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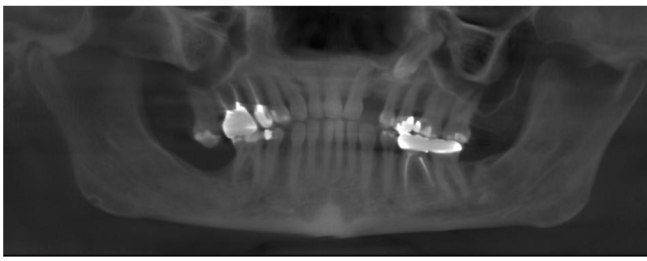
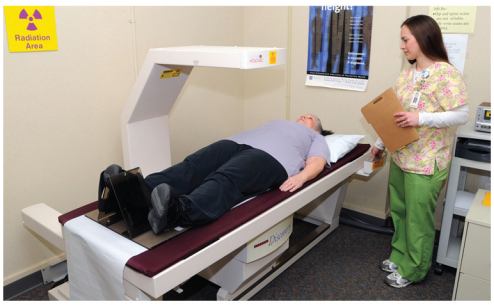
Radiation Protection Guidance for Diagnostic and Interventional X-Ray Procedures

Federal Guidance Report No. 14





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Radiation Protection Guidance for Diagnostic and Interventional X-Ray Procedures

November 2014

Interagency Working Group on Medical Radiation
U.S. Environmental Protection Agency
Washington, D.C. 20460

Dedication

Doreen G. Hill, MPH, PhD, was a long-term member of the ISCORS Medical Workgroup. Sadly, she passed away before she could see her work on Federal Guidance Report No. 14 completed. She represented the Department of Labor's Occupational Safety and Health Administration on the workgroup in an admirable fashion. Doreen brought to the workgroup a high degree of professionalism, a great interest in x-ray safety, a strong work ethic, and a focus on ensuring that we remained sensitive to OSHA regulations and policies. She was our editor, a self-imposed and thankless task, and enforced a clear writing style. She transformed our jargon and incomprehensible run-on sentences into language that conveyed meaning in a straightforward way. Whenever she was unavailable during a web conference, someone else would attempt to fulfill her role, albeit with nowhere near her style and grace, saying they were "channeling Doreen." After her passing, we continued to use the phrase and its intent during our meetings. Doreen brought with her a sense of humor that permeated our meetings. She often said she never wanted to miss a workgroup meeting because they were the most fun, entertaining, and enlightening meetings she had ever attended. It was she who made it so. We miss you, Doreen, and hope that our channeling of your spirit has kept the document's quality high and its readability good.

FOREWORD

The authority of the Federal Radiation Council to provide radiation protection guidance to federal agencies was transferred to the Environmental Protection Agency (EPA) on December 2, 1970, by Reorganization Plan No. 3. Under this authority, Federal Guidance Report No. 14 provides federal facilities that use diagnostic and interventional x-ray equipment with recommendations for keeping patient doses as low as reasonably achievable without compromising the quality of patient care.

Federal Guidance Report No. 14 is an update to the 1976 x-ray guidance in Federal Guidance Report No. 9. This guidance takes into account that in recent years there has been a significant increase in the use of digital imaging technology and high dose procedures, such as computed tomography (CT). Also, there have been many reports of unnecessarily high doses being given to children undergoing CT exams.

The guidance in this document was created by an Interagency Steering Committee on Radiation Standards Work Group, which included medical and radiation protection professionals from the EPA, the Department of Health and Human Services, the Department of Veterans Affairs, the Department of Defense (Departments of the Army, Navy, and Air Force), the Occupational Safety and Health Administration and the Commonwealth of Pennsylvania. The interagency collaborative effort highlights the importance of this guidance for federal healthcare facilities.

Federal Guidance Report No. 14 is being issued to all federal facilities that perform diagnostic or interventional x-ray procedures. Private healthcare facilities are encouraged to consider adopting any or all of the guidance and its recommendations as they consider appropriate.While not binding on any agency or facility, incorporating the best practices defined in this guidance will improve the safety of diagnostic and interventional imaging.

Gina McCarthy
Administrator

PREFACE

Federal Guidance reports were initiated under the Federal Radiation Council (FRC), which was formed in 1959, through Executive Order 10831. A decade later its functions were transferred to the Administrator of the newly formed U.S. Environmental Protection Agency (EPA) as part of Reorganization Plan No. 3 of 1970 (Nixon 1970). Under these authorities it is the responsibility of the Administrator to "advise the President with respect to radiation matters, directly or indirectly affecting health, including guidance for all federal agencies in the formulation of radiation standards and in the establishment and execution of programs of cooperation with States" (EPA 2012).

This document is Federal Guidance Report No. 14 (FGR 14), "Radiation Protection Guidance for Diagnostic and Interventional X-ray Procedures." It replaces Federal Guidance Report No. 9 (FGR 9), "Radiation Protection Guidance for Diagnostic X-rays," which was released in October 1976. As with FGR 14, the development of FGR 9 was the result of a growing recognition at the time among medical practitioners, medical physicists, and other scientists that medical uses of ionizing radiation represented a significant and growing source of radiation exposure for the U.S. population. Almost 40 years after its release, it is clear that FGR 9 was a groundbreaking achievement. FGR 9 served as the template for the current document, and the authors of FGR 14 are deeply appreciative of the work of their predecessors.

FGR 9 provided constructive guidance on the use of diagnostic film radiography, for which there was an incentive to deliver appropriate radiation doses and avoid retakes resulting from under- or over-exposing the film. This report, Federal Guidance Report No. 14, focuses on the transition to digital imaging. It extends the scope to include computed tomography (CT), interventional fluoroscopy, bone densitometry, and veterinary practice, and updates sections on radiography and dentistry that were covered in FGR 9. In addition, it addresses justification of the examination and optimization of radiation dose, and features an expanded section on occupational exposure.

There is no question that medical imaging has provided great improvements in medical care through the use of x-rays for diagnosis. As with much of medical care, x-rays provide great benefit when used properly, but are not without risk. Human exposures to medical radiation were neither controlled by law nor covered by consensus guidance. In 1972, the Federal Radiation Council released a report concluding that "...medical diagnostic radiology accounts for at least 90% of the total man-made radiation dose to which the U.S. population is exposed." In response, the EPA and the U.S. Department of Health, Education, and Welfare (predecessor of the Department of Health and Human Services (DHHS)) developed and issued FGR 9. The key recommendations in FGR 9 were subsequently approved by President Carter (Carter 1978) and published in the Federal Register on February 1, 1978. The basic approach for reducing exposure from diagnostic uses of x-rays in federal facilities involved three principal considerations: 1) eliminating clinically unproductive examinations, 2) assuring the use of optimal technique when examinations are performed, and 3) requiring appropriate equipment to be used (EPA 1976).

FGR 9 was the first Federal Guidance Report to provide a framework for developing radiation protection programs for diagnostic uses of x-rays in medicine. It introduced into federal guidance the concepts of:

- Conducting medical x-ray studies only to obtain diagnostic information,
- Limiting routine or elective screening examinations to those with demonstrated benefit over risk,
- Considering possible fetal exposures during examinations of pregnant or potentially pregnant patients,
- Ensuring diagnostic equipment operators meet or exceed the standards of credentialing organizations,
- Specifying that standard x-ray examinations should satisfy maximum numerical exposure criteria, and
- Recommending that each imaging facility have a quality assurance program designed to produce radiographs that satisfy diagnostic requirements with minimal patient exposure.

Much of FGR 9 has stood the test of time, but other parts have become obsolete. In particular, the advent of digital x-ray image acquisition has eliminated film blackening as a built-in deterrent to overexposing patients.

Digital imaging methodologies have improved medical care by increasing the quality of diagnostic images and significantly decreasing the need for exploratory surgeries. However, in some cases, the use of this newer technology was accompanied by a significant increase in patient radiation dose (Compagnone et al. 2006; Seibert et al. 1996). Some newly introduced technologies, e.g., computed tomography (CT), yielded higher patient doses than the radiographic procedures they replaced. Finally, increased utilization of imaging studies resulted in a greater radiation dose to the population.

The U.S. Food and Drug Administration's (FDA) performance standards for ionizing radiation emitting products address radiography, fluoroscopy, and CT equipment, and are codified in 21 CFR 1020 (FDA 2014g). The FDA revised these performance standards in 2005, in part to address some of the radiation dose issues discussed above.

The National Council on Radiation Protection and Measurements (NCRP) reports that medical radiation exposure to the average member of the U.S. population has increased rapidly and continues to do so. Their previous estimate, based on 1970's and early 1980's data, was that medical exposure accounted for 0.53 millisievert (mSv) or 53 millirem (mrem) per year, which was 15% of the total annual average (per capita) dose (NCRP 1989a). Based on 2006 data, this estimate was increased to 3 mSv (300 mrem) per year or 48% of the total. On a per capita basis, the average effective dose from all medical exposures in the U.S. in 2006 was approximately equal to that from natural background radiation, with medical x-rays accounting for the majority (NCRP 2009).

Concerns continue to be raised about the risks associated with patients' exposure to radiation from medical imaging (Amis et al. 2007; FDA 2010b; FDA 2014g). Because ionizing radiation can cause damage to deoxyribonucleic acid (DNA), exposure may increase a person's lifetime risk of developing cancer. Although the risk to an individual from a single exam may not itself

be large, millions of exams are performed each year, making radiation exposure from medical imaging an important issue for the public (Berrington de González et al. 2009; Brenner 2007; HPS 2010; Smith-Bindman et al. 2009). The accuracy of published cancer estimates is limited by the use of generalized exposure data, by assuming that cancer risk is a linear function of dose. The International Organization for Medical Physics recommends that, "Prospective estimates of cancers and cancer deaths induced by medical radiation should include a statement that the estimates are highly speculative because of various random and systematic uncertainties embedded in them" (Hendee 2013).

Two retrospective epidemiological cohort studies of cancer incidence after CT imaging of children and adolescents have been performed. One of these studies also included young adults. Both studies found an excess risk of cancer following CT scans, one involving brain cancer and leukemia (Pearce et al. 2012) and the other an increase in all cancers (Mathews et al. 2013). Both studies found a dose response trend. Despite the statistically significant elevation in relative risk, the excess absolute risks were small because of the low natural incidence of cancer in these populations. Furthermore, concerns have been raised, both about the methods used in these studies and about inconsistencies with respect to these findings and other epidemiological studies of cancer risk from ionizing radiation (NCRP 2012; Walsh 2013). There is a need for additional studies to confirm these findings. Although experts may disagree on the extent of the risk of cancer from medical imaging, not whether there is any, there is uniform agreement that the medical necessity of a given level of radiation exposure should be weighed against the risks.

The changes in the available technologies, the reported increase in annual dose from medical imaging, and the concerns addressed above have led EPA to issue this new guidance to the federal medical community. It is intended for federal agencies and federal facilities, which are facilities owned, leased, or operated by the federal government. The guidance presented here is also suitable for use by the broader medical community, including state, local, tribal, territorial, and other facilities. This guidance creates no binding legal obligation; rather, it offers recommendations for the safe and effective use of x-ray imaging modalities. Federal agencies that adopt these recommendations (e.g., into orders or standard operating procedures) should, at their discretion, strengthen these statements where appropriate. EPA believes that the information contained in this guidance will help users of diagnostic imaging equipment ensure that justification is performed for each procedure and patient, and that the dose delivered to each patient is optimized. This guidance also provides recommendations for radiation protection of medical workers. The goals of radiation dose management are to optimize radiation protection for patients, consistent with image quality requirements, and to keep worker radiation doses as low as reasonably achievable (ALARA).

This document is not concerned with methods to improve diagnosis. Rather, the goal is to improve the benefit:risk ratio by encouraging optimization of radiation dose and improvements in quality assurance, particularly for those imaging modalities that were not discussed in FGR 9. Specifically, FGR 14 establishes guidance for digital x-ray imaging and addresses protection aspects. These aspects of guidance and protection include:

- Newer dose metrics
- Imaging referral guidelines (e.g., ACR Appropriateness Criteria)
- CT, fluoroscopy (including interventional fluoroscopy), and bone densitometry as

modalities additional to medical and dental radiography
- Veterinary imaging.

In addition, FGR 14 further refines the concepts of exposure guides and dose optimization described in FGR 9, in accordance with current thinking on diagnostic reference levels.

It should be noted that FGR 14 does not address radiation therapy, and addresses nuclear medicine only when used in conjunction with x-ray imaging, e.g., positron emission tomography and CT (PET/CT). Nothing in this guidance relieves the federal facility from complying with Nuclear Regulatory Commission (NRC) requirements in Title 10 of the Code of Federal Regulations when using both x-ray devices and NRC-regulated materials in the same procedure or when workers or the public are exposed to radiation from both x-ray devices and NRC-regulated materials.

In carrying out its federal guidance responsibilities, EPA works closely with other federal agencies through its participation on the Interagency Steering Committee on Radiation Standards (ISCORS). Moreover, EPA recognizes, as it did in 1976, that the expertise needed to make sound recommendations for reducing unnecessary radiation exposure due to the medical use of x-rays in diagnostic and interventional procedures resides in several agencies. Therefore, this report was prepared by the interagency Medical Work Group of the ISCORS Federal Guidance Subcommittee that included physicians, medical physicists, health physicists and other scientists and health professionals from the U.S. Department of Defense (DoD), U.S. Department of Veterans Affairs (VA), U.S. Department of Labor, DHHS and EPA.

As in FGR 9, the recommendations contained in this report represent the consensus judgment of the Medical Work Group for the practice of diagnostic and interventional imaging by federal agencies. Since the body of knowledge on both the radiation exposure and efficacy of x-ray examinations is rapidly changing, comments and suggestions on the areas addressed by this report will assist EPA to conduct periodic reviews and to make appropriate revisions.

The references in this document are current though January 2014, and some may be updated or superseded in the future. The reader is encouraged to consult the publisher of any cited document to determine the most current version.

RECOMMENDATIONS FOR AGENCY ACTIONS

This section provides recommendations for agency actions. Related recommendations for facility actions are in the section on SUMMARY AND RECOMMENDATIONS FOR FACILITY ACTIONS.

1. Agencies should establish an infrastructure for collecting, storing and analyzing patient dosimetry data. Agencies should have their facilities track these data longitudinally. Infrastructure planning should address the data acquisition, networking, storage, analysis, reporting and security requirements of existing and planned future diagnostic devices.
2. Agencies should ensure that all radiation use in medical, dental, and veterinary imaging is justified and optimized. This is the responsibility of all who are involved. Dose management begins when a patient is considered for a procedure involving ionizing radiation, continues into equipment setup before the exam begins, and ends when any necessary radiation-related follow-up is completed.
3. It is strongly recommended that agencies ensure that the justification of medical exposure for an individual patient be carried out by the Referring Medical Practitioner, in consultation with the Radiological Medical Practitioner, when appropriate. Other members of the patient's care team may contribute to this process. (See section on REQUESTING AND PERFORMING STUDIES INVOLVING X-RAYS.)
4. Agencies should promote the development of national diagnostic reference levels for use as quality assurance and quality improvement tools in each type of examination.
5. Agencies should only adopt screening programs that have undergone rigorous scientific evaluation of efficacy to ensure that the risk posed to the population screened does not outweigh the benefits in detection of disease.
6. Agencies should, to the extent permitted by regulations, use methods for estimating individual occupational doses based on the goal of assigning accurate doses rather than overly conservative estimates of doses. ICRP concluded that the term "effective dose" (E) is simpler and less cumbersome than "effective dose equivalent" (ICRP 1991a), so it is the term used in this document. NCRP Report No. 122 provides recommended methods for determining effective dose (NCRP 1995). Federal regulatory agencies should establish consistent methods and procedures for this purpose.
7. Agencies should ensure that their facilities have adequate quality assurance and quality control programs. Quality assurance and quality control programs are used to ensure that equipment functions properly and that those who operate it are qualified to use the features of the equipment. These programs are an essential element of safety in medical, dental and veterinary imaging. A facility's participation in nationally recognized accreditation programs is one way to ensure that its quality assurance and quality control measures are adequate.
8. Agencies and their facilities should adopt recognized standard terminology, when available, in their information reporting systems and databases.
9. Agencies should adopt recognized standards for sharing clinical reports of radiological procedures within each agency, among agencies, and with non-governmental health care facilities in order to make clinical information available to health care providers and to avoid unnecessary duplicate examinations.

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INTRODUCTION

The following concepts are integrated throughout this document.

1. This guidance was written without regard to specific models of equipment.
2. It is intended to be a practical and appropriately prescriptive tool.
3. A balance was struck between being sufficiently specific and keeping the document generic enough to remain current.
4. All radiation use in medical, dental and veterinary imaging should be justified and optimized.
5. Dose reduction technology should be incorporated into the equipment.
6. Dose reduction technology only works when it is used, and used appropriately.
7. Operators should have initial and periodic refresher training, easy to use tools (e.g., checklists), and encouragement.
8. Dose reduction strategies should be integrated into protocols, where possible.
9. Improvements in imaging and equipment will continue.
10. This is a guidance document that makes recommendations ("should") but creates no binding legal obligation. The words "must" and "shall" are used only when referring to the existing requirements of federal laws and regulations.
11. This guidance does not apply to the medical use of NRC-regulated radioactive material, except in situations in which exposures include both electronically-generated x-rays and radiation from radioactive material. NRC does not have jurisdiction over exposure solely from electronically-produced radiation, and references to NRC regulations in that case are for informational purposes only.

The fundamental objective in performing an x-ray examination is to obtain the required diagnostic information with only as much radiation dose as is required to achieve adequate image quality for the clinical task. Achievement of this objective requires: 1) selecting appropriate equipment and using appropriate protocols, 2) assuring equipment is functioning properly and calibrated, 3) assuring equipment is operated only by competent personnel, and 4) appropriately preparing the patient and performing the examination.

Even more so than when the original FGR 9 (EPA 1976) was published in 1976, imaging in 2014 plays a critical role in medical care within the United States. In the approximately thirty years that have elapsed since the early 1980s, medical imaging has grown rapidly in utilization and capability (NCRP 1989a; NCRP 2009). Computed tomography (CT) provided a new cross sectional imaging method, initially for evaluating the contents of the skull and then for other body cavities and organs, for assessing tissues and organs that previously required surgery for evaluation. The use of CT resulted in fewer exploratory surgical procedures and permitted more accurate, non-invasive diagnoses. For many years, the number of CT procedures grew at a rate greater than 10% per year (NCRP 2009).

Smaller image detector elements increased the spatial resolution of CT imaging. Other technological improvements have included improved mechanical function, multi-row detector CT scanners, more capable computer technology, and improved x-ray tubes. As a result CT now permits evaluation of physiologic characteristics as well as anatomy, and permits pediatric exams

previously limited by motion artifact. Indications for imaging have increased as have use of multi-sequence studies that allow organs to be evaluated during several phases of contrast enhancement.

Improvements in fluoroscopy detector systems and improvements in techniques and equipment (e.g., catheters, stents, embolic agents) facilitated an increase in the number and variety of image-guided interventions. These procedures replaced many open surgical procedures and now provide new therapy options for many diseases.

With the increased availability and use of CT and fluoroscopy systems, there has been a marked increase in the contribution of radiation dose from x-ray based medical studies to the overall radiation dose to the U.S. population. CT imaging studies increased from 3 million in 1980 to 62 million in 2006. During this period, the estimated per capita effective dose from all x-ray-related medical procedures other than radiation therapy increased from 0.39 to 2.23 millisievert per year (mSv/y) (39 to 223 millirem per year (mrem/y)), or from 11% to 36% of the total U.S. population dose (ACR 2007; NCRP 2009).

National and international organizations have classified ionizing radiation (including x-rays) as a known human carcinogen (NTP 2011). These groups include the National Toxicology Program and the World Health Organization's International Agency for Research on Cancer (IARC 2012). Human epidemiological studies have demonstrated the potential of ionizing radiation to induce cancer at effective doses greater than approximately 0.1 Sv (UNSCEAR 2011). However, it is prudent to consider that lower doses might also carry a risk.

Technological advances have improved diagnostic capabilities and image quality. Some of these advances entail increases in patient dose. However, others have provided new and effective methods for reduction of radiation exposure. Improvements in film and film-screen (also known as screen-film) technology permitted reduction in the amount of radiation dose necessary to obtain radiographic images like the chest radiograph. Improvement in image intensifiers and digital image receptors decreased the amount of radiation necessary for fluoroscopic studies. The advent of pulsed fluoroscopy permitted even further reduction in the radiation required for a given imaging study. Simple advances such as "last image hold" that cause the last image acquired to remain on the video display screen after fluoroscopy is stopped can markedly reduce the dose of radiation involved in these studies. Improved systems also significantly reduced the radiation dose necessary for mammography. In CT, improvements in detector composition and function, dose modulation based on the patient's size and body part examined, advanced reconstruction algorithms, and prospective acquisition gating during the cardiac cycle have all provided methods to significantly reduce the radiation dose from imaging studies.

Research has demonstrated that these dose-reduction techniques are not always employed or used to best advantage in medical imaging, and medical education does not typically provide focus on the effects of and protection from radiation exposure (ICRP 2000b). Seemingly simple and obvious strategies, like altering the energy and amount of radiation used in imaging children as compared with adults, have not been adopted universally (Paterson et al. 2001). Some units with pulsed fluoroscopy capability have never been used in that mode. This document is intended to assist the reader in appreciating the need for understanding doses from procedures

and maximizing the benefit:risk ratio in the use of medical imaging systems.

The primary goal of medical imaging with x-rays is to answer a clinical question or guide an intervention. Using only as much radiation dose as is required to achieve adequate image quality should be the second goal. When image quality is inadequate or the number of images is inadequate to answer the clinical question, radiation has been administered without benefit to the patient. There are many appropriate ways to reduce radiation dose without compromising diagnostic quality. These are discussed in the sections specifically dedicated to each imaging modality.

Other important ways to reduce radiation exposure to patients are to avoid duplicate studies and to avoid any study that does not contribute effectively to the primary goal of answering the clinical question. Sharing digital images among facilities reduces patient radiation doses by precluding unnecessary duplicative imaging. Each individual requesting an imaging examination should have sufficient knowledge of the approximate radiation doses associated with imaging examinations to be able to request the most effective imaging study that provides the necessary information at the lowest radiation dose. When appropriate, examinations not involving ionizing radiation are preferable. Organizations such as the American College of Radiology (ACR) and American College of Cardiology (ACC) have published guidance that can help health professionals choose the most appropriate examinations to answer their clinical questions (AAPM 2011b; ACCF/SCAI/STS/AATS/AHA/ASNC/HFSA/SCCT 2012; ACR 2012a).

As an example, in the evaluation of a patient with cough and fever, a standard two view chest x-ray series may provide adequate information for the diagnosis and treatment of pneumonia at a small fraction of the radiation dose that would be delivered by a chest CT examination. Similarly, a CT angiogram may provide visualization of a large vascular distribution in a single imaging run with a lower radiation dose than the multiple digital subtraction angiographic sequences that may be required to adequately visualize the same area.

Once a specific imaging study is selected, technical aspects of the image acquisition become the most critical influence on both the radiation dose delivered to the patient and the quality of the resulting images. Although reduction of radiation exposure should be a goal, reduction of dose to a level that results in an increased number of unsatisfactory examinations requiring repeat imaging will actually increase patient dose overall and should be avoided as much as excessive dose should be. In the use of film-screen technology, over and under exposure were evident on the resulting image, but with digital based imaging, these conditions are not as apparent. Digital image quality may continue improving with increasing dose, even beyond what is needed or adequate. As a result, good clinical practices include effective quality control programs, optimized imaging protocols that provide only the necessary sequences, adjustment of technical factors and radiation dose for patient size and age, and employment of the best available dose reduction technologies existing in the equipment in use.

The information in this document represents the working group's understanding of the state of knowledge as of 2014. The document is divided into sections based on imaging modality.

RADIATION SAFETY STANDARDS AND GENERAL CONCERNS

BIOLOGICAL EFFECTS OF IONIZING RADIATION

Biological effects resulting from radiation exposure are traditionally divided into stochastic effects and deterministic effects. The classification of some injuries (such as cataracts) as deterministic or stochastic is uncertain.

Stochastic injuries (e.g., cancer induction) arise from misrepair of damage to the DNA. The result is a genetic transformation. The likelihood of stochastic effects increases with the total radiation energy absorbed by the different organs and tissues of an individual, but their severity is independent of total dose. The probability of a radiation-induced malignancy due to an invasive procedure is small compared with the baseline probability of developing a malignancy (Mettler et al. 2008).

Deterministic effects (also known as tissue effects or tissue reactions) are largely caused by the death or radiation-induced reproductive sterilization of large numbers of cells. This is not expressed clinically until these cells unsuccessfully attempt division or differentiation. The severity of the effect varies with radiation dose. A dose threshold usually exists. The threshold dose is subject to biologic variation (ICRP 2012).

GENERAL PRINCIPLES OF RADIATION PROTECTION

The International Commission on Radiological Protection (ICRP) has formulated a set of three fundamental principles for radiation protection (ICRP 2007a; ICRP 2007b). These principles are *justification*, *optimization of protection*, and *application of dose limits*. The first two principles apply to a source of exposure, and thus are intended to support protection for all individuals who may be exposed to that source. The third principle applies to occupational and public exposure, but explicitly excludes medical exposure of patients.

The principle of *justification* states that, in general, "any decision that alters the radiation exposure situation should do more good than harm. This means that by introducing a new radiation source, by reducing existing exposure, or by reducing the risk of potential exposure, one should achieve sufficient individual or societal benefit to offset the detriment it causes" (ICRP 2007a; ICRP 2007b). With regard to medical exposures specifically, "the principal aim of medical exposures is to do more good than harm to the patient, subsidiary account being taken of the radiation detriment from the exposure of the radiological staff and of other individuals" (ICRP 2007a).

The ICRP (ICRP 2007a) addresses justification in medicine as follows:

For radiation use in medicine:
"The principle of justification applies at three levels in the use of radiation in medicine. At the first level, the use of radiation in medicine is accepted as doing more good than harm to the patient. This level of justification can now be taken for granted."

For specific imaging examinations:
"At the second level, a specified procedure with a specified objective is defined and justified (e.g., chest radiographs for patients showing relevant symptoms, or a group of individuals at risk to a condition that can be detected and treated). The aim of the second level of justification is to judge whether the radiological procedure will usually improve the diagnosis or treatment or will provide necessary information about the exposed individuals."

For individual patients:
"At the third level, the application of the procedure to an individual patient should be justified (i.e., the particular application should be judged to do more good than harm to the individual patient). Hence all individual medical exposures should be justified in advance, taking into account the specific objectives of the exposure and the characteristics of the individual involved."

The principle of *optimization of protection* states that "the likelihood of incurring exposures, the number of people exposed, and the magnitude of their individual doses should all be kept as low as reasonably achievable, taking into account economic and societal factors. This means that the level of protection should be the best under the prevailing circumstances, maximizing the margin of benefit over harm" (ICRP 2007a; ICRP 2007b).

The concept of patient radiation dose optimization is used throughout this document. Dose optimization means delivering a radiation dose to the organs and tissues of clinical interest no greater than that required for adequate imaging and minimizing dose to other structures (e.g., the skin (FDA 1994)). Patient radiation dose is considered to be optimized when an imaging study is performed with the least amount of radiation required to provide adequate image quality under the prevailing clinical circumstances and, for fluoroscopy, to provide adequate imaging guidance (NIH-NCI-SIR 2005). There is disagreement among experts as to what protocol and radiation dose is optimal in a particular circumstance. There is no single optimal technique or protocol suitable for use with all imaging equipment.

The goal of every imaging procedure is to provide images adequate for the clinical purpose. What constitutes adequate image quality depends on the modality being used and the clinical question being asked. Imaging requirements depend on the specific patient and the specific procedure. Reducing patient radiation dose to the point where images are inadequate is counterproductive; it results in radiation dose to the patient without answering the clinical question, ultimately resulting in the need for additional radiation dose. Improving image quality beyond what is clinically needed subjects the patient to additional radiation dose without additional clinical benefit. The goal of patient radiation management is to keep patient radiation dose optimized (i.e., as low as reasonably achievable consistent with the use of appropriate

equipment and the imaging requirements for a specific patient and a specific procedure) (ICRP 2007a).

The principle of *application of dose limits* states that "the total dose to any individual from regulated sources in planned exposure situations other than medical exposure of patients should not exceed the appropriate limits recommended by the (International) Commission (on Radiological Protection)" (ICRP 2007a; ICRP 2007b). It is important to note this principle explicitly excludes medical exposure of patients. Dose limits do not apply to medical exposure, which is defined by the ICRP as "the exposure of persons as part of their diagnosis or treatment (or exposure of a patient's embryo/fetus or breast-feeding infant) and their comforters and carers (caregivers) (other than occupational)" (ICRP 2007b). As the ICRP has stated, "Provided that the medical exposures of patients have been properly justified and that the associated doses are commensurate with the medical purpose, it is not appropriate to apply dose limits or dose constraints to the medical exposure of patients, because such limits or constraints would often do more harm than good" (ICRP 2007b).

While dose limits do not apply to medical exposures, radiation doses to patients should always be optimized. All responsible parties should always strive to minimize patient irradiation to the dose that is necessary to perform the procedure with adequate image quality. The recommendation against establishing absolute dose limits should not discourage a facility from implementing diagnostic reference levels for imaging and interventional procedures. Exceeding these levels should prompt a review of practice at the facility as a quality assurance measure. Dose notification and alert values for CT, notification levels for use during interventional procedures, and trigger levels for follow-up after interventional procedures are also appropriate QA measures (NCRP 2010; NEMA 2010).

Ideally, radiation dose would be measured or estimated accurately in relevant tissues and organs in real time for all examinations. As of 2014, this is not practical. Currently, radiation dose is measured differently for CT, fluoroscopy and radiography due to the endpoint health effect of interest (cancer or acute tissue damage) and the nature of the modality. Different dose metrics are managed in different ways. For example, during fluoroscopically-guided procedures, it is desirable to optimize kerma-area product and cumulative air kerma (indicators of patient dose) while also minimizing peak skin dose. However, some dose metrics that are not doses to the patient may be of considerable utility for operational and quality assurance purposes (e.g., the exposure index (EI) in radiography reflects the dose to the image receptor. The most appropriate dose metrics available should be used.

FEDERAL STANDARDS FOR PROTECTION AGAINST RADIATION

Federal facilities must have safety programs in place to protect workers from adverse health effects, as required by Public Law 91-596, Section 19, "Federal Agency Safety Programs and Responsibilities" (Congress 2004) and Executive Order 12196, "Occupational Safety and Health Programs for Federal Employees" (Carter 1980). The U.S. Occupational Safety and Health Administration (OSHA) sets standards for radiation protection from x-rays in 29 CFR 1910 (OSHA 2014a). The NRC sets standards for ionizing radiation protection from NRC-licensed

radioactive materials (10 CFR 20 (USNRC 2014d)) and for medical uses of NRC-licensed radioactive materials (10 CFR 35 (USNRC 2014e)). NRC requirements apply to the total dose to an individual from both licensed and unlicensed sources (e.g. PET/CT) that are under the control of the licensee (10 CFR 20.1001(b) (USNRC 2014a)).

Portions of the NRC and OSHA regulations, when considered together, establish: dose limits for staff; requirements for the wearing of dosimeters; requirements for the posting of warning signs; requirements for periodic employee training and hazard communication; requirements for comprehensive record keeping for exposure monitoring results; periodic facility radiation safety assessments, and preventive interventions; and requirements for timely reporting of results of exposure monitoring and exposure incidents to individual employees, including exposures to staff that exceed regulatory limits. It is important to note that these dose limits are for occupational exposure and do not specifically limit the exposure that a person may receive as a result of medical evaluation or treatment in the process of obtaining personal health care. As of 2014, and consistent with recommendations from ICRP, there is no regulatory limit on the amount of radiation a patient may receive.

Minors as Workers

Readers of this document should be aware that the federal regulations cited above also provide direction concerning occupational radiation exposure to individuals below the age of 18. Dose limits for these individuals are generally 10% of the occupational dose limits for adults.

Embryos or Fetuses of Pregnant Workers

NRC regulates radiation dose to the embryo or fetus of a declared pregnant woman who is exposed to radiation from licensed radioactive materials (USNRC 2014c). Although workers who are exposed only to electronically-produced radiation are not subject to NRC regulations, it is recommended to apply the NRC dose limits for each declared pregnant woman. As of 2014, the occupationally received dose equivalent to the embryo or fetus of an employee or other worker who has voluntarily declared her pregnancy in writing should not exceed 5 mSv (0.5 rem) during the remainder of the pregnancy, or an additional 0.5 mSv (0.05 rem) if the gestation limit has been or is within 0.5 mSv (0.05 rem) of being exceeded when the declaration is made (NCRP 1993). This limit does not pertain to the exposure of an embryo or fetus resulting from a medical procedure to a pregnant worker. When a radiation worker informally advises the facility that she is, might be, or is attempting to become pregnant, her past and current exposure values should be evaluated and risks associated with radiation exposure to the fetus should be discussed. If she formally declares her pregnancy (i.e., becomes a “declared pregnant woman,”) she should be issued a dosimeter to be worn on the lower abdomen, under the radiation protective apron (sometimes generically referred to as a “lead apron”), at the level of the fetus, that should be exchanged monthly, unless such a dosimeter is already being worn. The facility should monitor the radiation dose to the worker’s fetus, provide adequate radiation safety measures (Best et al. 2011), strive to achieve dosimeter readings as far below 0.5 mSv/month as

reasonably achievable, consistent with the worker performing her duties, and avoid monthly dosimeter readings above this level.

Members of the Public

The effective dose to an individual member of the public should not exceed 1 mSv (100 mrem) in a year from occupancy in unrestricted areas in or near medical radiation facilities. This is consistent with NCRP guidelines (NCRP 2004a). In health care facilities, all non-radiation workers (e.g., janitorial staff, secretaries) should be afforded protection consistent with that afforded members of the public. This is relevant to the design of radiation shielding, which considers occupancy factors.

GENERAL RADIATION PROTECTION CONCEPTS

There are several principles by which workers can minimize their exposure to x-rays. Most of them are based on certain fundamental concepts concerning x-rays:

1. Time – Reducing the duration of exposure reduces the dose,
2. Distance – Increasing the distance from the radiation source reduces the dose, because x-ray intensity is inversely proportional to the square of the distance from the source (Inverse Square Law), except at short distances, and
3. Shielding – X-rays can be attenuated by shielding.

Those who are exposed to radiation should judiciously use time, distance, and shielding to limit their radiation dose.

Humans should be exposed to the unattenuated primary radiation beams of x-ray imaging equipment in medical facilities only for medical purposes. For this definition, "medical purposes" include research involving the exposure of human subjects conducted in accordance with the Federal Policy for the Protection of Human Subjects (OSTP et al. 1991). In particular, humans may not be exposed to these unattenuated beams solely for training, for quality assurance purposes, to test equipment, or to obtain images for accreditation. The only exceptions to this principle are that precision assessments and cross-calibrations may be made in dual-energy x-ray bone densitometry in accordance with the guidelines of the International Society for Clinical Densitometry (ISCD) (CRCPD 2006; ISCD 2007a; ISCD 2007b).

Optimization of protection is at the heart of a successful radiation control program. It includes evaluating and, where practical to do so, incorporating measures to reduce collective and individual doses and minimizing the number of workers and members of the public exposed. In accordance with the ICRP's principle of optimization of protection, each facility should use, to the extent practicable, procedures and engineering controls to achieve occupational doses and doses to members of the public that are as low as reasonably achievable (ALARA), with economic and social factors being taken into account. The ALARA approach is applied after it has been determined that a proposed activity will not exceed any mandatory dose limit.

The ALARA approach requires that only individuals whose presence is necessary are permitted in the examination room while images are acquired. Caregivers (guardians, spouses, parents) are an exception, when the responsible imaging team believes their support will result in an improved procedure and better patient experience (e.g., reduced anxiety, greater patient cooperation). Using radiation protective apparel and portable shields, and maintaining as much distance as reasonable from the point where the x-ray beam intersects the patient, will provide radiation protection for staff and caregivers. To limit worker dose, the operator should be behind a shielded barrier, wear radiation protective apparel, or be otherwise protected during image acquisition. This is not always practical with mobile radiography.

RADIATION SAFETY PROGRAM

Each facility should establish a radiation safety program. A radiation safety program is the mechanism by which an institution ensures that:

1. each individual involved in image selection, acquisition and interpretation is appropriately trained on radiation safety (ICRP 2009),
2. the use of ionizing radiation within its purview is performed in accordance with existing laws and regulations,
3. individual health care providers and technologists are equipped with knowledge of the options available to them as they contribute to making benefit:risk assessments and selecting the appropriate examination and protocol for each individual patient, and
4. x-ray equipment users and the surrounding public receive adequate radiation protection.

The primary objective is to obtain necessary diagnostic information or interventional results with no more irradiation of the patient than is required. This also helps keep exposure to staff and members of the public at a minimum.

The key personnel and activities involved in managing a radiation safety program include:

Radiation Safety Officer

The Radiation Safety Officer (RSO) is responsible for radiation safety. The RSO may be the same person designated for radiation safety for NRC purposes under 10 CFR 35 (USNRC 2014e). An RSO should be designated for each facility that uses ionizing radiation for medical imaging, and should be appointed in writing by the facility director or agency. The RSO shall be permitted to directly communicate with facility executive management. The RSO, whenever possible, should be a qualified expert as defined in this document. The RSO should be a person having knowledge and training in ionizing radiation measurement and evaluation of safety techniques and the ability to advise regarding radiation protection needs (for example, a person certified in diagnostic medical physics by the American Board of Radiology, or in health physics by the American Board of Health Physics, or those having equivalent qualifications).

The RSO has the following specific responsibilities:

1. Establish and implement radiation safety procedures and review them periodically to assure their conformity with regulations and good radiation safety practices.
2. Instruct personnel in regulatory requirements and proper radiation protection practices before they begin working with radiation and periodically thereafter to maintain and update that knowledge.
3. Conduct or supervise radiation surveys where indicated and keep records of such surveys and tests, including summaries of corrective measures recommended and/or instituted.
4. Assure that area monitoring and personnel monitoring devices are used as required and records are kept of the results of such monitoring. This function requires:
    a. reviewing the monitoring reports promptly to ensure that public and personnel doses do not exceed regulatory limits and are ALARA, and
    b. making their own dosimetry records available to workers at any time, and periodically informing workers of their dose records. These records will be kept in a suitable organized file (readily retrievable but not necessarily on site) for the life of the facility or as legally required.
5. Ensure that any warning signals on imaging equipment and suites are regularly checked for proper function and that required signs are properly posted.
6. Monitor compliance with the requirements of regulations and the requirements specified in the facility's standard operating procedures.
7. In conjunction with a qualified medical physicist (QMP), promptly investigate each known or suspected case of excessive or abnormal exposure by:
    a. determining the causes,
    b. taking steps to prevent its recurrence,
    c. monitoring corrective actions, and
    d. making appropriate reports.
8. Ensure that required notifications and reports in cases of personnel overexposures and radiation medical events are submitted as required by regulations.
9. Promptly notify facility executive management of:
    a. significant safety hazards,
    b. significant violations of regulations,
    c. exposures of staff or members of the public that exceed regulatory requirements, and
    d. radiation medical events.
10. Review or have a QMP review, prior to construction or modification, plans for rooms in which x-ray producing equipment is to be installed, including:
    a. room layout,
    b. shielding (AAPM 2006c; NCRP 2004a),
    c. viewing and communications systems, and
    d. verifying that the shielding is installed according to plan and functions as designed before clinical use of the equipment.

Qualified Medical Physicist

The services of a QMP are essential for the optimal use of medical imaging. The physicist should be a person having knowledge and training in medical imaging physics and technology, and its clinical utilization. A person should either be certified in diagnostic medical physics by the American Board of Radiology or have equivalent qualifications. (Due to their unique mission requirements, the uniformed services may need to develop their own criteria for determining when a physicist is a QMP as defined in this document.) The following services should be performed by or under the supervision of a QMP:

1. Participation in evaluation and selection of equipment
2. Acceptance testing of new equipment
3. Testing of radiation emitting medical equipment after repairs or modifications
4. Monitoring imaging system performance at least annually
5. Evaluating, in conjunction with the RSO, radiation medical events
6. Oversight of the technical QC program
7. Investigation of the root causes of image quality issues and identify appropriate solutions
8. Design or review and approve x-ray room radiation shielding
9. Verification surveys of x-ray room shielding
10. Periodic review of existing imaging protocols
11. Assistance with development and evaluation of new and revised imaging protocols
12. Patient-specific radiation dose calculations (e.g., fetal dose calculations)
13. Providing training on quality control and radiation safety
14. Ensuring that instruments used to monitor x-ray imaging systems are appropriate for the task, appropriately calibrated for the task (e.g., energy and dose rate measurements), and maintained
15. Evaluating the radiation-related aspects of research protocols

Protection of the Patient

Patient Safety

As with all medical procedures, there are critical elements of patient safety that must be observed. The first critical element is ensuring that the correct patient undergoes the correct diagnostic test or interventional procedure, and that the examination is performed on the correct body part. To that end, methods for verification of patient identity prior to events such as administration of medication or surgical procedures should be extended to diagnostic and interventional imaging. If the medical procedure involves intervention or a specific side of the patient's anatomy, the specific body part should be confirmed prior to the procedure. The precautions should be commensurate with the risk from the examination or procedure, with greater precautions being taken for procedures of greater risk.

Special Patient Populations

Specific special patient populations addressed here include:

1. Pregnant patients
2. Pediatric patients
3. Patients enrolled in a research protocol

Occupational radiation exposure to minors and to the fetus of a pregnant worker is discussed in the section General Standards for Protection Against Radiation.

Pregnant patients

Because of the special risk that radiation exposure poses to the embryo or fetus, each facility should establish and implement procedures to determine, before conducting an examination or procedure, whether a female patient of childbearing age may be pregnant. The precautions should be commensurate with the risk from the examination or procedure to be performed, with greater precautions being taken for procedures imparting larger radiation doses to the abdomen or pelvic region of the patient. If a pregnancy test is indicated, it should be obtained within 72 hours before the examination. A confirmatory pregnancy test would not be necessary if pregnancy can be excluded by documented surgical, medical or gynecological (i.e., menopause) history.

For pregnant patients, consideration should be given to alternate tests or procedures, such as ultrasound, that would not expose the embryo or fetus to ionizing radiation, or to modifying the examination or procedure to reduce the radiation dose to the embryo or fetus (ACR-SPR 2013). For procedures that may impart a clinically important dose to the fetus, especially for doses exceeding 0.05 Gy (5 rad), the anticipated dose and associated risks should be included as part of informed consent unless a physician determines that delay caused by the extended consent discussion would harm the patient (Dauer et al. 2012). The physician might consider delaying the procedure, if possible, until after pregnancy to prevent exposure to the embryo or fetus. Procedures that may impart a dose to the embryo or fetus exceeding 0.05 Gy (5 rad) are prolonged fluoroscopic procedures to the abdomen or pelvis and CT imaging involving multiple scans of the abdomen or pelvis (Dauer et al. 2012).

Evaluation of the benefit:risk ratio in relation to the radiation dose from medical imaging in a pregnant woman is very complex (NCRP 2013). In instances where a study using ionizing radiation is deemed necessary, every effort should be made to avoid exposing the fetus to the direct radiation beam. If a patient is pregnant, a radiologist, radiation oncologist or other physician knowledgeable in the risk from the radiation exposure should work with the patient in making the decision whether to perform the examination or procedure (Dauer et al. 2012). There should be a discussion of the benefits and risks with a pregnant patient prior to the imaging unless an emergent need for the imaging or her condition precludes this (ACR-SPR 2013). If a previously unrecognized pregnancy is identified after a procedure, the referring physician should be notified and the patient counseled as appropriate. The dose to the fetus should be estimated if fetal dose is of concern (see below).

If the dose to the embryo or fetus could exceed 0.05 Gy (5 rad), a formal dose assessment should be performed by a QMP and provided with consultation to the referring physician so that the patient can be advised accordingly (NCRP 2013). Doses at or above 0.1 Gy (10 rad) warrant discussions between the patient and her physician of potentially adverse fetal effects, and the fetal dose assessment should be included in the medical record. Whenever a pregnant patient expresses concern about the risk to her fetus, the dose and risk should be addressed.

Each facility should establish a policy for determining which procedures, when performed on women of child-bearing age, require pregnancy testing and informed consent. In general, for procedures likely to impart a fetal dose greater than 0.05 Gy (5 rad), pregnancy testing should be performed and informed consent should be obtained. For procedures likely to impart a fetal dose <0.05 Gy (5 rad), informed consent should be obtained according to facility policy. If informed consent is not required, the facility should not require a pregnancy test, either. Examples of examinations where neither informed consent nor pregnancy testing is necessary include those for which the dose to the fetus is not significant, e.g. upper extremity radiography, CT of the head and neck, mammography and dental radiography (ACR-SPR 2013; Dauer et al. 2012).

Most facilities should post signs in suitable locations, such as patient reception areas and procedure rooms, asking female patients to notify staff if they might be pregnant. These signs are not necessary in dental facilities where expected fetal doses are very low.

Pediatric patients

In children, some organs are more sensitive to radiation induced stochastic effects than in adults (UNSCEAR 2013), and children also have greater expected remaining life spans than adults. As such, children represent a population at greater risk for subsequent development of radiation-induced cancer than adults (ICRP 2013b). This difference in the benefit:risk ratio should be considered in the prescription of medical imaging requiring ionizing radiation. Alternative imaging modalities that do not use ionizing radiation, such as ultrasound or MRI, should be considered. However, it is also appropriate to consider factors other than radiation, such as sedation, comfort and cost.

Protocols for all ionizing radiation imaging should be “child-sized” or optimized so that the dose is appropriate for the size of the infant or child (FDA 2001; ICRP 2013b; Strauss et al. 2010). For radiography, fluoroscopy and CT, this key principle holds true. Also, unlike abdominal CT studies performed in adults, pediatric CT studies usually do not require multiple passes through the child’s body. This reduces the radiation dose to the child without compromising diagnosis.

Subjects enrolled in a research protocol

All research involving human subjects that is conducted, supported or otherwise subject to regulation by any federal department or agency must conform to the most current version of the Federal Policy for the Protection of Human Subjects (FPPHS) (OSTP et al. 1991). This policy

requires approval of research protocols by a properly constituted institutional review board (IRB) and obtaining informed consent from the research subject.

Many protocols use radiation that is *medically indicated (*also referred to as *"standard-of-care")*. Medically-indicated radiation is used to diagnose or guide treatment as a non-research medical procedure for clinical management of the research subject. The radiation dose from a medically-indicated procedure done as part of a research study should not require additional justification, review, and approval by an IRB.

When the radiation exposure is described as *indicated for research* (the radiation use does not meet the criteria of "medically indicated") it must be reviewed and approved. IRBs have responsibility for oversight of research involving human subjects, but should seek the advice of the institution's Radiation Safety Committee regarding the radiation risk from any non-medically indicated radiation use that is a component of the research**.**

Analysis of Risk to Research Subjects from Radiation

An analysis of risk to the human research subjects, including that from radiation exposure, must be performed prior to seeking informed consent and prior to review of the research study by the IRB. The risks of both deterministic and stochastic effects from the radiation exposure should be considered (see section on BIOLOGICAL EFFECTS OF IONIZING RADIATION). For consideration of the risk of deterministic effects, the maximal doses to individual organs and tissues at risk should be estimated, although dose rate and dose fractionation may also be considered. Ideally, the risk from stochastic effects (e.g., cancer) should be calculated by estimating doses to individual organs and tissues and using organ and tissue specific risk coefficients that account for the age and gender of the subject. The International Commission on Radiation Units and Measurements (ICRU) provides useful information for determining patient dose (ICRU 2005). However, for many imaging procedures, this approach would consume considerable resources and requiring it would discourage many research studies from being performed.

The ICRP developed the quantity *effective dose* (E) for radiation protection purposes to assess the risk of detriment to workers from stochastic effects caused by occupational exposure to ionizing radiation (Harrison and Streffer 2007; ICRP 1991a). This quantity utilizes mean tissue weighting values for humans averaged over both sexes and all ages, and thus does not relate to the characteristics of particular individuals (ICRP 2007a). Although effective dose was not intended to be used for assessing risk from medical exposures, it is commonly used to convey the potential risk from radiation exposure for subjects participating in investigational protocols (Martin 2007). The effective dose can be estimated for many imaging procedures. Furthermore, effective dose provides a *single* quantity that represents possible detriment from radiation exposure due to participation in a research study and can be compared to other sources of radiation exposure (e.g., medical procedures and natural background radiation). From the research subject's perspective, this comparison is simple and expresses the risk in a meaningful way. Effective dose may be used for estimating the risk of stochastic effects for human research subjects, but should not be used without considering its appropriateness in light of the

characteristics of the study population, including their ages, genders, genetic predisposition, the body parts being irradiated, and their expected life-spans. The use of effective dose can provide a general indicator of risk (usually within 30% for populations under 50) and is not likely to be off by more than a factor of 3 (in older populations) (Ivanov et al. 2013). ICRP Publication 62 (ICRP 1991b) provides guidance on the use of effective dose in estimating risk to reference persons.

Informed Consent for Research Involving Radiation

To enroll in any research study using human subjects, participants must be knowledgeable about the risks, benefits, privacy considerations and other related matters. They must participate voluntarily and must provide written informed consent using an IRB-approved consent form. Requirements for human research in x-ray imaging facilities are addressed in the Federal Register (OSTP et al. 1991) and are specified in the current Code of Federal Regulations sections that apply to individual facility operations (e.g., 32 CFR 219 for DoD, 45 CFR 46 for DHHS, 40 CFR 26 for EPA, and 38 CFR 16 for VA(DHHS 2014; DoD 2014; EPA 2014; VA 2014)). Appendix A contains sample informed consent templates for the research use of radiation, adapted from those used by NIH in 2014 (NIH 2008a; NIH 2008b; NIH 2010).

These consent documents have been developed for use when patients are irradiated for research purposes, as opposed to being irradiated for clinical care. These documents explain risk based on effective dose. The maximum level of radiation risk should be expected to be minimal, minor to intermediate, or moderate when the respective societal benefit is minor, intermediate to moderate, or substantial (ICRP 1991b). The radiation dose for each of these ranges may vary according to the specific IRB and the specific research population. The sample consent templates in Appendix A may be used as a starting point for IRB consideration for the general adult population. These consent templates should be modified as appropriate to meet the particular requirements or needs of a given study.

Protection of the Worker and the Public

Occupational Radiation Safety Training

Each facility should train staff who operate x-ray producing equipment or who are routinely exposed to radiation by the equipment (ICRP 2009). Training should be provided initially prior to utilization of the equipment and at least annually thereafter. The training should be performed by a qualified individual and should be commensurate with risk to the staff and to the patient. It should include:

1. the risks from exposure to ionizing radiation,
2. regulatory requirements,
3. recommendations of this guidance document,
4. facility requirements,
5. proper operation of the specific equipment to be used,

6. methods for maintaining doses to staff within regulatory limits and as low as reasonably achievable, and
7. guidance for protecting the patient and embryo or fetus.

Training need not be performed at or by the medical facility, provided that the facility determines that it meets these requirements, and the facility obtains written certification of successful completion of the training.

Personnel and Area Monitoring

Each worker who is expected to receive more than 10% of the applicable annual dose limit (NRC) or more than 25% of the quarterly dose limit (OSHA) is required to wear one or more dosimeters. There shall be a procedure for regular issuance and replacement of dosimeters for exposure evaluation, and records of the doses received shall be retained as required by OSHA in 29 CFR 1910.1096 (OSHA 2014a) and NRC in 10 CFR 20 (USNRC 2014d). When a radiation protective apron is worn, a dosimeter should be worn at the collar outside the apron. A second dosimeter may be worn on the abdomen under the apron. The two-dosimeter method provides a more accurate method of assessing effective dose (NCRP 1995). Monitoring of hand dose is recommended for workers who may receive an annual equivalent dose to their hands greater than 50 mSv (NCRP 2010). When multiple dosimeters are issued to an employee, each dosimeter should be labeled to indicate the location on the body where it is to be worn. Facilities should ensure that workers wear dosimeters as required, and in the designated locations; failure to do so can result in incorrect dose assessments. The appropriate use of one properly positioned dosimeter is preferable to multiple improperly positioned dosimeters (Durán et al. 2013). Periodic assessments and feedback to employees regarding their exposures are particularly important. If there is a question regarding the amount of radiation a person might receive near rooms in which x-rays are produced, the facility can post dosimeters in or near those areas in order to estimate the person's radiation dose.

Facilities and agencies should use methods for estimating individual doses based on the goal of assigning accurate doses. As of 2014, OSHA establishes dose limits to the head and trunk and so the radiation dose indicated by the collar dosimeter must be used to assess compliance with this limit. However, the NRC, whose dose limits regarding NRC-licensed radioactive materials, are based in part on the quantity effective dose equivalent, permits the use of two personal dosimeters, one under the protective garments and one at the collar outside the protective garments, for assessment of compliance with its dose limits (USNRC 2002). Federal regulatory agencies should adopt methods and procedures consistent with NCRP Report No. 122, which provides recommended methods for determining effective dose (E) (NCRP 1995).

Radiation Safety Procedures for Fluoroscopy

It is strongly recommended that, other than for the patient being examined, only staff and ancillary personnel required for the procedure, or those in training, be in the room during the fluoroscopic examination (AAPM 1998; ACR-AAPM 2013a). Caregivers (guardians, spouses,

parents) are an exception, when the responsible imaging team believes their support will result in an improved procedure and better patient experience (e.g., reduced anxiety, greater patient cooperation). Only the patient should be exposed to the primary beam. However, if primary beam exposure to another person is unavoidable, it should be minimized. It is essential that all personnel in the room during fluoroscopic procedures be protected from scatter radiation by either whole-body shields or radiation protective apparel. For procedures performed using microampere fluoroscopy systems ("mini C-arms"), a QMP should determine if aprons are required.

For workers, aprons should provide the desired protection at an acceptable weight, because the apron weight itself can pose a substantial ergonomic risk to its wearer. Apron weight can be reduced by using thinner lead or by replacing lead, completely or partially, with a combination of one or more other materials that have the same or better attenuation for the scattered radiation from fluoroscopic beams. Though 0.5 mm lead-equivalent aprons are considered the standard as of 2014, an apron with thinner lead equivalence may provide adequate protection. Based on the calculation of effective dose (E) from dual dosimeters, a 0.3 mm lead-equivalent apron will result in a value of E that is only moderately higher (7 to 16%) than a 0.5 mm lead-equivalent apron (NCRP 1995). The two-dosimeter method described above under PERSONNEL AND AREA MONITORING may be preferable for monitoring personnel in the room during high dose interventional procedures. Monthly dose monitoring can also ensure that staff members who use garments with < 0.5 mm lead equivalent thickness keep their occupational dose below the required dose limits. With these precautions in place, it is quite possible to provide adequate protection with a 0.35 mm or less lead equivalent thickness (NCRP 2010). The lead-equivalent thickness should not be less than 0.25 mm.

Due to the risk of radiation-induced cataract formation (Ciraj-Bjelac et al. 2010; ICRP 2010; Vano et al. 2013), the staff exposed to radiation during fluoroscopically-guided interventional procedures should be appropriately protected from radiation. When the x-ray beam is activated, they should be behind a ceiling-suspended (or floor-mounted) shield or else should protect their eyes (NCRP 2010). All protective eyewear should have the correct optical prescription, fit properly, and have side shields or be of a wraparound design. In any event, the eyes must be protected to keep the lens dose less than current regulatory limits and should also be protected to keep the lens dose less than the ICRP dose recommendations (ICRP 2011). As appropriate, protective eyewear should also be made available to individuals who perform other non-interventional fluoroscopic procedures.

It is strongly recommended that radiation protective apparel (e.g., aprons, gloves, thyroid collars) undergo visual and manual evaluation at least annually for radiation protection integrity (Miller et al. 2010b; NCRP 2010). If a defect in the attenuating material is suspected, radiographic or fluoroscopic inspection may be performed as an alternative to immediately removing the item from service to determine if it is still protective. The facility should establish rejection criteria; examples can be found in the literature (Lambert and McKeon 2001). Radiation exposure of staff should be minimized by minimizing the use of fluoroscopy for inspections or by appropriately protecting the inspector. Radiation protective aprons, gloves and thyroid shields should be hung or laid flat and never folded, and manufacturer's instructions should be followed.

Notification and Reporting Requirements

If radiation exposures to staff or members of the public exceed regulatory limits, the facility shall make notifications and reports as required by the appropriate regulatory authority (e.g., OSHA or the NRC) (OSHA 2014a; USNRC 2014d).

STRUCTURAL SHIELDING AND DOOR INTERLOCK SWITCHES

To prevent inadvertent patient injury or the need to repeat exposures of patients, it is strongly recommended that interlock switches that terminate x-ray production not be placed on doors to any diagnostic or interventional x-ray room (NCRP 2004a). Instead, appropriate access control measures for radiation safety should be instituted.

To the greatest extent possible, administrative controls and personal protective equipment should not be used as substitutes for engineering controls and appropriate facility design. For the structural shielding of rooms containing x-ray imaging or x-ray-producing devices, the shielding design goal should be 5 mGy in a year to any person in controlled areas. For uncontrolled areas, the shielding design goal should be a maximum of 1 mGy to any person in a year (0.02 mGy per week) (NCRP 2004a). Shielding design for and acceptance testing surveys of imaging rooms should be performed or reviewed by a QMP using appropriate methodology such as is provided in NCRP reports. Whenever room modifications are performed or the assumed shielding parameters change (e.g., new equipment, increased workload, or altered use of adjacent spaces), the suitability of the design should be reviewed by a QMP. The shielding design calculations, as-built shielding plans, and the report on the acceptance testing of the structural shielding should be kept for the duration of use of the room for x-ray imaging. The American Association of Physicists in Medicine (AAPM) guidance should be used as appropriate, for modalities not covered in NCRP reports. At the time of this writing, this includes guidance for PET/CT shielding (AAPM 2006c). In evaluating the need for structural shielding for SPECT/CT, the radiation from the radioactive material in the patient should also be considered.

Mobile radiographic equipment is frequently used for bedside examinations. Effective radiation protection in these circumstances is normally provided through exposure time and distance (NCRP 1989b; NCRP 2000; NCRP 2004a). When mobile radiographic or fluoroscopic equipment is used in a fixed location, or frequently in a particular location, it is strongly recommended that a qualified expert evaluate the need for structural shielding (NCRP 2004a). When radiographic or fluoroscopic equipment is used in a temporary facility (e.g., field hospital), the effective use of distance, exposure time, or non-structural shielding may eliminate the need for structural shielding.

REQUESTING AND PERFORMING STUDIES INVOLVING X-RAYS

This report uses the terms Referring Medical Practitioner and Radiological Medical Practitioner. The Referring Medical Practitioner is a health professional who, in accordance with state and federal requirements, may refer individuals to a Radiological Medical Practitioner for medical exposure (IAEA 2011b). The Radiological Medical Practitioner is a health professional, with education and specialist training in the medical uses of radiation, who is competent to independently perform or oversee procedures involving medical radiation exposure in a given specialty (IAEA 2011b). The qualifications and responsibilities of these practitioners are discussed below.

REQUESTING STUDIES: REFERRING MEDICAL PRACTITIONERS (REQUESTING HEALTH PROFESSIONALS)

A medical procedure should only be performed on a patient if it is appropriately justified and optimized for that particular patient. In this context, "appropriateness" is generally defined in terms of benefit and risk. The RAND corporation has developed a definition of "appropriate" that is widely used: the expected health benefit (i.e., increased life expectancy, relief of pain, reduction in anxiety, improved functional capacity) exceeds the expected negative consequences (i.e., mortality, morbidity, anxiety of anticipating the procedure, pain produced by the procedure, misleading or false diagnoses, time lost from work) by a sufficiently wide margin that the procedure is worth doing (NHS 1993; Sistrom 2008). In other words, the anticipated clinical benefits should exceed all anticipated procedural risks, including radiation risk. This implies that radiation should be included in the benefit:risk evaluation for each patient both before and during any procedure.

As with any medical procedure, the requesting or "ordering" provider (i.e., the Referring Medical Practitioner) should have adequate knowledge of the patient, understand the nature of the proposed and alternative imaging procedures, and fully comprehend the medical diagnostic and treatment options available in order to be able to assess the benefit:risk ratios for the imaging procedure. These ratios balance the benefit of the diagnostic examination being requested against the stochastic and deterministic risks to the patient from radiation exposure during imaging, as well as the benefits and risks from alternative radiological and non-radiological procedures. The Referring Medical Practitioner (with privileges at the facility or within the healthcare network for the ordering of radiographic studies) should have determined that sufficient clinical history, symptoms, signs or findings exist to necessitate the examination. All exposures to radiation should involve a consideration of benefit and risk, in order to ensure that the expected benefits of the examination outweigh the potential risks, and that the most appropriate radiological or non-radiological procedure is selected on the basis of its benefit:risk ratio. Of necessity, this estimate of benefit and risk is usually qualitative. In all cases, the use of radiation in diagnostic medical imaging should be justified and optimized. This is the responsibility of all involved providers and technologists. Dose management begins when a patient is considered for a procedure involving ionizing radiation, involves equipment setup before the exam begins, and ends when any necessary radiation-related follow-up is completed.

Physicians and other licensed independent practitioners (Referring Medical Practitioners) who have the legal authority and privileges to request diagnostic imaging studies involving ionizing radiation should have a basic understanding of radiation effects and protection methods (ICRP 2009). They should also have an appreciation for the radiation dose involved in a study and the potential effects of this dose over the lifetime of the patient to properly assess the benefit:risk ratio. The justification of medical exposure for an individual patient should be carried out by the Referring Medical Practitioner, in consultation with the Radiological Medical Practitioner when appropriate. Other members of the patient's care team may contribute to this process.

Each health care facility should establish a formal mechanism whereby Referring Medical Practitioners have sources of information available at the time of ordering. These sources should provide information regarding appropriate diagnostic imaging methods to answer the clinical question, and comparison of the radiation doses associated with these methods. These may include decision support software, imaging referral guidelines (e.g., ACR Appropriateness Criteria (ACR 2012a)), screening recommendations (USPSTF, ACR, ACS), and diagnostic algorithms (ACR 2013; ACS 2013; DHHS 2012a). These information sources are important tools for justification of imaging procedures. A mechanism for consultation with Radiological Medical Practitioners should also be made available.

One of the most important methods for reducing radiation exposure is the elimination of clinically unproductive examinations. This continues to be a significant, but largely unrealized opportunity. Appropriate education of the requesting physician, utilization of existing current recommendations (such as the ACR Appropriateness Criteria (ACR 2012a)) and consultation with a Radiological Medical Practitioner prior to generation of the examination request can all improve the likelihood that the most appropriate examination is performed relative to the clinical question. Ideally, electronic ordering systems will have the capability to inform referring providers of appropriate examinations, and will alert them to unnecessary repeat examinations.

Follow-up examinations are commonly done so that significant changes in clinical information are obtained for making proper decisions on continuation or alteration of the management of the patient. These examinations may result in unnecessary patient exposure if repeated before significant changes in patient status occur; therefore, it is recommended that they be done only at time intervals long enough to make proper decisions concerning continuation or alteration of treatment.

Qualifications to Request X-ray Examinations

Requests for imaging examinations involving the use of x-rays in federal health care facilities should be made only by physicians or other Referring Medical Practitioners who are licensed in the United States or one of its territories or possessions and privileged within the healthcare facility or network. Properly trained individuals such as physician assistants and persons in postgraduate medical training status do not have to meet the above requirements, but should be under the general supervision of licensed independent practitioners with appropriate privileges.

It is recognized that medical students, interns, residents and some physician assistants may not

have developed medical judgment as to which test would be most efficacious. Such lack of experience is remedied by work under conditions where there is sufficient expert supervision, so that the appropriateness of examination requests can be monitored based on the clinical history and Radiological Medical Practitioners are available for consultation and assistance. Inexperienced individuals should be encouraged to contact a Radiological Medical Practitioner when questions arise about the appropriateness of an imaging examination.

In addition to the privileges for which broad qualifications are needed, there are a number of specialties which require only limited types of x-ray examinations. For example, Doctors of Dental Surgery or Dental Medicine may request appropriate examinations of the head, neck and chest, although such requests are normally confined to the oral region.

Variances to the above qualification requirements should occur only for emergency or life-threatening situations, such as natural disasters. Also, non-peacetime operations in the field or aboard ship could require such variances.

PERFORMING AND SUPERVISING STUDIES: RADIOLOGICAL MEDICAL PRACTITIONERS AND TECHNOLOGISTS

Facility policies

Responsible use of medical, dental and veterinary x-ray equipment involves restricting its operation to properly qualified and supervised individuals. Such a policy should be established for each x-ray facility by the responsible authority upon the recommendations of medical, dental and veterinary staff. Eligible Radiological Medical Practitioners include those who are granted privileges for equipment use based on the needs of patients served by the facility. These are privileges to use or supervise the use of radiation-emitting equipment and are separate from privileges to perform procedures. Such privileges might include, as part of their practice, the use of CT equipment by radiologists, vascular surgeons and cardiologists; the use of fluoroscopes by cardiologists, radiologists, urologists, orthopedic surgeons, general surgeons and others; the use of x-ray imaging equipment by podiatrists and chiropractors; and the use of dental x-ray equipment by dentists. Before Radiological Medical Practitioners are granted equipment use privileges, it is strongly recommended that they receive adequate training in equipment use and radiation protection (ICRP 2009). However, specific protocols limiting equipment use privileges to specified types of Radiological Medical Practitioners should be part of the facility's written policy statement.

Radiologic technologists who have completed an accredited educational program and been certified by a state or voluntary credentialing organization should be able to perform radiologic examinations with appropriate image quality and lower average patient doses than incompletely-trained or non-credentialed operators.

Each facility should ensure that any individual performing or supervising x-ray imaging studies at the facility is properly trained, both initially and at periodic intervals thereafter. Records

should be kept of the training. The records should include the date(s) of training, the name(s) of the person(s) providing the training, the topics included in the training, the duration of the training, and the names of the persons successfully completing the training. Training need not be performed at or by the facility, provided that the facility determines that it meets these requirements and was sufficiently recent, and the facility obtains written certification of successful completion of the training. Specific training recommendations are addressed in the GUIDANCE BY DIAGNOSTIC MODALITY section.

In order to achieve lower patient doses, the operator's manual should be readily available to the user, and equipment operation should be guided by the manufacturer's instructions, including any appropriate adjustments for optimizing dose and ensuring adequate image quality. If automated protocols are not available so that technique charts are necessary, they should be available to the operator to ensure proper selection of the radiographic technique.

Radiological Medical Practitioners

A Radiological Medical Practitioner is a health professional, with education and specialist training in the medical uses of radiation, who is competent to independently perform or oversee procedures involving medical exposure in a given specialty. Within the Radiology department, this individual is typically a radiologist. Other individuals who use ionizing radiation for imaging, usually outside the Radiology department (e.g., cardiac catheterization or fluoroscopy in the operating room), are also considered Radiological Medical Practitioners. These individuals, when acting as Radiological Medical Practitioners, have the same responsibilities for imaging protocols and for supervising equipment operation that would otherwise be assigned to a radiologist. The Radiological Medical Practitioner is also responsible for optimizing the dose of ionizing radiation. As experts in medical imaging, Radiological Medical Practitioners share the responsibility for justification of examinations with Referring Medical Practitioners.

Radiologists

A radiologist is a licensed physician or osteopath who is certified in Radiology or Diagnostic Radiology by the American Board of Radiology or the American Osteopathic Board of Radiology, or has completed a diagnostic radiology residency program approved by the Accreditation Council for Graduate Medical Education (ACGME) or the American Osteopathic Association. Within the Radiology department, the radiologist generally serves as the Radiological Medical Practitioner. In addition to interpreting imaging studies, radiologists set protocols for examinations involving x-ray systems and play a critical role in the performance of studies. Imaging protocols should be devised for each imaging system and each imaging study. These protocols should provide adequate image and study quality while optimizing the radiation dose, particularly to radiosensitive tissues. Considerations include identifying the appropriate area of coverage, collimation, number of views to be acquired, and image quality needs (which dictates the required x-ray beam energy and intensity). For CT, this includes CT-specific technique factors, area of coverage, and the number of CT examination phases. Radiologists are a source of knowledge on the advantages and disadvantages of different imaging modalities and

should be consulted when that expertise is needed.

Medical Radiologic Technologists

Medical Radiologic Technologists (MRT) and Registered Cardiovascular Invasive Specialists (RCIS) having appropriate radiation and other training are the personnel who operate the imaging equipment, deliver the radiation to the patients, and capture the diagnostic images. As such, they are extremely important in the optimized use of diagnostic imaging. Operator competence is normally achieved by successful completion of a training program that provides both a didactic base and sufficient practical experience. The training program should be accredited by a mechanism acceptable to the appropriate credentialing organization, e.g., the American Registry of Radiologic Technologists (ARRT) or Cardiovascular Credentialing International (CCI). The uniformed services should encourage their non-credentialed service member technologists to become certified by a state or voluntary credentialing organization. Continuing competence and professional growth should be encouraged with specific opportunities to further the technologist's knowledge and skills through attendance at workshops or by other means of training.

The radiologic technologist should be familiar with and facile at utilizing the imaging systems and the techniques and technology available to them to reduce patient radiation dose while producing clinically adequate images. As a critical part of the healthcare team, they should be empowered to question techniques and requests when alternatives which would deliver lower doses are available.

After completion of an accredited educational program and certification by a state or voluntary credentialing organization, radiologic technologists should be able to produce radiographic images of diagnostic quality with lower average patient doses than incompletely-trained or non-credentialed operators. Non-credentialed operators may have little or no formal training in anatomy, patient positioning or radiation protection practices. Inadequately trained operators are likely to irradiate patients and themselves unnecessarily (EPA 2000). Personnel responsible for image acquisition should be trained in patient preparation and positioning, selection of technique factors and acquisition parameters, radiation protection measures, routine equipment quality control (QC), image processing and digital image post-processing. They should also be able to reduce to a minimum the number of repeat examinations.

Performance of imaging examinations by incompletely trained personnel is not justified except for emergent or life-threatening circumstances, such as natural disasters. Also, non-peacetime operations in the field or aboard ship could require such variances. In such cases, these individuals should be provided sufficient training to safely perform these tasks while producing diagnostic quality images.

SCREENING AND ADMINISTRATIVE PROGRAMS

Screening programs using ionizing radiation should be justified, and the doses should be optimized for screening. It is important to keep requirements current with technological advances. There are several reasons why individuals without known disease or symptoms may be referred for imaging examinations. Some are specifically for administrative or occupational safety programs such as the annual posterior-anterior chest radiograph acquired to evaluate for pneumoconiosis in coal, silica and asbestos workers. With the increased capabilities of imaging systems and particularly with CT imaging, there has been an increased interest in and demand for use of this technology to screen for pre-clinical disease in the general population. Self-referral by patients for screening imaging to evaluate for disease in the absence of symptoms is an increasingly common occurrence. Its appropriateness should be weighed and people requesting it should be counseled on the benefits and risks. If screening has been shown to have a positive benefit:risk ratio, it is generally warranted. Such screening programs should be subjected to rigorous scientific evaluation, as has been done for mammography, to ensure that the risk posed to the person or population being screened does not outweigh the benefits of detecting the disease (ACR 2009b). Most screening and elective x-ray examinations should not be performed on pregnant women; exceptions are addressed in ACR guidelines (ACR-SPR 2013).

Chest Radiography

Screening for tuberculosis is no longer performed in the United States with chest radiography, although this technique may still be required during public health, disaster relief and humanitarian operations, especially in other parts of the world. Low dose CT is an appropriate early detection tool for lung cancer in certain high risk populations, including current or former smokers, when performed according to professional guidelines (ACS 2013). Chest radiography is not appropriate for lung cancer screening.

“Routine” radiographs without specific indications or symptoms should not be performed on admission to the hospital or while an inpatient.

Standard posterior-anterior chest radiographs are performed periodically to evaluate certain populations with high occupational risk for lung disease. These populations include coal miners, asbestos workers, silica workers and a few other specific populations. There are typically specific requirements for these images; yet, as with all other images, it is important to optimize the radiation dose delivered to the individual.

Mammography

Breast cancer is a common and significant health risk in the United States. Because of the importance of early detection in control and survival, mammography is an important screening modality. This technique has improved considerably since the publication of Federal Guidance Report 9 (EPA 1976), especially with respect to reducing radiation dose per examination. Women and their health care providers are encouraged to refer to the most current NCI

recommendations when deciding upon breast cancer screening examinations. Mammography facilities, except for VA mammography facilities, must comply with FDA's regulations implementing the Mammography Quality Standards Act (MQSA) (FDA 2014c). VA mammography facilities are required to comply with the basic requirements of MQSA, but VA is responsible for enforcement and oversight of its on-site mammography facilities (Congress 1996).

PHYSICIAN SELF-REFERRAL EXAMINATIONS

There are two types of self-referral. One is patient self-referral, whereby patients refer themselves for imaging procedures without having physician requests (referrals), and sometimes without having personal physicians. (See guidance on patient self-referral in the section on SCREENING AND ADMINISTRATIVE PROGRAMS.) The other is physician self-referral, whereby physicians see patients, decide to perform imaging procedures on those patients, and then refer the patients to themselves or their own medical practices for the procedures.

In this context, self-referral examinations are examinations requested or ordered by the same physician or other licensed independent practitioner who subsequently performs or interprets them. Some of these examinations might occur because of patient convenience, i.e., not requiring the patient to travel to another facility for the examination.

Unnecessary radiation exposure caused by self-referral practices that are not medically indicated generally need not occur in federal health care institutions, where radiology services are readily available. Exceptions could be small operational units, such as ships, field units or isolated stations where the normal workload does not justify a staff radiologist. Thus, the conduct of self-referral x-ray examinations should be permitted only by a physician whose qualifications to supervise, perform, and interpret diagnostic radiological procedures have been demonstrated to the appropriate authorities.

It is recognized that limited self-referral type examinations are performed in federal medical facilities in certain clinical specialties. The use of such self-referral x-ray examinations should, however, be limited to studies unique to and required by the specialty of the physician performing them and be subject to peer review.

Self-referral practices in federal facilities are expected to be immune to economic considerations for the referring physician. Self-referral practices in contract civilian facilities should conform to those in federal facilities. Exception may be made in remote areas where no practicable alternative exists.

COMMUNICATION AMONG PRACTITIONERS

Optimal medical care requires communication between the Referring Medical Practitioner and the Radiological Medical Practitioner. The information technology system also plays an important role. Requests for x-ray examinations should be considered as medical consultations

between the Referring Medical Practitioner and the Radiological Medical Practitioner. A request should state the diagnostic objective of the examination, and when appropriate, should detail relevant medical history including results of previous diagnostic x-ray examinations and other relevant tests.

Whenever possible the Radiological Medical Practitioner should review all examination requests requiring fluoroscopy, CT, or other complex or high-dose studies before the examination is performed, and ideally before it is scheduled. For this reason, it is important that a thorough and accurate patient history be included with each examination request. Based upon the clinical question, history, and relevant available previous studies, the Radiological Medical Practitioner should direct the examination using standard protocols, with any appropriate addition, substitution or deletion of views or sequences. Whenever possible, there should be communication between the requesting health care provider and the imaging expert before any adjustment is made to the examination protocol for any patient.

Effective communication of the findings is an essential component of imaging studies. Facilities are strongly encouraged to have policies on the communication of findings that are consistent with the guidelines of accrediting organizations and professional societies (ACR 2010). Standardized reporting formats, if available, should be used.

The provision of care by more than one medical facility may result in duplication of imaging studies. To prevent this, and as technology permits, the Referring Medical Practitioner should review the patient's medical record to determine whether the proposed imaging study is an unnecessary duplication of a previous study. All members of the patient's health care team should cooperate to help prevent unnecessary studies. This requires that the reports and images from all studies are accessible through the patient's Electronic Health Record (EHR) (Congress 2007). Facilities should ensure that patient information in EHRs at all medical facilities is shared, ideally through a common interface, and available to the practitioner. Structured reporting can facilitate this sharing of information (ACCF 2009).

When referral from one facility to a second is anticipated, only the studies needed for proper referral should be performed in the first facility. Those imaging studies should be made available to the second medical facility concurrent with the transfer, either electronically or in hard copy format.

TECHNICAL QUALITY ASSURANCE

Quality assurance refers to those steps that are taken to ensure that a facility consistently produces images that are adequate for the purpose with optimal patient exposure and minimal operator exposure. Quality assurance is a shared responsibility of all involved in patient health care. In radiological imaging, quality assurance requires effective communication and interaction among the Radiological Medical Practitioners, equipment operators, QMPs and others servicing and assuring quality performance of the equipment.

Quality assurance includes those organizational steps taken to make sure that testing techniques are properly performed and that the results of tests are used to effectively maintain a consistently high level of image quality. An effective quality assurance program includes assigning personnel to determine optimum testing frequency of the imaging devices, evaluate test results, schedule corrective action, provide training, and perform ongoing evaluation and revision of the program.

Quality control comprises the procedures used for the routine physical testing of the primary components of the imaging chain from the x-ray source, through processing to the viewing of images, as addressed in Table 1. Each facility, through its radiation quality control team (e.g., QMP, imaging physicians, radiologic technologists, biomedical maintenance personnel), should track maintenance and monitoring procedures.

Each facility performing medical imaging with x-rays should establish in writing and implement a technical quality assurance and quality control program that conforms to current professional society recommendations (e.g., the "ACR Technical Standard for Diagnostic Medical Physics Performance Monitoring of Radiographic and Fluoroscopic Equipment" (ACR 2011), the "ACR/AAPM Technical Standard for Diagnostic Medical Physics Performance Monitoring of Computed Tomography (CT) Equipment" (ACR-AAPM 2012), and the ACR Computed Tomography Quality Control Manual (ACR 2012b)). The program should include all aspects of the imaging process from image acquisition through image display (see sections on QUALITY ASSURANCE for each modality below). Display monitors for interpretation of grayscale images should be calibrated to the DICOM Grayscale Standard Display Function (GSDF) (NEMA 2009) and their performance should be periodically assessed (AAPM 2005). It is also highly desirable that operators' console monitors and quality control (QC) workstations, which directly impact image presentation at other display devices, maintain the luminance response requirements of diagnostic monitors; ideally, these should also be calibrated to the DICOM GSDF. There are advantages to using vendor-neutral phantoms for testing of image quality and evaluation of patient dose metrics for each modality; this permits comparison of performance among equipment from various manufacturers.

TECHNIQUE FACTORS AND IMAGING PROTOCOLS

Technique factors should be established for each imaging procedure and may be unique for each system. Technique factors (and resulting dose) for the same patient may vary with the manufacturer and model of the imaging equipment used in order to obtain necessary image quality. For radiographic examinations, examples include kilovoltage (kV); milliampere (mA);

exposure time, if automatic exposure control is not used; and perhaps choice of image receptor. For mammography, this can include target-filter combination. For CT examinations, these include kV, mA, rotation time, pitch, selection of a mode in which mA is modulated during the scan with vendor-specific image quality index, and method of post-acquisition image reconstruction.

Technique factors may be programmed into the imaging device, or they may be manually selected. Technique factors for specific examinations are now commonly stored on the imaging systems as "protocols." The operator typically selects a protocol for the specific examination, instead of manually selecting the individual technique factors, although these may need to be adjusted for the individual patient. Technique factors and protocols should be chosen that produce a clinically-adequate image at an optimized dose to the patient, not an ideal image. Technique factors should be adjusted to the thickness of the patient. In the case of pediatric imaging, the age of the patient should not be substituted for thickness since thickness does not necessarily correlate to age

If the review of technique factors and protocols used clinically or the comparison of dose indices to diagnostic reference levels or scaled results indicate that an optimum balance has not been achieved between patient dose and image quality, the technique factors, whether posted in a chart or programmed into the imaging device, and/or selection of image receptor, should be modified as necessary.

TESTING BY A QUALIFIED MEDICAL PHYSICIST

It is strongly recommended that the technical quality assurance program includes testing by or under the supervision of a QMP of all imaging equipment producing x-rays. The equipment should be tested after installation but before first clinical use, annually thereafter (or at intervals of up to 2 years for intra-oral and panoramic dental radiography equipment and up to 3 years for veterinary equipment), or less frequently for DoD facilities if justified by unique mission requirements. After any repair or modification that may affect patient dose or image quality, testing should be performed by or under the supervision of a QMP. The testing, including a summary of methods, instruments used, measurements and deficiencies identified, should be documented in a written report signed by the QMP. The testing should include the items in Table 1 below:

Table 1. Testing Frequency of Imaging Equipment that Produces X-Rays

TASK	INITIAL	AFTER MODIFICATION OR REPAIR (a)	ANNUAL
Perform an acceptance test	X	X (c)	
Measure radiation output parameters, including beam intensity and beam quality	X	X	X
Test modes of operation used clinically, such as automatic control systems (e.g., automatic exposure controls of radiographic systems, automatic exposure rate controls of fluoroscopy systems.)	X	X	X
Assess image quality	X	X	X
Verify accuracy of displayed dose metrics (e.g., Detector Exposure Index) (b)	X	X	X
Assess the typical patient dose metrics delivered for various examinations and compare to diagnostic reference levels	X	X	X
Review the overall technical quality control program (d)			X
Review all acquisition protocols (d)	X		X

(a) Testing following repairs or modifications may be limited to features and parameters that would be affected by the repairs or modification.
(b) Determine accuracy of displayed dose indices (e.g., for radiography, according to AAPM TG116 methodology (AAPM 2009)) and manufacturer's recommendations if available.
(c) Relevant acceptance tests should be performed when major repairs (e.g., new x-ray tube) are performed.
(d) The review should be performed together by a Radiological Medical Practitioner, technologist and QMP. Staggering annual reviews throughout the year should be considered to maintain momentum without impacting schedules.

The QMP may be assisted by other properly trained persons (e.g., the manufacturer's service representative or facility's biomedical service representative) in obtaining test data for performance monitoring. These persons should be trained by the QMP in the techniques for performing the tests, the function and limitations of the imaging equipment and test instruments, the reasons for the tests and the importance of the test results. The QMP should be present at the facility for the initial and annual testing. Exceptions to this can be made in extreme circumstances, such as facilities in other countries or on military vessels. In the latter case, the QMP should promptly review, interpret, and approve all data measurements and test results.

EQUIPMENT FAILURE

When x-ray imaging equipment fails to meet its performance specifications, a decision must be made regarding the severity of the deficiency in order to determine the time frame in which

repairs must be made. Most minor deficiencies should be corrected within 30 days. If the deficiency can have significant impact on diagnosis or patient or operator safety, the equipment should be removed from clinical use until repairs are made and verified. After correction of significant deficiencies the equipment should be tested, by or under the supervision of a QMP, to verify that the deficiency was corrected and that the correction did not cause other deficiencies. The QMP is the final arbiter of whether the equipment should be removed from service or safely returned to clinical use. It is best that verification testing occur while the service technician is present, so that the technician can promptly perform adjustments or repairs to address deficiencies revealed by the QMP's testing and the QMP can then confirm their adequacy. However, if an x-ray imaging system is in a remote location, it may not be feasible for the QMP to test the system before it is returned to clinical service. An acceptable alternative for remote locations is to have a person trained by the QMP perform the QMP's verification tests and submit them to the QMP for review, interpretation and approval. Records should be made of the deficiency, its severity and its correction. These records should be kept in accordance with the organization's record keeping policy.

DOSIMETRY

Patient dose indices should be available for review. They should be obtained from patient examinations or measured by or under the supervision of a QMP, using clinical protocols. As dose metrics change over time, agency recommendations for specific metrics may change. As of 2014, for radiography, entrance skin exposures for common projections should be measured and recorded for a patient of typical thickness. For CT, computed tomography dose index (CTDI), and dose length product (DLP) measurements for common examinations should be recorded for a patient of typical thickness. The fluoroscopic dose rate for a standard patient thickness should be measured and recorded for each fluoroscopic mode of operation that is used clinically. For fluoroscopy systems that display patient dose indices (e.g., cumulative air kerma or dose-area product), the accuracy should be measured and recorded. At facilities where pediatric patients are imaged, dosimetry data for radiography, CT and fluoroscopy should be measured and recorded for small, average and large patient thicknesses.

DIAGNOSTIC REFERENCE LEVELS AND ACHIEVABLE DOSES

For each type of examination there exists, within available technology and for each specific imaging device, a combination of technique factors to produce adequate images at optimized doses. Hence, it is important to evaluate each system's performance to determine whether dose is optimized and to maintain this by establishing appropriate procedures and conducting periodic monitoring (NCRP 2012). Dose optimization is a process, not a final end point.

Diagnostic reference levels (DRLs) and achievable doses (ADs) are values used as quality assurance and quality improvement tools to help optimize radiation dose (NCRP 2012). Quality improvement uses quantitative and qualitative methods to improve the safety, effectiveness and efficiency of health care delivery processes and systems.

DRLs were first introduced in the 1990s (ICRP 2003; Wall and Shrimpton 1998). DRLs are used to help avoid radiation dose to the patient that does not contribute to the medical imaging task (ICRP 2003). They are intended to provide guidance on what is achievable with current good practice rather than optimum performance, and help identify unusually high radiation doses or exposure levels (ACR-AAPM 2013b; IAEA 1996). DRLs are a guide to good practice, but are neither dose limits nor thresholds that define competent performance of the operator or the equipment (Vañó and Gonzalez 2001). For assessments where the dose metric is determined using a phantom, a value above the DRL requires investigation. On the other hand, for interventional procedures, if the mean dose metric for a number of cases of a procedure exceeds the DRL, it does not always mean that the procedure has been performed improperly. Furthermore, a mean dose metric for a procedure that is less than the DRL does not guarantee that the procedure is being performed optimally (Vañó and Gonzalez 2001).

A DRL is derived from dosimetric data for a well-defined patient, the 'standard' patient. The value is based on exposure to a standard plastic phantom or a 'standard' adult patient (typically weighing 75-85 kg) for a specific procedure, measured at a number of representative clinical facilities. DRLs are set at approximately the 75th percentile (third quartile) of these measured data (ACR-AAPM 2013b; Gray et al. 2005; McCollough et al. 2011). It is important, however, to emphasize that, with good technique, practicable levels of exposure for most patients will be below these levels.

The use of DRLs is supported by national and international advisory bodies (Amis et al. 2007; ICRP 2000a). These and other organizations have provided guidelines on measuring radiation dose metrics and setting DRLs (IAEA 1996; ICRP 1991a; ICRP 1996; ICRP 2007b; Wall and Shrimpton 1998). DRLs can be specific to the country or region, and may be derived from multinational, national or local data (ICRP 2003; ICRP 2007a). As of 2014, U.S. DRLs for many examinations are available (ACR-AAPM 2013b; NCRP 2012). In order to generate national DRLs for the U.S., institutions where these procedures are performed should submit radiation dose metrics to a central dose registry.

ADs are an adjunct to DRLs. ADs are set at approximately the median (50th percentile) of the dose distribution (ACR-AAPM 2013b; NCRP 2012). This means that half of the facilities are operating below this level, so presumably the local facility can achieve these dose levels as well. ADs are a target, and can be used in conjunction with DRLs as a guide to gauge the success of optimization efforts.

Each institution or individual practitioner should use DRLs and ADs as quality improvement tools by collecting and assessing radiation dose data. Standard phantoms are used where the procedure is standardized (e.g., chest radiograph or head CT). Patient dose metric data are collected if the procedure is individualized for each patient (such as fluoroscopically guided interventions) and should be collected for standardized procedures as well. The mean radiation dose for the examination is then compared to the DRL and the AD for that examination (ICRP 2003). If the mean radiation dose at the facility exceeds the DRL, equipment and clinical practices should be investigated in order to reduce radiation doses (NRPB 1990; Wall 2001). Equipment function should be investigated first, followed by review of the clinical protocol (Vañó and Gonzalez 2001). Whenever the radiation dose or examination protocol is changed,

image quality should be evaluated. Investigations are also appropriate where local values are substantially below the DRLs, as excessively low doses may be associated with poor image quality (Balter et al. 2008; IAEA 2009). Operator performance should be assessed if no other cause is found. The development of DRLs and ADs requires consideration of the technique factors which most affect patient exposure.

The *Nationwide Evaluation of X-ray Trends* (NEXT) is a program conducted by the FDA in conjunction with the States and the Conference of Radiation Control Program Directors (CRCPD) (FDA 2010a). The NEXT data provide a profile of aspects of medical and dental imaging using ionizing radiation in the United States at the time of survey. These data provide a window into clinical practice because they reflect the myriad of combinations of imaging equipment, technique factors and the skill of equipment operators. Therefore, regardless of the specific details of technique or combinations of all these factors, the frequency distributions of dose derived from the NEXT data were assumed to be sufficiently representative of the complex interaction of Referring Medical Practitioner preference, Radiological Medical Practitioner preference, operator technique, and x-ray equipment performance for each of the selected standard examinations. Thus, NEXT data, when available and current, serve as a useful source for the development of national DRLs and ADs in the U.S. (ACR-AAPM 2013b; NCRP 2012).

It is expected that U.S. DRLs will decrease over time as outlier institutions improve their equipment and practices. In the United Kingdom, DRLs derived from data in the 2000 review were approximately 20% lower than those derived from data in the 1995 review, and approximately half those determined in the mid-1980s (Hart et al. 2009).

It is desirable to compare dose metrics from as many types of examinations as is practical with DRLs and ADs. In the absence of national reference levels, agencies and individual healthcare facilities should use interim reference levels. Sources of these may be reference levels from other countries or unions of countries (e.g., the European Union), multi-institutional studies (Hausleiter et al. 2009; Miller et al. 2012b; Miller et al. 2009), or other sources, such as dose information from reputable institutions.

Interventional Procedures

The ICRP considers DRLs a useful tool to help optimize patient radiation dose in fluoroscopically guided interventional (FGI) procedures (ICRP 2007b). As of 2014, some studies have presented DRLs for cardiac procedures (Balter et al. 2008; D'Helft et al. 2009; Miller et al. 2012b; Neofotistou et al. 2003; Peterzol et al. 2005) and a limited number of interventional radiology procedures (Aroua et al. 2007; Brambilla et al. 2004; Hart et al. 2009; Miller et al. 2009; Tsalafoutas et al. 2006; Vano et al. 2008a; Vano et al. 2009; Vano et al. 2008b; Verdun et al. 2005). Unfortunately, the observed distributions of patient doses for most types of FGI procedures are very wide, because the dose for each instance of a procedure is strongly dependent on each individual patient's clinical circumstances. The same considerations apply to CT-guided interventions. A potential approach is to include the 'complexity' of the procedure in the analysis (Balter et al. 2008; IAEA 2009; ICRP 2007b). As of 2014, complexity cannot be quantified (with the exception of some interventional cardiology procedures), so this adjustment

is not possible for most FGI procedures (Balter et al. 2008; IAEA 2009). Because of the high individual variability of patient dose in cases of FGI procedures, the number of cases recommended in the literature as sufficient to provide adequate radiation dose data for a single facility varies from 10 to >50 (Vano et al. 2008a; Wall and Shrimpton 1998).

GENERAL GUIDELINES FOR CLINICAL IMAGING

Subsequent sections address radiography, fluoroscopy, CT, and bone densitometry as used in medical, dental and veterinary practice. Once it has been determined that an x-ray examination is justified, other factors become important in limiting patient exposure and ensuring quality. Optimization of patient dose may not be accomplished, even when well-designed equipment is used, unless appropriate quality assurance programs exist to keep the equipment functioning properly, appropriate imaging protocols are established for its use, and those who operate it are properly qualified to use the features of the equipment. These latter considerations are discussed in the chapter on Technical Quality Assurance in Medical Imaging with X-Rays. It is important not to confuse image quality with study quality. Image quality might be good as measured by noise, contrast, and lack of artifacts, but the study quality may be poor if improperly performed.

All x-ray equipment used for the imaging of humans for medical and dental purposes should be maintained so that it conforms, throughout its useful lifetime, to applicable FDA regulations (FDA 2014h). Furthermore, users should be aware of upgrades to software and hardware that enhance safety. These should be evaluated and considered for implementation. To ensure that x-ray equipment is justifiably representative of present day technological advances, facilities should develop and periodically review a planned replacement schedule for all types of diagnostic and interventional x-ray equipment used in their programs.

The qualifications of all x-ray imaging equipment operators should be defined by the agency's responsible authority in a written policy. This policy should be reviewed and revised as required and should detail:

1. who may operate x-ray imaging equipment and the supervision required,
2. the education, training and proficiency requirements for x-ray imaging equipment operators, and
3. requirements for continuing education and demonstration of proficiency.

Except in emergency situations, informed consent should be obtained from the patient or the patient's legal representative and appropriately documented prior to the initiation of any procedure that is likely to expose the patient, or fetus if the patient is pregnant, to significant risks and potential complications. When obtaining informed consent for image-guided procedures that are known to be potentially-high radiation dose procedures (as defined in the glossary), an estimation of the anticipated risks from the radiation dose should be communicated to the patient as part of the overall discussion of risks (NCRP 2010). When a delay in treatment would jeopardize the health of a patient and informed consent cannot be obtained from the patient or the patient's legal representative, an exception to obtaining informed consent is made (ACR-SIR 2011).

Immediately prior to each examination requiring ionizing radiation, staff should verify that patient identity, intended procedure and positioning, and equipment are correct. Also, the technologist should confirm the patient's pregnancy status and, if contrast media is to be used, that the patient is not allergic to it. Invasive procedures and CT examinations require both pre-procedure "verification" and "time-out" processes. Those processes should be as specified by The Joint Commission for invasive procedures under the Universal Protocol (The Joint

Commission 2012a; The Joint Commission 2012b).

Ideally, facilities should be accredited by a deemed body (e.g., ACR, IAC, or TJC) for all applicable modalities. Accreditation programs evaluate conformance to established standards for personnel qualifications, adequacy of facility equipment, quality control procedures and quality assurance programs. While accreditation is a desirable goal, it is not feasible in all federal facilities.

MEDICAL IMAGING

RADIOGRAPHY

General radiography is a service usually provided by a Radiology Department, either in a central department or satellite facilities. Requests for general radiography services are performed based on protocols for standard views of each anatomic area, modified, if needed, to suit special requests or circumstances. Authorized variations to these protocols should be made for patient age and body habitus. Each medical facility should have a written policy for the safe use of radiographic equipment. This policy should apply to all radiographic equipment, whether fixed or portable. This policy should:

1. specify required testing of the radiographic equipment by a QMP (or under a QMPs guidance for facilities or locations where it is not practicable to provide such staffing),
2. specify required training and credentialing of operators and Radiological Medical Practitioners directing the operation of radiographic equipment, and
3. specify procedures for the safe use of the equipment, including dose management and recordkeeping.

Equipment

Radiography can be performed using fixed or mobile radiographic systems. Mobile radiographic systems are used for bedside radiography. Nearly all fixed radiographic systems have automatic exposure controls, which terminate each x-ray exposure when the image receptor has received a pre-determined amount of radiation. As of 2014, mobile radiographic systems typically lack automatic exposure controls, and so the technique factors for each examination must be manually set by the technologist. Furthermore, fixed radiographic systems have image receptors whose anti-scatter grids are set in alignment with the x-ray tube, whereas in mobile radiography the grid and image receptor must be manually aligned by the technologist. In general, mobile radiography should only be used when it is not reasonable to perform the examinations using fixed radiographic systems.

Beginning in the 1990s, a transition occurred from film-screen (also known as screen-film) radiography to digital radiography (radiography using other image receptors). These newer image receptor technologies include storage phosphor plates and several direct-image-capture technologies. Radiography in which images are stored on photostimulable phosphor plate receptors is sometimes called computed radiography (CR). All of these digital radiography technologies produce digital images that are most commonly viewed on display monitors, although the images may also be printed on film using a laser printer, or chemically developed, then examined on a view box.

With film-screen radiography, there is feedback to the technologist if technique factors result in an excessive exposure to the patient. The pertinent measure of the response to radiation exposure is the optical density of the film. Optical density is a non-linear function of radiation exposure. In

film-screen radiography, when imaging a specific projection of a particular patient, only a narrow range of patient exposures will produce an adequate image. An exposure greater than this range produces an "overexposed" film with excessive optical density and inadequate image contrast, and an exposure below this range produces an "underexposed" film with excessively low optical densities and inadequate image contrast. Thus, provided that an appropriate x-ray tube voltage is used and the film is properly developed, the choice of film-screen combination determines the quantity of radiation exposure to a patient of a given size required to provide an adequate image.

There are advantages and disadvantages to digital image receptors in comparison to film-screen receptors. Digital receptors respond to radiation nearly linearly over a wide range of exposures. The statistical noise in the image varies with the exposure, with higher exposures producing images with relatively less statistical noise. Since digital imaging can accommodate wide dose ranges while producing diagnostic quality images, exposure indices, indicating the doses to the image receptors, are now displayed by digital radiography (DR) systems and can guide optimizing the doses to the patients. Another advantage is that images acquired with overly high exposures and some of those acquired with overly low exposures may still be useful, thereby avoiding retakes. An image acquired with an excessively low exposure will have excessive statistical noise, but this may not render the image uninterpretable.

There are also disadvantages to digital radiography. Digital image receptors facilitate easily acquiring multiple images, which may contribute to the acquisition of more images than are clinically necessary. This makes the automated analysis of repeat examinations critical when DR is used. Radiography with storage phosphor plates may require significantly larger patient exposures, by a factor of 1.5 to 2, than rare-earth phosphor film-screen systems to produce images of equivalent quality (Compagnone et al. 2006; Seibert and Morin 2011; Seibert et al. 1996). As of 2014, doses when using some direct digital radiography image receptors can be substantially less than those when using film screen or CR receptors (Compagnone et al. 2006). Adoption of improvements in CR technology and storage phosphor plates (e.g., new phosphor materials, dual-side readout, and needle phosphor plates) might result in doses that are comparable to or lower than those with film-screen imaging (Fernandez et al. 2008; Gruber et al. 2011; Ludewig et al. 2010; Semturs et al. 2012).

In digital radiography, an excessive exposure decreases statistical noise and will likely produce an image that is of higher quality than needed for the clinical task. Furthermore, it may not be apparent to either the technologist or the Radiological Medical Practitioner that the exposure was excessive. Thus, there may be a tendency for technologists to routinely use unnecessarily high exposures, a phenomenon called "dose creep" or "exposure creep" (Freedman et al. 1993; Seibert and Morin 2011; Seibert et al. 1996; Willis and Slovis 2005). Excessive exposures are especially likely when using manually selected technique factors instead of automatic exposure control. Examinations made using mobile radiographic machines are particularly susceptible to excessive or unacceptably low exposures, because most lack automatic exposure control. Excessive exposures can also occur due to improper calibration of the automatic exposure control system, the incorrect configuration of protocols or the use of an inappropriate protocol when automatic exposure control is used. Deliberate use of a protocol that provides an excessive exposure to avoid retakes or criticisms due to underexposure should be avoided.

Other quality issues introduced with advent of digital radiography include the use of post-exposure masking instead of collimation. Proper radiographic technique mandates collimating the radiographic field to the area being imaged, in order to avoid irradiating tissue outside the field. With digital radiography it is possible, after the image is obtained, to electronically mask structures outside of the area of interest in a manner that mimics collimation. This creates the mistaken impression that the radiation was confined to the masked area. Also unique to digital radiography is the ability to discard suboptimal radiographic images electronically in a way that is not apparent to anyone other than the operator. With both of these issues, there is the potential for excessive radiation use that is difficult or impossible to detect as part of the quality assurance process.

Quality Assurance

Quality assurance measures for radiographic imaging using film-screen image receptors are well established, and are described in the literature (AAPM 2006b; ACR 2011; NCRP 1989b). These measures include, among others, cleaning of image intensifying screens; establishing technique charts for exposures; and monitoring film processing, darkroom conditions, film storage, retakes, inadequate images, view boxes and viewing conditions. Digital radiography retains some of the quality assurance issues seen with film-screen image receptors, eliminates others, and adds new ones (AAPM 2005; AAPM 2006a; ICRP 2004).

Storage phosphor image receptor systems and many direct image capture systems provide the capability to monitor the exposure to the image receptor from each individual imaging exposure with a quantity termed the exposure indicator. The exposure indicator relates to receptor exposure, and not directly to patient dose. Initially, each manufacturer of these systems defined, calculated and named its exposure indicator differently. These proprietary exposure indicators were not consistent. Some were proportional to the exposure and others were proportional to the logarithm of the exposure. Some increased as the exposure to the image receptor increased and others decreased as the exposure increased.

A standard indicator of exposure to the image receptor (called the Exposure Index) for adoption by all manufacturers was developed and published in 2009 and adopted by the International Electrotechnical Commission (AAPM 2009; IEC 2008). As of 2014, systems are transitioning to the IEC Exposure Index while also displaying their proprietary indices. Each facility should have a program for monitoring indices of exposure to image receptors, and work toward adopting the standard index and DICOM structured dose reporting (IEC 2008) in order that the data can be exported for internal review and external national comparisons. It is particularly important to monitor these indices for radiographic systems that do not provide automatic exposure control because manual control of technique factors may introduce an additional source of error. Mobile radiographic equipment typically lacks automatic exposure control.

Facilities should work with their Radiological Medical Practitioners and QMPs to develop procedures and establish target Exposure Index values and respective ranges by category of examination and patient population.

Quality assurance measures should be adopted for digital radiography (ACR-AAPM-SIIM 2012a). Table 2 below in the procedures section lists these measures.

It is strongly recommended that radiographic technique factors be established for common examinations. Either these should be programmed into the x-ray machine or a technique chart should be immediately available to the operator. For examinations for which automatic exposure control is not used, the chart should provide the technique factors for various thicknesses of the body part being radiographed. Because of the phenomenon of dose creep, the use of appropriate technique factors is especially important in digital radiography. The technique factors for imaging protocols should be optimized for the body part, projection, and thickness of the patient. Although a QMP can assist with this process, protocol optimization also requires the efforts of a Radiological Medical Practitioner. This process can benefit from the involvement of a technologist and the vendor, as well. The preset vendor protocols may not be optimal, and as such, may result in unnecessary radiation dose. The target exposure index for each protocol should be adjusted as part of the dose optimization process. The target exposure index should then be used to calibrate the radiographic device's automatic exposure control systems, if present. It is particularly important to optimize the technique factors for radiographic imaging protocols performed on infants and children.

Pediatric imaging imposes additional concerns. It is strongly recommended that particular attention be paid to dose optimization for pediatric patients (ICRP 2013b). For pediatric patients the operator should determine the need for an anti-scatter grid (if removable) and patient immobilization. Collimation should be adjusted appropriately. A manual technique chart (e.g., for voltage, tube current, exposure time and added filtration) customized to the radiation source and detector should be used for those body parts that do not cover the sensor of the automatic exposure control device. Whether using a manual technique or the automatic exposure control capabilities of the imaging device, the technologist should gauge the thickness of the body part to be imaged since pediatric patients' ages are a poor indicator of their body part thickness (Kleinman et al. 2010).

Personnel

Each person who directs the operation or operates radiographic equipment should be trained in the safe use of radiographic equipment in order to ensure adequate image quality and optimize patient dose. Sample recommendations on the content of training can be found in ICRP Publication No. 113 (ICRP 2009). Also see the section on PERFORMING AND SUPERVISING STUDIES: RADIOLOGICAL MEDICAL PRACTITIONERS AND TECHNOLOGISTS. Training should be managed and recorded as addressed in the PERFORMING AND SUPERVISING STUDIES section.

Radiological Medical Practitioner

Radiographic equipment should be operated under the general supervision of a physician. This

individual fulfills the responsibilities of the Radiological Medical Practitioner. Depending on the study, the responsible individual may be a radiologist, a surgeon, a cardiologist, a gastroenterologist, a podiatrist or another medical specialist. This individual should be appropriately trained in the imaging modality, should be familiar with the principles of radiation protection, and should have a sufficient understanding of the medical imaging modality's features to determine the appropriate protocol to evaluate the patient's clinical symptoms (ICRP 2009; ICRP 2013a; NCRP 2000; NCRP 2010).

Technologist

The technologist is responsible for using facility-approved imaging protocols and radiation protection measures. Technologists should be trained to produce adequate quality radiographic images and to assist in the quality assurance program. They should also be able to optimize various technique factors of the x-ray equipment to produce an adequate radiographic image at the lowest practicable patient dose and to use optimal procedures in working with patients and ancillary equipment to reduce to a minimum the number of repeat examinations. Operators should have formal training in anatomy, patient positioning and radiation protection practices. Performance of x-ray examinations by inadequately trained individuals is not justified except for emergencies.

Other personnel

Only personnel with specific, appropriate training should be permitted to operate x-ray equipment. The use of x-ray equipment by other individuals is warranted only in an urgent or emergent situation when qualified personnel as specified above are not available to perform the examination in a timely fashion.

Procedures

It is strongly recommended that a radiologist provide general supervision in facilities performing radiography. A board certified radiologist is preferred. Periodic review of the radiographic images should be performed as part of the routine quality assurance process.

X-ray examinations should be performed in accordance with approved imaging protocols. The technologist should not perform any examination that has not been requested by an authorized person.

Collimation restricts the useful beam to the clinical area of interest. Collimation to exclude body areas not being examined should be used to minimize unnecessary exposure. Masking portions of a digital image is not a substitute for collimation.

If it does not interfere with the examination (e.g., obscure the anatomy of interest or interfere with automatic exposure control), contact or shadow shielding, using aprons or other shields, should be employed to shield those parts of the patient that are particularly radiosensitive and are

within the primary beam. Gonadal shielding should be used whenever the gonads are in the irradiated field, the patient is or will be capable of reproduction, and the shielding will not interfere with the examination. It is strongly recommended that breast shielding be used for scoliosis examinations on girls and young women. All shields should be placed between the x-ray source and the tissue to be shielded. When shielding is used, an automatic exposure control sensor should be selected that is not within the shadow of the shield, or manual exposure control should be used. Sometimes positioning can be used in lieu of shielding to reduce radiation dose to sensitive tissues (e.g., PA positioning can reduce dose to the thyroid and breast) (ACR-SPR 2009).

A written outline containing the minimum number of views to be obtained and the type of equipment to be used for each requested examination should be made available to each Radiological Medical Practitioner and equipment operator in every radiology facility. Beyond the specified minimum views, the examination should be individualized according to a patient's needs.

The outline of policies and procedures should indicate who may authorize deviations from the standard set of views for any examination. Every effort should be made to reduce to a minimum the number of standard views for any examination. The necessity of additional views, such as comparison views, should be determined by the Radiological Medical Practitioner.

A periodic review of all standard examination procedures and their associated radiation exposure estimates should be performed to determine if the established routine is achieving the objectives and whether modifications are warranted. Continuation of a standardized examination procedure should be predicated on satisfying the following criteria:

1. the efficacy of the examination is sufficiently high to assure that the diagnosis could not have been made with less risk by other non-radiological means or a smaller number of views,
2. for examinations performed with multiple projections (views), all projections are necessary and are sufficient for diagnosis, and
3. the yield or outcome of the examinations offsets the radiation exposure delivered.

A periodic review should be performed at least annually by experts designated by departmental leadership, and with the input of referring physicians. These reviews should consider applicable regulations as well as the consensus and advice of professional societies concerning the efficacy of radiologic examinations.

Other quality assurance measures are listed in Table 2 below. The specifics of these measures may change over time. The user should consult the relevant AAPM testing protocols and the manufacturers' recommendations.

Table 2. Quality Assurance Measures for Film and Digital Radiography		
Film-Screen Radiography		
Task	**Frequency**	**Methodology**
QMP testing	See Table 1	See section on Technical Quality Assurance in Medical Imaging with X-Rays.
Processor Monitoring	Daily	Clean crossover racks and perform densitometry test.
Darkroom Cleaning	Weekly	Check for dust, clutter, etc.
Processor Preventive Maintenance	Monthly	Perform deep cleaning and evaluate darkroom chemicals as recommended by the manufacturer.
Screen Cleaning	Monthly	Clean all screens in inventory according to manufacturer's recommendations
Repeat Analysis	Quarterly	Track the rate of repeated or rejected images and ensure it is less than or equal to 7% (NCRP 1988). Trends indicating deterioration in performance or increase in patient dose should be investigated.
Testing of removable anti-scatter grids	Annually	Image grids for damage that might cause artifacts.
View box performance and cleaning	Annually	Assess luminance with calibrated photometer, replace bulbs if indicated, and clean view box if dirty. Follow additional standards for mammography (ACR 1999).
Darkroom Fog	Annually and after bulb or filter change	Lightly expose a film (image a step wedge at 70 kVp, 5 mAs). In the darkroom with safelight on, cover half the latent image with an opaque material for at least 2 minutes then develop the film. A visible line between the two parts of the image indicates a darkroom fog problem.
Film-Screen Contact Test	Annually	Follow film-screen contact test tool instructions.
Review Local Radiation Protection and Quality Control Operating Instructions	Annually	Revise as needed.

Computed Radiography		
Task	**Frequency**	**Methodology**
QMP testing	See Table 1	See section on Technical Quality Assurance in Medical Imaging with X-Rays. Testing should be consistent with current professional organization recommendations, e.g., AAPM (AAPM 2006a).
Image Plate Erasure	Weekly or daily if unsure of status	Perform primary erasure of each plate following manufacturer's instructions. This should be performed before use if the status of the plate is unknown or fogging is anticipated. Plates in storage do not require erasing until just prior to use (AAPM 2006a).
Operator Console	At least Monthly	View and evaluate QC pattern (AAPM 2005), clean display monitors.
Quality Control Phantom Image Acquisition	Monthly	Follow manufacturer's and/or QMP's recommendations.
Transmit Phantom Image to Interpreting Medical Treatment Facility	Monthly	For Teleradiology Sites Only: after acquisition of QC image, transmit to interpreting facility for verification of image quality.
Detector Exposure Index Monitoring	Monthly or quarterly	Review exposure indicators according to AAPM TG116 methodology (AAPM 2009) and/or manufacturer instructions and compare with guidance levels.
Repeat Analysis	Quarterly	Track the rate of repeated or rejected images and ensure it is less than or equal to 7% (NCRP 1988). Trends indicating deterioration in performance or increase in patient dose should be investigated.
Image Plate Cleaning	Quarterly	Follow manufacturer's recommendations for proper cleaning technique using approved cleaning solution and proper safety precautions.
Testing of removable anti-scatter grids	Annually	Image grids for damage that might cause artifacts.
Review Local Radiation Protection and Quality Control Operating Instructions	Annually	Revise as needed.

Direct Digital Radiography		
Task	**Frequency**	**Methodology**
QMP testing	See Table 1	See section on Technical Quality Assurance in Medical Imaging with X-Rays.
Operator Console	At least Monthly	View and evaluate QC pattern using a recognized method, e.g., AAPM On-Line Report No. 03 (AAPM 2005); clean display monitors.
Quality Control Phantom Image Acquisition	Monthly	Follow manufacturer's and/or QMP's recommendations.
Transmit Phantom Image to Interpreting Medical Treatment Facility	Monthly	For Teleradiology Sites Only: after acquisition of QC image, transmit to interpreting Medical Treatment Facility for verification of image quality.
Detector Exposure Index Monitoring	Monthly or Quarterly	Review exposure indicators according to AAPM TG116 methodology (AAPM 2009) and/or manufacturer's instructions and compare with guidance levels.
Repeat Analysis	Quarterly	Track the rate of repeated or rejected images and ensure it is less than or equal to 7% (NCRP 1988).
Testing of removable anti-scatter grids	Annually	Image grids for damage that might cause artifacts.
Review Local Radiation Protection and Quality Control Operating Instructions	Annually	Revise as needed.

Interpretation and QC Display Monitors		
Task	**Frequency**	**Methodology**
User task: visual assessment using QC test pattern	Daily	AAPM TG-18 Online Report 3, table 8a or equivalent (AAPM 2005)
Display monitor cleaning	Monthly as needed	Clean display monitors with cleaner approved by manufacturer
QMP, technologist tasks: display system performance	Monthly or Quarterly	AAPM TG-18 Online Report 3, table 8b or equivalent (AAPM 2005)
QMP tasks: display system calibration verification	Initially and Annually	AAPM TG-18 Online Report 3, table 8c, or equivalent (AAPM 2005)

Other External Equipment	
Task	**Frequency and Methodology**
Printer quality control	Follow manufacturer's recommendations
Digitizer quality control	Follow manufacturer's recommendations

Hand-Held Units

As of 2014, hand-held, battery-powered x-ray devices are available for radiographic imaging. Please see dental section on HAND-HELD UNITS for guidance on these units.

FLUOROSCOPY

Fluoroscopy may be employed by a variety of clinical services in a medical facility to image patients and to guide procedures. It can be performed with fixed, mobile or portable fluoroscopy systems. Some fluoroscopically guided procedures can deliver a large radiation dose to the patient, even when performed properly. When justifying these procedures, consideration also should be given to the radiation burden of associated pre- and post-procedure imaging studies (Thakor et al. 2011; White and Macdonald 2010).

Some prolonged fluoroscopically guided procedures may result in patient radiation injury, including non-healing skin ulcers, and other tissue injuries (Balter et al. 2010; FDA 1994; ICRP 2011; ICRP 2013a; Koenig et al. 2001a; NCRP 2010). Because staff must remain with the patient in the procedure room during interventional fluoroscopy, their occupational radiation doses might approach occupational dose limits. Each medical facility should have a written policy for the safe use of fluoroscopic equipment. This policy should apply to all fluoroscopy equipment, whether fixed, mobile or portable, e.g., mobile C-arm systems and mini C-arm systems. This policy should:

1. require testing of the fluoroscopic equipment by or under the direction of a QMP,
2. require training and privileging of persons operating or directing the operation of fluoroscopic equipment,
3. specify procedures for the safe use of the equipment, including dose management and recordkeeping,
4. require a clinical QA/QI program for fluoroscopy, and
5. specify levels of dose metrics and required methods for clinical follow-up of patients who may have received high skin doses.

Although the aggregate population effective dose is larger from the use of general purpose diagnostic equipment and CT (NCRP 2009), the highest organ doses (especially skin doses) to individuals, other than in radiation oncology, generally result from interventional fluoroscopic procedures. These procedures may require high exposure rates for long periods of time; thus, it is of utmost importance that federal health care facilities give particular attention to fluoroscopic examinations. Even for simple and low-dose fluoroscopic examinations, proper training is required to perform the procedure with the optimal radiation dose. Therefore, x-ray equipment capability should not exceed the medical mission of the facility, i.e., fluoroscopy should not be available in facilities where qualified medical personnel are not assigned. Equipment, physicians and staff should all meet current guidelines of the American College of Radiology Technical Standard for Management of the Use of Radiation in Fluoroscopic Procedures and its successors (ACR-AAPM 2013a).

Equipment requirements and training requirements for operators differ depending on whether the

procedures to be performed will be relatively low dose or potentially high dose (ICRP 2009; NCRP 2010). Fluoroscopically guided procedures should be classified as potentially high radiation dose if more than 5% of cases of that procedure result in a cumulative air kerma exceeding 3 Gy or a kerma-area product (KAP) exceeding 300 Gy·cm^2. Low dose procedures are below these levels (NCRP 2010).

Equipment

If the medical mission requires fluoroscopy, only image-intensified units (with image intensifiers or flat panel detectors) should be used (ICRP 2010). Since mid-2006, all fluoroscopic equipment sold in the United States provides a display of cumulative air kerma at a reference point. This simplifies the process of measuring and recording radiation dose in the medical record.

Some operative procedures, both minimally invasive and open surgical, performed both inside and outside the operating room, (e.g., hip replacement, transsphenoidal hypophysectomy, some endoscopic procedures) may require fluoroscopic assistance. In general, these procedures tend to be relatively low-dose (ICRP 2010). For these procedures, to the fullest extent practicable, only equipment with features such as last-image-hold and pulsed fluoroscopy with reduced dose rate and low pulse rate, or equipment with similar dose-reducing features, should be used. The advantage of this technology is that the radiation exposure can be reduced compared to continuous fluoroscopy, while adequate image quality is maintained.

For procedures with a potential for high patient doses (this includes most interventional radiology, interventional cardiology, interventional neuroradiology and endovascular surgical procedures), additional requirements apply for both equipment and personnel (Hirshfeld et al. 2004; ICRP 2009; ICRP 2013a; Lipsitz et al. 2000; Miller et al. 2003a; Miller et al. 2003b; NCRP 2010; Padovani and Quai 2005; Suzuki et al. 2006). Fluoroscopy equipment intended for these procedures should, at a minimum, be compliant with the version of International Electrotechnical Commission Standard 60601-2-43 (IEC 2010) applicable to the equipment at the time of purchase. New fluoroscopic imaging systems should incorporate high heat-loading tubes, adjustable-rate pulsed fluoroscopy capability, adjustable thicknesses of additional beam filtration, and automatic exposure control logic to properly manage radiation so as to optimize patient dose and ensure adequate image quality throughout the procedure. As future systems incorporate improved methods for both tracking and management of patient dose during fluoroscopically-guided procedures, purchasers and operators should take advantage of them when appropriate. The additional cost of dose-reduction technology is justified because the reduction in both patient and operator radiation dose can be considerable.

Proper patient dose management during fluoroscopically-guided interventions requires appropriate use of the various features of the fluoroscopic equipment. This will permit patient dose to be optimized and staff dose to be minimized. There is extensive literature on this subject which can be used for guidance (Chambers et al. 2011; ICRP 2010; Koenig et al. 2001a; Koenig et al. 2001b; Miller et al. 2010a; NCRP 2010; Stecker et al. 2009; Steele et al. 2012). The configuration and setup of the operational features of the fluoroscope may require additional changes if pediatric imaging will be performed (Strauss 2006).

Measurement or estimation of skin dose is desirable for all procedures which are high dose or have the potential to result in high patient dose. The quantity of interest is the peak skin dose (PSD), the highest dose at any point on the patient's skin. This determines the severity of a radiation-induced skin injury. Ideally, equipment should also provide the operator with a near real-time indication of skin dose, including PSD in the current radiation field. The operator would then be able to modify technique during the procedure to minimize skin dose (FDA 1994; Miller et al. 2002). Skin dose can be measured with special films, an array of thermoluminescent dosimeters (TLDs), optically stimulated luminescence (OSL) dosimeters or real-time point-measurement devices (Balter et al. 2002). Currently, these methods are not commonly used in routine clinical practice. Ideally, software-based systems that estimate and map skin dose in real time should be widely available and used routinely.

Cumulative air kerma (cumulative air kerma at the reference point; also called reference air kerma, reference point dose, reference point air kerma or cumulative dose) is measured in Gy and displayed automatically on all fluoroscopic equipment in the United States sold after mid-2006 per 21 CFR 1020.32(k) (FDA 2014e). It is the dose at a pre-defined reference point. This point is separately defined for different types of fluoroscopic equipment (FDA 2014d; FDA 2014e). For C-arm units, this point is located along the central ray of the x-ray beam, 15 cm from the isocenter towards the x-ray source (IEC 2010). Cumulative air kerma is not the same as skin dose. Cumulative air kerma is measured at a point in space that is fixed with respect to the gantry and can move with respect to the patient when the table is moved or the gantry is angled. Cumulative air kerma does not take table height or these motions into account. As a result, cumulative air kerma is usually greater than PSD (IEC 2010; Miller et al. 2003a; Miller et al. 2012a; Weinberg et al. 2013).

Kerma-area product (KAP, also called dose-area product or DAP) is the product of the air kerma and the area of the irradiated field and is measured in $Gy \cdot cm^2$. It does not change with distance from the x-ray tube. It is a good measure of the total energy delivered to the patient, and therefore a good measure of the risk of stochastic effects. It is not a good indicator of the risk of tissue reactions (deterministic effects) (Kwon et al. 2011; Miller et al. 2012a; NCRP 2010).

Fluoroscopy time has been the standard dose metric. It is easy to measure and the capability to measure it is widely available. However, fluoroscopy time does not reflect the effects of fluoroscopic dose rate or the radiation dose from radiography (e.g., digital subtraction angiography or cinefluorography) and is a poor indicator of patient dose. As recommended in a joint Society of Interventional Radiology/Cardiovascular and Interventional Radiological Society of Europe (SIR/CIRSE) guideline, use of fluoroscopy time as the sole dose metric is not advisable, and should not be done unless no other dose metric is available (Stecker et al. 2009). Even then, the number of images and cine frames should also be recorded. Procedures with a potential for high patient doses should not be performed using fluoroscopy equipment that is not compliant with IEC 60601-2-43 or its successors (IEC 2010).

For patient care and for quality assurance purposes, it is highly desirable for all radiation data to be transferred automatically to the picture archiving and communication system (PACS), radiology information system (RIS), and Electronic Health Record (EHR) as part of the study

data (along with images and demographic information) if the fluoroscopy unit is connected to a PACS. These data should include the peak skin dose, if available; the cumulative air kerma from both fluoroscopy and from image acquisition, if available; the kerma-area product, if available; and the cumulative fluoroscopy time and number of images or cine frames recorded (Miller et al. 2012a; NCRP 2010).

There are several relatively new technologies as of 2014 (e.g., cone-beam CT, surgical O-arms,) (ACR-AAPM 2013a; Orth et al. 2008; Wallace et al. 2008). Others will likely appear in future interventional fluoroscopy equipment. Some of these technologies are intended to provide greater technical capability for complex surgical or interventional procedures. Currently, most of these technologies are designed to enhance the fluoroscopy unit's surgical capability for procedures performed outside the Radiology Department. Mobile equipment with these technologies is smaller in size than its conventional fixed counterpart, but it can be just as dangerous to the operator and patient. Facilities should establish procedures for the testing and use of these types of equipment, and for the training and credentialing of its operators.

Quality Assurance

Equipment testing for quality assurance should be performed by or under the direction of a QMP after installation but before first clinical use, annually thereafter, and after each repair or modification that may affect patient dose or image quality. Testing should be performed as specified in the section of this document entitled Technical Quality Assurance in Medical Imaging with X-Rays.

Personnel

Fluoroscopy can deliver a significant radiation dose to the patient, even when used properly. Also, fluoroscopy presents the potential for greater radiation dose to the operator as compared with other imaging modalities. Therefore, all fluoroscopic examinations should be performed by or under the direct supervision of a physician with demonstrated competence, who has received training in fluoroscopy and has been privileged by the facility to perform fluoroscopy.

In fluoroscopy, the operator effectively determines, prescribes and delivers the required x-ray dose to the patient in real-time. These systems are often used to guide imaging or interventions. Patient dose is directly related to the complexity of the procedure and inversely related to the skill of the individual performing the procedure. Individuals who hold privileges to use these systems, and particularly the high-dose-capable systems used in interventional procedures, should have a thorough understanding of the biological effects of radiation exposure, the dose from this radiation exposure and its likely deterministic and stochastic risks, and of the available technique and technology based methods for minimizing the radiation dose to any portion of the patient's tissue during the examination.

Every person who operates or directs the operation of fluoroscopic equipment should be trained in the safe use of fluoroscopic equipment in order to optimize patient dose. Initial training should include didactic training, hands-on training and clinical operation under a preceptor.

Didactic training is a formal course of instruction in radiation safety which meets guidelines established by the responsible authority. It should include, but need not be limited to, the following topics:

1. Physics of x-ray production and interaction.
2. The technology of fluoroscopy machines, including modes of operation.
3. Characteristics of image quality and technical factors affecting image quality in fluoroscopy.
4. Dosimetric quantities, units, and their use in radiation management.
5. The biological effects of radiation.
6. Principles of radiation protection in fluoroscopy.
7. Applicable federal regulations and agency requirements.
8. Techniques for minimizing dose to the patient and staff.

This phase of training should include successfully completing a written examination. Some Radiological Medical Practitioners may be able to fulfill the didactic portion of the initial training through training in radiation physics, radiation biology and radiation safety they receive during their residency or fellowship, but they must be able to demonstrate this knowledge by completing a written examination successfully.

Hands-on training is conducted by a qualified individual who is familiar with the equipment (ICRP 2009; ICRP 2013a; NCRP 2010). Hands-on training means operation of the actual fluoroscope that is to be used clinically (or an essentially similar fluoroscope), including the use of controls, activation of various modes of operation, and displays. This phase of training could include demonstrations of the effect of different modes of operation on the dose rate to a simulated patient and could include demonstration of the dose-rates at various locations in the vicinity of the fluoroscope.

Clinical operation under a preceptor means operation of the fluoroscope for clinical purposes under the direct supervision of a preceptor experienced in the operation of the device. Completion of this phase of training should include written attestation, signed by the preceptor, that the individual has achieved a level of competency sufficient to function independently as a fluoroscopy operator.

Training specific to fluoroscopy should be conducted initially and then at periodic intervals. Records should be kept of both the didactic and hands-on training. The records should include the date(s) of training, the name(s) of the person(s) providing the training, the topics included in the training, the duration of the training, the test questions, the names of the persons successfully completing the training, and the test scores of these persons. The training records should also include the signed preceptor statements described above. Training need not be performed at or by the medical facility, provided that the facility determines that it meets these requirements and was sufficiently recent, and the facility obtains written certification of successful completion of the training. Periodic refresher training should include the didactic training. At the facility's

discretion, it may also include hands-on-operation and clinical operation under a preceptor physician.

Each person who operates or directs the operation of fluoroscopic equipment should be privileged in fluoroscopy by the medical facility. Privileging should be contingent upon successful completion of training as described above. Maintenance of privileges should be contingent upon successful completion of periodic refresher training and on complying with agency and facility requirements for the safe use of fluoroscopic equipment. In particular, it is not permissible for a physician or other medical professional who has not completed this training, and who is not privileged, to direct the operation of a fluoroscopy unit even if it is operated by a radiologic technologist.

Operators who perform fluoroscopically-guided procedures with the potential for high patient doses require additional knowledge and training beyond that necessary for operators whose practice is limited to low-dose fluoroscopy procedures (ICRP 2000a; Vano 2003). Operator knowledge includes all the information described in the current American College of Cardiology Foundation (ACCF)/ American Heart Association (AHA)/ Heart Rhythm Society (HRS)/ Society for Cardiovascular Angiography and Interventions (SCAI) fluoroscopy clinical competence statement and its successors (Hirshfeld et al. 2004). In general, radiologists and interventional cardiologists who were trained recently have received most or all of this information as part of their training, and are tested on this knowledge as part of the board certification processes by their respective Boards. Physicians in other medical specialties may or may not have received training or been examined on this subject matter during their residency or fellowship, and they may require additional training.

Procedures

Fluoroscopic procedures should be performed so that procedure dose is optimized and skin dose is minimized. This requires the appropriate use of various features of the fluoroscopic equipment. Further details are available in the published literature (ICRP 2013a; Miller et al. 2010b; NCRP 2010; Sidhu et al. 2009; Stecker et al. 2009; Wagner et al. 2000).

Some interventional fluoroscopy procedures may expose the patient to so much radiation that they result in patient injury. This typically manifests as skin injury, although it may also involve deeper structures (Balter et al. 2010; Koenig et al. 2001a). While the principle of application of dose limits does not apply to medical imaging, it is still incumbent upon operators to be aware of the amount of radiation being used, and to limit it to the extent possible consistent with achieving the desired clinical result (NCRP 2010). This means that patient radiation dose must be monitored during the procedure, using one or more of the available dose metrics (see "Equipment" above). It is common for the operator to concentrate on the clinical requirements of the interventional procedure and lose awareness of the patient's radiation dose. Designation of another person (a technologist, nurse or another individual) to monitor dose and to inform the operator when certain notification values have been reached can prevent this from occurring. Suggested notification values are available in the literature (NCRP 2010; Stecker et al. 2009). As

patient dose increases, the operator should increase efforts to control radiation use, as long as these efforts do not jeopardize the clinical result or increase procedure risk.

If the patient's radiation dose reaches a Substantial Radiation Dose Level, as defined in the literature (ICRP 2013a; NCRP 2010; Stecker et al. 2009), consideration should be given to consulting another operator or postponing the remainder of the procedure, if clinically appropriate. However, no procedure should be terminated or postponed exclusively because of radiation dose if doing so would jeopardize achieving an essential clinical result.

If there is no overlap of the entrance beam ports on the patient's skin during different procedures that involve substantial doses of ionizing radiation, then each procedure can be considered separately. However, if a procedure is performed in stages, or a portion is postponed because of radiation dose concerns, the time course of tissue recovery from radiation damage should be considered when planning the interval between procedures. Tissue recovery involves both the repair of sublethal damage in the DNA of viable cells and the replacement of killed cells by repopulation. DNA repair is essentially complete within 1 day of exposure, but repopulation can take up to several months (Balter et al. 2010). In addition, the patient's skin should be examined before each subsequent procedure.

Dose estimation

Methods for estimating PSD can be ranked from most reliable to least reliable. Peak skin dose estimation software is the most reliable, followed by estimation of cumulative air kerma, KAP, and, finally, fluoroscopy time combined with a count of the number of radiography frames or images. Dosimeters placed on the skin are useful but can provide underestimates for PSD if placed outside the area of highest skin dose. This area may be quite small (Miller et al. 2003a). PSD and KAP are now the most useful predictors for deterministic and stochastic injury, respectively. Cumulative air kerma is displayed on fluoroscopy units purchased after mid-2006, but it does not correlate well with PSD in individual cases (Miller et al. 2003a; Miller et al. 2003b; Neil et al. 2010; Weinberg et al. 2013). However, in general, it is an acceptable substitute for PSD (Miller et al. 2003a; NCRP 2010). Fluoroscopy time alone does not correlate with PSD (Fletcher et al. 2002). Monitoring fluoroscopy time alone also underestimates the risk of radiation-induced skin effects (O'Dea et al. 1999).

All statements of patient radiation dose contain some degree of uncertainty. For example, as of 2014, cumulative air kerma displays in fluoroscopes have an allowed calibration accuracy of ±35% (FDA 2014e). Even the most sophisticated dose-measurement instrumentation has unavoidable uncertainties related to variations in instrument response with changes in beam energy, dose rate and collimator size. Converting these measurements into skin dose introduces yet further uncertainties related to beam orientation and inconsistencies in the relationship between the patient's skin and the interventional reference point. Finally, clinically available cumulative air kerma and KAP measurements ignore the effect of backscatter from the patient and, when the x-ray source is below the patient, attenuation by the patient table and pad (Jones and Pasciak 2011). Backscatter causes the skin dose to exceed air kerma at the same location by 10% to 40%, depending on the beam area and energy (ICRU 2005). Skin doses estimated from

cumulative air kerma, KAP or fluoroscopy time may differ from actual skin dose by a factor of two or more. Users of dose data should be aware of these uncertainties. Federal facilities should strongly encourage the purchase of equipment with features that enhance the accuracy and clinical value of dosimetry systems.

Recordkeeping

A record should be kept of each fluoroscopic procedure. Whenever possible, this should be performed electronically, with automatic transfer of the necessary data, as appropriate, from the fluoroscopy unit to a PACS, RIS and/or EMR (see above, under *Equipment* and below, under Medical Imaging Informatics). The record should list the individual fluoroscopy unit, the date of the procedure, the procedure (e.g., barium enema, iliac artery angioplasty and stent placement), information identifying the patient, and the name of the physician operating or directing the operation of the device. The record should also list the cumulative air kerma from both fluoroscopy and from image acquisition, if available; the kerma-area product, if available; the cumulative fluoroscopy time and number of images recorded; and other dose metrics as they are developed. This record should be maintained according to the requirements of the responsible authority.

It is strongly recommended that patient radiation dose data be recorded in the patient's medical record, including patient skin dose data and a skin dose map whenever possible. Where and how these data are recorded is subject to the policies and procedures of the individual facility. However, the choice of dose metrics to be recorded should be guided by published recommendations (ACCF/AHA/SCAI 2011; ICRP 2013a; Miller et al. 2012a; NCRP 2010).

When the dose to one or more areas of a patient's skin may have exceeded a threshold dose for deterministic effects, the physician performing the procedure should be advised of this event and should place an appropriate notation in the patient's medical record (ICRP 2013a; NCRP 2010; Stecker et al. 2009). The information should include information on the beam entry sites and the estimated skin dose for each, if available. Provisions should be made for clinical follow-up of those areas for monitoring radiation effects. The possibility of overlap of two separate adjacent fluoroscopic fields, where skin dose of the overlapping area may have exceeded the threshold dose, should be taken into account. Ideally, skin dose from radiation therapy and imaging modalities other than fluoroscopy should also be considered. It is recognized that at the time this report was prepared, no simple method for measuring or estimating skin dose is widely available. As a substitute, cumulative air kerma may be used (NCRP 2010; Weinberg et al. 2013). Threshold values recommended by professional societies or advisory bodies, such as the ACR, SIR, ICRP and NCRP, should be consulted (ACR-AAPM 2013a; ICRP 2000a; Stecker et al. 2009). As of 2014, these threshold values are typically a PSD of 3 Gy or cumulative air kerma of 3–5 Gy (ACR-AAPM 2013a; NCRP 2010).

Patient management

Management of patients who have received radiation doses that may be high enough to cause

deterministic effects should be guided by recommendations from appropriate advisory bodies, medical specialty societies and other organizations, and by current practice (ACR-AAPM 2013a; Balter and Moses 2007; NCRP 2010; Stecker et al. 2009). For these patients, this includes justifying and documenting the high radiation dose in their medical record, notifying the patient or their health care proxy (legally authorized representative) of the radiation dose that has been administered and the likely consequences, and follow-up by the physician who performed the procedure to determine whether a skin injury has occurred (Balter et al. 2010; NCRP 2010).

Device related deaths, including those related to radiation dose, must be reported by the device user facility to the FDA and to the device manufacturer or, if the manufacturer is unknown, to the FDA in accordance with 21 CFR 803.10 (FDA 2014b). Device-related serious injuries, including those resulting from radiation, must be reported by the device user facility to the device manufacturer or, if the manufacturer is unknown, to the FDA. A serious injury is an injury or illness that is life-threatening, results in permanent impairment of a body function or permanent damage to a body structure, or necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure. Permanent means irreversible impairment or damage to a body structure or function, excluding trivial impairment or damage (FDA 2014a).

If a patient's skin receives an absorbed dose that meets The Joint Commission's definition of a reviewable sentinel event from a fluoroscopically guided procedure, or a dose likely to result in a serious injury, the event also should be reported to the Radiation Safety Officer and the facility's Patient Safety Manager or designee (Balter and Miller 2007; The Joint Commission 2006).

Quality process

All QA/QI programs for interventional fluoroscopy should address patient radiation safety. This includes evaluation of operator performance in dose optimization and of procedures where patients received a radiation dose that caused a radiation injury.

A review of radiation doses delivered to patients during fluoroscopically guided interventional procedures is an essential aspect of any performance improvement program. The dose metrics for all procedures should be reviewed at intervals (quarterly, for example) for their magnitude and for the dose distribution of these cases. This will provide a picture of dose utilization; any abnormally high doses can be reviewed for appropriateness. For example, doses can be compared to available DRLs (Miller et al. 2012b; Miller et al. 2009). Any recommendations and actions for improvement should then be implemented.

Analysis of overall dosimetric performance for interventional fluoroscopy procedures, incorporating the effects of equipment function, procedure protocols and operator performance, requires a different process than the DRLs used for radiography (NCRP 2010; NCRP 2012). It also requires a more detailed presentation of the reference data set. Reference data for an interventional fluoroscopy procedure are generated by obtaining data for all instances of that procedure from a number of different facilities (Balter et al. 2011; NCRP 2010). These data are used to generate DRLs. The facility data set includes the data for all instances of the procedure at

each facility. This differs from the data set used to generate DRLs for diagnostic examinations, which typically includes only a single datum from each facility (Balter et al. 2011).

Radiation doses for interventional fluoroscopy procedures usually demonstrate a lognormal distribution. The high dose tail is of particular interest, because this tail represents the cases where doses may be high enough to cause deterministic effects. Because differences between the shapes of the collected reference data from multiple facilities and the local facility data are potentially useful, the FGI-procedure reference data sets should characterize the entire distribution, rather than just the 50th percentile values used for ADs and the 75th percentile values used typically for DRLs. Also, in order to provide a basis for comparison for facilities that use locally derived substantial radiation dose levels (NCRP 2010; Stecker et al. 2009), these data sets should indicate the percentage of instances of each procedure that exceed specific radiation dose levels. Ideally, for cumulative air kerma, these percentages should be presented at 0.5 Gy intervals from 2 Gy to the maximum value observed in the data set (Miller et al. 2012b).

Reference data and DRLs can be used, to some extent, in a fashion similar to DRLs for diagnostic examinations, but the lognormal shape of dose distributions for interventional fluoroscopy procedures mandates that the local median (50th percentile) be used for comparison. Also, high-dose interventional fluoroscopy cases require further evaluation. It is possible for the facility's median dose for a procedure to be within an acceptable range (below the 75th percentile of the reference data) at the same time that there are an excessive number of cases with a radiation dose greater than the 95th percentile of the reference data. It is necessary to compare the percentage of cases at the facility that exceed the local substantial radiation dose level (the radiation dose level that triggers radiation follow-up) with the percentage of cases in the reference data that exceed the same level. Local percentages that are markedly above or below the value obtained from the reference data should be investigated (NCRP 2010).

The following method, using cumulative air kerma as the radiation dose metric, is suggested as one method of evaluating dose utilization for interventional fluoroscopy procedures (NCRP 2010). It is not the only possible method. Kerma-area product could also be used to evaluate general dose performance. Kerma-area product can be used in conjunction with cumulative air kerma to evaluate operator performance with respect to collimation. However, it does not provide an unambiguous identification of the cases where a very high skin dose may result in deterministic effects.

An appropriate published reference data set for the selected procedure (the reference data) is used as the starting point, although published reference data for FGI procedures are sparse as of 2014 (Balter et al. 2008; Bleeser et al. 2008; Brambilla et al. 2004; IAEA 2009; Miller et al. 2012b; Miller et al. 2009; Vano et al. 2008a; Vano et al. 2009).

A facility should judge its dose performance for interventional fluoroscopy procedures in several steps.

1. The first step is to compare the local substantial radiation dose level to the reference data. The facility's local substantial radiation dose level is either a value taken from the literature (ACR-AAPM 2013a; Mahesh 2008; Stecker et al. 2009) or a locally determined

value. The percentage of procedures in the reference data set that exceed this value can now be determined.

2. The next step is to characterize the dose distribution for all instances of a specific procedure performed at the facility. Evaluation of subsets of these data sorted by procedure room and operator can be useful as well, as discussed below. The percentage of instances exceeding the local substantial radiation dose level, and the median value of the entire local data set (and appropriate subsets) is calculated.
3. The local median can be compared with the 10^{th}, 50^{th} (median) and 75^{th} percentiles of the reference data. A median value below the 10^{th} percentile of the reference data may indicate incomplete procedures. A median value between the 50^{th} and 75^{th} percentile of the reference data could be due to clinical differences between the reference data population and the local facility population or other factors. Understanding the relevant reasons may be useful. An investigation is warranted if the local median exceeds the 75^{th} percentile of the reference data (IAEA 2009; NCRP 2010). This step is analogous to the analysis performed using DRLs for radiographic examinations. For facilities where pediatric patients are imaged, this analysis should be performed on patients with similar body part thicknesses.

The percentage of instances exceeding the local substantial radiation dose level can be compared to the percentage of instances exceeding the substantial radiation dose level in the reference data. Local percentages significantly above or below the value obtained from the reference data should be investigated.

It can be useful to perform the same analysis using a cumulative air kerma value of 3 Gy as well as the local substantial radiation dose level. An interventional fluoroscopy procedure is in the potentially-high radiation dose category if more than 5% of instances of that procedure exceed a cumulative air kerma of 3 Gy (NCRP 2010). If fewer than 5% of the instances of the procedure at the local facility exceed this value, then the procedure, as performed at the local facility, is not in that category. At that local facility, the procedure may be performed safely in a fluoroscopy suite that does not meet the requirements of IEC 60601-2-43 (IEC 2010). Also, those procedures at the local facility that are not in the potentially-high radiation dose category may be audited less frequently than those that are in that category.

Lastly, the overall distribution of the local data may be compared to the distribution of the reference data. Displacement or distortion of the local distribution histogram relative to the reference data may be due to differences in equipment, clinical complexity or other factors.

The analysis may be extended to individual operators or interventional fluoroscopy procedure rooms by comparing operator- or room-specific data to either a facility's local distributions or to pooled distributions of data for multiple facilities (Miller et al. 2009). Care should be taken in such an analysis to account for statistical interactions (e.g., statistical confounding between the operator and the interventional fluoroscopy procedure room).

Procedures resulting in a substantial patient radiation dose should be reviewed on a regular basis as part of the institution's formal QA process, but not necessarily on a case-by-case basis. Reported radiation injuries should be reviewed on a case-by-case basis at the regular QA

meeting, with any available diagnoses, planned patient follow-up, and outcomes. If a radiation injury occurred, the procedure should be reviewed for appropriate use of radiation in the clinical context. It may be appropriate to periodically re-report on the status of known radiation injuries. Additionally, reporting of these cases to the institution's Radiation Safety Officer is desirable.

Staff safety

Current regulations and guidelines for occupational radiation protection in fluoroscopy should be followed (Durán et al. 2013; Miller et al. 2010a; OSHA 2014a). Other than the patient who is being examined, only staff and ancillary personnel required for the procedure, or those in training, should be in the room during the fluoroscopic examination. For routine diagnostic fluoroscopic examinations, caregivers (guardians, spouses, parents) necessary for patient well-being may be permitted in the examination room. No body part of any staff or ancillary personnel involved in a fluoroscopic examination should be in the primary beam (Miller et al. 2010b). If primary beam exposure is unavoidable, it should be minimized. As required by various states, all personnel in the room during fluoroscopic procedures should be protected from scatter radiation by either protective aprons or whole-body shields of not less than 0.25 mm of lead-equivalent material. An apron with lead equivalence of at least 0.35 mm is recommended. The thyroid should be protected if the potential exposure to the worker will exceed 25% of the annual regulatory dose limits. It is strongly recommended that protective aprons, thyroid collars and gloves be evaluated at least annually for radiation protection integrity (Miller et al. 2010b; NCRP 2010).

Due to the risk of radiation-induced cataract formation (Ciraj-Bjelac et al. 2010; ICRP 2010; Vano et al. 2013), the staff exposed to radiation during fluoroscopically-guided interventional procedures should be appropriately protected from radiation. When the x-ray beam is activated, they should be behind a ceiling-suspended (or floor-mounted) shield or else should protect their eyes (NCRP 2010). All protective eyewear should have the correct optical prescription, fit properly, and have side shields or be of a wraparound design. In any event, the eyes must be protected to keep the lens dose less than current regulatory limits and should also be protected to keep the lens dose less than the ICRP dose recommendations (ICRP 2011). As appropriate, protective eyewear should also be made available to individuals who perform other non-interventional fluoroscopic procedures.

Pregnant individuals involved in fluoroscopically guided procedures generally do not need to limit their time in the procedure room to remain below the dose limit for the embryo and fetus, as long as they use appropriate protective garments and radiation protection methods, and their occupational exposure is adequately monitored (NCRP 2010). The shielding provided by a single protective apron is sufficient to protect the embryo and fetus for typical exposure to staff involved in interventional procedures (NCRP 2010). A wraparound apron will provide protection from radiation exposure from the side or back of the individual.

COMPUTED TOMOGRAPHY

CT is an imaging modality that utilizes one or more x-ray beams to acquire projection images from many angles around the patient. The projection images are mathematically manipulated to obtain tomographic images that depict x-ray attenuation in a two dimensional cross section or projection, or three dimensional representation of the subject's anatomy.

CT was introduced in the mid-1970s. There have been important technological advances that have greatly increased the clinical usefulness of CT imaging. However, some of these improvements have also led to increased use of CT, imaging of larger volumes of the body, and acquiring an increased number of image sequences either during the various phases of tissue enhancement following contrast injection or to dynamically evaluate areas affected by motion. Modern CT systems are powerful diagnostic tools that are invaluable for patient management and allow the elimination of more dangerous invasive procedures, such as exploratory surgery. But with this great benefit has come a price: there has been an increase in radiation dose to the population, as well as to the individual patient.

In the U.S., the number of CT procedures performed annually increased by 10% to 11% per year from 1993 to 2006 (NCRP 2009), but the growth rate has flattened in the last several years (Levin et al. 2012a; Levin et al. 2012b). Although CT procedures comprise only about 17 % of all medical x-ray imaging procedures, they now impart about 49% of the cumulative effective dose from medical procedures received by the population of the U.S. (Mettler et al. 2008; NCRP 2009). As reported in 2008, a typical single CT imaging procedure of the chest, abdomen or pelvis of an adult imparted an effective dose on the order of 3-7 mSv (McCollough 2008; Mettler et al. 2008). These values are for single-phase examinations and the effective doses for multiple phase examinations are correspondingly larger. As of 2014, advances in technology permit these exams to be performed with substantially lower patient doses, if appropriate protocols are used. Patient dose varies according to the body part examined and institutional protocol. Certain CT examinations impart some of the largest patient doses per procedure in diagnostic medical imaging. Except in the circumstance of improperly-performed examinations resulting in extremely high patient doses, CT studies will not cause deterministic effects such as erythema or epilation (hair loss). Instead, the main concern is stochastic effects, particularly cancer. The risk to the patient is determined mainly by the doses to organs in or near the scanned portion of the patient, the age and gender of the patient, and the likely remaining lifespan of the patient (Linet et al. 2012).

In 2001, it was reported that standard adult technique factors were commonly used for CT imaging of patients in the U.S. regardless of body habitus, including children and even infants (Brenner et al. 2001; Paterson et al. 2001). If adult technique factors are used for imaging the abdomen or thorax of a small child or infant, the larger doses (up to 3 times greater than an adult dose) (Strauss et al. 2009), together with the larger risk of cancer per unit dose is estimated to pose a risk of fatal cancer on the order of one per thousand examinations (Brenner et al. 2001). Therefore, it is essential to optimize dose when imaging children (FDA 2001). Of the many methods for adjusting CT techniques for children, perhaps the simplest and most widely used techniques utilizes the Broselow method familiar to clinical providers as a way to estimate weight, drug dosing and equipment sizing for children. Many sites have developed specific CT

protocols that adjust the kVp and mAs based on the approximate size of a child matching each Broselow color scheme category. Professional societies provide excellent guidance on imaging, such as the "Image Gently" campaign (Goske et al. 2008; Strauss et al. 2010).

Many advances in CT technique and technology have specifically targeted reduction of the radiation dose delivered to the patient during CT examinations. To be effective, these techniques must be used, and used properly. It is imperative that Radiological Medical Practitioners, physicists and technologists involved in CT imaging keep abreast of current developments and utilize all techniques available to them to reduce the patient's radiation exposure as much as possible while obtaining the clinically needed information.

Equipment

Technological developments in image reconstruction, increases in computer processor power, equipment innovation (e.g., automated tube current modulation), and optimization techniques now make it possible to obtain diagnostic quality images at markedly lower patient doses than was possible with previous CT scanners (Haaga et al. 1981; Jakobs et al. 2002; Kalender et al. 1999a; Kalender et al. 1999b; Kalra et al. 2004; McCollough et al. 2006; Yu et al. 2011; Yu et al. 2010). These improvements should be implemented to the fullest extent practicable.

Several phantom-derived dose indices specific to CT have been defined; these are described in the literature (McNitt-Gray 2002). Two indices in common use are the volumetric computed tomography dose index ($CTDI_{vol}$), which is approximately the average dose in the scanned volume of a standard phantom, and the dose-length product (DLP), defined as the $CTDI_{vol}$ multiplied by the scanned length. These indices indicate the radiation exposure delivered by the CT scanner to a phantom, not the specific radiation energy (i.e., dose) received by any patient (AAPM 2011b). Both of these measures may be available from current CT scanners, and future devices may incorporate more accurate and useful dose metrics. The DLP and the portion of the patient that is scanned (e.g., head, thorax, or abdomen) may be used to estimate the effective dose to a patient whose body size and attenuation are similar to that of the standard phantom (ICRP 2000b). Effective dose is an indicator of stochastic risk. A method has been developed to calculate size-specific dose estimates (SSDE) that adjusts the $CTDI_{vol}$ for the body size of the patient being scanned (AAPM 2011b). Organ-based doses can be estimated by a medical physicist using manual techniques or via electronic information systems (ICRP 2007a). Appropriate CT dose indices should be recorded as part of the patient record in the imaging report or medical record and for QA purposes.

The dose of radiation to a patient, in conjunction with the attenuation provided by the part of the patient that is scanned and the presence or absence of radiographic contrast material, determines the signal-to-noise ratio in the resultant images. The signal-to-noise ratio needed for diagnostic confidence depends upon the diagnostic task. Smaller and thinner patients require smaller doses than larger and thicker patients to produce similar signal-to-noise ratios in the images. However, CT examinations of infants and small children may require larger signal to noise ratios than are required for larger patients (Kalra et al. 2004; McCollough et al. 2006; Wilting et al. 2001). Imaging procedures to detect or assess larger structures and structures with more inherent or

enhanced contrast (difference in density and/or atomic number) can be performed with smaller doses than imaging procedures to detect or assess smaller structures and those with less inherent contrast.

Stand-alone CT scanners have been complemented by the development of hybrid modalities such as positron emission tomography/CT [PET/CT] and single photon emission computed tomography/CT [SPECT/CT]. These hybrid modalities use two equipment components to acquire two types of images of a patient in the same setting, without changing the patient's position on the imaging system table. This allows co-registration of image data so that the anatomic detail provided by CT can be matched to the physiologic imaging information from the other modality to provide more specific information about the location and extent of disease. Also, x-ray CT image sets can be used for attenuation correction of the PET and SPECT images. These CT devices may be operated at much lower doses if the CT portions of the exams are not intended to be used for diagnosis independent of the SPECT or PET exam.

Facilities should use equipment that provides relevant patient dose information. Facilities should implement suitable Notification Values and Alert Values on CT scanners that comply with the National Electrical Manufacturers Association (NEMA) Computed Tomography Dose Check standard (NEMA 2010). CT scanners in compliance with this standard (essentially all new CT scanners sold after 2012) can be configured to inform users when scan settings would likely yield values of $CTDI_{vol}$ or DLP that would exceed pre-assigned values. Compliant scanners allow users, before proceeding with scanning, to confirm or correct settings that might otherwise lead to unnecessarily high exposures (AAPM 2011a). Facilities may use the Dose Check features to avoid excessively high patient exposures by identifying dose indices that are much higher than typical for a given examination type, thereby providing an opportunity for the operator to confirm or change settings before proceeding (AAPM 2011a). It is the facility's role to determine appropriate numerical values for Notification and Alert Values. Recommendations for numerical values of Notification and Alert Values are available (AAPM 2011a). Since different facilities use different models of CT scanners from different manufacturers, scan protocols differ and average patient body habitus may differ, the advice of the Michigan Department of Licensing and Regulatory Affairs is relevant: "Determination of what the expected values should be for each protocol is left to the experience, knowledge, and professional judgment of both the interpreting physician and medical physicist" (Michigan 2012).

Quality Assurance

Equipment testing for quality assurance should be performed after installation but before first clinical use, annually thereafter, and after each repair or modification that may affect patient dose or image quality. Testing should be performed as specified in the section of this document entitled Technical Quality Assurance in Medical Imaging with X-Rays (AAPM 1993; AAPM 2008; EC 2012). In addition, the recommendations found in the current version of ICRP Publication 102 (NCRP 1989b) should be followed when applicable.

A quality control program should be established. The program should substantially conform to the ACR Computed Tomography Quality Control Manual (ACR 2012b) and Technical Standard

for the Diagnostic Medical Physics Performance Monitoring of Computed Tomography (CT) Equipment(ACR-AAPM 2012) or equivalent guidance.

The quality assurance program should include the monitoring of CT dose metrics from individual examinations. The purposes of this monitoring include the detection of errors, both in the performance of individual examinations and in body part- and clinical indication-specific CT imaging protocols, and to provide dose information to guide the optimization of such protocols. Ideally, the collection, archiving, analysis and reporting of dose data should be automated. DICOM and IHE provide standards for the sharing and collection of dose information; these are briefly discussed in the section entitled Medical Imaging Informatics. As of 2014, both commercial and shareware software is available for this purpose (Cook et al. 2011; Sodickson et al. 2012). In the absence of such dose monitoring software, dose data should be collected manually. However, due to the large number of examinations performed daily by each CT scanner, it may not be feasible to manually record the dose information from all examinations. As a minimum, CT dose data should be collected and reviewed for every imaging protocol, after the installation of a new CT scanner, after each modification to a protocol, and periodically, perhaps annually or every two years.

The quality assurance program should also include the monitoring of CT examinations that must be repeated, including those repeated because of patient motion, and examinations that are interpretable, but of inadequate quality.

Personnel

CT systems should only be operated by Radiologic Technologists registered by the ARRT or equivalent, preferably with advanced certification in CT, operating under the supervision of Radiological Medical Practitioners with appropriate training in CT physics, radiation safety and CT image interpretation.

Ideally, a PET/CT or SPECT/CT should be operated by a technologist certified in both nuclear medicine and CT. However, a PET/CT or SPECT/CT may also be operated by a nuclear medicine technologist with Certified Nuclear Medicine Technologist (CNMT) or Radiological Technologist Nuclear qualified (RT(N)) certification and additional training in CT imaging sufficient to safely operate a CT system. Alternatively, a PET/CT may be operated by a technologist who is qualified to operate a CT system and who also has additional training in PET imaging sufficient to safely operate a PET system. If a technologist who meets these requirements is not available, the PET/CT or SPECT/CT system should be operated by two technologists, one a nuclear medicine technologist qualified to operate the PET or SPECT system and the other a radiological technologist or a radiation therapist qualified to operate the CT system and registered by the ARRT or equivalent, preferably with advanced certification in CT. Utilization and training requirements for the operation of other hybrid modalities should be evaluated as new combinations of modalities emerge.

Procedures

Other than the patient who is being examined, only staff and ancillary personnel required for the procedure, those in training, and caregivers (guardians, spouses, parents) necessary for patient well-being should be in the room during the CT examination. All personnel in the room during CT procedures should be protected from scatter radiation by either protective aprons or whole-body shields of not less than 0.25 mm lead equivalence.

One of the most effective ways to optimize the dose of radiation delivered to the patient in a CT study is to tailor the study to the patient's specific needs. It is important to image only the area of anatomy in question and acquire only the necessary sequences. This is accomplished by determining the imaging protocol for the examination. Where appropriate, the Radiological Medical Practitioner should select and adjust the protocol to ensure that the patient is examined using the appropriate techniques and dose.

A CT protocol specifies the parameters for the image acquisition and largely determines the dose to the patient. It defines the portion of the patient's anatomy to be imaged, whether and how contrast agents will be administered, the number and timing of imaging sequences, and acquisition technical parameters. Imaging sequences in a multiphase study may include several phases, such as a pre-contrast phase, an arterial phase, a venous phase and/or a delayed phase. Acquisition technical parameters may include pitch (incremental table movement per x-ray tube rotation divided by the nominal x-ray beam width at isocenter), collimation (beam width), kV, mA (constant or modulated), index of image quality (when mA is modulated), rotation time, physiologic gating, image quality factors, and reconstruction method. Considerations when constructing or modifying a protocol include:

1. Eliminate unnecessary imaging sequences in a multiphase study.
2. In some cases, the kV may be adjusted to accommodate patient size or the type of examination (e.g., contrast-medium-enhanced angiography) (Hough et al. 2012; McCollough 2005; Yu et al. 2011; Yu et al. 2010). If the patient is very large, a high kV (e.g., 140 kV) may be needed to adequately penetrate the patient. For iodine-enhanced scans, one can lower radiation dose in smaller patients while achieving the same or similar contrast-to-noise ratio (CNR). One also can increase iodine CNR with lower kV and improve image quality using the same dose as at a higher kV, as long as the patient is relatively small and/or the scanner can compensate for the lower kV with higher mA. A lower kV also may permit reducing the iodine volume delivered to patients when renal function is an issue.
3. Automatic tube current modulation should be used whenever technically feasible and clinically appropriate. If automatic tube current modulation is used, the protocol should specify the parameters that determine the balance between image noise and patient dose. If constant mA is used, the protocol should utilize a chart for adjusting the mA for the patient's size (girth or thickness).
4. Methods should be considered to protect organs. Organ-specific tube current modulation, where available, technically feasible and clinically appropriate, should be considered to protect organs, such as the breast in younger female patients and the lens of the eye.

5. Where applicable, the image acquisition technique factors should take into account the availability of advanced image reconstruction techniques to decrease the required patient dose.
6. Appropriate techniques and available technology should be used in all contrast-medium-enhanced studies to ensure appropriate timing of image acquisition relative to the enhancement of the tissues of interest to avoid failed examinations and the resulting repeat imaging. Protocols should be designed to minimize radiation dose delivered during the bolus tracking component of the examination.
7. Low dose protocols should be established for certain follow-up and screening examinations (e.g., renal stone screening, lung nodule follow-up). For gated cardiac CT imaging, utilize (when available) the feature that reduces or terminates the beam current during portions of the cardiac cycle that will not be used for image reconstruction (ICRP 2013a).
8. Once the image sequence is acquired, the user can select alternative reconstruction parameters (e.g., reconstructed slice thickness) to view the images differently without having to rescan the patient. This also may permit diagnostic information to be extracted from a poor quality examination, thereby avoiding the need for repeating the examination.
9. Each protocol should carefully define the anatomic limits for each sequence. For multisequence protocols, it is not always necessary for each sequence (e.g., non-contrast, post-contrast) to have the same anatomic limits.

Optimization of CT protocols is important for minimizing patient dose. The facility's standard protocols for CT imaging should be reviewed by a radiation protocol workgroup or committee (Texas 2013) that includes a physician expert in CT, a technologist expert in CT, and a QMP:

1. when the protocol is developed,
2. when the protocol is significantly modified,
3. on a regular basis (preferably annually), and
4. after an equipment upgrade or replacement.

The appropriate physician expert may vary depending on the organ system or anatomic region being examined; for example, a neuroradiologist is likely the appropriate physician expert for examinations of the central nervous system.

It is strongly recommended that procedures be established to avoid inadvertent or unapproved modification of CT protocols. Methods, such as limiting access through the use of passwords, should be adopted to implement these procedures. Superseded protocols should be archived for future reference (NEMA 2012).

Reviews and revisions should align protocols with current clinical practice, evaluate the magnitude of delivered radiation doses, and optimize the radiation dose. Modifications of the protocol to suit the needs of an individual patient generally do not require a specific review, but the impact on radiation dose should be understood and considered.

Each CT protocol should be documented in two ways. The first way is a document detailing all relevant information. The second way provides a more limited subset of programmable information, primarily acquisition parameters, stored on the imaging device.

The technologist performing the study is responsible for properly positioning the patient within the scanner and limiting the length of the portion of the patient being scanned to the minimum clinically necessary. The technologist is also responsible for setting up the CT system so that the correct protocol is used and the imaging parameters are appropriate for the patient's size, age and intended examination. Before performing the study, but after acquiring the localizer radiograph, the technologist should confirm that the technical parameters and the radiation dose metrics are appropriate for the patient and planned study. To prevent accidental overexposure, the projected dose should correspond to the doses normally associated with the protocol, within reasonable variability based on patient size and similar factors. This should be confirmed again after the patient has been scanned.

Operator selectable parameters on CT scanners that affect the dose to the patient include the voltage applied to the x-ray tube (kV), the x-ray tube current (mA) or current-time product per x-ray tube rotation (mAs), and the pitch. The radiation dose to the patient within the scanned volume is approximately proportional to the square of the kV and is proportional to the effective mAs (the mAs divided by the pitch). Technique factors should be appropriate for the size (and not just the age) of the patient and the body part being imaged. In particular, adult technique factors should not be used for children and infants. Technique factors should be chosen that produce a diagnostically adequate image rather than a "perfect image," thus matching the radiation exposure to the diagnostic requirement. If available on the CT scanner, automated modulation of the tube current should be used for those procedures for which it produces substantial dose savings, e.g., scans of the thorax. Using this feature appropriately can reduce dose significantly, whereas errors in its use have produced substantial increases in dose.

BONE DENSITOMETRY

Bone densitometry noninvasively measures certain physical characteristics of bone that reflect bone strength. These characteristics are, typically reported as bone mineral content or bone mineral density. Bone densitometry is used for diagnosing osteoporosis, estimating fracture risk and monitoring changes in bone mineral content or density, whether from age, conditions causing bone mineral loss, or treatment (Hamdy and Lewiecki 2013; ICRP 2013b). Devices that measure bone mineral content are called *bone densitometers*. Non-invasive methods for measuring bone mineral content are based on the transmission of x-rays or gamma rays through the bone. The radiation beams can be produced as pencil or fan beams. The advantage of the latter is that it is faster, but the radiation dose is increased by a factor of about 4.

There are also devices that use the transmission of sound waves through bone to assess bone structure. These are ultrasound devices that do not directly measure bone mineral density, but are also commonly called densitometers.

Equipment

The principal methods in routine clinical use in 2014 for the non-invasive measurement of bone mineral content using ionizing radiation are x-ray absorptiometry and quantitative x-ray computed tomography (QCT). X-ray absorptiometers measure attenuation of two x-ray beams of well-separated average photon energies to discriminate between bone mineral and soft tissue. This method is called dual-energy x-ray absorptiometry (DXA, formerly DEXA). DXA is considered the standard of reference to diagnose osteoporosis in the absence of fragility fractures (which are diagnostic of osteoporosis after localized causes of bone demineralization have been excluded).

In 2014, DXA is the most widely used method to measure bone density and diagnose osteoporosis (Blake et al. 2013). The World Health Organization developed criteria to categorize the patient's bone mineral density into osteoporosis, osteopenia or normal categories (Kanis and Gluer 2000; Kanis et al. 1994; NOF 2013). This classification is specific for DXA (total hip or femoral neck, PA lumbar vertebrae, or distal one-third of the radius) and cannot be applied to any other technology (ISCD 2007a; ISCD 2007b). As of 2014, DXA is also the most commonly used technology for monitoring changes in bone mineral density (BMD).

Bone mineral density can be assessed non-invasively at several sites in the axial and appendicular skeleton. DXA is most commonly used to assess the lumbar spine, proximal femur, distal radius and calcaneus (Kanis and Gluer 2000; Kanis et al. 1994). DXA measurements of the thoracic spine cannot be performed because the ribs and sternum overlap the thoracic vertebrae. Measurements of the proximal femurs are commonly referred to as "hip" measurements, but the bone mineral content measurements are limited to the proximal femurs and do not include the hip joint. The standard evaluation of bone mineral density includes evaluation of at least one proximal femur and the lumbar spine in the frontal plane. A site that is one third of the radius length from the wrist (termed the distal one-third radius or 33% radius site) should be measured

if the hip and/or spine cannot be measured or interpreted, if the patient has hyperparathyroidism or if the patient's weight exceeds the table's weight limit.

Some DXA devices permit the acquisition of projection images of the thoracic and lumbar lateral spine for vertebral morphometry to detect vertebral compression fractures. This is called vertebral fracture assessment (VFA). Detection of atraumatic or low-trauma vertebral compression fractures is an independent method for diagnosing osteoporosis. This is performed with imaging of the thoracic and lumbar spine in the lateral plane. Exposure to radiation is higher with VFA than with DXA, but still considerably lower than for conventional radiography of the same area (Ferrar et al. 2005; Genant et al. 1996; Link et al. 2005).

Some DXA devices allow the C-arm holding the x-ray tube and detector to rotate to a position permitting lateral bone mineral density measurements of the lumbar spine in the supine patient, in addition to the usual measurements. Furthermore, some DXA devices permit scans of the entire body for body composition analysis, providing an estimation of total bone mineral mass, lean body mass and fat mass.

QCT measurements are usually performed of the lumbar spine, but there are options to perform measurements at other anatomical sites as well. Unlike DXA, QCT is able to differentiate mineral content in the bone as opposed to mineral content outside bones, such as in osteophytes or aortic calcifications. The presence of these extra-osseous calcifications makes DXA of the vertebrae less reliable in older people. QCT, on the other hand, is able to focus on the trabecular or cortical component of bone. QCT may be performed with a standard CT system, however, a special phantom and software are needed. Quantitative ultrasound (QUS) is used to measure sites in the appendicular skeleton, most commonly the calcaneus, but cannot be used to monitor the skeletal effects of treatment for osteoporosis.

Quality Assurance

Each facility performing bone densitometry should have a quality assurance program designed in consultation with a QMP. The procedures for this program should be documented in writing. The program should conform to manufacturer's recommendations and recommendations of professional societies such as ISCD and the ACR. An annual review should be conducted, preferably by a QMP, to ensure the elements of the QA program are being implemented.

The quality assurance program should include testing of each DXA unit on each day of use and periodic assessments of precision. A cross calibration should be performed whenever the densitometer is replaced, modified or repaired such that performance might be affected. These practices help ensure proper measurement of bone mineral content, detection of osteoporosis, estimation of fracture risk, and detection of changes of bone mineral content over time, regardless of equipment changes.

Accuracy check

Accuracy is the degree to which a measurement value estimates the actual value of the quantity being measured. QC assessments, performed using a manufacturer-supplied phantom, determine whether the equipment consistently produces measurements that are within acceptable limits of a calibration standard. This test should be successfully completed each day of use prior to human testing.

Precision

Precision is the degree to which the same value is obtained when a measurement is repeated (ACR-SPR-SSR 2013; Bonnick and Lewis 2006; CRCPD 2006; ISCD 2012). The better the precision, the smaller the Least Significant Change (LSC) (i.e., the smaller the change in BMD that can be detected.)

Precision assessments evaluate the technologist's skills at positioning the patient reproducibly. Patient factors that affect positioning, and thus precision, are obesity, arthropathies, pain, deformities, fractures, and other conditions that limit patient mobility. Assessments using phantoms cannot be used to determine precision. Given these clinical variables and the lack of appropriate phantoms, precision assessments should be conducted on patients who are representative of the bulk of the population scanned at the particular facility. For instance, if most patients scanned in a facility are over the age of 65 years, precision assessments should not be done in that facility on young athletes.

Precision assessments are performed by using repeated measurements, with repositioning of the patients after getting them off the table between measurements. These can be done on either 30 patients scanned twice (after the patient is repositioned in between scans) or 15 patients scanned 3 times, also after repositioning in between each scan (Schousboe et al. 2013). The technologist's or facility's precision is then used to calculate the Least Significant Change (LSC) to determine whether an observed change in BMD over a period of time is significant (greater than the LSC) or not (less than the LSC).

Each facility should establish limits of acceptable precision performance for each anatomical site routinely measured and ensure that each technologist meets these standards. However, precision values should not exceed the limits established by professional organizations (ISCD 2013). If a facility has more than one technologist, an average precision error combining data from all technologists should be used to establish precision error and LSC for the facility.

Each technologist should complete a precision assessment after basic scanning skills have been learned and at least every 2 years. A repeat precision assessment should be done if a new DXA system is installed or if a technologist's skill level has changed. Retraining should occur if a technologist's precision is worse than values recommended by professional societies, e.g., ACR and ISCD.

Cross-calibration

Cross-calibration is a method to derive equivalent BMD values when measured on the original densitometer and a modified or new densitometer. Cross-calibration should be performed when repairing, modifying or replacing the entire system or any portion of the system that might alter the absolute BMD value. The measurements obtained from old and new densitometers should be compared for a limited number of patients to develop a cross-calibration formula for converting data obtained using the old densitometer to values obtained with the new densitometer. As with precision assessments, phantoms are not appropriate for cross calibration. Cross-calibration is conducted in-vivo by scanning at least 30 patients with a wide range of bone densities (normal to osteoporosis) on both the old and new densitometer.

Justification for quality assurance assessments involving patients

Precision and cross-calibration assessments are tools to maintain and improve the quality of DXA results and hence patient care. Precision assessments on patients cannot be substituted by scanning phantoms. Poor precision may change the densitometric diagnosis of osteoporosis. This may have serious implications as patients may end up being treated unnecessarily or alternatively may be denied treatment when treatment may reduce the risk of fractures. Similarly, without knowing the precision at a facility, it is not possible to draw any meaningful conclusion as to whether an observed change is clinically relevant. With bone densitometry, the ability of the technologist to reposition patients in exactly the same position is of such paramount importance that ISCD (the only organization to accredit facilities, technologists, and clinicians for performing and interpreting scans) takes into consideration the facility's precision before accrediting it. Precision assessments are endorsed by ISCD and should be standard clinical practice (ISCD 2013). CRCPD affirms that the BMD assessment is of no value without precision testing (CRCPD 2006).

Patients enrolled in quality assurance assessments benefit indirectly and may also benefit directly because the results are more reliable and allow for a better comparison to be made with future scans done on the same or different equipment. It is in a patient's best interest to be scanned at a facility where precision and LSC have been determined, as the results are more reliable and comparisons with other scans are more meaningful. Although each scan results in a low effective dose to the individual patient, radiation doses to the individual patient can be reduced further by scanning a larger number of patients a fewer number of times each and by not including a patient in both precision and cross-calibration assessments. It is recommended to obtain consent from patients who participate in precision or cross-calibration assessments (Baim et al. 2005; CRCPD 2006; ISCD 2014). Patients or staff should not be scanned solely for the purpose of training.

Cross-calibration should be performed when changing the entire system or any portion of the system that might alter the absolute BMD value.

Patient radiation dose should be determined by a QMP after installation, after service that may affect the radiation dose, and at least annually thereafter.

In most cases, structural shielding will not be required for DXA devices or for QCT devices designed for use only on the appendicular skeleton. Nonetheless, the RSO or a QMP should make a determination of whether shielding is needed. After device installation, whether or not additional shielding is installed, dose measurements should be made in adjacent areas and at the operator's station (which may be inside the room) and should be documented in a written report. This will help determine the need for occupational dosimetry and provide a historical record to ensure proper equipment functioning.

Personnel

Each person performing bone densitometry should meet the requirements of their agency, receive training in the use of the densitometer they are going to operate (since knowing how to operate one densitometer does not qualify for operating another type as different protocols are used by different manufacturers) and, ideally, meet at least one of the following qualifications:

1. ARRT post-primary certification in Bone Densitometry.
2. Certification by the International Society for Clinical Densitometry as a Certified Bone Densitometry Technologist.
3. State license or limited license in Bone Mineral Densitometry, when the license requires successful completion of the ARRT Limited Scope Bone Densitometry Examination.

As an alternative, the individual could have formal training in bone densitometry with one of the following:

1. Certification by ARRT in Radiography or Nuclear Medicine Technology.
2. Certification by the Nuclear Medicine Technology Certification Board.
3. Qualification as a Medical Radiologic Technologist (MRT).

However, it is always recommended that this individual obtain formal certification in bone mineral densitometry.

Individuals who perform absorptiometry also should have documented training in the use of the absorptiometry equipment they are operating, including performance of manufacturer-specified and facility QA procedures. The facility should evaluate the competence of each technologist, particularly their performance in precision assessments and in maintaining an appropriately low repeat rate.

Interpretation of the results is important. A report should be generated by a Radiological Medical Practitioner who is knowledgeable in bone densitometry and preferably is a Certified Clinical Densitometrist (CCD). Reliance on the report generated by the equipment alone is inadequate. The individual generating the report should examine the raw and generated data and the images.

Procedures

Facilities that use bone densitometry should refer to current versions of procedures or position statements issued by professional organizations (ISCD 2007a; ISCD 2007b; ISCD 2010; ISCD 2013). The following guidance applies to DXA scans.

Before the DXA scan, the technologist should:

1. Ensure that the various quality assurance parameters have been fulfilled.
2. Verify that there are no contraindications to the DXA scan. A pregnant patient or patient likely to be pregnant should not have a DXA scan. A central DXA scan should not be performed on a patient whose weight exceeds the weight limit of the densitometer as the results may not be accurate and the densitometer table may be damaged. A scan of the non-dominant distal forearm is recommended in these cases.
3. Verify that there are no conditions or objects that might adversely affect the results. In particular, a patient who has a prosthetic hip or orthopedic device in the lumbar vertebrae should not have this part of the body scanned to evaluate osteoporosis. It is also recommended not to scan a patient who has taken calcium supplements the day of the scan as the calcium tablet may be in the path of the x-rays and artificially elevate the mineral content of the area scanned. Similarly, a patient who has undergone radiological contrast studies on the abdomen should not be scanned until the contrast material is no longer in the patient's body. A patient should not have metallic objects on the parts scanned, including navel rings, which interfere with the absorption of radiation. Other common artifacts include zippers, buttons and wallets.
4. Enter and verify the accuracy of all the relevant patient demographic information, such as the age, race, gender, weight and height. Any erroneous information will invalidate the subsequent calculation of the T- and Z-scores and hence the validity of the scan.
5. Position the patient according to the criteria set by the manufacturer. If it is not possible to position the patient as per the recommendations because the patient is unable to be placed in that position because of pain or limitation of movement, the technologist should make a note to that effect.
6. Note the scan mode (e.g., fan beam or pencil beam), the type of leg block used, and any deviation from the routine protocol.

During the DXA scan:

1. The patient must refrain from moving.
2. The technologist should:
    a. Ascertain that the patient's positioning is adequate (if the patient positioning is not as per the accepted recommendations, the subsequent analysis of the scan will not be valid).
    b. Ascertain that there are no artifacts.
    c. Ascertain that all the regions of interest are clearly visualized.
    d. Stop the DXA scan and restart it if positioning is not adequate, if there are artifacts or if the regions of interest are not clearly visualized.

Analysis of the DXA scan:

1. Before the analysis, the technologist should ascertain that:

a. The patient's demographics are correctly noted.
b. The patient's positioning was adequate.
c. There are no artifacts.
d. The various regions of interest are clearly visualized.

2. During the analysis, the technologist should follow the manufacturer's recommended procedure to identify the various regions of interest.

After the analysis, the technologist archives the information and forwards the results to the Radiological Medical Practitioner.

Reporting the DXA scan results:
The Radiological Medical Practitioner writes the final report, archives it and sends it to the Referring Medical Practitioner. Reports automatically generated by the equipment should be modified to meet the needs of the Referring Medical Practitioner. Other information also may be added, such as risk factors for osteoporosis and fracture risk assessment FRAX scores for hips and other major fracture sites. FRAX is the World Health Organization's (WHO's) Fracture Assessment Tool, a computer program used to estimate the probability of the patient sustaining a hip or other major osteoporotic fracture in the following ten years (WHO 2004; WHO 2012). Reporting templates are available from densitometer manufacturers. Reports may also include information about recommended diagnostic tests and treatment options (ISCD 2013). It is important, however, to tailor the reports to the needs of the referring physicians. Structured reports should be used if electronic records are maintained by the facility.

DENTAL IMAGING

Diagnostic imaging is an integral part of dentistry. Dental radiography is estimated to contribute much less than one percent of the total population's effective dose. The effective dose to the U.S. population in 2006 from dental diagnostic radiographic procedures was estimated as 0.006 mSv per capita (NCRP 2009). The dental health-care worker's goal is to keep radiation exposures to the minimum necessary to meet diagnostic requirements. In 2003, the NCRP updated its recommendations on radiation protection in dentistry (NCRP 2003). The American Dental Association (ADA), in conjunction with the FDA, updated its selection criteria for dental imaging, guidelines for the frequency of dental radiographs and radiation exposure recommendations in 2012 (ADA-FDA 2012). Both of these sets of recommendations were considered when developing the following guidelines.

EQUIPMENT

It is strongly recommended that intraoral and panoramic dental x-ray machines be operated in the 60-90 kVp range. For the same dose to the image receptor, increasing the x-ray tube voltage (potential difference) reduces the doses to superficial tissues. However, it also decreases image contrast, increases scattered radiation and, in the case of intraoral radiography, deposits more energy in tissues beyond the image sensor. The operating voltage of dental x-ray machines should not be less than 60 kV (EC 2004; NCRP 2003). For intraoral radiography, European Commission guidance recommends that 65 to 70 kV be used with conventional AC generators and 60 kV be used with high frequency inverter generators (EC 2004). Higher x-ray tube voltages may be used for extra-oral imaging, such as cephalometric, panoramic and cone beam CT imaging, to reduce dose, provided that mA or mAs is reduced appropriately.

X-ray beam filtration must be consistent with FDA requirements ((FDA 2014d) Table 1). Also, the beam indicating device (BID) for intraoral dental radiography should maintain a source-to-skin distance between 20 cm (8 in) and 40 cm (16 in) (NCRP 2003). Increasing BID length reduces both beam divergence and volume of patient tissue that is irradiated per exposure. A means should be provided to limit the field size to the size of the opening at the BID exit port. It is recommended that rectangular collimation be used for intra-oral techniques. It further restricts the beam to approximately the size of the film or digital imaging receptor being used, and reduces the exposed area by approximately half compared with round collimation (Gibbs 2000; NCRP 2003). This improves image quality by reducing scattered radiation, resulting in a radiograph with less noise and better contrast. However, the need for better positioning due to restricted field size and the need for training and practice may preclude using a 40 cm BID. In clinical practice, a 20 cm round BID is acceptable, while a longer BID (e.g., 30 cm) is preferable.

The dental health professional (dentist or dental hygienist) has a variety of image receptors to select from. These include conventional film and digital technologies (photostimulable imaging plates and digital imaging sensors). Studies have shown that digital image receptors can produce clinically-acceptable intraoral radiographs with radiation doses significantly less than those when using even F-speed film (Alcaraz et al. 2009; Berkhout et al. 2004). However, these dose reductions may not be achieved unless the radiographic technique factors are adjusted so as to

optimize the dose to the patient (UKHPA 2013). Moreover, the number of retakes (commonly due to poor positioning of the bulky sensors with their encumbering wires) may result in increased dose for the patient unless care is given to proper training and the use of image receptor positioning devices. Furthermore, due to the smaller active area of some sensors, more than one exposure may be required to cover the anatomical area imaged using a single conventional film. Therefore, it is recommended that an image receptor positioning device be used with digital imaging sensors and that specific and ongoing training be given to operators on ways to eliminate the need for retakes.

Where film is still used, the fastest appropriate film should be used. Since there are minimal diagnostic differences between the various intraoral films available in 2014, the use of faster films (E- or F-speed) is preferred because they reduce the radiation dose by up to 50% when compared with D-speed film (NCRP 2003). For periapical and bite-wing radiographs, only films of American National Standard Institute (ANSI) Speed Group "F" or faster are recommended.

For panoramic and other extraoral radiography, high-speed films should be matched to their rare earth intensifying screens. The higher speeds of the rare earth screen-film combinations (400 or higher system speed) are at least twice as fast as the now-obsolete calcium tungstate screen-film combinations with equivalent diagnostic value. Their use reduced patient dose by 50% to 75% (Miles et al. 1989). When selecting lateral cephalometrics or other extraoral studies, the x-ray beam should be collimated to the area of clinical interest.

The operator's manual for all imaging equipment should be readily available to the user, and the equipment should be operated and maintained following the manufacturer's instructions, including any appropriate adjustments for optimizing dose and image quality.

Radiation protective aprons were recommended for protection of the dental patient when dental x-ray equipment was poorly collimated and unfiltered, and films were much slower than those available in 2014. Given the advent of good collimation, filtration, direct current x-ray machines, faster film speeds, and digital sensors, gonadal and effective doses resulting from scattered radiation are extremely low and are not significantly reduced by the use of the aprons. Technological advancements have eliminated the requirement for radiation protective aprons on adult patients undergoing intraoral imaging when all of the following recommendations are followed: a 60-80 kVp operating voltage is used, the source-to-image receptor distance is between 20 and 40 cm, a rectangular collimator is used, and a minimum of E-speed equivalent exposure film or a digital sensor is used. If all four of these criteria are not met for the intraoral dental imaging procedure, then a radiation protective apron is still needed. Even if all 4 criteria are met, it is reasonable to have aprons available for patients who request them (NCRP 2003).

The thyroid gland is among the most radiation sensitive organs in children. NCRP Report No. 145 states, "thyroid shielding shall be provided for children, and should be provided for adults, when it will not interfere with the examination" (NCRP 2003). In cases where anatomy or the inability of the patient to cooperate makes beam-receptor alignment awkward, this recommendation may be relaxed. However, the thyroid is still exposed to scattered radiation during panoramic imaging. (Note that the positive projection-angle of the panoramic x-ray beam

of +4º to +7 º essentially eliminates the thyroid from the primary x-ray beam during panoramic imaging.)

Radiation protective aprons and thyroid shields should be hung or laid flat and never folded, and manufacturer's instructions should be followed. All radiation protective apparel should be evaluated for damage (e.g., tears, folds, and cracks) at least annually using visual and manual inspection (Miller et al. 2010b). If a defect in the attenuating material is suspected, radiographic or fluoroscopic inspection may be performed to confirm any defect before removing the item from service.

Hand-Held Units

Hand-held, battery-powered x-ray devices are available for intra-oral radiographic imaging. Some of these devices, sold online by manufacturers outside the U.S. and directly shipped to customers in the U.S., have not been reviewed by FDA and are not being sold legally. Some of these devices may emit hazardous amounts of leakage radiation. They may be advertised as "approved by the FDA," but FDA has not reviewed these devices. Only hand-held, battery-powered x-ray devices cleared or approved by FDA for sale in the U.S. may be legally marketed in the U.S. FDA's website provides information on how users can assess whether FDA has cleared or approved a hand-held, battery-powered x-ray device (FDA 2014i). Radiation safety precautions for hand-held devices should be emphasized, because there is a greater opportunity for radiation exposure compared to conventional radiographic units.

Each hand-held x-ray system should be used as outlined in the instructions that come with that unit. Aside from use in emergency situations, these devices should not be used in areas where there may be unintended exposure of other individuals (e.g., occupied waiting rooms and corridors). Exposures should be made only when the area adjacent to the clinical area is free of all individuals not directly involved in the imaging procedure.

Hand-held x-ray systems should use essentially the same amount of radiation as traditional fixed x-ray units since the amount of radiation needed to generate an adequate image is determined by the image receptor, not by the x-ray device. The technique factors for intraoral radiography with hand-held systems should be similar to those for conventional dental radiography systems.

A trigger on the handle of the hand-held x-ray system activates the device. Device operation, at first glance, poses several concerns that appear inconsistent with previously established dental radiological protection guidelines. These concerns include:

1. The x-ray tube assembly is hand-held by the operator rather than wall mounted,
2. The trigger for x-ray exposure is on the hand-held device and not remotely located away from the source of radiation, and
3. The operator does not stand behind a barrier.

However, dosimetry studies indicate that these hand-held devices present no greater radiation risk to the patient or the operator than standard dental radiographic units (Goren et al. 2008; Gray et al. 2012; Masih et al. 2006; Witzel 2008). No additional radiation protection precautions are

needed when the device is used according to the manufacturer's instructions. These include: (1) holding the device at mid-torso height, (2) orienting the shielding disk (also referred to as a shielding ring) properly with respect to the operator, and (3) keeping the cone as close to the patient's face as practical (ADA-FDA 2012). If the hand-held device is operated without the disk shield in place, the operator should wear a radiation protective apron.

All operators of hand-held units should be instructed on their proper storage. Due to the portable nature of these devices, they should be secured properly when not in use to prevent accidental damage, theft or operation by an unauthorized user. Hand held units should be securely stored in locked cabinets, locked storage rooms or locked work areas when not under the immediate supervision of authorized users. When units cannot be secured by one of the means above, the batteries should be removed or other methods taken to render the units inoperable.

Cone Beam CT

The emergence of cone-beam computed tomography (CBCT) has expanded the field of oral and maxillofacial imaging. CBCT is used for dental implant planning, orthodontics, surgical assessment of pathology, pre- and postoperative assessment of craniofacial fractures, and temporomandibular joint assessment (ADA 2012; Tyndall et al. 2012). It provides the dental clinician the ability to obtain three-dimensional volumetric image data of dental and maxillofacial structures with short scanning times and high geometric accuracy (actual size of item imaged without distortion) (Scarfe et al. 2006).

A major advantage of CBCT over multi-row detector CT systems (MDCT) is the potential to perform procedures with lower radiation dose. A CBCT scanner utilizes a tightly collimated cone beam of radiation that can scan both the maxilla and mandible at one time. It also permits scanning of fields of view that are as small as individual teeth. Although CBCT radiation doses are less than those produced during conventional medical computed tomography, the radiation doses to tissue are higher than those of conventional dental radiographic techniques. The effective dose of an optimized CBCT examination is 2% to 5% of a conventional CT of the same region, but approximately 7 times greater than that from a panoramic image (Ludlow and Ivanovic 2008; Scarfe et al. 2006).

CBCT should be considered as an adjunct to standard oral imaging modalities and should be used only after a review of the patient's health and imaging history and the completion of a thorough clinical examination. The examination is justified if the required information is not available with conventional dental imaging and anticipated diagnostic yield outweighs the risks associated with radiation. The diagnostic yield should benefit patient care, enhance patient safety and improve clinical outcomes significantly (AAE-AAOMR 2010; ADA 2012). The smallest volume size that will yield the diagnostic objective of the CBCT study should be used because, if all other parameters remain the same, the smallest volume size will provide the least amount of radiation to the patient (Ludlow and Walker 2013).

To ensure radiation doses to the patient are ALARA, it is recommended that metrics of patients' doses be monitored on a regular basis. Effective dose, considered to be the best overall indicator

of patient dose, is a calculated quantity and cannot be measured directly. Dose-area product (DAP) is recognized as providing good correlation with effective dose and overall patient risk, although the correlation is not as good for smaller fields of view (Ludlow 2009). An increasing number of CBCT systems display DAP for each examination.

Structural Shielding

Structural shielding criteria are provided by NCRP Reports No. 145 and 147 (NCRP 2003; NCRP 2004a). Prior to the first clinical use of a newly installed or relocated dental x-ray imaging unit, a shielding evaluation should be performed by qualified expert and this evaluation should be documented in a written report. The need for structural shielding is dependent on the physical size of the room, the workload and the uses of the adjacent areas, including areas above and below. After installation of the unit, a qualified expert should perform a survey to verify that any additional structural shielding was correctly installed and that the radiation exposures in adjacent areas are in compliance with the guidance provided in NCRP Report No. 147. Copies of both reports should be maintained by the facility. Commonly, it is not necessary to line the walls with lead to meet this requirement for intraoral or panoramic equipment. A wall constructed of a suitable thickness of normal building materials may be sufficient for use of this equipment in the average dental office (NCRP 2003).

QUALITY ASSURANCE

Quality assurance (QA) refers to those steps that are taken to make sure that a dental facility or imaging facility consistently produces images that are adequate for the diagnostic treatment purpose with optimal patient and minimal operator exposure. It includes those organizational steps taken to make sure that testing techniques are properly performed and that the results of tests are used to effectively maintain a consistently high level of image quality. An effective QA program includes assigning personnel to determine optimum testing frequency of the imaging devices, evaluate test results, schedule corrective action, monitor repeat images, provide training, and perform ongoing evaluation and revision of the program.

Each dental service should designate a quality control team, including a dentist and other dental service personnel, a qualified medical physicist (QMP), and biomedical maintenance personnel, to establish and maintain a QA program. The program should include the routine testing of the primary components of the dental imaging chain, from the x-ray machine and image receptor, through processing to the viewing of dental images. The QMP should participate in the selection of the technical aspects of imaging protocols and in the design and oversight of the QA program.

Dental clinics that use film should process the film following the manufacturer's guidance, should establish a QA program for film processing, and should evaluate film processing darkrooms and daylight loaders for light leaks and safelight performance (ADA-FDA 2012; NCRP 2003).

All dental x-ray imaging equipment should be subjected to acceptance testing by a QMP before use on patients and to periodic constancy testing thereafter. When a new (or relocated) CBCT system has been installed, the RSO should request that a qualified expert complete a CBCT acceptance test to ensure that the equipment's performance is in agreement with the manufacturer's technical specifications. Acceptance testing should include radiation output repeatability, radiation output reproducibility, kVp accuracy, kVp repeatability, kVp reproducibility, beam quality, radiation field of view, image quality, accuracy of linear measurements, accuracy of patient dose metric indication, and patient dose assessment. Some manufacturers provide phantoms and specify procedures to perform machine-specific QA tests not suggested in these recommendations; it is suggested that these tests be completed as recommended by the manufacturer, in addition to the tests outlined in these recommendations. The data and documentation from these tests should be maintained in the facility.

CBCT equipment should be tested annually by a QMP. Other dental x-ray imaging equipment may be tested by a QMP either annually or every two years. After any repair or modification that may affect patient dose or image quality, testing should be performed by or under the supervision of a QMP. More information on such testing may be found in the sections above entitled TESTING BY A QUALIFIED MEDICAL PHYSICIST and EQUIPMENT FAILURE. These sections also note variances for these recommendations in certain circumstances.

In order to ensure that consistent diagnostic information is acquired while maintaining radiation doses as low as reasonably achievable, a quality assurance (QA) Program should be implemented within the facility. Considerations for such a program should include:

1. **Performance testing.** Each unit should undergo periodic quality control tests to ensure that the performance of the machine has not significantly deteriorated and it is operating within the manufacturer's technical specifications.
2. **QA test with a phantom.** If the manufacturer provides a phantom and specifies procedures to perform QA tests, these tests should be completed as recommended by the manufacturer. The data and documentation from these tests completed by the qualified expert can be reviewed and a trend analysis performed on the data, which may reflect equipment trends that require repair and/or replacement. This is particularly relevant to CBCT systems.
3. **Qualitative assessment.** A qualitative assessment of the image quality is recommended to ensure the study reflects the proper contrast and resolution, as well as uniformity with the least amount of noise and artifact for diagnosis. It is suggested that such a qualitative visual check be performed on all studies obtained with the use of a reference study.
4. **Monitoring of retakes.** A system to monitor retakes should be established to help identify problems such as equipment function deficiencies, imaging protocol deficiencies and those technicians who require additional training in patient positioning and image receptor placement.
5. **Assessment of display monitors.** Display monitors used for image viewing and interpretation should be assessed by regular checks. Over time and with use, display monitors will deteriorate, and may need replacing during the lifetime of the imaging system.
6. **Proper viewing conditions.** Viewing conditions during image interpretation are important. Ideally, the room should have indirect lighting of adjustable intensity.

Dimming the ambient lighting will usually improve the perception of contrast, but the room should not be too dark. Precautions should be taken so that bright objects (e.g., windows) do not cause reflections on the face of the display monitor or view box.

7. **Monitoring of dose metrics.** After installation of a new CBCT unit, and following any major maintenance or modification of a CBCT protocol program, it is suggested that the metrics of the radiation doses to patients be monitored by recording and assessing dose metrics from a sample of cases periodically (e.g., annually). These dose metrics can include patient dose data such as DAP, and related information such as kV, mAs and field for a representative sample of patient studies. Any negative trends identified through this process should be reported immediately to the qualified expert for further assessment of the CBCT unit.
8. **Comparison of patient doses to DRLs and ADs**. Each dental service should collect data on radiation doses to patients and compare it to available diagnostic reference levels (DRLs) and achievable doses (ADs), as described above in the section entitled DIAGNOSTIC REFERENCE LEVELS AND ACHIEVABLE DOSES (NCRP 2003; NCRP 2012). During physics testing of the equipment, the QMP should collect dose data using the facility's technique factors and compare it to DRLs and ADs. Some imaging systems display dose data after each examination; these data should also be periodically compared to appropriate DRLs and ADs. Dose data also should be evaluated similarly after modification of an imaging protocol that may affect the dose to the patient. If the mean radiation dose metric at the facility exceeds a DRL, equipment and clinical practices should be investigated in order to reduce radiation doses (NRPB 1990; Wall 2001). Whenever the radiation dose or examination protocol is changed, image quality should be evaluated.
9. **Input from a QMP.** A QMP should assist in the development of the QA program. However, the facility is responsible for implementing the daily QA program.
10. **Review.** In conjunction with annual or biennial testing, the QMP should review the QA program and provide a written report to Dental Service Chief and the RSO. This written report may include findings that suggest negative trends in image quality and identify corrective actions taken.

PERSONNEL

As in general medical radiology, it is important to eliminate unproductive radiation exposure in dentistry, thus, privileges to order dental x-ray examinations should be limited to Doctors of Dental Surgery or Dental Medicine who are licensed in the United States or one of its territories or commonwealths. Exception may be granted for persons in post-graduate training status under the supervision of a person meeting such requirements. Variances to the above qualification requirements should occur only for emergency or life-threatening situations, such as natural disasters. Also, non-peacetime operations in the field or aboard ship could require such variances. Dental equipment operators should receive appropriate education and training in anatomy, physics, technique and principles of radiographic exposure, radiation protection, radiographic positioning, and image processing that is relevant to dental imaging. Proficiency can be demonstrated by satisfying existing state certification programs for dental auxiliaries.

Also, proficiency can be improved by reviewing dental radiology practice recommendations from the ADA (ADA-FDA 2012).

Operators of dental x-ray equipment may be exposed to the x-ray beam, leakage radiation from the tube housing and scattered radiation. Protective measures are required to minimize their occupational exposure. There are three basic methods to reduce the occupational dose from x-rays: position, distance and shielding. The most effective way of reducing operator exposure to scattered radiation is to enforce strict application of the *position and distance rule* (i.e., the operator should stand at least 2 m (6 ft) away from the tube head of the dental x-ray generator). If the operator cannot stand at least this far from the patient during the exposure, he or she should stand behind an appropriate barrier or outside the operatory behind a wall. In clinics or field situations, where the operator is required to be in the immediate exposure area, the operator should be positioned at the location of minimum exposure. This location, also known as the safe quadrant, is at an angle between 90 and 135^{o} to the primary beam. Dental personnel should not hold image receptors in patients' mouths. If a patient has to be restrained during exposure, a relative or friend of the patient should do so. This individual should be provided with a radiation protective apron and, if the image receptor is to be held in the mouth, radiation-protective gloves. These will provide protection during exposure.

In panoramic imaging, scattered radiation is typically low due to the narrow beam of radiation and the shielding incorporated into the image receptor. With a typical workload, operators can produce panoramic images without the use of shielding as long as they are at least 2 meters (6 feet) from the unit. An appropriate shield should be used if this distance cannot be maintained.

Any individual who is likely to exceed a designated fraction of the regulatory dose limit shall be enrolled in a radiation monitoring program (OSHA 2014a). Historically, dental radiation workers have not approached these limits and have not required radiation monitoring when good radiation practices have been used. To determine if dosimeters are required, evaluations of occupational dose should be conducted by a QMP when a program is initiated, facilities are significantly modified, or equipment or processes change. The evaluation may consist, for example, of monitoring personnel for a period of time or assessing the radiation field around the equipment. With regard to workers who have declared their pregnancy, NCRP Report No. 145 states that "Personal dosimeters shall be provided for known pregnant occupationally-exposed personnel" (NCRP 2003).

PROCEDURES

Justification applies equally to imaging in dentistry as it does to all other medical imaging. The number of images obtained should be the minimum necessary to obtain essential diagnostic information. Dental radiographs should be prescribed only following an evaluation of the patient's needs that includes a health history review, a clinical dental history assessment, a clinical examination and an evaluation of susceptibility to dental diseases. Selection criteria for new and recall dental examinations for children, adolescents and adults, as well as dentate and edentulous patients, were initially established in 1987 and updated most recently in 2012 (ADA-FDA 2012). In cases where emerging new dental imaging technologies are used by physicians

for non-dental evaluations, these physicians should request these studies through their medical imaging ordering procedures as determined by their local facility.

Optimization also applies to imaging in dentistry. In order to achieve lower exposures, the operator's manual should be readily available to the user, and the equipment should be operated following the manufacturer's instructions, including any appropriate adjustments for optimizing dose and ensuring adequate image quality. An image receptor holding device should be used for proper film, photostimulable phosphor (PSP) plates or sensor positioning whenever possible. Protocols may be relaxed in the cases where anatomy or the inability of the patient to cooperate makes beam-receptor alignment awkward.

Either patient size-based technique charts or imaging protocols with suggested parameter settings should be established to ensure that radiation exposure is optimized for all patients (ADA-FDA 2012). Technique charts are tables that indicate appropriate settings on the x-ray unit for a specific examination and can ensure the least amount of radiation exposure is used to produce consistently good-quality images. Technique charts should be used for all systems with adjustable settings, such as tube potential, tube current, and time or pulses. Technique charts should list the type of exam, the patient size (e.g., small, medium, large) for adults and a pediatric setting or settings. The speed of film used, or use of a digital receptor, should also be listed on the technique chart. The chart should be posted near the control panel where the technique is adjusted for each x-ray unit, or otherwise immediately available. A technique chart that is regularly updated should be developed for each x-ray unit. Alternatively, technique factors may be programmed into imaging protocols stored on the imaging systems. The technique charts or protocols should be updated when a different film or sensor, new unit or new screens are used. After a modification to a technique chart or protocol that may affect patient doses, appropriate dose metrics should be measured and compared to previous values and also to diagnostic reference levels and achievable doses, as described above.

Signs asking female patients to notify staff if they might be pregnant are not necessary in dental facilities where expected fetal doses are very low.

VETERINARY IMAGING

Diagnostic radiology is an essential part of present-day veterinary practice. The typical imaging workload in a veterinary practice is low on the average, however, certain practices unique to veterinary radiology can expose the staff at a greater rate than typical operators. In veterinary medicine, the possibility that anyone may be exposed to enough radiation to create deterministic effects is extremely remote.

There are two main radiation protection issues to be considered. First, veterinary imaging personnel should be considered radiation workers and their dose should be maintained as low as reasonably achievable. Secondly, personnel in the vicinity of veterinary radiology facilities and the general public require adequate protection (AAE-AAOMR 2010; ADA 2012; NCRP 2004b; OSHA 2014a; USNRC 2014d).

EQUIPMENT

Unlike x-ray equipment intended for use on humans, x-ray emitting devices intended solely for use on animals are not subject to the FDA's pre-market clearance or approval processes. However, manufacturers of these devices must maintain certain records and must comply with certain radiological health reporting and notification requirements as specified by FDA (FDA 2014h). The recommendations pertaining to the use of medical radiographic equipment and shielding requirements for humans apply to the use of similar equipment in veterinary medicine. The following points are highlighted for veterinary applications:

1. In a fixed facility, the floors, walls, ceilings and doors should be built with materials providing adequate radiation protection to workers.
2. The shielding should be constructed to form an unbroken barrier.
3. In a fixed facility, a control booth should be provided for the protection of the operator. Mobile protective barriers are not considered adequate as a control booth except for facilities requiring no shielding at 1 meter from source, or where 1/20 of permissible dose equivalent limits are not likely to be exceeded at 1 meter.
4. The control booth should be located, whenever possible, such that the radiation has to be scattered at least twice before entering the booth. In facilities where the radiation beam may be directed toward the booth, the booth becomes a primary barrier and should be shielded accordingly.
5. The control booth should be positioned so that during an irradiation no one can enter the radiographic room without the knowledge of the operator.
6. Required warning signs should be posted on all entrance doors of each x-ray imaging room.
7. When mobile radiographic or fluoroscopic equipment is used in a fixed location, or frequently in a particular location, it is strongly recommended that a qualified expert evaluate the need for structural shielding.
8. Protective aprons, gloves and thyroid shields used for veterinary x-ray examinations should provide attenuation equivalent to at least 0.25 mm of lead-equivalence at x-ray tube voltages of up to 150 kVp. Monthly dose monitoring can ensure that staff members who use garments with <0.5 mm lead equivalent thickness keep their occupational dose

below the required dose limits. For protective gloves, protection should be provided throughout the glove, including fingers and wrist. Further discussion is provided in the section on RADIATION SAFETY PROCEDURES FOR FLUOROSCOPY.

As of 2014, hand-held, battery-powered x-ray devices are available for veterinary radiographic and fluoroscopic imaging. Unless specifically designed to be hand-held, neither the portable x-ray generator nor the image receptor should be held in the hand (NCRP 2004b). Whenever practicable, a mechanical device should be used to support the x-ray generator and image receptor; if this is impractical and it becomes necessary to hold the x-ray generator or image receptor occasionally, the operator should always wear radiation protective apparel (Tyson et al. 2011). As of 2014, certain battery-powered radiographic systems have been designed to be operated by the operator holding the x-ray generator. These "hand-held" systems have specially designed shielding of the x-ray tube housing and an integral radiation shield to minimize backscatter and have seen use in dental and veterinary radiographic imaging. While studies with one hand-held manufacturer's radiographic system reported that, in human intraoral dental use, operators received lower radiation doses using this system than they did with traditional units (Gray et al. 2012), it may not be appropriate to extrapolate these data to veterinary practice. When performing radiography on large animals, the x-ray generator should not be held in the hands routinely, as this may result in annual operator radiation doses that exceed regulatory limits (Tyson et al. 2011). Operators of hand-held fluoroscopic units could also receive annual radiation doses exceeding current dose limits, as when imaging horses (Thomas et al. 1999). Radiation safety precautions for hand-held devices should be emphasized, because there is a greater opportunity for radiation exposure compared to conventional radiographic and fluoroscopic units.

Each portable hand-held x-ray system should be used as outlined in the instructions that come with the unit. Exposures using this unit should be made only when the area adjacent to the examination area is free of all individuals not directly involved in the imaging procedure. When standard radiology protocols are utilized according to manufacturer instructions, with the disk shield (if so equipped) in place, there is no indication for additional radiation protection recommendations. Aside from use in field or emergency situations, these devices should not be used in areas where there may be unintended exposure of other individuals (e.g., occupied waiting rooms, corridors and classrooms).

Portable hand-held x-ray systems should use essentially the same amount of radiation as traditional fixed x-ray units since the amount of radiation needed to generate an adequate image is determined by the image receptor, rather than the x-ray device. The technique factors for veterinary radiography with hand-held systems should be similar to those for conventional veterinary radiography systems.

The hand-held exposure device is activated by a trigger on the handle of the device. Device operation, at first glance, poses several concerns that appear inconsistent with previously established radiological protection guidelines. These concerns include:

1. The x-ray tube assembly is hand-held by the operator rather than wall mounted.
2. The trigger for x-ray exposure is on the hand-held device and not remotely located away from the source of radiation.

3. The operator does not stand behind a barrier.

Dosimetry studies for hand held x-ray systems used in dental practices indicate that these devices present no greater radiation risk than standard radiographic units to the patient or the operator (Goren et al. 2008; Gray et al. 2012; Masih et al. 2006; Witzel 2008). It is expected these results also pertain to veterinary use especially considering the traditional low radiographic workload of veterinary clinics. No additional radiation protection precautions are needed when the device is used according to the manufacturer's instructions. These include:

1. holding the device at mid-torso height,
2. orienting the shielding disk properly with respect to the operator, and
3. keeping the cone as close to the patient's area being imaged as practical.

If the hand-held device is operated without the disk shield in place, it is recommended that the operator wear a radiation protective apron.

All operators of hand-held units should be instructed on their proper storage. Due to the portable nature of these devices, they should be secured properly when not in use to prevent accidental damage, theft or operation by an unauthorized user. Hand held units should be securely stored in locked cabinets, locked storage rooms or locked work areas when not under the direct supervision of authorized users. When units cannot be secured by a method above, batteries should be removed or other methods taken to render the units inoperable. The names of individuals who are granted access and use privileges should be recorded and the records kept current.

QUALITY ASSURANCE

Since veterinary equipment is generally identical to medical equipment, all the quality assurance tasks associated with medical equipment can be applied to veterinary equipment; however, based on the typical workload, a reduced quality assurance program is probably warranted in most cases. A typical testing and QA program should consist of at least the following:

1. Complete a radiation safety survey on all new veterinary x-ray equipment by or under the direction of a QMP. As stated in NCRP Report No. 148 (NCRP 2004b), "Resurveys shall be made following replacement of irradiation equipment, or modifications that could change the radiation source, whenever the workload increases significantly, or if other operating conditions are modified that could affect the radiation dose in occupied areas. Resurveys are required after the installation of supplementary shielding to determine the adequacy of the modification" (NCRP 2004b).
2. Perform a radiation exposure survey prior to the first use of a mobile fluoroscope. Operate the equipment with the x-ray beam at maximum operating potential, with an appropriate test phantom in place, to determine the perimeter of the area within which individuals without radiation protection apparel should not be present (NCRP 2004b).
3. Take steps to minimize the need for repeat exposures due to inadequate image quality. These repeats result in unnecessary radiation exposure to the patient, operator and members of the public (NCRP 2004b).

4. Perform a sensitometry and densitometry test each day a film-based system is used, in order to ensure consistent operation. A step wedge test may be used as a substitute for the standard sensitometry and densitometry test.
5. Evaluate darkroom integrity by performing a darkroom fog test annually. This is especially relevant if the darkroom is not a single use room.
6. Evaluate radiation protective apparel (e.g., aprons, gloves, thyroid collars) at least annually for radiation protection integrity using visual and manual inspection (Miller et al. 2010b; NCRP 2010). If a defect in the attenuating material is suspected, radiographic or fluoroscopic inspection may be performed as an alternative to immediately removing the item from service.

PERSONNEL

Veterinary x-ray equipment operators, similar to medical x-ray equipment operators, should receive appropriate education and training in the areas of anatomy, physics, technique and principles of radiographic exposure, radiation safety, radiographic positioning, and image processing that are relevant to veterinary imaging. Only personnel with specific, appropriate training should be permitted to operate x-ray equipment. It is strongly recommended that the veterinary medical application of x-ray equipment be performed only by or under the general supervision of a veterinarian properly trained and credentialed to operate such equipment. Individuals who routinely use veterinary radiological equipment need a basic understanding of the following:

1. Demonstrated competence in animal handling and behavior by all parties involved, so that the animal's distress and physical restraint are minimized and personnel are protected;
2. Animal positioning techniques to allow for minimal radiation exposure for employees;
3. Basic principles and concepts of radiation in general and x-radiation in particular;
4. Component parts and workings of the x-ray machine and the production of x-rays;
5. Factors affecting the quality of the x-ray beam and the radiographic image;
6. Effects of ionizing radiation on living tissues;
7. Radiation bioeffects, health and safety;
8. Radiation protection procedures for the operator and the patient;
9. Selection of appropriate imaging surveys, image receptor types, duplicating, and record keeping;
10. Technique of proper image processing, handling and record keeping;
11. Viewing techniques and principles of interpretation;
12. Digital imaging and alternate imaging modalities;
13. Appearances of normal radiographic landmarks, artifacts and shadows; and
14. Requirements for monitoring and documenting occupational radiation exposure to staff, including those who are pregnant (see section on EMBRYO OR FETUS OF PREGNANT WORKERS).

PROCEDURES

The procedures pertaining to the use of veterinary radiography are generally equivalent to procedures for medical (human) radiography. The following recommendations will minimize the dose to veterinary facility staff and clients from veterinary diagnostic radiographic procedures while producing images of adequate quality. There are methods available for technique optimization (Copple et al. 2012). All suggestions will secondarily minimize the dose to the radiation operator and consequently, the results may be considered as a double benefit to the patient and the worker. The guidelines and procedures outlined in this section are primarily directed toward occupational health protection. Adherence to these guidelines will also provide protection to visitors and other individuals in the vicinity of an x-ray facility. However, the safe work practices and procedures for using various types of x-ray equipment should be regarded as a minimum to be augmented with additional requirements, when warranted, to cover special circumstances in particular facilities. To achieve optimum safety, operators should make every reasonable effort to keep exposures to themselves and to other personnel as low as reasonably achievable.

Veterinary clinic setup

1. An x-ray room should be used for only one x-ray procedure at a time.
2. All entrance doors to an x-ray room should be kept closed while a radiographic procedure is being performed.
3. Where a control booth or protective barrier is available, it is strongly recommended that operators remain inside the booth or behind the barrier when making an irradiation. If a control booth or protective screen is not available, the operator should always wear protective clothing.
4. When film-screen imaging is used, the fastest combination of films and intensifying screens consistent with diagnostically acceptable results and within the capability of the equipment should be used.
5. When digital x-ray imaging is used, procedures should be established to prevent excessively high doses, also known as dose creep, as addressed in the radiography section of this document.

Personal protective equipment

1. Personnel should use radiation protective apparel, as appropriate.
2. Radiation protective aprons, gloves and thyroid shields should be hung or laid flat and never folded, and manufacturer's instructions should be followed.
3. Personnel should understand that radiation protective gloves may not protect against bites. Such bites could puncture the lead and compromise the radiation protection provided by the gloves (NCRP 2004b). Armored gloves (welding gloves) should be used to augment restraint of fractious animals when needed, but should not replace knowledge and utilization of appropriate handling techniques and proper pain control, sedation and anesthesia for patients.

Animal restraint

1. If necessary, the animal should be sedated or holding devices used during radiography. However, if this is not possible and a person must restrain the animal, that person should wear appropriate radiation protective equipment (aprons, gloves, etc.) and avoid direct irradiation by the primary x-ray beam. No person should routinely hold animal patients during x-ray examinations (NCRP 2004b).
2. Individuals under the age of 18, or potentially pregnant women should not be permitted to hold animals during radiography.

Use of x-ray equipment

1. X-ray equipment should be operated only by or under the direct supervision of qualified individuals.
2. A qualified operator should maintain control of an x-ray machine once it is powered on and ready for an exposure. The x-ray room should contain only those persons whose presence is essential when a radiological procedure is carried out.
3. The radiation beam should always be directed toward adequately shielded or unoccupied areas.
4. The radiation beam and scattered radiation should be attenuated as closely as possible to the source.
5. Personnel should keep as far away from the x-ray beam as is practicable at all times (2 m). Exposure of personnel to the x-ray beam should never be allowed unless the beam is adequately attenuated by the animal and by protective clothing or barriers.
6. A hand-held radiographic cassette or image receptor should not be used.
7. For table-top radiography when the sides of the table are not shielded, a sheet of lead at least 1 mm in thickness and slightly larger than the maximum beam size should be placed immediately beneath the cassette or film.
8. Veterinarians should not allow veterinary diagnostic radiation devices under their control to be used on human beings (NCRP 2004b), except under extenuating circumstances.
9. Technique charts should be developed for all animal types that are routinely radiographed.

Personal dosimetry

1. The x-ray imaging workload in a typical veterinary clinic may not be sufficient to require the issuance of personal dosimetry, however, a qualified expert should be consulted for a clinic's particular situation and to conduct evaluations of occupational dose.
2. Personal dosimeters, if assigned, should be worn in a manner consistent with regulatory requirements and standard practice so that radiation doses can be determined accurately. See the section on PERSONNEL AND AREA MONITORING.

3. Occupational radiation dose limits in veterinary and human medical practice should be the same. See the section on PERSONNEL AND AREA MONITORING.

IMAGING INFORMATICS

Digital information systems are used for the ordering, scheduling, tracking, processing, storage, transmission and viewing of imaging studies and providing the reports of study interpretations. These systems should be used to the greatest extent possible. They include picture archiving and communication systems (PACS), teleradiology systems, radiology information systems, clinical decision support software, hospital information systems, and the Electronic Health Record (Congress 2007). For efficiency of workflow, these systems do not operate independently, but instead are connected to the imaging devices and each other by computer networks and exchange information in accordance with standards such as the Internet Protocol Suite (Transmission Control Protocol/Internet Protocol, or TCP/IP), DICOM, HL7, and IHE. These information systems are complex and will not be discussed in detail in this report. However, there are certain aspects of these systems that indirectly can affect the radiation doses to patients from imaging studies. Proper planning, design, management and use of these systems can help avoid performing unnecessary or inappropriate studies and repeat studies.

Agencies should adopt recognized standards for sharing clinical reports of radiological procedures within each agency, among agencies, and with non-governmental healthcare facilities in order to make clinical information available to health care providers and to avoid unnecessary duplicate examinations.

Clinical decision support software can help avoid the ordering of unnecessary or inappropriate imaging studies. At the time that a Referring Medical Practitioner places the request for an imaging study, the system can provide decision support regarding the appropriateness of the study for the particular patient and notification of alternatives that may impart less or no radiation. These information systems can also notify the Referring Medical Practitioner of previously acquired studies that may render an additional imaging study unnecessary (ACCF/SCAI/AATS/AHA/ASE/ASNC/HFSA/HRS/SCCM/SCCT/SCMR/STS 2012; ACCF/SCAI/STS/AATS/AHA/ASNC/HFSA/SCCT 2012; ACR 2012a; Sistrom et al. 2009).

Inability to retrieve an imaging study can create the need for a repeat study. Digital information systems and procedures for their use should be designed to protect against data loss. Such measures should include administrative, physical and technical safeguards, including storing information on stable media, ensuring the storage location is secure from natural and human threats, ensuring the stored information is secure from deliberate or accidental erasure or modification, storing duplicate backup copies of the information on media in a remote location or locations, and precautions against loss of information from media wear and aging and media obsolescence. As part of their effort to manage patients and their disease progression within and among facilities, agencies should develop retention policies for images and related data. Additionally, the facility should have a disaster plan in place to guide operations when the network is inoperable or power outage affects operation of the PACS system. It is the responsibility of the institution to meet the records retention, security, privacy and retrieval requirements of its agency and other federal requirements (e.g., HIPAA and associated federal regulations) (ACR-AAPM-SIIM 2012b; ACR 2009a; DHHS 2012b), and to address the aforementioned issues.

Digital information systems also provide an important quality assurance function (AAPM 2009; IEC 2008) and can be used in optimizing doses from imaging procedures. They should facilitate monitoring of patient dose indices, the doses to radiographic image receptors, and the number of retakes and inadequate images. This requires both capture and storage of this information and appropriate software tools for data analysis and display. Equipment manufacturers should continue to work with professional societies and standards organizations, such as NEMA and IHE, to develop and implement standardized dose reporting systems. Ideally, these systems should provide estimated patient radiation dose for individual examinations and documentation of estimated radiation dose for individual patients. They should also have the capability to present these data in ways that facilitate QA and QI, and should be capable of transmitting de-identified patient radiation dose data to a central dose registry. The DICOM Standard describes standard information objects, called Radiation Dose Structured Reports (RDSRs), that x-ray imaging devices can use to send information about the radiation exposures of patients from individual examinations (NEMA 2011).The IHE Radiation Exposure Monitoring (REM) Profile describes standard methods for archiving RDSRs and for sending the dose information to reporting systems, including sending de-identified dose data to national dose registries (IHE 2013; O'Donnell 2011). To this end, federal facilities should give preference to equipment with these standardized dose reporting systems when making purchasing decisions. In order to participate in central dose registries, agencies and facilities should adopt recognized standard terminology in their information reporting systems and databases.

Ideally, robust informatics infrastructure systems should be developed to record all aspects of the QC program pertaining to all modalities across an institution. Agencies should encourage the development of such systems and their utilization as they become available.

SUMMARY AND RECOMMENDATIONS FOR FACILITY ACTION

GENERAL

In addition to these general recommendations, the reader is referred to recommendations below on specific modalities and their use in dental and veterinary imaging.

1. Federal facilities should evaluate each imaging system's performance to optimize dose, and maintain this by establishing appropriate procedures and conducting periodic monitoring. An optimal dose is neither too high nor too low for the clinical purpose.
2. Each facility should establish a formal mechanism whereby Referring Medical Practitioners have sources of information available at the time of ordering regarding appropriate diagnostic imaging methods to answer the clinical question and to optimize ionizing radiation dose to the patient, as well as avoiding unnecessary duplicate procedures. These may include decision support software or imaging referral guidelines. Radiological Medical Practitioners, familiar with those guidelines, should be available to consult with Referring Medical Practitioners.
3. Facilities should establish technique factors or protocols for common examinations. These either should be programmed into the imaging system or a technique chart should be immediately available to the operator.
4. The Universal Protocol should always be followed to ensure the right patient gets the right procedure.
5. Healthcare providers should always strive to limit patient irradiation to that necessary to perform the procedure with adequate image quality.
6. Facilities should ensure that operators of imaging equipment that use x-rays:
    a. are adequately trained to produce acceptable quality images,
    b. know how to produce these images with appropriate patient doses,
    c. periodically demonstrate continuing competence, and
    d. can minimize the need for retakes.
7. Facilities should ensure that the operator's manual is readily available to the user, and the equipment is operated following the manufacturer's instructions, including any appropriate adjustments for optimizing dose and ensuring adequate image quality.
8. Facilities ideally should use equipment that facilitates monitoring of relevant patient dose indices.
9. Facilities should use the dose information from individual patient imaging procedures that is provided by imaging equipment as part of the quality assurance program for identifying opportunities to reduce dose.
10. Facilities should use diagnostic reference levels and achievable doses as quality improvement tools by collecting and assessing radiation dose data and comparing them to diagnostic reference levels and achievable doses. Each facility should also submit its radiation dose data to a national registry.
11. Facilities should be aware of upgrades to software and hardware of x-ray imaging systems that enhance safety. These should be evaluated and considered for implementation.

12. Facilities should assess the radiation exposures of workers and provide periodic feedback to them. In addition, each worker who is expected to receive more than 10% of the applicable dose limit should be required to wear one or more dosimeters.
13. Facilities should have adequate quality assurance and quality control programs for each of their modalities. A facility's participation in a nationally recognized accreditation program is one way to ensure that its quality assurance and quality control measures are adequate.
14. Facilities should ensure that for all x-ray imaging, regardless of the imaging modality used, efforts are made to restrict the x-ray field to the area of clinical interest by collimation or, in the case of CT, restriction of scan length. Whenever possible, protect particularly radiation-sensitive organs (e.g., gonads in patients of reproductive capability, lenses of the eyes, and breasts in younger females).

RADIATION SAFETY PROGRAM

1. Facilities should ensure that sufficient staffing is maintained to appropriately address radiation safety issues. The number of staff members will to a degree be based on the scope of services and the number of radiation workers at the facility, but at a minimum will consist of a Radiation Safety Officer and the services of a QMP.
2. Facilities should to the extent practicable use engineering controls (e.g. installed lead shielding), personal protective equipment (e.g. lead aprons), and appropriate procedures (e.g. distance) to achieve occupational doses and doses to members of the public that are as low as reasonably achievable (ALARA), with economic and social factors being taken into account.
3. Facilities should ensure that no one is unnecessarily exposed to radiation. Only the patient being examined, staff and ancillary personnel required for the procedure, including those in training, should be in the room during the examination. Caregivers (e.g., guardians, spouses, parents) are sometimes made an exception when the responsible imaging team believes their support will result in an improved procedure and better patient experience (e.g., reduced anxiety, greater patient cooperation).
4. Facilities should ensure that when a monitored radiation worker declares her pregnancy she wears a dosimeter on the lower abdomen, underneath the apron at the level of the fetus. The dosimeter should be exchanged monthly. She should be issued this dosimeter unless such a dosimeter is already being worn.

SPECIAL PATIENT POPULATIONS

1. Facilities should ensure that, when children are imaged, technique and imaging protocols are appropriate for each child's size to ensure adequate image quality and optimize radiation dose.
2. Each facility should establish a policy for determining which procedures require pregnancy testing and informed consent when performed on female patients of child-bearing age.

3. In general, facilities should ensure that neither screening nor elective x-ray examinations where the fetus is near or in the x-ray beam are performed on pregnant women.

INFORMED CONSENT

1. Facilities should ensure that, except in emergency situations, informed consent is obtained from the patient or the patient's legal representative and is appropriately documented prior to the initiation of any procedure that is likely to expose the patient, or fetus if the patient is pregnant, to significant risks and potential complications.
2. For procedures that may impart a clinically important dose to the fetus, and especially for doses exceeding 0.05 Gy (5 rad), the anticipated dose and associated risks should be included as part of any informed consent unless a physician determines that the delay caused by the extended consent discussion would harm the patient.
3. Informed consent should be obtained for potentially-high radiation dose procedures. It should include a description of the anticipated risks from the radiation dose as part of the overall discussion of risks.

REQUESTING AND PERFORMING STUDIES INVOLVING X-RAYS

1. Facilities should ensure that appropriate information is obtained and reviewed at the time a study is requested. The purpose is to ensure that the study is justified and to optimize the choice of study and protocol so that radiation dose and clinical value are optimized.

TECHNICAL QUALITY ASSURANCE

1. Each facility that performs imaging with x-rays should establish in writing and implement technical quality assurance and quality control programs that conform to the most recent version of current professional society recommendations.
2. Facilities should ensure that their technical quality assurance program includes testing, by or under the supervision of a QMP, of all x-ray imaging equipment.
3. Each facility should review their technical quality control program annually and involve a Radiological Medical Practitioner, technologist and QMP.

DIAGNOSTIC REFERENCE LEVELS AND ACHIEVABLE DOSES

1. Facilities should submit radiation dose data to a national registry as part of a continuing effort to develop national DRLs and ADs that are specific for the U.S. population. The on-going nationwide collection of these data from government and non-government facilities, such as by NEXT and ACR, is important to this effort.
2. Facilities should ensure that a representative sampling and assessment of exposure indicators from each modality is performed at least annually. It should be reviewed by the chief technologist. This effort should be performed under the guidance of a QMP.

3. Facilities should use DRLs and ADs as quality assurance and quality improvement tools to optimize radiation dose. The goal is a radiation dose at or below the AD that yields an image quality adequate for the clinical purpose.
4. Facilities should investigate equipment if local practice at that facility results in a mean radiation dose that is greater than the DRL. If the equipment is functioning properly and within specification, operator technique and procedure protocols should be examined.
5. Facilities should ensure that whenever an imaging protocol for an examination is modified in order to optimize radiation dose, image quality is evaluated in order to ensure that the change does not result in inadequate image quality.

RADIOGRAPHY

In addition to the specific recommendations provided for radiography, the reader is referred to the GENERAL recommendations section above.

1. Each facility should track, as part of its quality assurance program, the rate of images repeated or rejected for technical reasons. Deterioration in performance should be investigated.
2. Each facility should monitor, for clinical examinations, the indices of radiation dose to the image receptors of radiographic systems, especially those systems that do not provide automatic exposure control. Mobile radiographic systems typically lack automatic exposure control.

FLUOROSCOPY

In addition to the specific recommendations provided for fluoroscopy, the reader is referred to the GENERAL recommendations section above.

1. The facility's procedures should be written with the understanding that fluoroscopy can deliver a significant radiation dose to the patient, even when used properly.
2. The facility should ensure that every person who operates or directs the operation of fluoroscopic equipment is trained in the safe use of the equipment.
3. The facility should ensure that Radiological Medical Practitioners only supervise studies that they themselves are appropriately trained to perform.
4. When a facility purchases fluoroscopic equipment, the additional cost of including dose-reduction technology is justified because the reduction in patient radiation dose can be considerable.
5. Some types of fluoroscopic procedures are considered potentially high-dose (i.e., >5% of cases result in a cumulative air kerma >3 Gy). The facility should ensure that there are additional training requirements for operators and additional equipment requirements for these types of procedures.
6. The facility should ensure that patient radiation dose data, including patient skin dose data when available, are collected and reviewed for QA purposes and are recorded in the patient's medical record.
7. The facility should have a policy that ensures that when a patient may have received a radiation dose high enough to result in a tissue injury, the operator is informed of the

radiation dose, places an appropriate notation in the patient's medical record, and provides clinical follow-up, as appropriate.

COMPUTED TOMOGRAPHY

In addition to the specific recommendations provided for computed tomography, the reader is referred to the GENERAL recommendations section above.

1. Facilities should ensure that advances in techniques and technology that reduce radiation dose are used, and used properly.
2. Facilities should implement suitable Notification Values and Alert Values on CT scanners that comply with the National Electrical Manufacturers Association (NEMA) Computed Tomography Dose Check standard.
3. Facilities should image only the area of anatomy in question, acquire only the necessary sequences, and select and adjust the protocol to ensure that the patient is examined using the appropriate techniques and dose.
4. It is strongly recommended that facilities establish procedures to avoid inadvertent or unapproved modification of CT protocols.
5. The facility should establish a radiation protocol workgroup or committee that includes a physician expert in CT, a technologist expert in CT, and a QMP to review and optimize CT protocols.
6. The facility should ensure that CT dose indices are recorded as part of the patient record in the imaging study or medical record and are monitored as part of the quality assurance program.
7. Each facility should track, as part of its quality assurance program, the number of studies repeated or rejected for technical reasons, patient motion, and other causes.

BONE DENSITOMETRY

In addition to the specific recommendations provided for bone densitometry, the reader is referred to the GENERAL recommendations section above.

1. Each facility's quality assurance program should assess accuracy by scanning a phantom on each day of use, and should assess precision by performing repeated examinations of a limited number of patients with their consent. When replacing hardware that may affect accuracy or when replacing an entire DXA system, the facility should perform cross-calibration by scanning a limited number of patients, with their consent, before and after the change.
2. Facilities should establish a range of acceptable precision performance and ensure each technologist is trained and meets this standard.
3. Facilities should ensure that patients imaged for precision and cross-calibration studies are representative of the facility's patient population.
4. Facilities should ensure that practitioners who interpret bone densitometry results are knowledgeable in this field and do not rely solely on a report produced by the equipment.

DENTAL IMAGING

In addition to the specific recommendations provided for dental imaging, the reader is referred to the GENERAL and DIAGNOSTIC REFERENCE LEVELS recommendations sections above.

1. Facilities should prescribe dental radiographs only following an evaluation of the patient's needs that includes a health history review, a clinical dental history assessment, a clinical examination and an evaluation of susceptibility to dental diseases.
2. Facilities using film should use the fastest and most appropriate film. For panoramic and other extraoral projections using film, the film should be spectrally matched to its appropriate rare earth intensifying screen.
3. Facilities should use image receptor holding devices for proper film, PSP or sensor positioning whenever possible.
4. When it will not interfere with the examination, facilities shall provide thyroid shielding for children and should provide it for adults.
5. Dental clinics that use film should process the film following the manufacturer's guidance, and establish a QA program for monitoring film processing that includes monitoring film processing darkrooms and daylight loaders for light leaks and safelight performance.
6. Dental clinics should review their imaging protocols, and ensure that the x-ray beam is collimated to the area of interest. For intraoral imaging, rectangular collimation is preferable. For cone beam CT (CBCT), the smallest field-of view that achieves the diagnostic objective should be used.
7. Facilities should consider CBCT as an adjunct to standard oral imaging modalities and use it only after reviewing the patient's health and imaging history and completing a thorough clinical examination.
8. Facilities should monitor retakes and provide training on ways to reduce the number of retakes.

VETERINARY IMAGING

In addition to the specific recommendations provided for veterinary imaging, the reader is referred to the GENERAL recommendations section above.

1. Facilities should ensure that the veterinary medical application of x-ray imaging equipment is performed only by or under the general supervision of a veterinarian properly trained and credentialed to operate such equipment.
2. Facilities should ensure that individuals who routinely use veterinary x-ray imaging equipment have a basic understanding of animal handling and behavior, animal positioning techniques, and the use of medical x-rays.
3. Facilities should ensure that armored gloves (welding gloves) are used to augment restraint of fractious animals, when needed, but should not replace knowledge and utilization of appropriate handling techniques and proper pain control, sedation, or anesthesia for patients. Lead-lined gloves will not protect against bites that could puncture the lead.
4. Facilities should have animal sedatives and holding devices available, and ensure they are used appropriately by trained and authorized individuals to provide the least restraint

required to allow the specific procedure(s) to be performed properly; minimize fear, pain, stress and suffering for the animal; and protect both the animal and personnel from harm.
5. Facilities should not allow anyone to routinely hold animal patients during x-ray examinations.

IMAGING INFORMATICS

1. Facilities should establish infrastructure for collecting, storing, reporting and analyzing dosimetry data from patient examinations. Facilities should track these data longitudinally and use them to facilitate dose optimization. Facilities should address the data acquisition, networking, storage, analysis, reporting and security requirements of existing and planned future diagnostic devices.
2. Facilities should use interoperable digital information systems to the greatest extent possible.
3. Facilities should give preference to equipment with standardized dose reporting systems when making purchasing decisions.
4. Facilities should ensure that their health professionals use digital information systems, in part to help avoid the ordering of unnecessary or inappropriate imaging studies.
5. Facilities should ensure that patient information in EHRs at all medical facilities is shared, ideally through a common interface, and available to the practitioner.

ACRONYMS AND ABBREVIATIONS

AAPM	American Association of Physicists in Medicine
ACC	American College of Cardiology
ACCF	American College of Cardiology Foundation
ACGME	Accreditation Council for Graduate Medical Education
ACR	American College of Radiology
ACS	American Cancer Society
AD	Achievable dose
ADA	American Dental Association
AHA	American Heart Association
ALARA	as low as reasonably achievable
ARRT	American Registry of Radiologic Technologists
ATSDR	Agency for Toxic Substances and Disease Registry
BEIR	Biological Effects of Ionizing Radiation
BID	beam indicating device
BMD	bone mineral density
CBCT	cone beam computed tomography (cone beam CT)
CFR	Code of Federal Regulations
CIRSE	Cardiovascular and Interventional Radiology Society of Europe
cm	centimeter
CNMT	Certified Nuclear Medicine Technologist
CR	computed radiography
CRCPD	Conference of Radiological Control Program Directors
CT	computed tomography
CTDI	computed tomography dose index
$CTDI_{vol}$	volumetric CTDI
DAP	dose-area product (units are Gy-cm^2)
DC	direct current
DDR	Direct digital radiography
DDS	Doctor of Dental Surgery
DEXA	see DXA
DHHS	U.S. Department of Health and Human Services
DLP	dose length product
DoD	U.S. Department of Defense
DR	digital radiography
DRT	Diagnostic Radiologic Technologist
DXA	dual-energy x-ray absorptiometry (formerly DEXA)
EHR	Electronic Health Record
EI	exposure index
EPA	U.S. Environmental Protection Agency
ESE	entrance skin exposure
ESEG	entrance skin exposure guide
FDA	U.S. Food and Drug Administration
FGI	Fluoroscopically-guided interventional
FGR	Federal Guidance Report

FOV	field of view
GI	gastrointestinal
GSD	genetically significant dose
Gy	gray (radiation dose, equal to 100 rem). Subunit is mGy (milligray)
HRS	Heart Rhythm Society
IAC	Intersocietal Accreditation Commission
ICRP	International Commission on Radiological Protection
IEC	International Electrotechnical Commission
IRB	Institutional Review Board
ISCD	International Society for Clinical Densitometry
ISCORS	Interagency Steering Committee on Radiation Standards
KAP	kerma area product
kerma	kinetic energy released in matter (type of radiation measurement in air)
kV	kilovolts
kVp	kilovolts potential (or kilovolts peak)
LSC	least significant change
mA	milliampere
mAs	milliampere-second
MDCT	multi-row detector computed tomography (multi-detector CT)
MQSA	Mammography Quality Standards Act
mrem	millirem
mSv	millisievert
NCI	National Cancer Institute
NCRP	National Council on Radiation Protection and Measurements
NEMA	National Electrical Manufacturers Association
NEXT	Nationwide Evaluation of X-ray Trends
NIH	National Institutes of Health
OSHA	Occupational Safety and Health Administration
OSL	optically stimulated luminescence
PACS	picture archiving and communication system
PET	positron emission tomography
PSD	peak skin dose
PSP	photostimulable phosphor
QA	quality assurance
QC	quality control
QI	quality improvement
QMP	Qualified Medical Physicist
RCIS	Registered Cardiovascular Invasive Specialists
rem	Traditional radiation unit for equivalent dose (product of absorbed dose [rad] and radiation weighting factor). Subunit is mrem (millirem) or μrem (microrem)
RSO	Radiation Safety Officer
RT(N)	Radiologic Technologist Nuclear qualification
SCAI	Society for Cardiovascular Angiography and Interventions
SPECT	single photon emission computed tomography
SIR	Society of Interventional Radiology
SSD	source-to-skin distance

SSDE	size-specific dose estimate (AAPM 2011b)
Sv	sievert (International System of Units for equivalent dose or effective dose). Subunit is mSv (millisievert) or μSv (microsievert)
TJC	The Joint Commission
TLD	thermoluminescent dosimeter
USPSTF	U.S. Preventive Services Task Force
USN	United States Navy
VA	U.S. Department of Veterans Affairs

GLOSSARY

As needed, the source of the definition is referenced at the end of the definition.

Acceptance test – a test carried out after new equipment has been installed or major modifications have been made to existing equipment, in order to verify compliance with the manufacturer's specifications, contractual specifications and applicable local regulations or equipment standards.

Achievable dose (AD) level – a dose set at approximately the median (50th percentile) of a dose distribution as a target that can be used in conjunction with DRLs as a guide to gauge the success of optimization efforts (ACR-AAPM 2013b; NCRP 2012).

Adequate image – an image that provides the information needed to answer the clinical question at an optimized dose, i.e., the lowest dose possible to produce that image.

Adequate image quality – image quality sufficient for the clinical purpose. Whether the image quality is adequate depends on the modality being used and the clinical question being asked.

ALARA (as low as reasonably achievable) – a principle of radiation protection philosophy that requires that exposures to ionizing radiation be kept as low as reasonably achievable, economic and social factors being taken into account. The protection from radiation exposure is ALARA when the expenditure of further resources would be unwarranted by the reduction in exposure that would be achieved.

Alert value – see dose alert value.

Ancillary personnel – personnel beyond the operational medical staff who provide support services.

Angiography – radiography of vessels after the injection of a radiopaque contrast material; usually requires percutaneous insertion of a radiopaque catheter and positioning under fluoroscopic control (Stedman 2006).

Attenuation – reduction in radiation intensity by interaction with matter, such as by the use of shielding.

Backscatter – a Compton scattering event in which a photon strikes an object and deflects at an angle greater than 90°, i.e., in a direction back toward its source.

Beam indicating device (BID) – a lead lined tube attached to an x-ray tube head through which the primary x-ray beam will travel; used by the operator, especially in a dental setting, to align the beam with the image receptor.

Benefit – the probability or quantifiable likelihood that health will improve or deterioration will be prevented as a result of performing or not performing a medical procedure.

Benefit:risk ratio – a determination (possibly subjective) of the benefit to the patient from undergoing a procedure involving imaging using ionizing radiation compared with the risk to the patient from receiving a radiation dose associated with the consequent imaging. Maximizing the benefit:risk ratio involves balancing the benefit:risk ratio to the patient from an x-ray procedure against that from alternatives (e.g., ultrasound, MRI, or no action).

Bone densitometry – the noninvasive measurement of certain physical characteristics of bone that reflect bone strength (typically reported as bone mineral content or bone mineral density); used for diagnosing osteoporosis, estimating fracture risk, and monitoring changes in bone mineral content.

Caregiver – a family member or other individual who regularly looks after a child or a sick, elderly or disabled person

Collimator – a device used to reduce the cross-sectional area of the useful beam of photons or electrons with an absorbing material.

Computed radiography (CR; also see DR and DDR) – a projection x-ray imaging method in which a cassette houses a sensor plate rather than photographic film. This photo-stimulable phosphor-coated plate captures a latent image when exposed to x-rays and, when processed, releases light that is converted to a digital image.

Computed tomography (CT) – the production of a tomogram by the acquisition and computer processing of x-ray transmission data (NCRP 2000).

Cone – an open-ended device on a dental x-ray machine designed to indicate the direction of the central ray and to serve as a guide in establishing a desired source-to-image receptor distance (NCRP 2000).

Cone Beam Computed Tomography (CBCT) – A digital volume tomography method used in some imaging applications. It employs a two dimensional digital detector array and a cone-shape x-ray beam (instead of fan-shaped) that rotates around the patient to generate a high-resolution, 3D image with high geometric accuracy. Reconstruction algorithms can be used to generate images of any desired plane.

Controlled area –a limited-access area in which the occupational exposure of personnel to radiation is under the supervision of an individual in charge of radiation protection. This implies that access, occupancy and working conditions are controlled for radiation protection purposes (NCRP 2004a).

Credential – diploma, certificate or other evidence of adequate educational performance that gives one a title or credit.

CTDI – computed tomography dose index. The integral of the dose profile along a line perpendicular to the tomographic plane divided by the product of the nominal tomographic section thickness and the number of tomograms produced in a single scan (FDA 2014f). The unit of measure is mGy.

$CTDI_{vol}$ – a radiation dose parameter (in units of mGy) derived from the $CTDI_w$ (weighted or average CTDI given across the field of view), measured with a specific phantom. The formula, modified to work for both axial and helical scans (McNitt-Gray 2002), is:

$CTDI_{vol} = N \cdot T \cdot CTDI_w / I$, where

$CTDI_w$ = weighted or average CTDI given across the field of view

N = number of simultaneous axial or helical sections per x-ray source rotation,

T = nominal thickness of one section (mm), and

I = table increment per axial scan or table travel per rotation for a helical scan (mm).

$CTDI_w$ – weighted or average CTDI given across the field of view.

Cumulative air kerma (also called Reference Air Kerma) – air kerma at a reference point that is selected for reporting purposes and established by regulation (FDA 2014e) or by convention (IEC 2010).

Declared pregnant woman – a woman who is an occupational radiation worker and has voluntarily informed her employer, in writing, of her pregnancy and the estimated date of conception (USNRC 2014b; USNRC 2014c).

Deterministic effects (also called tissue effects) – effects that occur in all individuals who receive greater than the threshold dose and for which the severity of the effect varies with the dose (NCRP 2003).

Diagnosis – the determination of the nature of a disease, injury or congenital defect (Stedman 2006).

Diagnostic reference level – a level used in medical imaging to indicate whether, in routine conditions, the dose to the patient in a specified radiological procedure is unusually high or low for that procedure.

Digital radiography (DR) – an x-ray imaging method (or radiography) which produces a digital rather than film projection image. Includes both CR and DDR.

Direct digital radiography (DDR; also see CR and DR) – an x-ray imaging method in which a digital sensor, rather than photographic film, is used to capture an x-ray image. DDR is a cassette-less imaging method (providing faster acquisition time than cassette-based CR) using an electronic sensor that converts x-rays to electronic signals (charge or current) when exposed to x-rays.

Dose – a measure of the energy deposited by radiation in a target. Used in this report as a generic term unless the context refers to a specific quantity, such as absorbed dose, committed equivalent dose, committed effective dose, effective dose, equivalent dose or organ dose, as indicated by the context. Specific dose terms are listed below.

Air kerma – sum of the kinetic energy released in a small volume of air at a specific point in space during a specified event or time frame when irradiated by an x-ray beam.

Cumulative air kerma – see definition above Cumulative dose – (1) total radiation dose delivered to any specific organ or tissue, (2) term previously used in the clinical literature for cumulative air kerma.

Dose-area product (DAP) – see kerma-area product.

Dose alert value - a value of $CTDI_{vol}$ (in units of mGy) or of DLP (in units of mGy·cm) that is set by the facility to trigger an alert to the operator prior to scanning within an ongoing examination if it would be exceeded by an accumulated dose index on acquisition of the next confirmed protocol element group. An alert value represents a value above which the accumulated dose index value would be well above the institution's established range for the examination that warrants more stringent review and consideration before proceeding. (See dose notification value.)

Dose equivalent – the product of the absorbed dose at a point in the tissue or organ and the appropriate quality factor for the type of radiation giving rise to the dose.

Dose length product (DLP) – an indicator of the integrated radiation dose from a CT sequence or series of CT sequences of the same anatomic area. It addresses the total scan

length by the formula DLP = $CTDI_{vol}$ x scan length, with the units mGy·cm.

Dose notification value – a value of $CTDI_{vol}$ (in units of mGy) or DLP (in units of mGy·cm) that is set by the operating institution to trigger a notification to the operator prior to scanning when exceeded by a corresponding dose index value expected for the selected protocol element. (See dose alert value.)

Dose registry – see registry.

Effective dose (E) (traditionally called effective dose equivalent (H_E)) – the radiation protection quantity used for setting limits that help ensure that stochastic effects (i.e., cancer and genetic effects) are kept within acceptable levels. The SI unit of effective dose is the J kg^{-1}, and is abbreviated H_E. The unit of E and H_T is joule per kilogram ($J \cdot kg^{-1}$), with the special name sievert (Sv). It is numerically equal to a radiation weighting factor (ω_R, also written w_R) multiplied by a tissue weighting factor (ω_T, also written w_T) and the absorbed dose from that radiation in tissue T ($D_{T,R}$) in gray. Identically, it is the equivalent dose multiplied by a tissue weighting factor. 1 Sv = 100 rem (NCRP 2003). (See equivalent dose, tissue weighting factor, gray, rad, rem and sievert.) The formula is:

$$H_E = \sum_T w_T \sum_R w_R D_{T,R} = \sum_T H_T w_T$$

where

H_E = the effective dose (formerly effective dose equivalent) to the entire individual,

w_T = the tissue weighting factor in tissue T,

H_T = the equivalent dose (or dose equivalent),

w_R = the radiation weighting factor, and

$D_{T,R}$ = the absorbed dose to tissue T from radiation type R.

Equivalent dose (H_T) (traditionally called dose equivalent) – the radiation protection quantity used for setting limits that help ensure that deterministic effects (e.g., damage to a particular tissue) are kept within acceptable levels. The SI unit of equivalent dose is the J kg^{-1}, and is abbreviated H_T. The unit for H_T is J kg^{-1}, with the special name sievert (Sv). It is numerically equal to a radiation weighting factor (w_R) [or quality factor (Q)] multiplied by the absorbed dose in tissue T ($D_{T,R}$). 1 Sv = 100 rad (NCRP 2003). (See effective dose, tissue weighting factor, gray, rad, rem and sievert.) The formula is:

$$H_T = \sum_R w_R D_{T,R} \text{ or } \sum_R Q_R D_{T,R}$$

where

w_R = radiation weighting factor,

$D_{T,R}$ = absorbed dose to tissue T from radiation type R, and

Q_R = quality factor.

Kerma-area product (KAP) (also called dose-area product (DAP)) – the product of the air kerma and the area of the irradiated field. It is measured in $Gy \cdot cm^2$. It does not change with distance from the x-ray tube. KAP is a good measure of total energy delivered to the patient, and an indicator of the risk of stochastic effects, but is not a good indicator of the risk of tissue (deterministic) effects.

Reference point dose – see cumulative air kerma.

Skin dose – radiation dose to the dermis.

Dose creep – an increase in exposure that goes unnoticed as there is no optical density reference. This normally does not apply to a decrease in exposure since it would be evident by

increased noise level in images (Seibert and Morin 2011).

Dosimeter – dose measuring device (NCRP 2003).

Electronic Health Record (EHR) – an electronic record of health-related information on an individual that is created, gathered, managed and consulted by authorized health professionals and staff (Congress 2007).

Engineering controls – In the context of radiation protection, these controls focus on the source of the hazard (i.e., ionizing radiation), unlike other types of controls that generally focus on the employee exposed to the hazard. The basic concept behind engineering controls is that, to the extent feasible, the work environment and the job itself should be designed to eliminate hazards or reduce exposure to hazards. While this approach is called engineering control, it does not necessarily mean that an engineer is required to design the control (OSHA 2014b).

Exposure – in this report, exposure is used most often in its general sense, meaning to be irradiated. When used as the specifically defined radiation quantity, exposure is a measure of the ionization produced in air by x or gamma radiation. The unit of exposure is coulomb per kilogram (C kg^{-1}). The special unit for exposure is roentgen (R), where 1 R = 2.58×10^{-4} C kg^{-1}.

Exposure categories:

Medical exposure – exposure incurred by patients for the purpose of medical or dental diagnosis or treatment; by caregivers associated with medical, dental and veterinary procedures; and by volunteers in a program of biomedical research involving their exposure as research subjects.

Occupational exposure – exposure of workers incurred in the course of their work.

Public exposure – exposure incurred by members of the public from sources in planned exposure situations, emergency exposure situations, and existing exposure situations, including incidental medical exposure, but excluding any occupational or prescribed medical exposure.

Exposure index (EI) – a dimensionless quantity equal to 100 times the image receptor air kerma (in μGy) under the calibration conditions (K_{cal}) (IEC 2008). EI = $100xK_{cal.}$

Federal facility – a facility that is owned, leased or operated by the federal government. The guidelines do not specifically apply to federally funded research protocols conducted in any other type facility that is part of local, state, tribal, territorial or other entities, even if federally funded. However, such facilities are encouraged to use this guidance.

Film/film radiograph – film is a thin, transparent sheet of polyester or similar material coated on one or both sides with an emulsion sensitive to radiation and light; a radiograph is a film or other record produced by the action of x-rays on a sensitized surface (NCRP 2003).

Filtration – material in the useful beam that usually absorbs preferentially the less penetrating radiation (NCRP 2003).

Fluoroscopy – the process of producing a real-time image using x-rays (NCRP 2003).

Gamma ray – a photon emitted in the process of nuclear transition or radioactive decay.

Gray (Gy) – the special SI name for the unit of the quantities absorbed dose and air kerma.

1 Gy = 1 J kg^{-1} (see rad, rem, gray and sievert).

Guidance level – optimal range of detector exposure index values that should be based on patient body habitus, anatomical view, clinical question and other relevant factors.

Health physics – the field of science concerned with radiation physics and radiation biology and their application to radiation protection. Health physicists may specialize in nuclear power, environmental and waste management, laws and regulations, dosimetry, emergency response, medicine or a host of other sub-specialties where radiation is utilized. Of particular interest for this document is the medical health physics sub-specialty.

Health physicist – a health professional with education and specialist training in the concepts and techniques of applying physics in medical, environmental or occupational settings, or competent to practice independently in one or more of the subfield specialties of medical physics or in health physics.

Health professional – an individual who has been formally recognized through appropriate national procedures to practice a profession related to health (e.g., medicine, dentistry, chiropractic, podiatry, nursing, veterinary medicine) (adapted from (IAEA 2011a)).

Helical – spiral in form; a curve traced on a cylinder (or human body) by the rotation of a point crossing its right section at a constant oblique angle.

Image – representation of an object produced by machine-produced ionizing radiation.

Image receptor – a system for deriving a diagnostically usable image from the x-rays transmitted through the patient (NCRP 2003).

Imaging referral guidelines – evidence-based guidelines that are intended to assist Referring Medical Practitioners in selecting the most appropriate imaging examination for a specific clinical condition in a specific patient. Imaging referral guidelines are an important tool for justification of imaging procedures.

Incidental exposure – exposure not associated with the primary purpose for which it was delivered.

Informed consent – voluntary agreement given by a person or that person's legally authorized representative (DHHS 2013b) (e.g., a parent) for participation in a study, immunization program, treatment regimen, invasive procedure, etc., after being informed of the purpose, methods, procedures, benefits and risks. The essential criteria of informed consent are that the subject has both knowledge and comprehension, that consent is freely given without duress or undue influence and that the right of withdrawal at any time is clearly communicated to the patient. Other aspects of informed consent in the context of epidemiologic and biomedical research, and criteria to be met in obtaining it, are specified in International Guidelines for Ethical Review of Epidemiologic Studies (Chanaud 2008; CIOMS/WHO 2009) and International Ethical Guidelines for Biomedical Research Involving Human Subjects (CIOMS/WHO 2002).

Intensifying screen – a device consisting of fluorescent material, which is placed in contact with the film in a radiographic cassette. Radiation interacts with the fluorescent material, releasing light photons. (adapted from (NCRP 2003)).

Interlock – device that automatically shuts off or reduces the radiation emission rate from a radiation producing device to acceptable levels (e.g., by the opening of a door into a radiation area). In certain applications, an interlock can be used to prevent entry into a treatment room.

Intraoral image – image produced on an image receptor placed intraorally (inside the mouth) and lingually or palatally to the teeth (adapted from (NCRP 2003)).

Intervention – any measure taken to alter the course of medical diagnosis whose purpose is to improve a health outcome.

Isocenter – the small point in space (or generally spherical or elliptical volume) where the central axes of radiation beams emitted during the rotational swing of an x-ray tube gantry intersect.

Justification – the process of determining for a planned exposure situation whether a practice is, overall, beneficial, i.e., whether the expected benefits to individuals and to society from introducing or continuing the practice outweigh the harm (including radiation detriment) resulting from the practice (IAEA 2011a).

Kerma (kinetic energy released per unit mass, or kinetic energy released in matter) – the sum of the initial kinetic energies of all the charged particles liberated by uncharged particles (e.g., x-rays) in a material of mass δm (IAEA 2011a). The unit for kerma is $J \cdot kg^{-1}$, with the special name gray (Gy). Kerma can be quoted for any specified material at a point in free space or in an absorbing medium (e.g., air kerma).

Kerma-area product (KAP, also called dose-area product or DAP) – the product of the air kerma and the area of the irradiated field, measured in $Gy \cdot cm^2$. It does not change with distance from the x-ray tube. KAP is a good measure of total energy delivered to the patient, and an indicator of the risk of stochastic effects, but is not a good indicator of the risk of tissue (deterministic) effects.

Licensed independent practitioner – any individual permitted by law and by the organization to provide care and services, without direction or supervision, within the scope of the individual's license and consistent with individually granted clinical privileges (see Referring Medical Practitioner and Radiological Medical Practitioner).

Mammography – the use of x-rays to produce a diagnostic image of the breast.

Medical exposure – exposure incurred by patients for the purposes of medical or dental diagnosis or treatment; by carers and comforters (caregivers); and by volunteers subject to exposure as part of a program of biomedical research (IAEA 2011a).

Medical health physics – the profession dedicated to the protection of healthcare providers, members of the public and patients from unwarranted radiation exposure. Medical health physicists are knowledgeable in the principles of health physics and in the applications of radiation in medicine. While medical physics and medical health physics have a number of similarities and overlapping fields of study and interest, the emphasis of practice or day-to-day routines may be different.

Medical physics – an applied branch of physics concerned with the application of the concepts of physics to the diagnosis and treatment of human disease. It is allied with medical electronics, bioengineering and health physics. The Medical Physicist's clinical practice focuses on methods to assure the safe and effective delivery of radiation to achieve a diagnostic or therapeutic result as prescribed in patient care.

Medical physicist – a health professional with education and specialist training in the concepts and techniques of applying physics in medicine, competent to practice independently in one or more of the subfield specialties of medical physics (IAEA 2011a).

Medical radiologic technologist (MRT) – a health professional with specialist education and training in medical radiation technology, competent to carry out radiological procedures, on delegation from the Radiological Medical Practitioner, in one or more of the specialties of medical radiation technology (IAEA 2011a).

Members of the public – all persons who are not already considered occupationally exposed by a source or practice under consideration. When being irradiated as a result of medical care, patients are a separate category.

Notification Value – see dose notification value.

Occupational exposure – exposure to an individual that is incurred in the workplace as a result of situations that can reasonably be regarded as being the responsibility of management (exposures associated with medical diagnosis or treatment of the individual are excluded) (NCRP 2003).

Optically stimulated luminescent (OSL) dosimeter – a dosimeter containing a crystalline solid for measuring radiation dose, plus filters to help characterize the types of radiation encountered. When irradiated with intense light, OSL crystals that have been exposed to ionizing radiation give off light proportional to the energy they receive from the radiation (NCRP 2003).

Optimal dose – the minimum radiation dose required to be delivered by an x-ray imaging system to produce an image that is of adequate quality for the intended purpose. This requires that the x-ray generator and imaging equipment are working appropriately. (See adequate image.)

Optimization of protection – the process of determining what level of protection and safety would result in the magnitude of individual doses, the number of individuals (workers and members of the public) subject to exposure and the likelihood of exposure being "as low as reasonably achievable, economic and social factors being taken into account" (ALARA) (as required by the System of Radiological Protection). For medical exposures of patients, the optimization of protection and safety is the management of the radiation dose to the patient commensurate with the medical purpose. "Optimization of protection and safety" means that optimization of protection and safety has been applied and the result of that process has been implemented (IAEA 2011a).

Peak skin dose – the maximum absorbed dose to the most heavily irradiated localized region of skin (i.e., the localized region of skin that lies within the primary x-ray beam for the longest period of time during a fluoroscopically guided procedure). PSD is measured in units of Gy (ICRP 2013a).

Personal protective equipment – specialized clothing or equipment (e.g., lead or lead equivalent radiation protection apron, gloves, thyroid collar, eyeglasses) worn by an employee to protect against a hazard. General work clothes not intended to serve as a protection against a hazard are not considered to be personal protective equipment.

Phantom – as used in this report, a volume of tissue- or water-equivalent material used to simulate the absorption and scattering characteristics of the patient's body or portion thereof.

Picture archiving and communications system (PACS) – electronic system for the archival storage and transfer of information associated with x-ray images.

Pitch – in CT, table incrementation per x-ray tube rotation divided by the nominal x-ray beam width at isocenter.

Potentially-high radiation dose procedure – a procedure for which more than 5% of cases of that procedure result in a cumulative air kerma exceeding 3 Gy or a kerma area product exceeding 300 Gy·cm^2 (NCRP 2010).

Prescribe – the process of requesting or ordering an exam to be performed, or the process of determining how an exam should be done in order to optimize the choice of study and protocol, and optimize the radiation dose.

Protocol – selected parameters for image acquisition that define the portion of the patient's anatomy to be imaged, whether and how contrast agents will be administered, the number and timing of imaging sequences, and acquisition technical parameters (pitch, collimation or beam width, kV, mA (constant or modulated and specifying the parameters determining the balance between image noise and patient dose), rotation time, physiologic gating, image quality factors, and reconstruction method.

Pulsed (as in pulsed fluoroscopy) – x-rays not produced continuously, but in rapid succession as pulses. Reduces dose by using a lower pulse rate (e.g., 15 or 7.5 pulses/sec) in conjunction with digital image memory to provide a continuous video display.

Qualified expert – for radiation protection, a person having the knowledge and training to measure ionizing radiation, to evaluate safety techniques, and to advise regarding radiation protection needs (e.g., persons certified in an appropriate field by the American Board of Radiology, or the American Board of Health Physics, or the American Board of Nuclear Medicine Science or persons otherwise determined to have equivalent qualifications). For diagnostic x-ray performance evaluations, a person having, in addition to the qualifications above, training and experience in the physics of diagnostic radiology (for example, persons certified in Radiological Physics, X Ray and Radium Physics or Diagnostic Radiological Physics by the American Board of Radiology or persons determined to have equivalent qualifications) (NCRP 1989b).

Qualified Medical Physicist (QMP) – an individual who is competent to practice independently in the relevant subfield of medical physics. For the purposes of this document, the relevant subfield is diagnostic radiological physics or medical health physics. Certification and continuing education and experience in the relevant subfield is one way to demonstrate that an individual is competent to practice in that subfield of medical physics and to be a QMP. Due to their unique mission requirements, the uniformed services may need to develop their own criteria for determining when a physicist is a "Qualified Medical Physicist" as defined in this document (http://www.aapm.org/medical_physicist/fields.asp).

Quality assurance – the function of a management system that provides confidence that specified requirements will be fulfilled. In medical imaging, quality assurance refers to those steps that are taken to make sure that a facility consistently produces images that are adequate for the purpose with optimal patient exposure and minimal operator exposure. It includes those organizational steps taken to make sure that testing techniques are properly performed and that the results of tests are used to effectively maintain a consistently high level of image

quality. An effective program includes assigning personnel to determine optimum testing frequency of the imaging devices, evaluate test results, schedule corrective action, provide training and perform ongoing evaluation and revision of the program.

Quality control – in medical imaging, quality control comprises the procedures used for the routine physical testing of the components of the imaging chain from x-ray production, through the viewing of images.

Quality improvement – in medical imaging, quality improvement is the use of quantitative and qualitative methods to improve the safety, effectiveness and efficiency of health care delivery processes and systems.

Rad – the special (traditional or historical) name for the unit of absorbed dose. 1 rad = 0.01 $J \cdot kg^{-1}$. In the SI system of units, it is replaced by the special name gray (Gy). 1 Gy = 100 rad (NCRP 2000). (See rad, rem, gray and sievert.)

Radiation medical event – a medical event which indicates that a facility had technical or quality assurance problems in administering the physician's orders. There is no scientific basis to conclude that such a medical event necessarily results in harm to the patient. These events indicate a potential problem in a medical facility's use of radiation (CRCPD 2014).

Radiation safety committee – a committee composed of such persons as a radiological safety officer, a representative of management and persons trained and experienced in the safe use of radioactive materials, as required for each license to possess radioactive material.

Radiation Safety Officer – the individual whose responsibility it is to ensure adequate protection of workers and the public from exposure to ionizing radiation.

Radiation weighting factor, w_R – a number (as specified in the System for Radiological Protection) by which the absorbed dose in a tissue or organ is multiplied to reflect the relative biological effectiveness of the radiation in inducing stochastic effects at low doses, the result being the equivalent dose (IAEA 2011a).

Radiation worker – see worker.

Radiography – the production of images on film or other record by the action of x-rays transmitted through the patient (NCRP 2003).

Radiological Medical Practitioner – a health professional with specialist education and training in the medical (also dental or veterinary) uses of radiation who is competent to perform independently or to oversee procedures involving medical exposure in a given specialty (IAEA 2011a) (see licensed independent practitioner).

Reference level – see diagnostic reference level.

Referring Medical Practitioner – a health professional who, in accordance with national requirements, may refer individuals to a radiological medical practitioner for medical exposure (IAEA 2011a), e.g., physicians, dentists, podiatrists, chiropractors, nurse practitioners, physician assistants (see licensed independent practitioner).

Registry – central national repository for patient radiation dose and equipment parameter data.

Rem – the special (traditional or historical) name for the unit of dose equivalent numerically equal to the absorbed dose (D) in rad, modified by a quality factor (Q). 1 rem = 0.01 J kg^{-1}. In

the SI system of units, it is replaced by the special name sievert (Sv), which is numerically equal to the absorbed dose (D) in gray modified by a radiation weighting factor (ω_R). 1 Sv = 100 rem (NCRP 2003). (see rad, rem, gray, and sievert).

Research – a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this document, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities. "Research subject to regulation," and similar terms are intended to encompass those research activities for which a federal department or agency has specific responsibility for regulating as a research activity, (e.g., Investigational New Drug and Investigational Device Exemption requirements administered by the Food and Drug Administration). It does not include research activities which are incidentally regulated by a federal department or agency solely as part of the department's or agency's broader responsibility to regulate certain types of activities whether research or non-research in nature (e.g., Wage and Hour requirements administered by the Department of Labor). (DHHS 2013a).

Resolution – see "spatial resolution (NCRP 2003).

Risk – the probability or quantifiable likelihood that a detriment to health will occur as a result of performing or not performing a medical procedure.

Roentgen – the special name for exposure, which is a specific quantity of ionization (charge) produced by the absorption of x- or gamma-radiation energy in a specified mass of air under standard conditions. 1 R = 2.58 x 10^{-4} coulombs per kilogram (C kg^{-1}) (NCRP 2003).

Screening – the evaluation of an asymptomatic person in a population to detect a disease process not known to be present at the time of evaluation.

Sievert (Sv) – The SI unit for both equivalent dose and effective dose is the J kg^{-1}, and the special SI name is the sievert (Sv). For equivalent dose, 1 Sv = 100 rad. For effective dose, 1 Sv = 100 rem. (See effective dose, equivalent dose, tissue weighting factor, gray, rad, rem.)

Signal-to-noise ratio – the ratio of input signal to background interference. The greater the ratio, the clearer the image (NCRP 2003).

Size-specific dose estimate (SSDE) – a patient dose estimate which takes into consideration corrections based on the size of the patient, using linear dimensions measured on the patient or patient images (AAPM 2011c).

Skin dose – radiation dose to the dermis, measured for example as entrance skin dose or peak skin dose.

Slice – a 2-dimensional reconstructed cross-sectional image depicting a patient's anatomy produced using x-rays, MRI, ultrasound, or other non-invasive means.

Spatial resolution – in the context of an imaging system, the output of which is finally viewed by the eye, it refers to the smallest size or highest spatial frequency of an object of given contrast that is just perceptible. The resolution actually achieved with imaging lower contrast objects is normally much less, and depends upon many variables such as subject contrast levels and noise of the overall imaging system (NCRP 2003).

Step wedge – a device with various thicknesses of aluminum used to verify the consistency of the x-ray and film processing systems. Typically each step of the step wedge is about 1 mm thick and about 3 to 4 mm wide with at least 6 steps. The device is placed on a film cassette and exposed under the exact same exposure parameters and geometry set up. The film is then developed and the steps are visually compared to the reference film identically exposed and processed in fresh solutions under ideal conditions. A reproducible change of one step or more in density should signal the need for corrective action.

Stochastic effects – effects, the probability of which, rather than their severity, is a function of radiation dose, implying the absence of a threshold. More generally, stochastic means random in nature (NCRP 2003).

Structured report – information, such as the clinical report of an imaging procedure, communicated using standardized content and definitions in a coherent, clinically relevant and predictable format.

Substantial Radiation Dose Level – An appropriately-selected reference value used to trigger additional dose-management actions during a procedure and medical follow-up for a radiation level that might produce a clinically-relevant injury in an average patient. There is no implication that radiation levels above an SRDL will always cause an injury or that radiation levels below an SRDL will never cause an injury. The quantities and their SRDLs recommended by NCRP are provided in Table 4.7 of NCRP Report No. 168 (NCRP 2010).

Supervision, general – means the procedure is furnished under the supervising individual's overall direction and control, but the supervising individual's presence is not required during the performance of the procedure. Under general supervision, the training of the personnel who actually perform the task and the maintenance of the necessary equipment and supplies are the continuing responsibility of the supervising individual (adapted from (DHHS 2012a)).

Supervision, direct – means the supervising individual must be present in the local area (for physicians, in the office suite) and immediately available to furnish assistance and direction throughout the performance of the procedure. It does not mean that the supervising individual must be present in the room when the task is performed (adapted from (DHHS 2012a)).

Supervision, personal – means the supervising individual must be in attendance in the room during the performance of the task (adapted from (DHHS 2012a)).

Technique factor – operator selectable parameter affecting the x-ray beam (e.g., kV, mA, time).

Tissue weighting factor, w_T – multiplier of the equivalent dose to an organ or tissue, as given by the System for Radiological Protection, used for radiation protection purposes to account for the different sensitivities of different organs and tissues to the induction of stochastic effects of radiation (IAEA 2011a).

Tomography – a special technique to show in detail images of structures lying in a predetermined plane of tissue, while blurring or eliminating detail in images of structures in other planes (NCRP 2003).

Uncontrolled area – for radiation protection purposes, any space not meeting the definition of controlled area (NCRP 2004a).

Universal Protocol – The Joint Commission's process, developed to address wrong site, wrong procedure, and wrong person surgeries and other procedures. The three principal components

of the Universal Protocol include a pre-procedure verification, site marking, and a timeout (The Joint Commission 2012a; The Joint Commission 2012b).

Unrestricted area – an area, access to which is neither limited nor controlled by the (facility) (USNRC 2014b).

Worker (i.e., radiation worker) – any person who works, whether full time, part time or temporarily, for an employer and who has recognized rights and duties in relation to occupational radiation protection (IAEA 2011a).

APPENDIX A – NIH INFORMED CONSENT TEMPLATES

The guidance in this appendix is suitable for research involving diagnostic and interventional x-ray procedures. It applies to radiation use indicated for research involving human subjects. It excludes radiation oncology research, in which radiation doses to subjects may be much higher. A discussion of human subjects research ethics, patient benefit:risk considerations and the role of Institutional Review Boards is beyond the scope of this document, but is an essential process prior to the conduct of research involving human subjects.

The risk from research protocols involving radiation use indicated for research, as described above, can be categorized into groups. A useful approach is to group risk as minimal, minor to intermediate, or moderate. The templates on the following pages are adapted from those used by the NIH in 2012 (less than 1 mSv (100 mrem) "minimal" and 1-50 mSv (100 mrem – 5 rem) "minor to intermediate"). Doses above 50 mSv (5 rem) may be considered to range from moderate to substantial. The specific ranges and text may be adjusted as required by the specific IRB (NIH 2001; NIH 2008a; NIH 2008b; NIH 2010). Another approach to selecting the dose ranges and descriptors for these templates is shown below.

Classification schemes for use of E
as a qualitative indicator of stochastic risk
for diagnostic and interventional x-ray procedures

Range of E (mSv)	Radiation Risk Descriptor			Expected Minimum Individual or Societal Benefit
	ICRP Publication 62[1] (ICRP 1991b)	Martin[1] (Martin 2007)	NCRP Report No. 168 (NCRP 2010)	
<0.1	Trivial	Negligible	Negligible	Describable
0.1-1	Minor	Minimal	Minimal	Minor
1-10	Intermediate	Very low	Minor	Moderate
10-100	Moderate	Low	Low	Substantial
>100	-	-	Acceptable (in context of the expected benefit)	Justifiable expectation of very substantial individual benefit

Table adapted from NCRP Report No. 168 (NCRP 2010)
[1] These columns are provided as historical comparisons (ICRP 1991b; Martin 2007).

NEGLIGABLE TO MINIMAL RISK
Adapted from NIH TEMPLATE A *(Total effective dose less than or equal to 1 mSv (100 mrem))*

This research study involves exposure to radiation from (*insert type of procedure or procedures*). Please note that this radiation exposure is **not** necessary for your medical care and is for research purposes only.

The total amount of radiation you will receive in this study is from (*insert maximum number*) of (*insert description of type of x-ray procedure*). The Radiation Safety Committee has reviewed the use of radiation in this research study and has approved this use as involving ***minimal*** risk and necessary to obtain the research information desired.

You will receive a total of (*XX) mSv or (YY)* rem to your *(insert highest-dosed organ, typically skin)* from participating in this study. All other parts of your body will receive smaller amounts of radiation. Although each organ will receive a different dose, the amount of radiation exposure you will receive from this study is equal to a uniform whole-body exposure of less than (*insert total effective dose value*). This calculated value is known as the "effective dose" and is used to relate the dose received by each organ to a single value.

For comparison, the average person in the United States receives a radiation dose of 3 mSv (300 mrem) per year from natural background sources, such as from the sun, outer space and from radioactivity found naturally in the earth's air and soil. The dose that you will receive from participation in this research study is about the same amount you would normally receive in *(insert number)* months from these natural sources.

While there is no direct evidence that the small radiation dose received from participating in this study is harmful, there is not sufficient evidence to guarantee that it is completely safe. There may be an extremely small increase in the risk of cancer.

MINOR TO LOW RISK
Adapted from NIH TEMPLATE B (*1 mSv < Total effective dose = < 50 mSv*) or *(100 mrem < Total effective dose = < 5 rem)*

This research study involves exposure to radiation from (*insert type of procedure or procedures*). Please note that this radiation exposure is **not** necessary for your medical care and is for research purposes only.

The total amount of radiation you will receive in this study is from (*insert maximum number*) (*scans or repetitions*) of (*insert description of type of x-ray procedure*). The Radiation Safety Committee has reviewed the use of radiation in this research study and has approved this use as involving ***low risk (more than minimal but less than moderate)*** and necessary to obtain the research information desired.

Although each organ will receive a different dose, the amount of radiation exposure you will receive from this study is equal to a uniform whole-body exposure of less than (*insert total effective dose value*). This calculated value is known as the "effective dose" and is used to relate the dose received by each organ to a single value. The amount of radiation you will receive in this study is less than the annual radiation dose of 50 mSv per year (5 rem per year) permitted for someone who works with radiation on a daily basis.

For comparison, the average person in the United States receives a radiation dose of 3 mSv (300 mrem) per year from natural background sources, such as from the sun, outer space and from radioactivity found naturally in the earth's air and soil. The dose that you will receive from participation in this research study is about the same amount you would normally receive in *(insert number)* months from these natural sources.

The effects of radiation exposure on humans have been studied for over 60 years. In fact, these studies are the most extensive ever done of any potentially harmful agent that could affect humans. In all these studies, no harmful effect to humans has been observed from the levels of radiation you will receive by taking part in this research study. However, scientists disagree on whether radiation doses at these levels are harmful. Even though no effects have been observed, some scientists believe that radiation can be harmful at any dose - even low doses such as those received during this research.

While there is no direct evidence that the radiation dose received from participating in this study is harmful, there is indirect evidence it may not be completely safe. There may be a small increase in the risk of cancer.

(INCLUSION OF THIS PARAGRAPH IS OPTIONAL) Some people may be concerned that radiation exposure may have an effect on fertility or cause harm to future children. The radiation dose you will receive in this research study is well below the level that affects fertility. In addition, radiation has never been shown to cause harm to the future children of individuals who have been exposed to radiation. Harm to future generations has been found only in experiments on animals that have received radiation doses much higher than the amount you will receive in this study

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NOTE: References are current as of the 2014 publication date, and some may be updated or superseded in the future. The reader is encouraged to consult the publisher of any cited document to determine the most current version.

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