) or particle (e.g., alpha, beta, and neutron radiation). Electromagnetic radiation is the traveling wave motion produced by changes in electric and magnetic fields. In order of increasing wavelength, the electromagnetic spectrum ranges from gamma rays and x-rays, to ultraviolet visible light and infrared to microwaves and radio waves (Fig. 14.1). X-rays, gamma rays, alpha particles, and beta particles are forms of ionizing radiation. They characteristically result in electron displacement, free radical formation, and ionization of atoms and molecules following propagation through matter such as air, water, and living tissue.

Radiation exposure is universally expressed in roentgens (R) and in SI units coulomb/kilogram (C/Kg). Radiation absorbed by a person or object is conventionally measured in radiation absorbed dose (rad) and in SI units, gray (Gy). One Gy is equal to 1 joule of energy deposited per kilogram of tissue. As different sources of radiation can have dissimilar medical effects, absorbed radiation is also expressed in dose-equivalents. For x-rays, dose equivalent and absorbed dose are equal. In contrast, the dose equivalent is 20-fold larger than the absorbed dose for alpha radiation as this type of radiation is much more damaging to the human body. Dose equivalents are expressed conventionally as roentgen-equivalent-man (rem) and in SI units as Sievert (Sv). Roentgen-equivalent-man is equal to the radiation absorbed

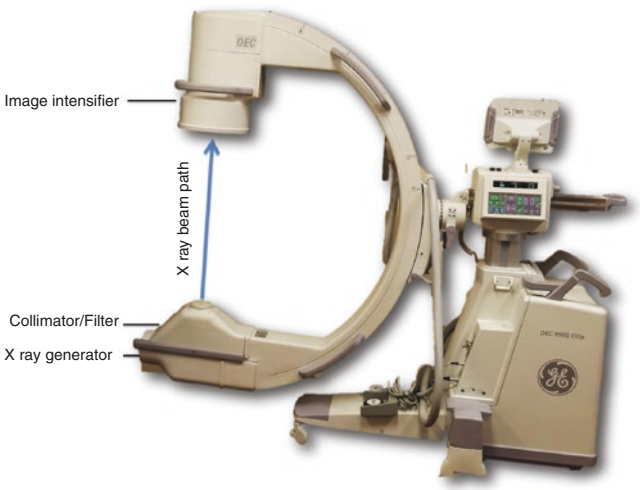

Fig. 14.1 Spectrum of Radiation Energy

K. D. Candido (✉)
Department of Anesthesiology, Department of Anesthesia and Pain Medicine, Advocate Illinois Masonic Medical Center, University of Illinois College of Medicine-Chicago, Chicago, IL, USA
e-mail: kenneth.candido@advocatehealth.com

T. Malcolm
Brigham and Women's Hospital, Department of Anesthesiology, Perioperative and Pain Medicine, Boston, MA, USA

C. W Hunter et al. (eds.), *Regenerative Medicine*, https://doi.org/10.1007/978-3-030-75517-1_14

dose multiplied by a quality factor (QF) specific to the type of radiation used (rem = rad × QF). Radiation exposure is believed to have stochastic and deterministic (also known as nonstochastic) health effects. Stochastic effects (e.g., hereditable effects, cancer) occur by chance without a threshold dose and at a rate proportional to the dose received. Deterministic effects (e.g., radiation-induced cataracts) are believed to occur after a threshold amount of radiation is reached and vary in severity proportional to exposure dose.

Biologic Effects

In living tissue, chromosomal DNA is believed to be the principal target mediating cellular effects of ionizing radiation. Error-prone repair of chemically complex double-strand DNA lesions gives rise to chromosomal aberrations, gene mutations, and apoptosis (defined as the death of cells which occurs as a normal and controlled part of an organism's growth or development). DNA damage response and repair processes are major determinants of postinjury effects within the cell. Extensive chromosomal damage and exhausted DNA repair mechanisms favor apoptosis. Oncogenesis (the development of a tumor or tumors) is often a result of perturbations in response, repair, and apoptotic mechanisms.

In tissue, deterministic effects typically involve loss of cellular reproductive capacity, fibrosis, and overall loss of function. Deterministic effects are most likely to be clinically apparent in cells and tissues most sensitive to ionizing radiation; namely highly proliferative cells and tissues such as hematopoietic cells, the gastrointestinal tract, the basal cell layer of skin, and male germ cells. Organs present in pairs or with functional subunits arranged in parallel (e.g., liver, kidney), rather than in series (e.g., gastrointestinal tract) are more resilient and least likely to demonstrate clinical signs of dysfunction. Organ-specific doses of radiation believed to result in a 1% risk of deterministic effects are shown in Table 14.1. After 3 Gy and 6 Gy, 1/100 women and 1/100 men, respectively, may experience permanent sterility [9]. Absorbed radiation doses of 1 Gy are associated with a 1/100 risk of death resulting from sequelae of bone marrow syndrome [9]. Bone marrow contains stem cells. Stem cells are sensitive to radiation exposure and excessive exposure may result in the formation of malignancies. In leukemia, a cancer of the blood, the bone marrow makes abnormal white blood cells. In aplastic anemia, the bone marrow does not make red blood cells. In myeloproliferative disorders, the bone marrow makes too many white blood cells. Each of these conditions can potentially occur in the face of radiation exposure in susceptible hosts.

Oncogenesis is a complex multifactorial process heavily affected by factors intrinsic and extrinsic to the cell. For the purposes of this discussion, it is oversimplified into four stages: (1) tumor initiation–irreversible genetic alterations lead to atypical cellular signaling; (2) tumor promotion–changes in the expression of the genome result in enhanced growth and development; (3) malignant conversion; and (4) tumor progression–the final stages are marked by genomic instability and invasive growth [10]. Animal models suggest the role of radiation is primarily limited to tumor initiation [11, 12]. Later, tumor stages are believed less dependent on the mutagenic properties of radiation due to inherent genomic instability characteristic of these advanced stages [11, 12].

Table 14.1 Estimated exposure to produce 1% risk of morbidity and mortality

Effect	Organ/tissue	Latency period	Exposure (Gy)
Morbidity			1% incidence
Male sterility	Testes	3 weeks	~6[a,b]
Female sterility	Ovaries	<1 week	3[a,b]
Erythema	Skin	1—4 weeks	<3—6[b]
Alopecia	Skin	2—3 weeks	~4[b]
Cataract	Eye	Several years	~1.5[a]
Mortality			
BMS	Bone marrow	30—60 days	~1[b]
GIS	Small intestine	6—9 days	~6[b]
Pneumonitis	Lung	1—7 months	6[b]

Adapted from PMC [14]
BMS, bone marrow syndrome; *GIS,* gastrointestinal syndrome
[a]ICRP (1984) [9]
[b]UNSCEAR (1988) [31]

X-Ray Generation and Propagation

With fluoroscopy, x-ray generation begins with passing a current (measured in milliamperes [mA]) through a heated, negatively charged filament (cathode). Cathode electrons are accelerated through an x-ray tube towards a positively charged anode. The electric potential energy (measured in kilovolt peak [kVp]) of accelerated electrons is transformed into kinetic energy prior to collision with anode orbital electrons. At the anode, tightly bound inner-shell orbital electrons are ejected after colliding with electrons accelerated through the x-ray tube. The filling of the newly created inner-shell orbital vacancies by outer-shell electrons results in the emission of photons forming the x-ray radiation that is ultimately projected through the patient to an image intensifier responsible for generation of a visual light image. Increasing kVp by 15% has the same effect on image brightness as doubling mAs. During fluoroscopy, high kVp (75 kVp—125 kVp) and low mA (2 mA—6 mA) are typically preferred during fluoroscopy in order to minimize patient exposure without drastic compromises in image quality.

After exiting the x-ray tube, the beam must first pass through a collimator and a filter before reaching the patient

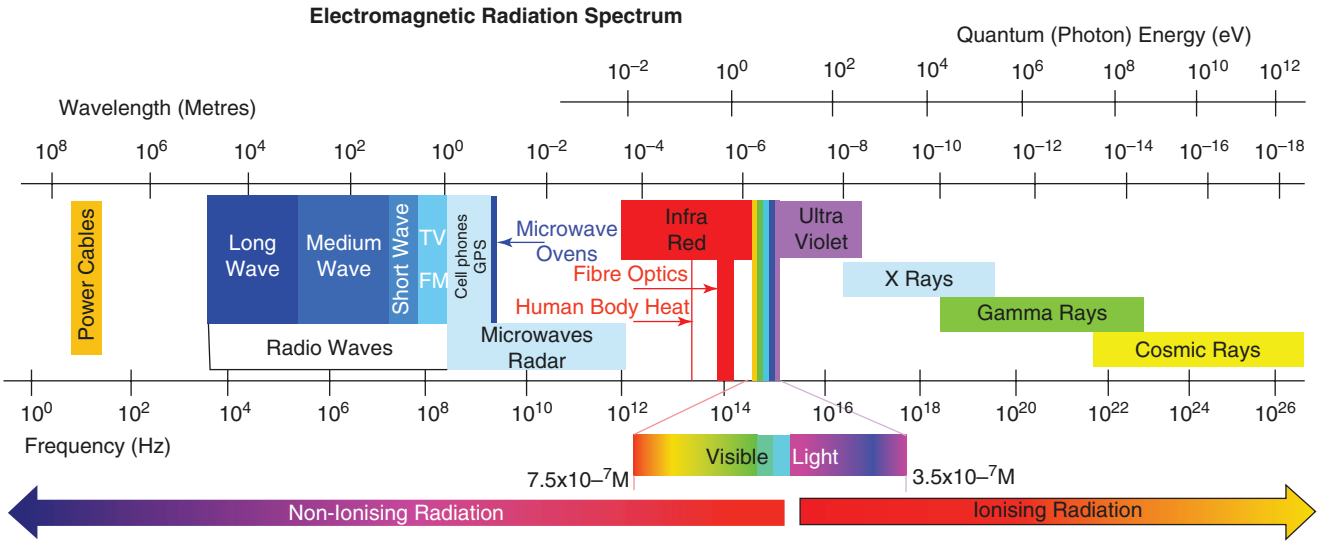

Fig. 14.2 Modern Fluroscope

(Fig. 14.2). The collimator typically contains both round and rectangular radiopaque shutter blades purposed to geometrically restrict the x-ray beam to the targeted anatomic area required for efficient visualization of the structures of interest. The round shutters are commonly known as variable aperture collimators (Iris collimators). Variable aperture collimators are smaller, produce a circular field, and automatically restrict the fluoroscopic beam to the useful field of view despite changes in magnification or source-image-distance. The rectangular shutters are larger, and can be manually adjusted to further limit beam size producing a rectangular field. Filtration helps remove low-energy x-rays that contribute to radiation exposure but do not to image quality. Aluminum and copper are the most popular x-ray filter materials.

In traversing the patient, x-ray radiation can have two important interactions involving either a complete or partial transfer of photon energy. The photoelectric effect entails the atomic process whereby a tightly bound inner-shell orbital electron completely absorbs the energy of an incident photon. The electron is ejected from the orbital and is now termed a photoelectron. In the filling of the newly created inner-shell vacancy by an outer-shell electron, a photon is emitted (secondary radiation) [13]. Compton scattering involves the collision and partial energy transfer between an incident photon and a loosely bound outer-shell orbital electron. The loosely bound electron is ejected and the incident photon deflected. Ejected electrons are responsible for radiobiologic effects associated with x-ray radiation [13]. Secondary radiation from the photoelectric effect and scattered radiation from the Compton effect do not lend to diagnostic value, but instead add to radiation exposure of nearby personnel.

Principles of Radiation Safety

There is no "safe" dose of ionizing radiation. The objectives of radiologic protection are complete prevention of deterministic effects and ensuring the risks of stochastic effects are as maximally diminished "as low as reasonably achievable, societal and economic factors being taken into account"—the ALARA principle [14]. According to the "linear-non-threshold" or LNT model, at exposure doses less than 100 mSv per year, the risks of stochastic effects are believed proportional to dose [14]. Even low doses are believed to carry an attributable risk of hereditary and oncogenic effects.

As per the 2007 International Commission on Radiation Protection (ICRP) recommendations, radiation protection can be subdivided into three core principles: justification, optimization, and application of dose limits. Justification is a principle common to the entire practice of medicine [14]. The benefit to an individual and society from an activity should outweigh the associated potential harm. In the context of fluoroscopic safety, the benefits of utilizing ionizing radiation should also outweigh the occupational risks imposed on the provider.

Dose limit recommendations are made for the United States by the National Council for Radiation Protection (NCRP) and internationally by the ICRP [14, 15]. Occupational dose limit recommendations made by the NCRP are shown in Table 14.2. The NCRP and ICRP share similar recommendations. The maximum permissible dose (MPD) of radiation to a provider is 20 mSv averaged over 5 years (i.e., 5 year MPD = 100 mSv) with no year exceeding 50 mSv [14, 15]. Maximum permissible doses should be considered extreme values with most interventionalists

Table 14.2 NCRP Recommendations for Maximum Permissible Doses during Occupational Exposure

Dose Quantity	Maximum Permissible Dose
Effective dose	
Annual	20 mSv/yr averaged over 5 years with no single year exceeding 50 mSv
Cumulative	10 mSv × age (yr)
Equivalent dose	
Lens of the eye[a]	150 mSv/yr
Skin[b]	500 mSv/yr
Hands and feet	500 mSv/yr

mSv, milliSievert; *yr*, year
[a]Likely to be changed to 50 mSv/yr
[b]Average dose over 1 cm^2 of the most highly irradiated area of the skin

experiencing less than 10% of maximum doses (i.e., between 2 and 4 mSv per year) [16]. Within the United States, x-ray regulations are governed by the Occupational Safety and Health Administration (OSHA) and all sources of ionizing radiation by the Nuclear Regulatory Commission (NRC). NRC requirements take precedence and are therefore most often implemented by hospital radiation safety officers. As per NRC regulations, all personnel likely to experience greater than 5 mSv are required to use an individual monitoring device (e.g., film badge, thermoluminescence dosimeter, etc.)

Optimization of radiation protection entails maintaining exposure remains "as low as reasonably achievable". Patient exposure can be minimized without undue concessions in image quality via optimization of equipment, x-ray beam filtration, and collimation, maximizing the source-object distance (at least 30 cm; optimum >182 cm [approximately 6 feet]), minimizing the object-image distance, limiting the field of direct radiation to only that of clinical interest, and reducing overall fluoroscopy time. The concepts driving these principles are discussed above.

Radiation exposure experienced by the provider is essentially all scatter from the patient. Maximizing the provider's distance from the irradiated field, use of all appropriate shielding devices, and limiting fluoroscopy time and images are the mainstays of optimizing a minimization of radiation exposure to the provider. Maintenance of appropriate distance from the source to the provider is simple yet effective. As exposure follows the inverse square law, doubling distance from the source quarters exposure. Standing a distance of 1 meter (100 cm) from the source yields an exposure dose approximately 0.1% of the entrance skin exposure. When shooting films in the lateral position, scatter doses up to 4 times higher occur on the side of the source compared to the image intensifier [17].

Appropriate shielding involves the use of personal protective shielding (i.e., aprons, leaded eyewear, thyroid shields, leaded gloves), patient-mounted shields, and movable room shields (ceiling-suspended shields, floor-mounted shields, and table-mounted shields). Due to decreasing limits for eye exposure (i.e., ICRP guidelines recommend an average 20 mSv over 5 years), eye shielding is likely to be of increasing importance in the future [14, 18]. A cumulative dose of 0.5 Gy is estimated to be the threshold dose for radiation cataracts [19–21]. Multiple studies have shown this limit may be easily reached without the use of proper protective equipment [22–24]. Within the ORAMED project, exposure levels of interventional radiologists and cardiologists at different hospitals throughout Europe were evaluated. Approximately half of interventional radiologists performing endoscopic retrograde cholangiopancreatography were exposed to eye radiation doses surpassing new ICRP recommendations [24]. Protective eyeglasses and ceiling-suspended shields have been shown to be an effective method of reducing exposure to the lens of the eye [25]. Koukorava et al. demonstrated a 90% decrease in eye exposure with the use of 0.5 mm lead glasses and a 93% decrease with the use of ceiling-suspended screens [19]. Protective eyewear is currently recommended for those expected to experience ocular exposure greater than 4 mSv per month. This threshold will likely be lowered with expected future decreases in MPD [20, 26, 27].

The MPD for the hands is 500 mSv per year [14, 15]. Wearing a ring badge is the current recommended method of measuring hand exposure. Minimizing exposure to the hands is best achieved with distance and shielding. Protective gloves with minimum 0.25 mm lead equivalent are useful but should not lull the wearer into a false sense of security. With automated brightness control, the lead gloves may be detected, resulting in automatically increased radiation output, at least partially negating the protection afforded by the gloves. Alternative measures such as the use of forceps or other holding devices are encouraged.

The recommended MPD for the torso and legs is 500 mSv [14, 15]. Exposure in these areas is significantly reduced with the use of single and two-piece lead apron. The apron is lead-impregnated vinyl or rubber with a shielding equivalent of at least 0.25 mm. Annual inspection of the lead apron is required by the Joint Commission on the Accreditation of Healthcare Organizations, with recommended disposal for defects greater than 15 mm^2 [28]. Thyroid shields with minimum 0.5 mm lead equivalent have been shown to significantly decrease thyroid exposure dose [29, 30]. The protection conferred with the use of a lead apron or thyroid shield is offset by the increased weight and decreased maneuverability associated with these devices.

Summary

Justification, optimization, and application of dose limits are the basic principles underlying radiation safety. Radiation exposure should be given judiciously for the sake of the patient, provider, and society. In with safe practices, radiation exposure should be maintained at doses "as low as reasonably achievable, societal and economic factors being taken into account"—the ALARA principle [14]. Provider exposure is best optimized by maximizing distance from the source of radiation, use of all appropriate shielding devices, limiting fluoroscopy time, and images. With appropriate safety practices, individual providers should rarely, if ever, exceed 10% of established maximum permissible doses of radiation.

References

1. Shope TB. Radiation-induced skin injuries from fluoroscopy. Radiogr Rev Publ Radiol Soc N Am Inc. 1996;16:1195–9.
2. United States Food and Drug Administration. Public Health Advisory: Avoidance of Serious X-Ray Induced Skin Injuries to Patients During Fluoroscopically Guided Procedures. Rockville: Center for Devices and Radiological Health, United States Food and Drug Administration; 1994.
3. FastStats. 2018. Available at: https://www.cdc.gov/nchs/fastats/leading-causes-of-death.htm. Accessed 23 Sept 2018.
4. The top 10 causes of death. World Health Organization. Available at: http://www.who.int/news-room/fact-sheets/detail/the-top-10-causes-of-death. Accessed 23 Sept 2018.
5. Fishman SM, Smith H, Meleger A, Seibert JA. Radiation safety in pain medicine. Reg Anesth Pain Med. 2002;27:296–305.
6. Lewis EB. Leukemia and ionizing radiation. Science. 1957;125:965–72.
7. Ulrich H. The incidence of leukemia in radiologists. N Engl J Med. 1946;234:45.
8. Yoshinaga S, Mabuchi K, Sigurdson AJ, Doody MM, Ron E. Cancer risks among radiologists and radiologic technologists: review of epidemiologic studies. Radiology. 2004;233:313–21.
9. Nonstochastic effects of ionizing radiation: a report of a task group of Committee 1 of the ICRP. Pergamon Press; 1984.
10. Pitot HC. The molecular biology of carcinogenesis. Cancer. 1993;72:962–70.
11. Ellender M, Harrison JD, Edwards AA, Bouffler SD, Cox R. Direct single gene mutational events account for radiation-induced intestinal adenoma yields in Apc(Min/+) mice. Radiat Res. 2005;163:552–6.
12. Sources and effects of ionizing radiation: United Nations Scientific Committee on the Effects of Atomic Radiation: UNSCEAR 2000 report to the General Assembly, with scientific annexes. United Nations; 2000.
13. Bushong SC. BOPOD—radiologic science for technologists: physics, biology, and protection. Elsevier Health Sciences; 2013.
14. PMC E. The 2007 recommendations of the international commission on radiological protection. ICRP publication 103. Ann ICRP. 2007;37:1–332.
15. Report No. 116—Limitation of exposure to ionizing radiation (Supersedes NCRP Report No. 91) (1993) | NCRP | Bethesda. Available at: https://ncrponline.org/shop/reports/report-no-116-limitation-of-exposure-to-ionizing-radiation-supersedes-ncrp-report-no-91–1993/. Accessed 30 Oct 2018.
16. Miller DL. Make radiation protection a habit. Tech Vasc Interv Radiol. 2018;21:37–42.
17. Valentin J. Avoidance of radiation injuries from medical interventional procedures. Ann ICRP. 2000;30:7–67.
18. Dauer LT, et al. Guidance on radiation dose limits for the lens of the eye: overview of the recommendations in NCRP Commentary No. 26. Int J Radiat Biol. 2017;93:1015–23.
19. Koukorava C, Carinou E, Ferrari P, Krim S, Struelens L. Study of the parameters affecting operator doses in interventional radiology using Monte Carlo simulations. Radiat Meas. 2011;46:1216–22.
20. Authors on behalf of ICRP et al. ICRP publication 118: ICRP statement on tissue reactions and early and late effects of radiation in normal tissues and organs—threshold doses for tissue reactions in a radiation protection context. Ann ICRP. 2012;41:1–322.
21. Neriishi K, et al. Radiation dose and cataract surgery incidence in atomic bomb survivors, 1986–2005. Radiology. 2012;265:167–74.
22. Vano E, Gonzalez L, Fernández JM, Haskal ZJ. Eye lens exposure to radiation in interventional suites: caution is warranted. Radiology. 2008;248:945–53.
23. Dauer LT, Thornton RH, Solomon SB, St Germain J. Unprotected operator eye lens doses in oncologic interventional radiology are clinically significant: estimation from patient kerma-area-product data. J Vasc Interv Radiol JVIR. 2010;21:1859–61.
24. Vanhavere F, et al. Measurements of eye lens doses in interventional radiology and cardiology: final results of the ORAMED project. Radiat Meas. 2011;46:1243–7.
25. Richman AH, Chan B, Katz M. Effectiveness of lead lenses in reducing radiation exposure. Radiology. 1976;121:357–9.
26. Center for History and New Media. Zotero Quick Start Guide. Available at: http://zotero.org/support/quick_start_guide.
27. Status of NCRP Scientific Committee 1–23 Commentary on Guidance on Radiation Dose Limits for the Lens of the Eye. Available at: https://www-ncbi-nlm-nih-gov.proxy.library.cornell.edu/pmc/articles/PMC4697269/. Accessed 29 Oct 2018.
28. Lambert K, McKeon T. Inspection of lead aprons: criteria for rejection. Health Phys. 2001;80:S67–9.
29. Müller LP, Suffner J, Mohr W, Degreif J, Rommens PM. Effectiveness of lead thyroid shield for reducing roentgen ray exposure in trauma surgery interventions of the lower leg. Unfallchirurgie. 1997;23:246–51.
30. Yang MS, et al. Evaluation of usability of the shielding effect for thyroid shield for peripheral dose during whole brain radiation therapy. J Korean Soc Radiother Technol. 2014;26:265–72.
31. United Nations Scientific Committee on the Effects of Atomic Radiation. UNSCEAR, 1988. Sources, effects and risks of ionizing radiation. United Nations, New York; 1988.