

REFERENCE LEVELS AND ACHIEVABLE DOSES IN MEDICAL AND DENTAL IMAGING: RECOMMENDATIONS FOR THE UNITED STATES



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Reference Levels and Achievable Doses in Medical and Dental Imaging: Recommendations for the United States

**Recommendations of the
NATIONAL COUNCIL ON RADIATION
PROTECTION AND MEASUREMENTS**

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[For detailed information on the availability of NCRP publications see page 122.]

Preface

The National Council on Radiation Protection and Measurements (NCRP) has a continuing interest in the operational safety and radiation protection of patients and medical staff in radiological diagnostic and therapeutic practices. Since 2000 NCRP issued Report No. 133 on *Radiation Protection for Procedures Performed Outside the Radiology Department* (2000); Report No. 147, *Structural Shielding Design for Medical X-Ray Imaging Facilities* (2004); Report No. 151, *Structural Shielding Design and Evaluation for Megavoltage X- and Gamma-Ray Radiotherapy Facilities* (2005); Report No. 155 on *Management of Radionuclide Therapy Patients* (2006); and Report No. 168 on *Radiation Dose Management for Fluoroscopically-Guided Interventional Medical Procedures* (2010). In addition, NCRP reports have been published on specialized topics related to radiation protection in medical procedures, including Report No. 140 on *Exposure Criteria for Medical Diagnostic Ultrasound: II. Criteria Based on All Known Mechanisms* (2002) and Report No. 145 on *Radiation Protection in Dentistry* (2003).

This Report represents an important addition to the existing series of NCRP reports on radiation safety and health protection in medicine. At the present time there are no consistent guidelines in the United States on the optimal radiation doses for diagnostic medical procedures. Other nations, including those in the European Union, have adopted a consistent set of data for guidance and management of radiation dose in medical imaging procedures. Diagnostic reference levels also should be adopted in the United States. This Report provides dosimetric data in a standardized format and the scientific basis supporting its use.

Diagnostic reference levels and achievable doses are dynamic values changing over time and with changes in technology. It is the responsibility of the professional medical imaging organizations, in cooperation with NCRP, to update these values as appropriate.

This Report is directed at medical imaging physicians, medical physicists, and staff working in medical imaging facilities using ionizing radiation. This Report was prepared by NCRP Scientific Committee (SC) 4-3 on Diagnostic Reference Levels and Achievable Doses, and Reference Levels in Medical Imaging: Recommendations for Applications in the United States. Serving on SC 4-3 were:

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John D. Boice, Jr.
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1. Executive Summary

Diagnostic reference levels (DRLs), which are a form of investigation levels (ICRP, 1996), represent an important tool to optimize image quality and the radiation dose delivered to patients. The goal is to manage the dose to the patient to be commensurate with the medical purpose. By surveying the radiation doses associated with imaging examinations throughout the country, DRLs can be established (typically at the 75th percentile of the distribution), based on actual practice patterns. However, the survey data must be robust and representative of the practice (*i.e.*, statistically valid). It should be noted that radiation doses may be either too high or too low with regard to the image quality desired. Too low a dose, for example, may result in an inadequate image. Consequently, it will be necessary to consider both image quality and patient dose since if the image quality does not provide the necessary clinical information the patient has been exposed needlessly to radiation. In fact, the consequence of poor image quality goes beyond the radiation dose to the patient—a false negative diagnosis may lead to a negative impact in terms of patient care.

DRLs provide the first step in the optimization process. However, to encourage optimization for the 75 % of facilities below the DRL, an achievable dose is provided.

Achievable doses represent the median (50th percentile) of the dose distribution which means that 50 % of the facilities are operating below this level already. DRLs and achievable doses have been used by the Health Protection Agency (HPA) (formerly the National Radiological Protection Board) in the United Kingdom for more than 20 y. Over this period of time HPA observed a 55 % reduction in the 75th percentile dose (Hart *et al.*, 2007). This Report from the National Council on Radiation Protection and Measurements (NCRP) includes recommended achievable doses where sufficient data are available.

Image quality and patient dose, both appropriate for the clinical goals, are essential. There is a possibility that facilities with low radiation doses may have inadequate image quality (*e.g.*, noise levels may too high) which could reduce the clinical effectiveness of the examination. Hence, low radiation dose images could be detrimental to patient care. Likewise, facilities with high radiation doses must also ensure that their image quality is appropriate for

the clinical task. Optimization in medical imaging is the process of achieving the appropriate balance between clinical image quality (*i.e.*, clinical effectiveness) and patient radiation dose. Optimization is essential to ensure that benefit of the x-ray examination significantly outweighs the potential risk from the radiation exposure. (Note: Clinical effectiveness or utility is of utmost importance but cannot be measured or quantified easily. Consequently, image quality is used as a surrogate for clinical effectiveness.)

Optimization requires a team with expertise in various areas. This team, often called the *clinical dose optimization team* (CDOT), should include imaging physicians (*i.e.*, radiologists, cardiologists, interventional specialists, and orthopedic specialists), a qualified medical physicist, radiographic technologists, as well as staff from other disciplines involved in medical imaging. It is the responsibility of the CDOT to review image quality, patient radiation doses, procedures, and imaging protocols and compare these to published national values. Whenever an institution's patient doses exceed DRLs or the image quality is not appropriate for the clinical examination, optimization is required.

In the United States, the most robust and representative survey data for ionizing radiation doses from medical imaging are provided by the Nationwide Evaluation of X-Ray Trends (NEXT) Program. The NEXT Program, started in the 1970s, is a cooperative effort of the U.S. Food and Drug Administration (FDA) and state radiation control offices through the Conference of Radiation Control Program Directors, Inc. (CRCPD), with additional funding provided by the American College of Radiology (ACR). Selected medical x-ray imaging examinations are evaluated periodically at randomly selected clinical imaging facilities. FDA is responsible for survey design, selection of the facilities, and publication of statistical summaries. The state radiation control program staff conducts the site visits, gathering comprehensive data on patient workloads, equipment inventory and features, and aspects of quality control and quality assurance. Surveyors also make measurements of radiation output from the imaging unit for selected examination using patient-equivalent phantoms and the routine clinical x-ray technique factors used by the facility. A similarly robust repository of comparable human dose data is not available in the United States. Consequently, this Report uses exclusively phantom-based survey data. The associated DRLs for radiography, fluoroscopy, and computed tomography (CT) are based on these data.

The use of phantoms for dose measurement [*e.g.*, incident air kerma for radiography and computed tomography dose index (CTDI) for CT] is advantageous for several reasons. Their use:

- eliminates the laborious alternative of collecting large amounts of data from patient examinations;
- standardizes the data collection process for multiple facilities;
- provides a means for facilities to implement their own data collection process for comparison to survey results as part of a dose management program; and
- permits the observation of trends in clinical practice over time as surveys are repeated in response to changes in clinical practice and technology.

Other, more recent survey data for CT doses have been made available through ACR's CT accreditation process. While these data are also based on phantom measurements, they suffer from a possible bias associated with the nature of accreditation programs. Sites seeking accreditation may have higher standards or may artificially lower their doses to comply with the accreditation standards. Thus, measured doses through the accreditation process may reflect temporary or recent adjustments to radiation dose and may not reflect true practice patterns across the United States.

The most recent NEXT survey for CT was performed in 2005 and 2006. The survey was comprised of 267 sites across 31 states. Given the depth of the data that were collected and the relatively limited resources for its analysis, the survey data from 2005 and 2006 are still being analyzed (FDA, 2010a). This Report is based on a subsample of 40 clinical sites randomly selected from the entire survey population.

Reference levels (RLs) are similar to DRLs in concept except that these are provided for other than diagnostic x-ray examinations (*e.g.*, interventional). RLs are derived directly from fluoroscopically-guided interventional (FGI) procedures, thus including factors such as equipment variation, skill of the interventionalist, complexity of the procedure and that of the examination including patient variables.

RLs for FGI procedures pose a unique challenge as compared with DRLs for diagnostic imaging procedures. Although DRLs in this Report are based on measurements with standardized phantoms, RLs for FGI procedures rely on patient-based data. Many factors confound determining RLs including the size (thickness) and clinical condition of the patient, the skill of the operating team, and the equipment used to perform the procedure. In 2003, the Radiation Doses in Interventional Radiology Procedures (RAD-IR) Study documented the radiation doses resulting from various FGI procedures throughout the United States (Miller *et al.*, 2003a;

2003b). Specifically, RLs were determined for 26 separate FGI procedures. This Report also provides guidance as to how RLs and substantial radiation dose levels (SRDLs) might be used in FGI procedures to guide process improvement efforts. As detailed in NCRP Report No. 168 (NCRP, 2010), SRDLs are values below which tissue reactions (deterministic effects) are highly unlikely and above which such injuries are possible.

Nuclear medicine procedures pose an additional challenge for establishing DRLs. Limited nuclear medicine survey data are available for the United States. Consequently, a survey¹ was performed of administered activities for nuclear medicine procedures throughout the United States. A range of administered activities was reported and compared to previously established minimum and maximum values recommended by the International Commission on Radiological Protection (ICRP, 1988). The results of the survey correspond well with ICRP published guidelines.

DRLs and achievable doses, and RLs are dynamic values changing over time and with changes in technology. NCRP examined the U.S. data reported by numerous groups and recognized that these various groups often used slightly different methods to gather and calculate the guidance values which are summarized in this Report. In some cases the data source is a sample of consecutive cases at an institution; at others it is a set of nonconsecutive measurements. Also, in some cases the 75th percentile is calculated using 30 cases, in others it is calculated using far more values. The method for defining procedures also lacks standardization. In other words, the data sources and measurement procedures are not standardized, and the methods are changing rapidly. Consequently, in the next 3 to 5 y it is incumbent on the professional societies, in cooperation with NCRP and others, to review the methodology used in determining guidance levels, standardize these methods wherever possible, select additional imaging examinations for analysis, update reported values, and add new values for the expanded array of procedures. This interval, while arbitrary, reflects a compromise between the pace of innovation and the available resources.

In summary, DRLs and achievable doses, and RLs pose a unique opportunity for medical imaging practitioners in the United States to optimize examination techniques with reductions in radiation dose while maintaining or improving image quality. The DRLs, achievable doses, and RLs are summarized in Tables 6.16, 6.17, and 7.1. Phantom-based survey data for radiography, fluoroscopy,

¹Bushberg, J.T. (2010). Personal communication (University of California, Davis, Sacramento, California).

and CT were used due to their availability and reproducibility. Patient-based dose data for FGI procedures were used due to the complexity of patient-related factors that influence the accumulative radiation dose for specific FGI procedures. For nuclear medicine, a recently conducted survey of administered activities was performed to document practice patterns within the United States for nuclear medicine imaging procedures. This Report concludes with recommended DRLs and achievable doses for selected radiological imaging examinations.

2. Introduction

2.1 Historical Background

2.1.1 *Diagnostic Reference Levels and Reference Levels*

ICRP introduced the concept of DRLs in Publication 60 (ICRP, 1991), and subsequently recommended their use in Publication No. 73 (ICRP, 1996). ICRP Publication No. 73 states:

“The Commission now recommends the use of diagnostic reference levels for patients. These levels, which are a form of investigation level, apply to an easily measured quantity, usually absorbed dose in air, or in a tissue-equivalent material at the surface of a simple phantom or representative patient. In nuclear medicine, the quantity will usually be the administered activity. In both cases, the diagnostic reference level will be intended for use as a simple test for identifying situations where the levels of patient dose or administered activity are unusually high. If it is found that procedures are consistently causing the relevant diagnostic reference level to be exceeded, there should be a local review of the procedures and the equipment in order to determine whether the protection has been adequately optimized. If not, measures aimed at reduction of the doses should be taken.”

Additional advice on DRLs was provided by ICRP (2001; 2007a). ICRP recognized the value of DRLs as a means to investigate and identify situations where the level of patient dose or administered activity is unusually high, relative to benchmark data. These values are easily measured quantities using a simple phantom for radiographic, fluoroscopic, and CT diagnostic imaging.

RLs are similar to DRLs in concept except that RLs are provided for other than diagnostic x-ray examinations (*e.g.*, interventional).

The overall impact of DRLs on medical imaging is primarily to reduce the radiation dose to patients and, secondarily, to health-care workers. In addition, the goal is to maintain or improve image quality appropriate to the clinical requirements of the procedure through the process of optimization.

If DRLs (either patient- or phantom-based) or RLs are exceeded, “there should be a local review of procedures and equipment in

order to determine whether the protection has been adequately optimized” (ICRP, 1991; 1996). However, *DRLs should not be viewed as absolute determinants of appropriate use of medical radiation*. Rather, they are targets to assist clinicians in reducing risks while achieving the notable benefits of imaging procedures. *DRLs are not intended for regulatory or commercial purposes, or to establish legal standards of care*. Dose reduction using DRLs requires practices to pay heed to the RLs and voluntarily adopt strategies to reduce doses below these levels.

The specific imaging examinations to be analyzed, and the values for these examinations that constitute DRLs, achievable doses, and RLs should be selected and reviewed by professional medical organizations, in cooperation with NCRP. It is incumbent upon these groups to update the reported values, and add new ones for an expanded array of procedures every 3 to 5 y. This interval, while arbitrary, reflects a compromise between the pace of innovation and the available resources. Some examinations or procedures tend to result in high patient radiation doses (*e.g.*, perfusion CT examinations) provide a challenge in developing DRLs due to the paucity of data. Interim DRLs can be developed from data available in the literature (Hausleiter *et al.*, 2009). However, limitations in these data should be acknowledged such as small sample size, data from a limited number of institutions, or lack of patient demographics.

When DRLs or RLs are exceeded, the facility’s CDOT should investigate, in consultation with the appropriate imaging physician and a qualified medical physicist. Available options to reduce patient dose should be balanced with the image quality necessary for good clinical care, and with case- or patient-specific considerations (*e.g.*, patient size, weight, motion). If higher levels are justified, then the higher levels are deemed acceptable.

In 1997, the European Union (EU) issued its medical dose directive requiring all member states to establish criteria for when imaging examinations should be performed, and DRLs for controlling medical radiation. Within the directive, reference doses were transformed into regulatory requirements for DRLs. The DRLs were defined in terms of a standard sized patient for a specific examination, and there was no suggestion that they should be applied to individual patients. However, the directive also requires that local review be performed when administered radiation doses consistently exceed DRLs. Experience from HPA and the Royal College of Radiologists has been quite positive. HPA initiated the use of DRLs in the mid-1980s. In a 2005 review the authors noted a 55 % decrease in the 75th percentile values in 11 radiographic projections (Hart *et al.*, 2007).

In the United States, an American Association of Physicists in Medicine (AAPM) task group on DRLs reviewed the work and findings of the European Commission (EC); the HPA; the Royal College of Radiologists; the International Atomic Energy Agency (IAEA); CRCPD; NEXT; and state specific data from New Jersey, Michigan, and Pennsylvania. AAPM selected DRLs at the 75th to 80th percentile of relevant survey data with the intent to represent the state-of-the-practice, not the state-of-the-art (Gray *et al.*, 2005). ACR *Technical Standard for Diagnostic Medical Physics Performance Monitoring of Radiographic and Fluoroscopic Equipment*, specifies annual evaluations of radiation dose to patients and comparison of those doses to appropriate recommendations or guidelines by a qualified medical physicist (ACR, 2011a). It is expected that about 25 % of facilities will have dose levels for some procedures that exceed the relevant DRLs; these facilities should review their procedures and dose optimization will likely be needed.

DRLs provide insight into patient radiation doses resulting from situations where variations in the imaging equipment and techniques are the major factors influencing system performance. However, in many cases, one should also consider how these same patient doses might be affected by variations in operator performance, patient factors, and operational environments. Dynamic examinations such as fluoroscopic procedures provide examples where system performance is dependent on the equipment available, imaging protocols, operator skill, patient factors, and operational environments. In such cases, RLs should be used for comparison purposes as these take into account the variability introduced by operator skill, patient factors, etc.

In summary, DRLs, achievable doses, and RLs provide a means for the medical imaging community to compare dose levels across the United States for diagnostic imaging and guidance for interventional procedures. Imaging professionals should ensure that equipment and clinical practice are optimized to provide the necessary diagnostic information with radiation doses that are as low as reasonably achievable (ALARA). As DRLs, achievable doses, and RLs represent the actual state of the collective practice in the United States, practitioners are encouraged to apply these to their respective practices commensurate with their particular clinical imaging needs. This is intended to further reduce radiation dose, respectful of the need to maintain image quality for diagnostic purposes.

2.1.2 Achievable Doses

DRLs provide the first step in the optimization process. Facilities in which radiation doses are above the DRL should work to

optimize their equipment and techniques to ensure that they are producing quality medical images at appropriate radiation doses. However, DRLs provide little information or incentive for the majority of facilities that are using radiation doses below the DRL for some or all of their examinations.

NRPB (1999) states “For those departments that are already well below reference dose levels, it is considered that the objective should be to reduce doses to those achievable by standard techniques and technologies in widespread use, without compromising adequate image quality. Indeed, in the longer term it should be possible to replace reference doses with achievable doses.”

It is usually easy and inexpensive to optimize medical image systems (CRCPD, 1988). Particular attention should be directed to optimum x-ray tube filtration, kilovoltage (CRCPD, 2008), screen-film combination, and digital image receptors. As an example, patient entrance skin doses can be reduced by 25 % by increasing the half-value layer (by adding aluminum to the beam) from 2.3 to 3.2 mm aluminum without a perceptible change in image contrast (Gray *et al.*, 1983). [It should be noted that FDA increased the requirement for the half-value layer for new equipment from 2.3 to 2.9 mm aluminum at 80 kVp (FDA, 2010b)]. A 50 % or greater reduction in patient entrance dose, can be obtained by increasing the kilovoltage, with the appropriate reduction in milli-ampere-seconds, for an anterior-posterior (AP) lumbosacral spine or abdomen projection from 65 to 75 kVp (Gray *et al.*, 1983), with no perceptible change in image contrast.

Although no formal system for determining achievable doses exists at the present time, the concept of achievable dose is straightforward. If one selected the median dose from the NEXT data as an achievable dose, then 50 % of the facilities are already producing images below that dose. In fact, NRPB found that facilities whose techniques met the EC (1996a) recommendations were able to achieve lower patient doses. These facilities had a mean dose that was similar to the median dose of the entire population of facilities. Consequently, the median dose of the NEXT data should serve as the achievable dose. It should be stressed, however, that clinically appropriate image quality and dose must always be considered. If the dose can be lowered while maintaining adequate clinical image quality, then the dose should be lowered. It is not appropriate to sacrifice clinical image quality in order to lower patient dose. In addition, facilities with patient doses significantly below the achievable dose should consider initiating a review of clinical image quality to determine whether such low doses are being obtained at the sacrifice of image quality and medical benefit to the patient.

Optimization, the process of ensuring clinical effectiveness of the images while achieving the appropriate radiation dose to the patient, is central to both DRLs and achievable doses. Many facilities are producing images with appropriate image quality and doses near or below the achievable dose levels. However, it is essential to ensure that clinical image quality, the surrogate for clinical effectiveness, is maintained, or improved, at these lower patient radiation doses. It is not acceptable to compromise image quality to the point that it may have deleterious effects on clinical effectiveness in order to reduce patient radiation doses.

2.2 Phantom Versus Patient Doses

Imaging equipment manufacturers have slowly adopted the ability to provide dosimetric data on an individual patient basis. The U.S. Federal Performance Standard for fluoroscopic equipment has required since June 2006 that manufacturers provide air-kerma rate and cumulative air-kerma display at the operators' location (FDA, 2009). While DRLs have been based on phantom survey data in the United States, it is tempting to use patient-based dose data for DRLs (as is done in Europe and most of the rest of the world) in the future. However, patient-based data in the United States are not sufficiently robust to allow for adequate DRL determination at this time due to the paucity of data available. It is possible that as patient dose data accumulate in the collective medical imaging databases, phantom-based survey data may be supplemented with patient-based data at some point in the future. For this Report, phantom-based data will provide a robust and reproducible tool for dose and dose-rate assessment. (It should be noted that patient-based dose registries are being developed. For example, the ACR Dose Index Registry currently collects dose information for CT scans but will expand to other modalities and will start collecting data based on patient size.)

Phantom-based DRL data include variability due to the x-ray imaging equipment and facility-to-facility variation in equipment use (*e.g.*, use of different kilovoltage at different facilities for the same projection). Patient-based DRL data are preferred by many countries since they are a function of two major variables (*i.e.*, equipment variability and dose variation due to the imaging techniques selected by the operator under the direction of the imaging physician). Variations in patient doses due to the selection of radiographic techniques can be quite significant. However, when using patient-based data, the variability in patient size adds another level of complexity to evaluating doses for comparison to DRLs.

2.3 Approach for Use of Diagnostic Reference Levels and Achievable Doses, and Reference Levels in the United States

DRLs provide guidance for equipment and protocol performance under controlled circumstances. Ideally, all imaging examinations that use ionizing radiation under the umbrella of DRLs would be included. However, sufficient phantom-based or standardized patient data must exist for DRLs to be applicable and robust.

Achievable doses provide guidance in diagnostic imaging as to the dose levels which are achievable. They are a guide for those facilities meeting the optimization goals of DRLs to further optimize their patient radiation doses. However, it is essential for the optimization process to ensure that clinical image quality appropriate for the imaging examination is maintained, or improved, as patient radiation doses are lowered. It is never acceptable to compromise image quality to the point that it may have deleterious effects on clinical effectiveness in order to reduce patient radiation doses.

During and after FGI procedures, SRDLs provide another guidance tool (NCRP, 2010) since exceeding these values warrants follow-up for possible tissue reactions (deterministic effects).

RLs provide guidance for overall system performance under working conditions. Developing RLs that adequately describe all the possible variations encountered during clinical operations is a laudable goal but it will require defining all the factors which influence radiation use and collecting enough data to construct a large catalog of RLs. At present, RLs have only been proposed for a few types of FGI procedures (Miller *et al.*, 2009).

Once DRLs and achievable doses, and RLs are established, professional guidelines must be developed to assist the practicing community with the local evaluation of clinical dosimetry for proper comparison with these values. This process is critical to the adoption of DRLs and achievable doses, and RLs in clinical practice. Finally, DRLs and achievable doses, and RLs should undergo periodic evaluation to incorporate trends in clinical practice and implement the most current and clinically applicable dosimetric data available. NEXT surveys, performed by the staff of state radiation protection agencies, with the cooperation and support of FDA, CRCPD (Frankfort, Kentucky), and ACR (Reston, Virginia), provide the largest collection of survey data applicable to DRLs and achievable doses in the United States.

2.3.1 Radiography and Fluoroscopy

NEXT survey data are available for adult and pediatric radiography. For adults, NEXT data are available for the posterior-anterior

(PA) chest radiograph, the AP abdominal radiograph, the AP lumbosacral spine radiograph, and two dental radiographs (bitewing and lateral cephalometric). For pediatric patients, NEXT data are available for the AP chest radiograph. NEXT data are also available for adult fluoroscopic evaluation of the upper gastrointestinal (GI) tract. Although pediatric fluoroscopic data are not available through NEXT, facilities are encouraged to work with their medical physicist to document available indicators of patient dose (*e.g.*, incident air-kerma rate) and related technical values as a means to generate local benchmark data.

In 2002, digital radiographic imaging, both computed and digital radiography accounted for 32 % of medical imaging (for abdomen and lumbosacral spine) (Moyal, 2006). The proportion of digital imaging will continue to increase in the future. This may impact DRLs in that the incident air kerma for digital modalities is typically slightly higher (~10 % on average) than for screen-film imaging (Moyal, 2006).

The use of DRLs and optimization are even more important with the use of digital imaging. Most digital imaging systems allow for doses over a wide dynamic range with clinically-acceptable image quality. In contrast, screen-film systems have a limited dynamic range with films becoming dark and unusable if the radiation exposure was increased significantly. Technologists trained at different institutions may use techniques which result in significant variations in patient dose. In addition, with digital systems doses may increase over time (Vano *et al.*, 2007). Consequently, it is essential to compare patient doses to DRLs on a periodic basis (*e.g.*, at least once per year) for a wide range of radiographic projections.

Published studies demonstrate differences in patient dose for digital imaging as compared to screen-film imaging. Compagnone *et al.* (2006), Seibert *et al.* (1996), and Spelic *et al.* (2010) demonstrated higher patient doses for computed radiography compared to screen-film systems and lower doses for digital radiography compared with screen-film imaging for PA chest radiographs. Compagnone *et al.* also found similar differences for a number of other radiographic projections. With the exception of chest radiography, insufficient data exist to recommend DRLs that are imaging technology specific. The DRLs recommended in this Report for chest, abdomen and spine radiography are based on data from the randomly selected NEXT data at the time of the survey.

2.3.2 Computed Tomography

The ACR CT Accreditation Program began in 2002 and provides a robust collection of survey data of CT practices in the United

States, in addition to the NEXT CT data. ACR data are available for adult head and abdominal CT examinations. In addition to the ACR Accreditation Program, ACR has established a Dose Index Registry which is a source of patient CTDI data (ACR, 2011b). NEXT data are available for adult head, chest, and abdomen-pelvis, and for pediatric head and abdomen-pelvis CT examinations.

It is important to point out that the NEXT survey is a random sample of doses while the ACR data are biased by the sample of participants seeking accreditation. The NEXT data are obtained from 250 to 300 randomly selected facilities in the United States. The ACR data are obtained through their accreditation program which limits the facility data to those practices wishing to obtain accreditation (*i.e.*, facilities potentially interested in patient dose and image-quality optimization).

DRLs and achievable doses are provided in this Report for only five examinations. However, CT scanners contain tens to hundreds of protocols. Consequently, the DRLs and achievable doses should be used to ensure that all protocols result in reasonable patient radiation doses by reviewing the protocols and technique factors used.

2.3.3 *Fluoroscopically-Guided Interventional Procedures*

The development and use of RLs for FGI procedures differ from processes found in other areas of medical imaging.

In the United States, DRLs are based on standardized phantoms. Exceeding these DRLs signals a need to assess the imaging equipment and protocol. This approach has clear advantages since phantom-based DRLs describe a system with relatively few variables. Furthermore, since system evaluation is independent of clinical operations, the periodic checks can be scheduled to avoid interfering with clinical workflow.

Establishing and using RLs for FGI procedures requires a different approach because the system being evaluated is substantially more complex. In interventional imaging, the system consists of the operator, patient, equipment and environment (Bucholz and Duncan, 2008; Duncan and Evens, 2009; Miller *et al.*, 2009; Sridhar and Duncan, 2008). Despite the advances in computer-based simulation of FGI procedures (Dawson and Gould, 2007), no phantoms are available that can recreate the variables encountered while performing image-guided procedures. These major variables fall into five categories: team skill, task difficulty, equipment capabilities, patient factors (*i.e.*, size, anatomy, vessel tortuosity), and environmental factors. Ideally, patients are treated by highly-skilled teams who employ the best available equipment and tightly-controlled environments to maximize the probability their

particular procedure is successfully accomplished with the least possible amount of ionizing radiation. In the real world, operational environments vary between routine daytime procedures to emergent after-hours cases. In addition, issues with equipment capability and availability can negate the benefit of recruiting even the most highly-skilled personnel. Finally, human factors such as prior experience with a particular type of procedure, equipment setup, or other team members (*e.g.*, the inclusion of residents and fellows at academic institutions) can markedly influence system performance (Duncan and Evens, 2009; Ericsson, 2004; Reagans *et al.*, 2005; Teplitz, 1991). As a result, RLs in FGI procedures must be developed with the overall system in mind.

An understanding of RLs in FGI procedures must include an understanding of task difficulty. Task difficulty reflects procedure type as well as patient-specific variables. This means separate RLs must be developed for different procedures. While it is common to describe procedures in general, descriptive terms such as renal stent, biliary drainage, or transjugular intrahepatic portosystemic shunt creation, local variations in both nomenclature and practice confound the resulting datasets. Fortunately, in the United States, billing records provide a more standardized nomenclature for these procedures: the Current Procedural Terminology (CPT) codes and their indications, the International Statistical Classification of Diseases and Related Health Problems [commonly known as the ICD (ICD-9)] codes. The advantage of using this nomenclature is that hospital and other providers have created reliable and robust methods of capturing these descriptors. In addition, the codes are updated yearly (AMA, 2010). (Note: Updating the codes is also a disadvantage as coding terms and conventions can change periodically.)

2.3.4 Nuclear Medicine

Robust data for the administered activities for various nuclear medicine procedures are lacking. Thus, local self assessment, according to Society of Nuclear Medicine (SNM), American Society of Nuclear Cardiology, and ACR guidelines may be necessary. Relevant procedures in the adult include myocardial perfusion scintigraphy, hepatobiliary scintigraphy, positron-emission tomography (PET), and bone scintigraphy. According to NCRP Report No. 160 (NCRP, 2009), PET is the fastest growing type of study in nuclear medicine. In children, relevant procedures include bone scintigraphy and renal scintigraphy. Some data are available from a survey carried out in 2010, with limited results provided in this Report.²

²Bushberg, J.T. (2010). Personal communication (University of California, Davis, Sacramento, California).

2.3.5 *Types of Examinations Excluded*

Diagnostic x-ray projections or examinations that are obtained in certain clinical practices will not be addressed in this Report.

CT-guided invasive and interventional procedures, and cardiac procedures, both diagnostic and therapeutic; have not been included in this Report due to the lack of sufficiently robust data on radiation doses in the United States.

Since 1992, the dose per image for screening mammography has been regulated by the Mammography Quality Standards Act (MQSA, 1992) at 3 mGy for a craniocaudal view of the breast, simulated with a standard breast phantom. The regulatory process precludes wide variability in mammography doses.

Chiropractic and podiatric examinations are not specifically mentioned in this text. However, the DRLs in this Report apply equally to all medical imaging facilities, including mobile-based imaging providers and chiropractic facilities. (The NEXT lumbosacral spine radiography survey includes radiation doses for a sample of chiropractic sites.) Radiation doses and image quality should be optimized using the same approaches for all medical imaging facilities.

Cone-beam computed tomography (CBCT) is a new technology with limited dissemination in the U.S. healthcare system. As such, limited experience and data are available for establishing DRLs for this technology. Consequently, no DRLs are provided in this Report for CBCT.

2.4 Implementing Diagnostic Reference Levels and Achievable Doses, and Reference Levels in Clinical Practice

DRLs and achievable doses, and RLs provided in this Report are meant to provide feedback to the medical imaging team at each institution. This team includes the imaging physician, qualified medical physicist, and radiologic technologist. By periodically comparing their results to these DRLs and achievable doses, and RLs the team can learn how their doses compare to the available data from multi-institutional studies. Although the data sets used to create these DRLs and achievable doses, and RLs are imperfect, such comparisons are still informative. Exceeding the DRL should trigger an investigation into equipment or protocol (technique) factors to determine the cause of the higher doses and to optimize all aspects of the examination. Consistently exceeding the RLs for FGI procedures [e.g., exceeding the reference level (RL) three consecutive times] should also trigger an investigation that evaluates what combination of equipment, protocols, personnel, patient or environmental factors caused the observed results. Once causes are

identified and addressed, the team should continually reevaluate system performance to confirm that results fall below the DRL and achievable dose or RL. In this manner, DRLs and achievable doses or RLs serve as signals or “trigger tools” to indicate when and where process improvement efforts are needed (Carey and Lloyd, 2001; Carey and Stake, 2003).

Most providers of medical imaging services are aware of the ALARA principle, which states that radiation doses should *be as low as reasonably achievable, economic and social factors being taken into account*. Though traditionally applied to occupational doses, it is appropriate to apply this principle to patient doses, as well. It is essential to keep in mind that medical imaging studies are performed to affect patient care. Hence, a medical imaging procedure performed at lower dose is only “reasonable” if it answers the clinical question. In other words, a lower dose procedure that is inadequate to answer the clinical question delivers radiation dose to the patient without the requisite benefit and is fundamentally “not reasonable.”

The process of self-assessment must be supported by a high-level institutional commitment to quality medical imaging and the appropriate delivery of radiation dose to patients needed to support the clinical management of each patient. The institutional commitment must include allocation of the necessary resources to accomplish these tasks. Essential resources include time for personnel to devote to the process, and time on imaging systems to test potential dose-reducing methods, where needed. Budgetary allocations may be needed to pay for services not performed by staff, or for replacement clinical coverage while staff members devote time to the self-assessment.

Armed with an institutional commitment, the team should be selected and charged with this important responsibility. Some facilities have formed *image quality – dose optimization* teams, so named to emphasize the essential balance to be maintained through the process. Others simply use the term *radiation dose optimization*, recognizing that this entails both dose and image-quality objectives. This Report uses the term *clinical dose optimization team* (CDOT).

CDOT must include the appropriate mix of expertise, including at a minimum: imaging physicians, medical imaging physicists, senior radiologic technologists, and imaging facilities management. Physicians from relevant specialty areas may include radiologists, cardiologists, dentists, neurovascular or interventional specialists, orthopedic specialists, emergency physicians, and other medical specialists who order and interpret medical images produced using

ionizing radiation. Additional contributions from nursing and other disciplines may also be valuable, depending on the complexity of the institution and level of patient care provided.

CDOT should develop and implement a plan to assess the appropriateness of radiation doses delivered to patients for medical imaging. CDOT should develop priorities appropriate to the facility's needs, with initial attention directed to the studies most commonly performed and those studies that deliver the most significant doses to patients.

With the proliferation of computer-based imaging systems, traditional technique charts have largely been replaced by anatomic or procedural protocols that are available at the operator's console. It remains good practice for the properly trained operator to have the flexibility to alter protocol parameters to best image a particular patient. For example, the abdomen of larger patients should not be imaged with the same protocols used for small pediatric patients. However, the *default* protocol values should only be changed with appropriate review and approval. CDOT should investigate the status of default protocols over the range of imaging modalities. Where software capability allows, default protocols should be "locked down," requiring management approval for changes. Where software security is not available, institutional policy should require management approval before alteration of default protocols.

As CDOT reviews protocols, doses, and image quality, it is important to remember that dose reduction may not be the end result of optimization. Since achieving the right level of image quality is essential to the clinical goal of the examination, it is possible that doses from some examinations may increase as a result of the self-assessment. For example, through the decade of the 1990s, screen-film mammography doses (mean glandular doses) actually increased modestly (FDA, 2010c). Breast imaging professionals expressed the need for higher contrast mammograms and screen-film manufacturers responded with a new generation of mammography film that had higher contrast in the higher dose (darker) regions of the film. To take advantage of the increased contrast, x-ray doses were increased, resulting in improved image quality and increased mean glandular doses. The result was improved mammographic image quality providing the potential for earlier detection of breast cancer.

The process of implementing DRLs will be facility dependent. CDOT is charged with examination-specific assessment of doses and image-quality needs, comparison with relevant DRLs, suggestion of possible protocol alternatives, pilot testing of protocol alternatives, and iteration of the process until an optimized protocol is

determined. CDOT should also periodically (*e.g.*, at least annually) review protocols and practices to ensure that protocols and techniques have not inadvertently changed periodically. Protocols for new equipment should be initially assessed before the equipment is used for patient examinations, and reassessed after a longer (*i.e.*, at three to six months) experience has been obtained. Finally, it is essential to communicate the results of the efforts of CDOT to imaging staff, to explain the process and benefits of change, and to encourage staff to raise concerns for specific protocols that may appear suboptimal. Facility management may also wish to consider how to communicate the process and results to referring physicians, patients, and local news media. Patients are increasingly aware of radiation dose from medical imaging procedures, and it may be beneficial to communicate this process to others who may ask “How do I know if I am getting too much radiation from this procedure?”

2.5 Future Methodology

NCRP Report No. 168 (NCRP, 2010) outlines the basics of statistical process control. These techniques are being increasingly applied to improve system performance in healthcare (Carey and Lloyd, 2001; Carey and Stake, 2003). The statistical process control hypothesizes that the observed variation in any process reflects statistical noise as well as causal factors (Deming, 2000). Other techniques, such as creating control charts where data are plotted as a time series, can be used to help identify causal and random variation. The statistical process control methodology will be used extensively in the future of optimization of image quality and patient radiation doses in medical imaging.

3. Phantoms for Determination of Diagnostic Reference Levels

Physical phantoms provide a convenient means of capturing dose data from a x-ray imaging system while ensuring that the data are representative of clinical applications. The development of radiographic phantoms dates back to the very early 1900s, and a comprehensive review can be found in the literature (ICRU, 1989; 1992a). The earliest phantoms were primarily directed at therapeutic dosimetry applications. Phantoms developed for the evaluation of medical x-ray imaging equipment became available in the mid-1900s. It is desirable that phantoms represent, as closely as possible, the x-ray attenuation characteristics of the anatomical structures they model. It is particularly critical in the practice of radiation therapy that appropriate phantom materials be used in order to ensure accurate calibration and dosimetry. The primary goal in medical imaging is to produce images of high clinical value using an optimized radiation dose to the patient.

Phantoms can be employed to estimate patient dose for a class of patients (*e.g.*, average-sized adults). A phantom also may be used to characterize image quality. Consequently, phantoms that are used to evaluate medical x-ray imaging equipment fall into one or both of two classes: dosimetry and image-quality assessment.

Dosimetry phantoms are designed to approximate the attenuating and scattering properties of humans specific to the imaging modality being investigated. Phantoms can be constructed of readily available materials including polymethyl-methacrylate (PMMA) [also known as acrylic, Lucite® (Lucite International, Inc., Cordova, Tennessee), or Plexiglas® (Altuglas International Arkema Inc., Bristol, Pennsylvania)], aluminum, and copper. The use of these materials also renders the phantoms simple to manufacture. However, depending on the modality, it is often convenient to work with other materials as well. While it is important to select materials which provide attenuation properties similar to real patients, the design criteria must also consider the particular modality being tested as well as the dosimetric endpoint. CT, for example, presents

a very different beam-patient geometry than a simple radiographic projection.

Anthropomorphic phantoms are available that closely represent a variety of tissues and structures, permitting accurate dosimetry. If one wishes merely to estimate the average patient dose, then a simpler phantom is appropriate.

The use of standardized phantoms permits institutional tracking of patient doses from room to room and over time. Their use also permits direct comparison of local dose measurements with available multi-site data sets collected on the same type of phantom. ACR promoted the use of a standardized mammography phantom through its mammography accreditation program beginning in the late 1980s (Bassett *et al.*, 1993). The NEXT survey captures dosimetric data nationwide using standardized phantoms (CRCPD, 2010). Phantom standardization, including choice of phantom and the associated protocol for data collection, allows the acquisition of consistent data throughout the United States.

Phantoms also provide a platform for the assessment of diagnostic image quality under conditions that are typical for the modality. If the primary task is to determine an index for patient dose then a patient-equivalent phantom should be used in order to drive automatic exposure controlled equipment to radiation output levels that are patient-representative. Newer CT systems are also capable of adjusting radiation output depending on patient size, however, the standard phantoms presently used for estimating CT doses (*e.g.*, values for CTDI) (uniform cylindrical phantoms with diameters of 16 and 32 cm) are not patient equivalent. While such phantoms are often constructed for this specific purpose, image-quality test objects can also be incorporated into dosimetry phantoms to determine patient dose and evaluate image quality at the same time. The ACR mammography accreditation phantom incorporates image-quality test objects, simulating fibers, specks and masses (ACR, 1999). The benefit of such phantoms is that image quality can then be assessed under simulated clinical conditions (provided that the phantom is appropriate for the dosimetry task).

3.1 Phantoms for Radiographic Projections of the Chest, Abdomen, and Lumbosacral Spine

The quantity of dosimetric interest for DRLs in projection radiography is patient incident air kerma ($K_{a,i}$) free-in-air. This dosimetric quantity should be evaluated under the guidance of a qualified medical physicist. Patient-equivalent phantoms, for specific patient sizes, should be used to simulate tissue absorption when evaluating automatic exposure control driven x-ray equipment. The x-ray

gantry and patient support device (radiographic table and Bucky) should be configured as they would be for clinical examinations. The setup geometry should be fully documented to permit any computations needed to determine the incident air kerma from the measurements. Beam quality (half-value layer) also should be determined for the estimation of effective dose, if desired.

The American National Standards Institute (ANSI) published a standard for performing sensitometry of medical film processors (ANSI, 1982). The standard included the specification for a radiographic phantom, referred to as the *basic test object*. This ANSI standard phantom was designed to provide x-ray attenuation similar to that of an anthropomorphic phantom. It consists of layers of PMMA and sheets of aluminum and could be modified for testing a variety of radiographic projections including chest (including an air gap), skull, pelvis, and extremities. Although the primary goal of this ANSI standard was to provide a means for characterizing the speed and contrast of screen-film-based radiographic systems, the phantom provided an economical means of testing radiographic systems under clinical conditions.

In the early 1980s the Center for Devices and Radiological Health (CDRH) developed phantoms similar to the ANSI phantoms in response to the increased use of automatic exposure control features on radiographic equipment. The “LucAl,” or CDRH, chest phantom, composed of Lucite® (PMMA) and aluminum, was clinically validated in multi-site testing to provide attenuation equivalent to an adult chest. This phantom simulates an adult with a mass of ~74 kg and height of ~1.7 m, and a 23 cm PA chest dimension (Conway *et al.*, 1984). AAPM published Report No. 31, *Standardized Methods for Measuring Diagnostic X-Ray Exposures* (Chu *et al.*, 2005) which summarizes the radiographic properties of several commercially-available dosimetry phantoms for selected diagnostic x-ray projections. The ANSI standard phantom as configured for chest radiography was found to result in estimates for patient entrance air kerma (PA projection) that are 33 % higher than comparable measurements obtained using the CDRH chest phantom (Chu *et al.*, 2005).

Similar phantoms are available for diagnostic projections of the AP abdomen and lumbosacral spine. The ANSI standard abdomen phantom is a modified version of the ANSI standard chest phantom with the inclusion of an additional 50 mm of PMMA in place of the air gap. The CDRH phantom is a combined abdomen and lumbosacral spine phantom and has been clinically validated to represent a standard adult patient with an ~22 cm AP abdomen dimension (Conway *et al.*, 1990). The geometry for the CDRH abdomen and

lumbosacral spine phantom is shown in Figure 3.1, including the large PMMA block and the strip on top of the phantom to simulate the increased absorption of the spine. AAPM Report No. 31 modified the standard ANSI abdomen configuration by adding a narrow 7 mm thick aluminum strip to model the spine (Chu *et al.*, 2005). This modified ANSI phantom was found to result in doses that were 15 % lower than those for the CDRH phantom (Chu *et al.*, 2005).

FDA developed a phantom for the survey of pediatric chest radiography which was used for the 1998 NEXT survey (Moyal, 2004). The survey found that this radiographic projection was primarily conducted using a manual x-ray technique rather than relying on automatic exposure control. The use of manual x-ray techniques for pediatric chest radiography precluded a rigorous validation of the phantom at clinical test sites. The CDRH pediatric phantom can be used for the evaluation of chest radiography for patients between the ages of 9 and 15 months. Presently the CDRH pediatric chest phantom is not commercially available.

3.2 Phantoms for Fluoroscopic Imaging

Fluoroscopy is a dynamic radiological imaging modality used to evaluate mobile structures, visualize contrast media, guide image recording (*e.g.*, GI examinations), or to guide interventional procedures. It involves the delivery of radiation to the patient over longer periods of time than are typical for projection radiography. A complete patient examination typically consists of both fluoroscopic imaging and one or more sequences of recorded images. Dosimetry is a complex task because each patient examination is unique regarding the distribution and total quantity of radiation delivered. The rate at which the radiation dose is delivered to the patient can be measured. Measurements of incident air-kerma rate are referenced to a location that approximates the skin entrance plane (*e.g.*, 1 cm above the table top for fixed-tube, under-table fluoroscopic systems). Contributions to patient dose from scout or overhead radiographs, and fluorographic (spot) image acquisitions should also be included in patient dosimetry for these procedures.

Contrast material is frequently used in fluoroscopy. It provides increased attenuation compared with surrounding soft tissue, with a corresponding increase in dose rate by the fluoroscopic system. During a GI study, for example, barium contrast material will drive the output of the fluoroscopic system to higher dose rates, often including an increase in kilovoltage (CRCPD, 2009). Dosimetry measurements should include the impact of contrast material on the patient radiation dose. The phantom includes a 1.6 mm copper sheet to simulate the presence of barium sulfate.

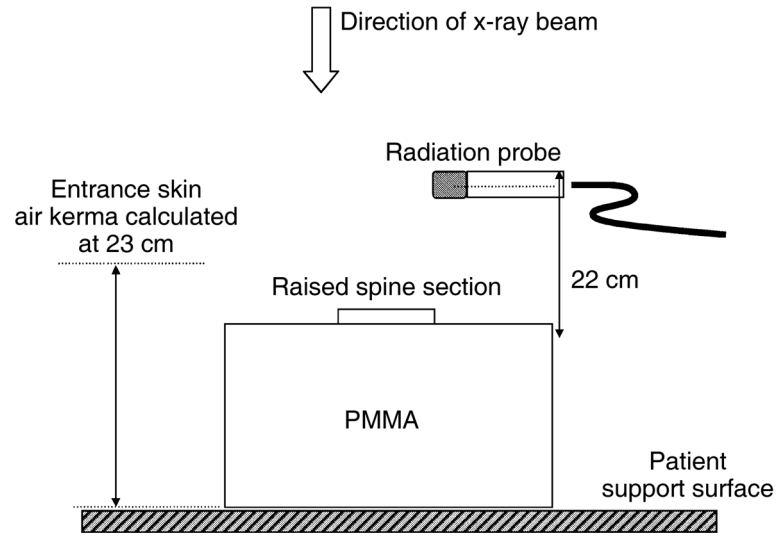


Fig. 3.1. Illustration of measurement geometry for determination of incident air kerma using the CDRH abdomen and lumbosacral spine phantom.

A dosimetry phantom is usually employed to drive the fluoroscopic system to radiation output rates that are typical for clinical examinations. The automatic dose rate control attempts to deliver a constant dose rate to the image receptor (image intensifier or flat-panel receptor). Dosimetry measurements acquired with a phantom should be reproducible. Consequently, an uniform phantom is recommended in order to avoid the dependence of the data on the positioning of the phantom with respect to the fluoroscopic gantry. For general testing of fluoroscopic systems, simple phantoms can be employed, such as copper or aluminum sheets. Such simple phantoms will generally not provide patient-equivalent attenuation across the range of beam energies encountered clinically. Patient-equivalent phantoms are recommended for proper characterization of patient dose during fluoroscopic examinations.

The Medical Imaging and Technology Alliance, a division of the National Electrical Manufacturers Association, developed a cardiovascular benchmarking phantom for fluoroscopy that can be configured representing several patient thicknesses, and includes sets of low-contrast and detail image-quality test objects. CDRH developed a fluoroscopy phantom that is based on the spine configuration of the CDRH combined abdomen and lumbosacral spine phantom (Suleiman *et al.*, 1997). This phantom was originally developed to

evaluate standard fluoroscopic equipment used for upper GI studies. The CDRH phantom can be used to characterize both fluoroscopic and fluorographic (spot image) dose to the patient. Similar to projection radiography, the fluoroscopic and fluorographic half-value layer should be determined as needed for dosimetric calculations.

Table 3.1 summarizes the radiography and fluoroscopy phantoms discussed in this Report. It is recommended that facilities adhere, as closely as possible, to the measurement procedures and conditions under which the reference data were gathered. The phantoms discussed in the preceding sections can be used to characterize patient doses for radiographic projections of adult chest, abdomen, and lumbosacral spine, and general fluoroscopy. The facility staff should consult with a qualified medical physicist prior to collecting data to ensure that the survey provides sufficient detail to estimate radiation doses. In addition, staff should ensure that the equipment is configured for both the specific projections and patient sizes, and appropriate techniques (kilovolt peak, milli-amperage, etc.) are used.

3.3 Phantoms for Computed Tomography

The dosimetric quantity of interest for computed tomography (CT) is the volumetric CTDI ($CTDI_{vol}$). Measurements are made using the standard CT phantoms which are cylindrical phantoms composed of PMMA with a 16 cm diameter (for adult and pediatric head examinations, and pediatric body examinations) or 32 cm diameter (for adult body examinations) (Figure 3.2). (These phantoms were not designed as patient-equivalent phantoms but to determine compliance with federal performance standards.) Many

TABLE 3.1—*Summary of radiographic and fluoroscopic phantoms.*

Phantom	Projection and Modality
Modified ANSI phantom	Radiographic chest, abdomen, lumbosacral spine (skull and extremities configuration also available)
CDRH chest phantoms: adult (PA) and pediatric (PA or AP)	Radiographic chest (adult and pediatric)
CDRH abdomen and lumbosacral spine phantom	Adult radiographic abdomen (AP) and lumbosacral spine (AP)
CDRH fluoroscopic phantom	Upper GI fluoroscopy (adult)

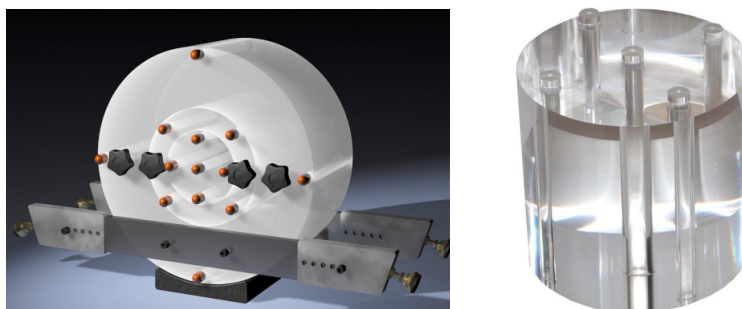


Fig. 3.2. (Left) CT dosimetry phantom. Black knobs are handles to make moving and aligning the phantom easier. Orange objects are PMMA rods to fill holes when ionization chamber is not in position (photo courtesy of CIRS, Inc., Norfolk, Virginia). (Right) close-up of 16 cm diameter PMMA head phantom.

CT systems have the ability to modulate the dose based on patient attenuation as the x-ray source rotates around the patient (*i.e.*, automatic exposure control). CT dosimetry continues to be based on the standard 16 and 32 cm diameter phantoms. However, these phantoms are not equivalent to a typical patient nor were they designed to evaluate automatic exposure control systems available today. Therefore, these phantoms should be used with a manually selected constant x-ray output. The technique factors (particularly the x-ray tube current) used for imaging a CT dosimetry phantom are typically those used for an average or standard patient. Thus, current DRLs for CT and the measurements for comparison with these DRLs are not entirely phantom-based, but are also affected by the selection of these technique factors from patient imaging examinations.

3.4 Phantoms for Fluoroscopic Equipment

The U.S. Code of Federal Regulations performance standard for fluoroscopic equipment specifies an upper limit for fluoroscopic air-kerma rate for prescribed imaging equipment geometry (FDA, 2009). It should be kept in mind that compliance of fluoroscopic equipment with this federal performance standard does not imply that equipment is optimized with regard to dose and image quality. In addition, FDA regulations apply only at the time of equipment purchase and installation, and place no requirement on the users of the equipment to ensure that the equipment continues to comply with federal regulations. However, there are requirements for equipment quality control, evaluation, and calibration in many states, but vary significantly from state to state.

Proper assessment of dose and image quality is the key to fluoroscopy system optimization. Fluoroscopic equipment manufactured after June 2006 must display, at the operator's location, the air-kerma rate and the cumulative air kerma to a specified reference point (FDA, 2009). The International Electrotechnical Commission provides a similar standard for fluoroscopic equipment and includes specification for the display of cumulative air-kerma area product (IEC, 2010). The dynamic display of doses can assist clinical staff in optimizing the practice of fluoroscopy. Cumulative doses can assist the medical physics community in assessing and managing patient dose. Most fluoroscopic equipment provides a display of cumulative fluoroscopy time for a complete examination. It is recommended that the fluoroscopic time not be the sole means of quantifying patient risk (Miller *et al.*, 2012; NCRP, 2010; Stecker *et al.*, 2009). Appropriate phantoms, such as those discussed in this section, should be used for proper comparison with recommended DRLs in fluoroscopy (for diagnostic, not interventional, procedures).

3.5 Phantoms for Fluoroscopically-Guided Interventional Procedures

State-of-the-art fluoroscopic equipment for fluoroscopically-guided interventional (FGI) procedures incorporates sophisticated technology for automatically adjusting the radiation output of the system based on both the attenuation characteristics of the patient and the clinical task. Such systems employ a C-arm that holds the image receptor and x-ray tube for complex angulations of the x-ray beam during procedures. A complete interventional procedure includes a combination of fluoroscopic imaging and digital recording of images at higher dose rates than used in fluoroscopy. While fluoroscopic systems must comply with state regulations for maximum radiation output rate when operated in available fluoroscopic modes, there is no radiation rate limit when the fluoroscopic equipment is operated in a digital acquisition mode (*i.e.*, recording or cine mode). Consequently, it is important that contributions to patient dose from both fluoroscopic and digital acquisition modes of operation be determined.

The range of patient doses can be very large, even with respect to a single procedure (*e.g.*, diagnostic coronary angiography) (Miller *et al.*, 2009). Factors that contribute to this large range of patient doses include patient size, equipment performance, technique factors selected by the users, complexity of the clinical task, and clinician skill and experience.

The CDRH fluoroscopy phantom may also be used to assess dose rates for fluoroscopic equipment for interventional procedures

(CRCPD, 2009). Most fluoroscopic equipment manufacturers incorporate additional beam filtration that is inserted automatically into the beam during clinical procedures based on patient attenuation. Phantoms used for characterizing patient radiation doses should be patient-equivalent in order to ensure that such automated systems select realistic, clinical techniques for dose measurements.

4. Methods for Characterizing Patient Dose

Two approaches exist for the characterization of patient dose from radiological procedures: patient-based dosimetry and phantom-based dosimetry. Which method provides an outcome most representative of routine clinical practice partly depends on the imaging modality and dosimetric endpoint. For instance, in routine chest radiography, the measurement of incident air kerma using a patient-equivalent phantom is typically sufficient. For FGI procedures a primary clinical concern is the potential for tissue injury (deterministic skin injury) (FDA, 1994; Miller *et al.*, 2010). The determination of peak skin dose for individual patients is therefore an important dose measurement. A number of methodologies for estimating dose to the skin have been developed. One method is the direct measurement of skin dose (including backscattered radiation) using small dosimeters placed directly on the patient skin. These dosimeters are typically either thermoluminescent dosimeters (Shrimpton, 1994) or optically-stimulated luminescent dosimeters (Botter-Jensen *et al.*, 2003; Landauer, 2012). Radiochromic dosimetry film is also used to provide a two-dimensional mapping of dose distribution for individual patients. Most fluoroscopic equipment is configured with the display of rate and cumulative values for one or more dose indices including cumulative air kerma at a specified reference point ($K_{a,r}$) (required on all fluoroscopic equipment manufactured after June 2006), and cumulative air-kerma area product (P_{KA}). Electronic dose displays should be monitored periodically during fluoroscopic procedures as a means to manage patient dose.

Doses to individual patients are affected by several variables. For example, the dose for a specific radiographic projection will vary by factors of 10 or more depending on the patient size. In addition, radiologic technologists may select different radiographic technique factors, namely peak tube voltage, or beam quality, which can result in a factor of 10 or more difference in patient dose. Digital radiography also provides the opportunity for the technologist to select a range of techniques that affect patient doses, with

little obvious impact on the image quality as seen by the imaging physician. Lower doses for digital radiography can result in noise in the image that may be apparent to the imaging physician. Conversely, the use of higher digital radiography doses may not be apparent to the imaging physician.

Phantom-based dosimetry is used to make measurements of a representative patient (*i.e.*, an average size patient). Phantom measurements are typically straightforward to make since relatively few measurements are required on x-ray equipment and can be made without interfering with patient examinations. These measurements eliminate several variables from the measurement process including patient size and the variability in dose introduced by individual radiologic technologists in selecting technique factors. Automatic exposure control systems in fluoroscopic x-ray imaging determine the radiation dose rate based on the attenuation of the patient, by controlling the peak tube voltage, tube current, filtration, or x-ray pulse width. Automatic exposure control systems in radiographic x-ray imaging determine the tube current-exposure time product based on the attenuation of the patient, for a preset peak tube potential. Consequently, a patient-representative phantom should be used to determine system response. The major advantages of this approach are the ability to collect dose data quickly for a representative patient, and to characterize doses across multiple facilities and rooms under standardized measurement conditions. In addition, image quality can be determined under simulated clinical conditions. The disadvantages include the initial effort required to develop such phantoms (or alternatively to fund their acquisition) and providing these phantoms for multi-site studies.

4.1 Units of Measure

4.1.1 *Fundamental Units*

The International Commission on Radiation Units and Measurements (ICRU) published recommendations in Report 60 (ICRU, 1998) and Report 85 (ICRU, 2011) for quantities and units of measurement for the characterization of ionizing radiation. ICRU Report 74 (ICRU, 2005) further discusses appropriate quantities and units pertaining to x-ray-based medical imaging. Two quantities, exposure and kerma, are commonly used to specify the quantity of radiation at a point of measurement. While these two quantities are often used interchangeably, they refer to fundamentally different processes involving the interaction of ionizing radiation with matter. Exposure refers to the quantity of electric charge of one polarity (negative or positive) produced in a volume of air

when all liberated charge-carrying particles are stopped in air (ICRU, 1998). Exposure is a measure of the amount of ionization caused by the radiation and is defined as (ICRU, 2011):

$$X = \frac{dq}{dm}, \quad (4.1)$$

where dq is the absolute value of the mean total charge of ions of a single polarity produced when all the electrons and positrons liberated or created by photons incident on a mass dm of dry air are completely stopped in dry air.

The SI unit for exposure is coulomb per kilogram (C kg^{-1}). Previously, the special unit for exposure was roentgen ($1 \text{ R} = 2.58 \times 10^{-4} \text{ C kg}^{-1}$). Dosimeters that provide a measurement of exposure usually employ an air-filled ionization chamber that is calibrated to a recognized standard (Johns and Cunningham, 1983; NIST, 2010).

The kinetic energy released per mass, or kerma, concerns the initial transfer of energy to matter. Kerma is more closely related to absorbed dose because it characterizes the initial transfer of energy by the radiation beam into the medium of interest. Kerma (K) is defined as (ICRU, 2011):

$$K = \frac{dE_{\text{tr}}}{dm}, \quad (4.2)$$

where dE_{tr} is the mean sum of the initial kinetic energies of all charged particles liberated in the element of mass dm . The SI unit of kerma is joule per kilogram (J kg^{-1}) with the special name gray (Gy) ($1 \text{ Gy} = 1 \text{ J kg}^{-1}$). Kerma can be quoted for any specified material at a point in free space or in an absorbing medium (*e.g.*, air kerma).

For medical imaging applications, air kerma is used. ICRU Report 74 (ICRU, 2005) expresses air kerma for monoenergetic x rays in the diagnostic energy range as:

$$K_{\text{a}} = \Psi \left(\frac{\mu_{\text{tr}}}{\rho} \right)_{\text{a}}, \quad (4.3)$$

where Ψ is the x-ray beam energy fluence, and $(\mu_{\text{tr}}/\rho)_{\text{a}}$ is the mass energy transfer coefficient for air. If the beam contains a spectrum of x-ray energies, then air kerma should be determined as the sum of the contributions from each energy. The SI unit for air kerma is also J kg^{-1} , with the special name gray. Air kerma can be determined approximately (ICRU, 1992b) from the measurement of exposure using the relation:

$$K_a = 0.00876 X. \quad (4.4)$$

Where K_a is air kerma free-in-air in gray and X is exposure in roentgen. This simple relationship holds for x-ray energies in the diagnostic range. Above these energies, exposure is not easily measured and the conversion factor becomes energy dependent (ICRU, 1992b).

Absorbed dose (D) characterizes the energy deposited in a medium by ionizing radiation. ICRU Report 60 (ICRU, 1998) defines absorbed dose as:

$$D = \frac{d\bar{\epsilon}}{dm}, \quad (4.5)$$

where $d\bar{\epsilon}$ is the mean energy imparted by ionizing radiation to matter of mass dm . The SI unit for absorbed dose is J kg^{-1} with the special name gray.

4.1.2 Clinical Dosimetry

For patient dosimetry, measurements and patient doses are often expressed in the United States in air kerma. The notation of ICRU Report 74 (ICRU, 2005) is used in this Report. Specifically, incident air kerma ($K_{a,i}$) designates the air-kerma incident on the skin-entrance plane of the patient or phantom without backscattered radiation. Entrance-surface air kerma ($K_{a,e}$) designates the air kerma at the point where the x-ray beam enters the patient or phantom and includes backscattered radiation.

For a discussion of the topic of uncertainty in diagnostic radiation dosimetry the reader is referred to the IAEA publication entitled *Dosimetry in Diagnostic Radiology: An International Code of Practice* (IAEA, 2007).

Backscattered radiation contributes to both patient dose and to field measurements of dose in diagnostic x-ray imaging. The inclusion of backscattered radiation in dose measurements is determined by the geometry of the experimental set-up. For example, the CDRH adult chest and adult abdomen and lumbosacral spine phantoms were designed to provide a geometry which minimizes backscattered radiation. For interventional fluoroscopic imaging equipment, IEC (2010) specifies radiation measurement geometries that minimize backscattered radiation contributions.

Incident air kerma and entrance-surface air kerma are both sufficient indicators of patient dose in projection radiography for tracking institutional and population trends with time. However, the quantity used is often determined by the preference of the investigator. For example, conversion coefficients are available in the literature for determining organ and tissue doses, and effective doses for

selected diagnostic x-ray examinations (Hart *et al.*, 1994). That publication provides conversion coefficients that are normalized to entrance-surface dose, which includes backscattered radiation.

Figure 4.1 shows the measurement geometry for determination of fluoroscopic air-kerma rate. For a C-arm gantry the U.S. performance standard specifies a maximum fluoroscopic air-kerma rate at a fixed distance (30 cm) with respect to the input surface of the image receptor. Dose display features available on newer fluoroscopic equipment routinely reference fluoroscopic dose indices (rate and cumulative values for air kerma) at a point in space located with respect to the isocenter of the gantry. In particular, FDA (2009) and IEC (2010) both specify a reference location of 15 cm from the isocenter toward the x-ray tube for the display of fluoroscopic dose indices on C-arm type fluoroscopic systems. IEC (2010) refers to this location as the *patient entrance reference point*. The air kerma referenced to this location is referred to as *air kerma at the reference point* ($K_{a,r}$).

Air-kerma area product (P_{KA}) is a quantity that expresses the total amount of radiation received by a patient during a procedure. P_{KA} is defined as the integral of the air-kerma free-in-air (*i.e.*, in the absence of backscattered radiation) over the area of the x-ray beam in a plane perpendicular to the beam axis.

4.2 Computed Tomography Dosimetry

To be useful clinically, DRLs must be easy to measure using techniques that are adopted uniformly. In computed tomography (CT), most reported DRLs are derived from the CT dose index ($CTDI$). Until recently, most $CTDI$ values were expressed as the weighted $CTDI$ ($CTDI_w$), measured in a phantom with a 100 mm long ionization chamber as follows (Bongartz *et al.*, 1998; McCollough *et al.*, 2008; McNitt-Gray, 2002):

$$CTDI_w = \frac{1}{3} CTDI_{100,center} + \frac{2}{3} CTDI_{100,edge}. \quad (4.6)$$

With the widespread use of helical CT imaging, a more useful dose metric was developed ($CTDI_{vol}$) that considers the dose to a volume of tissue encompassed by a single rotation of the x-ray gantry, as a function of the pitch of the helix:

$$CTDI_{vol} = \frac{CTDI_w}{pitch}, \quad (4.7)$$

where pitch is defined as the ratio of the patient couch advance to the nominal x-ray beam width.

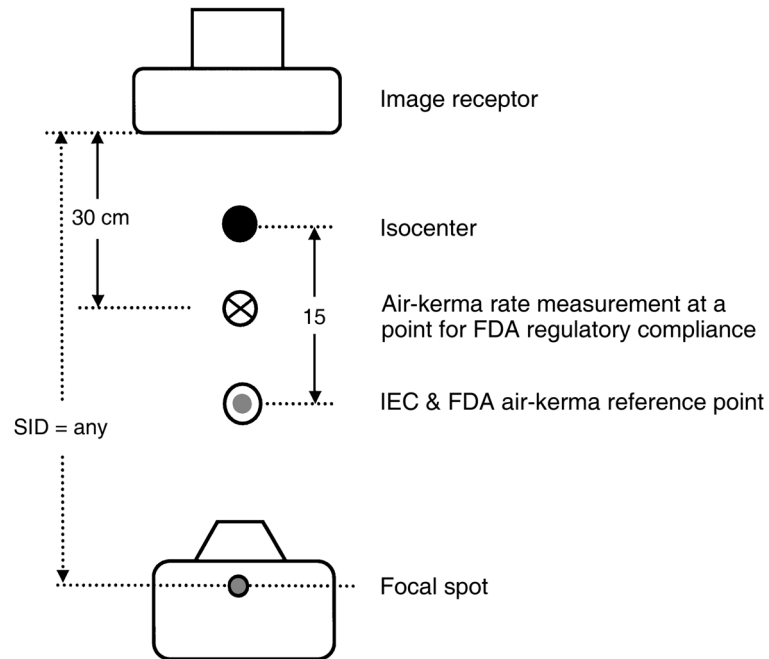


Fig. 4.1. Measurement geometry for fluoroscopic isocentric imaging systems (drawing not to scale).

$CTDI_{vol}$ is integrated over the scan length of a CT acquisition to obtain the dose-length product. The dose-length product can be used as a practical value for the estimation of effective dose. $CTDI_{vol}$, however, remains an important and useful metric in CT for comparing the performance of CT systems with regard to the utilization of radiation. As such, $CTDI_{vol}$ is regarded as the primary dose metric for CT DRLs in this Report. ICRU (2005) expresses similar quantities for CT in air kerma.