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 survey[1] 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,

[1]Bushberg, 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.