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Pediatric Information for X-ray Imaging Device Premarket Notifications

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Guidance for Industry and Food and Drug Administration Staff

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For questions about this document, contact the Office of In Vitro Diagnostics and Radiological Health at 240-402-5149 and Laurel Burk at 301-796-5933 or Laurel.Burk@fda.hhs.gov.



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Food and Drug Administration
Center for Devices and Radiological Health

Office of In Vitro Diagnostics and Radiological Health (OIR)
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Preface

Public Comment

You may submit electronic comments and suggestions at any time for Agency consideration to https://www.regulations.gov. Submit written comments to the Dockets Management Staff, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD 20852. Identify all comments with the docket number FDA-2012-D-0384. Comments may not be acted upon by the Agency until the document is next revised or updated.

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Guidance for Industry and Food and Drug Administration Staff

This guidance represents the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff or Office responsible for this guidance as listed on the title page.

I. Introduction

This guidance document outlines the current thinking of the Food and Drug Administration (FDA or the Agency) regarding information that should be provided in premarket notification submissions (510(k)s) and device labeling for x-ray imaging devices that are indicated for pediatric populations or general use x-ray imaging devices for which considerable pediatric application is anticipated. General use x-ray imaging devices typically neither include nor exclude specific populations in the indications for use and may be expected to be used in any population Because a large percentage of the hundreds of millions of x-ray examinations performed annually in the US are exams of pediatric patients[1], FDA expects that most general use x-ray imaging devices will be used for a considerable quantity of pediatric examinations unless a device's design precludes use in smaller sized patients. This guidance is intended to enhance clarity regarding the premarket review process of 510(k)s for x-ray imaging devices, to encourage the inclusion of pediatric indications for use for x-ray imaging device premarket notifications, and to provide recommendations regarding labeling, including the instructions for use.

X-ray imaging devices are subject not only to the medical device requirements in the Federal Food, Drug, and Cosmetic Act (FD&C Act), but are also electronic products under section

[1] Analysis by the National Council of Radiation Protection and Measurements in NCRP Report No. 160, "Ionizing Radiation Exposure of the Population of the United States," estimates that pediatric populations make up approximately 8% of total CT examinations and 15% of radiographic fluoroscopy examinations, for example.

531(2) of Subchapter C (Electronic Product Radiation Control (EPRC)) of the FD&C Act. As such, X-ray imaging devices are subject to the radiological health requirements in Title 21, Subchapter J, Parts 1000 through 1050 of the Code of Federal Regulations (CFR), including applicability of general and specific performance standards (21 CFR Parts 1010-1050) and other general requirements for reporting and recordkeeping (21 CFR Part 1002), notification and corrective actions for defective or non-compliant electronic products (21 CFR Parts 1003 and 1004), and importation (21 CFR Part 1005). For additional information, see in particular 21 CFR 1020.30-1020.33 ("Diagnostic x-ray systems and their major components;" "Radiographic equipment;" "Fluoroscopic equipment;" and "Computed tomography (CT) equipment") as applicable.

For the current edition of the FDA-recognized standard(s) referenced in this document, see the FDA Recognized Consensus Standards Database Web site at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm."

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidance means that something is suggested or recommended, but not required.

II. Background

A. Public Health Motivation

Like all other medical procedures, x-ray imaging exams present both benefits and risks. These imaging procedures have led to improvements in the diagnosis and treatment of numerous medical conditions. At the same time, these types of exams expose patients to ionizing radiation, which may elevate a person's lifetime risk of developing cancer. Exposure to ionizing radiation is of particular concern in pediatric patients for three reasons: 1) younger patients are more radiosensitive than adults (i.e., the cancer risk per unit dose of ionizing radiation is higher for younger patients);[2] 2) younger patients have a longer expected lifetime for the effects of radiation exposure to manifest as cancer; and 3) use of equipment and exposure settings designed for adult use can result in excessive radiation exposure to the smaller patient. The third point is of special concern because many pediatric imaging exams are performed in facilities where pediatric imaging is not a majority of the workload.[3]

[2]NAS National Research Council Committee to Assess Health Risks from Exposure to Low Levels of Ionizing Radiation. 2006. *Health risks from exposure to low levels of ionizing radiation: BEIR VII phase 2*. Washington, D.C.: National Academy of Sciences, National Academies Press.

[3]Larson, D.B. *et al*., "Rising Use of CT in Child Visits to the Emergency Department in the United States, 1995-2008," *Radiology*, vol. 259(3), pp. 793-801, 2011.

FDA strives to promote increased patient safety in medical imaging through two principles of radiation protection developed by the International Commission on Radiological Protection[4]:

- *Justification:* Examinations using ionizing radiation should be performed only when necessary to answer a medical question, help treat a disease, or guide a procedure.
- *Dose Optimization:* Examinations should use techniques that are adjusted to administer the lowest radiation dose that yields an image quality adequate for diagnosis or intervention (i.e., radiation doses should be "As Low as Reasonably Achievable").

Manufacturers of x-ray imaging devices are encouraged to promote dose optimization by designing their devices for optimal safe use and including dose-optimization information to end users in the labeling. This guidance focuses on recommendations to manufacturers for device features and instructions that would help medical professionals optimize radiation dose in x-ray imaging exams for pediatric patients.

Currently, many x-ray imaging devices are marketed with a general indications for use (IFU)[5] statement[6], and the use of the device is not limited to a specific population. The majority of these devices are expected to be used in a considerable number of pediatric patient imaging applications. However, experts have commented that many general use x-ray imaging devices are sold without features or labeling information that would help users to optimize clinically usable image quality in comparison to radiation exposure for use in pediatric imaging.[7]

Imaging professionals can safely use existing x-ray equipment without specific features or instructions for pediatric use by consulting recommendations provided by the Alliance for Radiation Safety in Pediatric Imaging (Image Gently Alliance)[8] and other organizations. FDA has reviewed the recommendations from the Image Gently Alliance and believes they are appropriate. However, FDA has received public comments that it can be challenging for imaging professionals to apply these recommendations without additional information from the manufacturer because x-ray imaging systems can be complex with a broad range of available settings. Accordingly, FDA believes that safety can be further improved if x-ray

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[4]The principles of radiation protection in medicine, including "optimization" and the "ALARA" principle are described in: International Commission on Radiological Protection. 2007. ICRP Publication 105: Radiological Protection in Medicine. *Ann. ICRP*, *37*(6), and NCRP. "*Limitation of exposure to ionizing radiation.*" NCRP Report No. 116. Bethesda, MD: National Council on Radiation Protection and Measurements, 1993. These principles are also emphasized in the federal guidance: Interagency Working Group on Medical Radiation. Federal Guidance Report No. 14. Radiation Protection Guidance for Diagnostic and Interventional X-Ray Procedures. Washington, DC: Environmental Protection Agency, 2014 .

[5]See FDA;s guidance entitled "General/Specific Intended Use" (http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm073945.pdf).

[6]See FDA's guidance entitled "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)] Guidance for Industry and Food and Drug Administration Staff" (https://www.fda.gov/downloads/MedicalDevices/.../UCM284443.pdf).

[7]See public comments to 2010 FDA's public meeting on Device Improvements to Reduce Unnecessary Radiation Exposure from Medical Imaging (https://www.regulations.gov/document?D=FDA-2010-N-0080-0001).

[8]http://www.imagegently.org/

imaging devices include additional design features and information for users that facilitate choosing optimized equipment settings for pediatric patients. Because of the heightened concerns about excessive exposure to radiation in children, FDA believes that new x-ray imaging devices should include clear information for the end user on the design features and instructions available for imaging patients outside the typical adult size range. FDA recommends that in order to minimize the risk of excessive exposure of radiation to children, manufacturers of x-ray imaging devices should, as part of their device design, peform a risk assessment that considers specific risks and mitigations arising from the use of their device in pediatric populations. With appropriate instructions, safety information, and a description of available pediatric-specific features, the end user can then make more informed decisions about use of the device on pediatric patients.

B. Past FDA Actions, Guidance and Public Meetings

In 2007, Congress passed the Food and Drug Administration Amendments Act of 2007 (FDAAA) (Pub. L. 110-85) that included Title III, the Pediatric Medical Device Safety and Improvement Act (PMDSIA). PMDSIA requires submission of information on pediatric subpopulations that suffer from the disease or condition that the device is intended to treat, diagnose, or cure for certain types of device applications and supplements

In February 2010, the FDA launched an "Initiative to Reduce Unnecessary Radiation Exposure from Medical Imaging"[9] and on March 30-31, 2010, the Agency held a public meeting entitled “Device Improvements to Reduce Unnecessary Radiation Exposure from Medical Imaging.”[10] At the meeting, the FDA sought advice on "steps that manufacturers of CT and fluoroscopic devices could take to reduce unnecessary radiation exposure through improved product design, enhanced labeling, or improved instructions and training for equipment use and quality assurance at medical imaging facilities."[11] The Agency asked whether manufacturers should incorporate special provisions for pediatric patients, particularly with regard to hardware and software features.[12] Recommendations received by FDA, which apply to all general-use x-ray imaging modalities, included making available pediatric protocols and control settings, targeted instructions and educational materials emphasizing pediatric dose reduction, quality assurance tools for facilities emphasizing radiation dose management, and dose information applicable to pediatric patients. Many of the recommendations from pediatric experts focused on expanding the flexibility or range of features already available on x-ray imaging devices, which may also improve adult imaging for non-standard applications.

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[9] http://www.fda.gov/Radiation-EmittingProducts/RadiationSafety/RadiationDoseReduction/ucm2007191.htm

[10] Agenda and transcripts available at: https://www.federalregister.gov/documents/2010/02/24/2010-3674/device-improvements-to-reduce-unnecessary-radiation-exposure-from-medical-imaging-public-meeting. Public docket submissions are available at: https://www.regulations.gov/document?D=FDA-2010-N-0080-0001.

[11] See 75 FR 8375, 8376 (Feb. 24, 2010).

[12] The Federal Register Notice lists all the questions asked at the meeting (see 75 FR 8375-8377 (2010)).

On July 16, 2012, the Agency held a public meeting entitled "Device Improvements for Pediatric X-ray Imaging."[13] At the meeting, FDA solicited public feedback on the draft of this guidance and requested help in identifying issues relevant to radiation safety in pediatric x-ray imaging that might benefit from standards development or further research. FDA requested specific comments on technical device design and pediatric safety questions. Since the 2012 meeting, many recommended device design improvements have been incorporated into FDA-recognized consensus standards and others are under consideration for future revisions of such standards. See Appendix B for a discussion of some relevant international consensus standards.

In 2014, the Agency issued a revised general pediatric guidance entitled "Premarket Assessment of Pediatric Medical Devices[14]." The guidance, which applies to all devices, defines pediatric subpopulations and the general information that should be provided for different types of premarket submissions for devices intended for use in pediatric populations.

C. The Approach of this Guidance

This guidance provides recommendations on the information that should be included in premarket notifications for x-ray imaging devices that are indicated for pediatric populations or general use x-ray imaging devices for which considerable pediatric application is anticipated. Manufacturers seeking marketing clearance for a new x-ray imaging device that could be used in pediatric populations should address pediatric use in their risk assessment and provide mitigations where approriate, regardless of whether the device has a specific pediatric indication. While including pediatric use is an important part of the risk assessment for all general use x-ray imaging devices[15], other parts of this guidance may only be applicable to certain devices. This guidance offers a framework for how manufacturers may address pediatric x-ray safety concerns in design, testing, and labeling of their device, but any specific device design issues discussed are provided only as a reference. FDA believes that development of, and conformance to, device-specific voluntary consensus standards, such as those discussed in Appendix B, can help to ensure implementation of x-ray device-specific pediatric safety design features industry-wide.

III. Scope

[13] Please refer to the following URL for a summary of the meeting, specific questions and topics on which the Agency requested public comment, and the list of comments received: https://www.regulations.gov/document?D=FDA-2012-N-0385-0002.

[14]Premarket Assessment of Pediatric Medical Devices - Guidance for Industry and Food and Drug Administration Staff: https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089740.htm.

[15] These devices typically do not include specific populations in the indications for use and may be expected to be used in any population.

This guidance document is generally applicable to all x-ray imaging devices that are specifically indicated for pediatric use or general use x-ray imaging devices for which considerable pediatric application is anticipated. Both new devices and modifications of existing x-ray imaging devices which require submission of a new premarket notification[16] are included within the scope of this guidance document, regardless of whether the device is a complete x-ray imaging system, a component part of an x-ray imaging device or an accessory (e.g., detectors and software).

This guidance provides a broad framework regarding the information which should be submitted to support premarket submissions for x-ray imaging devices indicated for pediatric populations and general use x-ray imaging devices for which considerable pediatric application is anticipated. While *Section V (Indications for Use)*, *Section VI (Risk Assessment)*, and *Section XI (Labeling*) are generally applicable to all x-ray imaging devices, other portions of the guidance document may only be applicable to certain devices. In particular, *Section VII (Pediatric Device Features)* contains specific information about device features that are only applicable to certain devices. For feedback about which information may be applicable to a particular x-ray imaging device, FDA recommends that manufacturers submit a Pre-submission.[17]

This guidance should be used in conjunction with device-specific guidance documents addressing premarket notification requirements and serves as a supplement to the general guidance document on the content and format of a 510(k) submission.[18,19]

IV. Pediatric Population

The FDA's Center for Devices and Radiological Health defines the age range of the pediatric population as birth through 21 years.[20] While the risk of radiation-induced cancer depends

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[16]See FDA guidance on "Deciding When to Submit a 510(k) for a Change to an Existing Device" (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080235.htm).

[17] For information on how to submit a pre-submission, see FDA's guidance entitled "Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff." (https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM311176.pdf).

[18]"Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s" (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm) .

[19]"The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]" (http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM284443.pdf).

[20]See FDA's guidance entitled "Premarket Assessment of Pediatric Medical Devices" (http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM089742.pdf)." Suggested age ranges in this guidance are: neonate (birth-1 month), infant (1 month-2 yrs.), child (2-12 yrs.), adolescent (12-21 yrs.). The subgroups suggested in this guidance are consistent with these age ranges.

on age[21], patient size (i.e., height, weight, body part thickness) is a more important factor than age for optimizing image quality and radiation dose for x-ray imaging exams.[22] Because the focus of this guidance is on device design, labeling, and evaluation of x-ray imaging devices, this guidance recommends division of the pediatric population into subgroups based on patient size rather than age.

Pediatric patients can range in weight from less than 500 grams (1 lb) to more than 120 kg (265 lb). As a result, a device designed for pediatric use (across all pediatric population subgroups) will also be adequate for the entire size range of the general adult population; conversely, devices designed only for adults may not be optimized for use on many smaller patients. For example, the 5th percentile U.S. adult female [51 kg (112 lb.); 151 cm (59 in) standing height] is similar in size to an average 12 year old.[23] A well-designed adult device that takes account of a broad individual size variation should be able to competently image average pediatric patients 12 years old and above, but would not necessarily address the needs of younger pediatric patients. Due to this size overlap between smaller adults and older pediatric patients, many of the recommendations in the following sections are expected to also improve imaging of smaller adults.

In the design of x-ray imaging devices, we recommend that manufacturers consider subgroups that are appropriate to the intended use of their device. Depending on the body part imaged, the appropriate subgroups will be different. While body part thickness is the most relevant metric for x-ray imaging of individual patients,[24,25] age and size may be more readily available metrics for describing "average" patients. It may therefore be appropriate to consider the applicable body part thickness corresponding to the following pediatric subgroups, defined according to age and approximate average height and weight measurements, which may be appropriate for body imaging: neonate/birth-1 month [1-2 kg

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[21]Based on reports of the lifetime incidence of cancer vs. age of exposure data, the pediatric subgroups defined by the Agency in the guidance entitled "Premarket Assessment of Pediatric Medical Devices" cover the region where the largest age dependence is expected for cancer risk. Risk decreases much less steeply as a function of age for individuals over 21 years of age. [See NAS National Research Council Committee to Assess Health Risks from Exposure to Low Levels of Ionizing Radiation. 2006. *Health risks from exposure to low levels of ionizing radiation: BEIR VII phase 2*. Washington, D.C.: National Academy of Sciences, National Academies Press.]

[22]Watson DJ, Coakley KS. Paediatric CT reference doses based on weight and CT dosimetry phantom size: local experience using a 64-slice CT scanner. Pediatr Radiol. 2010;40(5):693-703, and Jarvinen H, Seuri R, Kortesniemi M, et al. Indication-based national diagnostic reference levels for paediatric CT: a new approach with proposed values. Radiat Prot Dosim. 2015;165(1-4):86-90.

[23] McDowell, M.A., C.D. Fryar, C.L. Ogden, and K. M. Flegal. 2008. Anthropomorphic Reference Data for Children and Adults, United States, 2003-2006. National Health Statistics Reports, 10, 1-48. Available for download at: http://www.cdc.gov/nchs/data/nhsr/nhsr010.pdf.

[24]The following reference gives current data for anteroposterior and transverse body diameter for pediatric patients ranging in age from 0.5 to 20 years: Kleinman, P. L., K. J. Strauss, D. Zurakowski, K. S. Buckley, and G. A. Taylor. 2010. Patient size measured as a function of age at a tertiary care children's hospital. *American Journal of Roentgenology*, *194*, 1611-1619.

[25]The following reference used cylindrical phantoms with diameters of 8, 16, 24, and 32 cm to represent a neonate, 5 year old, 12 year old, and adult patient respectively: Siegel, M. J., et al. 2004. Radiation dose and image quality in pediatric CT: effect of technical factors and phantom size and shape. *Radiology, 233*(2), 515-522.

(2.2-4.4 lb) low end estimate], 1 year old [~11 kg (24 lb); recumbent length 100 cm (39.4 in.)], 5 year old [~21 kg (46 lb); 113 cm (44.5 in) standing height], 12 year old [~52 kg (115 lb); 156 cm (61.5 in) standing height] and adult [~80 kg (176 lb); standing height 170 cm (67.0 in)][26]. Subgroups for head imaging, where it is appropriate to define groups based on patient age, should include the following: 0-1 year, 1-2 years, 2-6 years, 6-16 years, and 16+ years.[27]

The above subgroups are listed as a general guide. Different subgroups that still cover the broad size range expected for pediatric patients may be appropriate depending on the intended use of the x-ray imaging device.[28]

V. Indications for Use

The 510(k) submission should clearly define the indication(s) for use (IFU), including all populations for whom the device is intended. When the needs of pediatric patients are specifically considered in the design and features of a device, the indications for use should specify the pediatric populations in which the device is intended to be used. When a device does not include specialized design features for pediatric populations and is intended to be used across a broad population range, the Indications for Use should state that the device is intended for general populations. For devices intended *only* for adult use, we recommend that you clearly state this as part of your IFU statement. For example, although most x-ray imaging devices for general use may be safely used in pediatric populations, some circumstances exist where restrictions on pediatric populations may be appropriate. One example may be extremity-only cone beam CT scanners designed for adult patients, if safety features do not exist to prevent radiation exposure outside the anatomy of interest when the patient falls outside the typical adult size range.

VI. Risk Assessment

[26] Size measurements are based on approximate mean values (averaged across males and females) from: McDowell, M.A., C.D. Fryar, C.L. Ogden, and K. M. Flegal. 2008. Anthropomorphic Reference Data for Children and Adults, United States, 2003-2006. National Health Statistics Reports, 10, 1-48. The weight given for the neonate subgroup is lower than the average to ensure that a broad range of sizes is adequately covered.

[27] These age ranges differ from those suggested for body imaging due to the difference in the growth rate of the head; the age ranges cited are those that appear in the American Association of Physicists in Medicine (AAPM) sample head protocols for pediatric patients: Pediatric Routine Head CT Protocols Version 1.1, *AAPM Alliance for Quality Computed Tomography*.

[28] For example, the following weight groups are used both in the European Guidelines on Diagnostic Reference Levels for Pediatric Imaging and approximate equivalent ages (European Commission. European Guidelines on Diagnostic Reference Levels for Paediatric Imaging, Radiation Protection 185. 2016. (European Union: Luxembourg) and in the ICRP "Diagnostic Reference Levels in Medical Imaging (ICRP Ref 4836-8337-6684, Draft published January 11, 2016) [Grouping Name (weight, age)]: Neonate (< 5 kg, < 1 m); Infant, toddler and early childhood (5 - < 15 kg, 1 m - < 4 y); Middle childhood (15 - < 30 kg, 4 - < 10 y); early adolescence (30 - < 50 kg, 10 - < 14 y); late adolescence (50 - < 80 kg, 14 - < 18 y).

A good risk assessment should include an examination of all foreseeable risks associated with a device. Even if a general use x-ray imaging device is not specifically indicated for pediatric use, it may be foreseeable that the device will be used on pediatric patients. Because the risk posed by the device may vary depending on the particular population (including different pediatric subgroups across a range of patient sizes), the risk assessment for x-ray imaging devices indicated for pediatric patients (and general use devices for which considerable pediatric use is anticipated) should include the additional hazards and means of mitigation associated with all patient populations on whom the device may be used. Your risk assessment should include a consideration of applicable critical factors outlined in FDA's guidance document entitled "Premarket Assessment of Pediatric Medical Devices: Guidance for Industry and Food and Drug Administration Staff."[29] If the results of the risk assessment demonstrate special features or labeling are not necessary to address pediatric use, then the premarket 510(k) submission should include that justification.

When developing features or user instructions aimed at reducing radiation exposure to pediatric patients, the balance of radiation exposure and image quality for the desired clinical task should be considered. While the clinician has the responsibility to determine the final settings of the device to meet image quality requirements, manufacturers have a responsibility to provide appropriate guidance.

An exam with poor image quality could result in a missed diagnosis or in a repeated exam (involving additional radiation exposure to the patient). An exam with a higher than necessary radiation exposure provides a level of image quality that is not needed for the clinical task as it does not contribute to the clinical purpose of the exam. Examples of hazardous situations that could result in unnecessary radiation exposure or poor image quality specific to pediatric patients include the following:

- Use of adult settings or protocols instead of appropriate pediatric settings or protocols;
- Design features that do not allow proper positioning of pediatric patients (e.g., a deep patient cradle interfering with lateral x-rays of a small patient);
- Automatic controls that are not calibrated for pediatric patients; and
- Absence of safety features to prevent radiation exposure outside the anatomy of interest when the patient falls outside the typical adult size range.

The above examples are not a comprehensive list. Consultation during the design phase with professionals who are knowledgeable regarding pediatric imaging may help identify other risks and situations specific to pediatric use of your x-ray imaging device.

VII. Pediatric Device Features

[29] https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM089742.pdf.

Based on the results of the risk assessment for the x-ray imaging device, manufacturers should include in the 510(k) any particular design features to address pediatric use as risk mitigations. The device description should describe those features specifically included to allow for imaging of smaller-size and pediatric patients, and these features should also be summarized in the Pediatric Summary section of the labeling (see *Section XI.A*). The Agency recommends consultation with knowledgeable pediatric imaging specialists (physicians, physicists, and technologists) and human factors specialists[30] during the design phase to ensure that the device is suitable for pediatric use.

Examples of pediatric use features to consider for x-ray imaging devices are:

- Automatic exposure control (AEC) designed and tested or evaluated, as appropriate, for a broad range of patient sizes, including pediatric;
- Pediatric protocols or pre-set control settings (which clearly specify the intended size range) and labeling that consider the balance of radiation exposure and image quality;[31]
- Display and recording of patient dose or dose index and ability to record other patient information, e.g., age, height, weight and patient body part thickness (either manual entry or automatic calculation);[32] while this recommendation also applies to adult imaging, it is especially important to include for pediatric imaging so estimates of patient-specific dose can be made reliably without assuming a "typical" or "standard" patient size, which are often based on adults; and
- Software interface features that guide the end user to important pediatric use issues (e.g., interactive software pop-ups that remind users of special pediatric issues when setting up the image acquisition).

All of the features listed above may not be appropriate for every device. For example, a CT scanner will likely have a more sophisticated software interface and capabilities for pre-programmed protocols than a general radiography or dental imaging device. Other design considerations may be specific to the type of x-ray imaging equipment; for an example of device-specific considerations, see the white paper by the Medical Imaging Technology Alliance (MITA) and Image Gently which discusses design considerations relevant to interventional x-ray equipment.[33] Relevant pediatric imaging design features may also be

[30]See the FDA guidance entitled "Applying Human Factors and Usability Engineering to Medical Devices" (http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm259760.pdf) and the standards AAMI /ANSI HE75:2009 (R2013), *Human factors engineering - Design of medical Devices* and ANSI/AAMI/IEC 62366:2007 (R2013), *Medical devices – Application of usability engineering to medical devices.*

[31] While full protocols with technique factors (e.g., tube current, tube voltage, etc.) may be appropriate for full x-ray systems, it may be challenging for a component part or accessory device to provide this information. However, alternative information may be appropriate. For example, information about IEC exposure index ranges may be appropriate for a detector-only device.

[32]Appendix, Table 1 entry "dose measurement, display, and documentation" includes relevant dose metrics and FDA-recognized standards for different modalities.

[33]"Essential Questions for Consideration in the Design of Interventional X-ray Equipment Intended for Pediatric Use," Image Gently and the MITA Interventional Fluoroscopy Working Group (IWG), published January 2015.

addressed in device-specific FDA guidance and device-specific FDA-recognized consensus standards.[34]

VIII. Protocols

Pediatric-appropriate protocols for common procedures appropriately adjusted for the patient's size and weight should be available for all complete x-ray imaging systems for which considerable pediatric application is anticipated. Ideally, special hardware and software design issues that affect safety and effectiveness of the device for pediatric use should be addressed in the design phase. For example, if use of automatic exposure control is recommended on pediatric patients, this feature should be designed for pediatric patients and calibrated using methods appropriate for the pediatric population.

The term "protocol" as used in this guidance includes, but is not limited to, a full set of any programmed technical factors, control functions and settings, including image processing settings, designed to optimize the image acquisition and display. In some cases (e.g., general radiography, dental radiography), these protocols may simply consist of instructions (e.g., exposure chart) on how to appropriately configure the equipment and adjust parameters for the patient weight or thickness, body habitus, and clinical anatomy. In other cases (e.g., CT), it may be appropriate to pre-program the protocols into software.

A list summarizing the available pre-configured, default pediatric protocols should be made available to the end user, either as part of the labeling or in downloadable electronic format (see *Section XI* of this guidance). This list should include the protocol name, brief description of exam purpose, anatomical region, intended size of patient, and the acquisition parameters used as starting points. As discussed in the following section, representative dose information (applicable to pediatrics) associated with each protocol should also be provided.

Component parts and accessories to x-ray imaging devices (e.g., detector-only devices) are unlikely to fully control all parameters that make up a complete imaging protocol for pediatric or adult patients. For these device types, providing some protocol-related information may still be appropriate. For example, for a detector-only system, recommended detector exposure indices for different types of exams and patient subgroups may be adequate instead of technique factors and dosimetric information.

For previously 510(k) cleared x-ray imaging devices, optimization of imaging parameters and provision of pediatric-specific protocols by manufacturers solely at the request of end users generally does not by itself necessitate submission of a new 510(k) submission.

[34] See Appendix B. For example, the current editions of device-specific International Electrotechnical Commission (IEC) performance standards, such as IEC 60601-2-43 and IEC 60601-2-54 contain requirements for equipment specified for pediatric applications, such as removable anti-scatter grids. Since the FDA public meetings in 2010 and 2012, the international standards community has continued to add to the pediatric design features included in the device-specific performance standards for x-ray imaging devices.

IX. Laboratory Image Quality and Dose Assessment

Performance of the x-ray imaging device should be assessed over the entire range of patient sizes for which the device is indicated. Because many x-ray imaging devices with general indications will experience significant use in pediatric populations, the entire range of patient sizes should include neonates through adults. The range of settings and conditions used for testing should represent the routine clinical use of the system (e.g., clinically-relevant radiation doses should be used). Appendix B provides relevant tests and applicable standards commonly used to evaluate the performance of x-ray imaging devices. While Appendix B is intended to be as inclusive as possible; not every test listed maybe appropriate for your device. If a device-specific FDA guidance document exists, please consult that guidance document for the recommended testing.

The image quality and radiation dose depends on the x-ray path length, so testing should address a range of representative path lengths and should be included in the 510(k) submission. The appropriate choice of patient sizes will depend on the indications for use of your device or device feature and the imaging physics of the specific device functions being evaluated. A device's 510(k) submission should include the rationale for selecting the patient sizes used in your testing. For example, for an abdominal CT protocol that employs AEC, it may be appropriate to assess image quality and radiation dose for each sized protocol provided; for an interventional x-ray imaging device, measuring air kerma with 10cm and 20cm PMMA phantoms may be sufficient for pediatric use. When selecting phantoms representative of the intended patient population, FDA recommends that manufacturers choose phantoms that are capable of replicating the range of representative of the intended range of patient size/diameter, rather than selecting phantom distribution based on age.

In cases where the performance of a device or device feature based on patient size is well understood (e.g., slice sensitivity profile (SSP), modulation transfer function (MTF), uniformity, CT number accuracy), the performance for the largest and the smallest patient sizes may be sufficient to demonstrate performance of the device across all patient sizes. In these instances, data on intermediate size patients may be extrapolated[35]. However, when the effect of patient size on the performance of a particular device is less well understood, or the device is known to behave non-linearly based on patient size (e.g., iterative reconstruction algorithms, AEC, automatic brightness control, tests of temporal resolution), it is more appropriate to demonstrate the performance of your device across a larger number of patient sizes.

The 510(k) submission should include:

[35] For an extended discussion of cases where data obtained for adult and adult-sized patients may be extrapolated to obtain information applicable to pediatric populations, refer to FDA's guidance "Leveraging Existing Clinical Data for Extrapolation to Pediatric Uses of Medical Devices: Guidance for Industry and Food and Drug Administration Staff" (https://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm444591.pdf). While the scope of that guidance is specific to clinical study data extrapolation, some of the concepts may be applicable to non-clinical bench testing or sample clinical image data.

- A summary of the tests conducted, the methods used, and the test results. The description of the test method should include the system settings (e.g., exposure settings such as tube voltage, tube current, and use of AEC) as well as a description of the phantoms used and the appropriateness of the phantoms. When reporting dose in CT, for example, you may indicate the corresponding phantom with which the measurement was acquired (e.g., CTDIvol (32 cm). FDA encourages the standardized development, manufacturer implementation, and physician use of Size Specific Dose Estimation (SSDE) for estimates of patient dose which more accurately represent the dose received by patients of varying sizes (including pediatric populations). If a test method has been described fully in the literature and was followed completely, a reference may be sufficient.
- The test conditions used for the assessment and why the selected test conditions are sufficient to demonstrate the performance of your device over the entire range of patient sizes for which your device is indicated.
- The measurement uncertainty, the trade name, characteristics, and accuracy of the measuring instruments used for performing quantitative tests, if applicable.

In some cases, a manufacturer may have previously demonstrated device performance for adult-sized patients. In order to demonstrate the performance of the device for the full range of indicated patient sizes in a subsequent premarket submission, it would typically be appropriate to amend this data with a new examination of device performance for smaller sized patients.

X. Clinical Image Quality Assessment

FDA encourages the use of laboratory testing methods to ensure the device is appropriately designed for imaging children due to the Agency's concerns with imaging pediatric patients with devices and the potential risks of exposing this population to medically unnecessary radiation exposure. Clinical images of pediatric patients will only be requested when laboratory testing is insufficient to demonstrate substantial equivalence and when extrapolation of the necessary data from adult images is not sufficient. If any images are provided to the Agency, they should be accompanied by corresponding dose information, exposure settings, and clinical information if available (e.g., type of exam, age, size, and sex of patient, and clinical indications).

For more information on the appropriate protections for pediatric populations, see FDA's guidance entitled "Premarket Assessment of Pediatric Medical Devices".[36] For questions regarding the need for images of pediatric patients, sponsors are encouraged to request a pre-submission meeting prior to 510(k) submission. For information on how to submit a pre-submission, see FDA's guidance entitled "Requests for Feedback on Medical Device

[36] https://www.fda.gov/RegulatoryInformation/Guidances/ucm089740.htm.

Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff."[37]

XI. Labeling

In addition to information describing the general operation of the device, the user manual should contain the following information specific to pediatric use. These labeling recommendations to address pediatric use of x-ray imaging devices are intended to be supplemental to other labeling recommendations and requirements and not intended to be all inclusive of the labeling information expected to be found on an x-ray imaging device. For a more detailed discussion of how the basic elements of labeling may be addressed for pediatric populations, please also refer to Section IX of FDA's guidance entitled "Premarket Assessment of Pediatric Medical Devices."[38].

A. Pediatric Summary Section

The labeling for end users should include a summary section (see *Appendix A*) addressing the specific features and labeling information (*B* though *F* below) for pediatric use of the x-ray imaging device. This information is recommended both for devices indicated for pediatric use and for general use devices that may be used on pediatric patients.

In order to emphasize the importance of safe device operation when imaging pediatric patients, the following caution statement should be included in the pediatric summary section: "*Use special care when imaging patients outside the typical adult size range.*[39]"

FDA believes that this statement and general references for pediatric imaging are appropriate to include in the labeling of *all* devices that may be used on pediatric populations, including devices with general indications or devices with specific pediatric indications and design features. *(*See *Section VI Risk Assessment* for more information.*)*

B. Contraindications, Warnings, and Precautions

Contraindications, warnings, and precautions for devices indicated for pediatric populations, or general use devices for which considerable pediatric appliacation is anticipated, should clearly address the potential risks and their association with the age, size, and condition of the pediatric subject and alert the user to specific hazards associated with the use of the device in the target population.[40] The contraindications, warnings, and precautions should

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[37] https://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm311176.pdf.

[38] https://www.fda.gov/RegulatoryInformation/Guidances/ucm089740.htm.

[39] See the sample Pediatric Summary in Appendix A for an example of a full caution paragraph which includes this language.

[40] See FDA's guidance entitled "Premarket Assessment of Pediatric Medical Devices"; (http://www.fda.gov/RegulatoryInformation/Guidances/ucm089740.htm).

address the risks specific to pediatric use that were identified during the risk assessment. If warnings and contraindications apply to some but not all pediatric subpopulations, the specific applicable subpopulations should be specified.

For devices where the risk of use in pediatric patients or certain pediatric subpopulations clearly outweighs possible benefits based on known hazards, we recommend that you include a contraindication for use in pediatric patients or pediatric subpopulations.

C. Device Description

The device description should include a list of the hardware and software features designed specifically for pediatric use. When different options are available for purchase, the labeling should describe the various options recommended for use in pediatric subgroups and, when feasible, present these options in tabular form by age, weight, or other appropriate criteria.

D. Instructions for Use

Instructions for how to properly configure the device for pediatric use (and how this may differ from adult use) should be provided.

The instructions for use should address radiation dose reduction strategies for pediatric patients. All user-configurable imaging parameters should be clearly explained, including their impact on patient dose. Combinations of certain parameters that can provide for optimal image quality/minimal dose under unusual circumstances (i.e., a difficult or obese patient) may be suggested but should be clearly indicated as such. Screenshots of the user interface software controls should be provided in the labeling, explaining how different parameters affect dose and image quality, particularly for pediatric patients. To mitigate the risk of user error, the following should be considered:

- User's manuals in downloadable electronic form with easily searchable interfaces, in addition to paper copies; and
- Leave-behinds/just-in-time educational material such as checklists that include any special pediatric issues during pre-acquisition, acquisition, and post-acquisition steps[41].

Instructions should consider the likely educational background of the end-user; for example, equipment likely to be used by professionals other than radiologists or radiologic technologists (e.g., dental x-ray or devices designed for cardiac imaging) should include information targeted at the appropriate professional groups (e.g., dentists, cardiologists).

[41] An example is the Image Gently/FDA "Digital Radiography Safety Checklist" (http://www.imagegently.org/Portals/6/Procedures/Attachment%20D.CR.DR%20%20checklist.pdf). FDA strongly encourages the inclusion of or reference to educational materials related to radiation protection for children in x-ray imaging procedures.

E. Quality Control Testing Recommendations

Quality control testing recommendations should include any tests (acceptance testing, annual and continuous testing) that ensure the device functions properly across the entire range of patient sizes in which the device may be used.

F. Additional Information

The end-user documentation should include a means to obtain additional information regarding the unique operating principles of the device pertaining to pediatric use.

A summary of the physical laboratory tests (See *Section IX* of this guidance) characterizing the performance of the device for pediatric use should be provided. Users can then employ this information in their evaluation of the importance of any tradeoffs between different characteristics of imaging performance.

A summary of pediatric protocols (brief description of purpose, acquisition parameters, and intended size of patient) should be provided in a separate section of the manual or in a downloadable electronic format. Dose information for each protocol should be included with the protocol and displayed by the software, where appropriate. Appendix B, Table 1 entry "dose measurement, display, and documentation" includes relevant dose metrics and FDA-recognized standards for different modalities.

If literature is used in support of particular pediatric design features and protocols, a summary should be available to users (e.g., table with references and pediatric use topics or applications and equipment settings covered in each).

XII. Training and Testing Materials for Users and Manufacturers' Personnel

A training program emphasizing production of acceptable quality images at an optimized radiation dose for the device's entire patient population should be made available to the clinical end user.[42] The user's manual may be considered part of this training program.

This training program should emphasize equipment-specific training and the optimal use of all built-in dose reduction and image quality improvement features.[43] It should explain clearly how to use the specific features of the equipment in all populations for which the device may be used. Training should be accessible, practical, and targeted at all different

[42]A model for such a training program for ultrasound devices (not covered by this guidance) is: *Medical Ultrasound Safety*, 2nd ed. (2009) published by the American Institute of Ultrasound in Medicine.
[43]Examples of training materials emphasizing pediatric dose reduction are available at the Image Gently Alliance website (http://www.imagegently.org).

types of end users. If testing questions accompany training sessions, they should address an understanding of pediatric use issues (e.g., dose saving features for children). In order to facilitate continuous learning, a DVD that includes the content of any in-person training sessions could be provided to the facility or made available in another format (e.g., as online modules).

The 510(k) submission should include a summary-level description of the training materials for the device. The description should point out any pediatric-specific topics covered.

Appendix A: Pediatric Summary Section for Instructions for Use

The following is an example of a pediatric summary section for inclusion in the instructions for use for any x-ray imaging device for which considerable pediatric appliacation is anticipated (both devices indicated for pediatric populations and general use x-ray devices not contraindicated for pediatric populations). For x-ray imaging devices without specific design features or labeling information, FDA recommends including the *Introduction* and *Section A* of the below summary in the instructions for use. For x-ray imaging devices with specific design features and labeling information to address pediatric use, the entire example is applicable (i.e., *Introduction, Section A,* and *Section B*).

Manufacturers should adapt the language below as appropriate for their device. For general information on radiation safety, FDA encourages device manufacturers to use available resources developed by national and international organizations rather than creating new material; literature developed by imaging and radiation protection experts is available for all of the different modalities covered by this guidance. FDA also encourages manufacturers to consider how their device can be better configured for pediatric use, and to provide that more specific information to the end user.

Example follows

Pediatric Use: Summary

Introduction: Special care should be exercised when imaging patients outside the typical adult size range, especially smaller pediatric patients whose size does not overlap the adult size range (e.g., patients less than 50 kg (110 lb) in weight and 150 cm (59 in) in height,measurements, which approximately correspond to that of an average 12 year old or a 5th percentile U.S. adult female.[44])

Exposure to ionizing radiation is of particular concern in pediatric patients because: 1) for certain organs and tumor types, younger patients are more radiosensitive than adults (i.e., the cancer risk per unit dose of ionizing radiation is higher for younger patients); 2) use of equipment and exposure settings designed for adults of average size can result in excessive and unnecessary radiation exposure of smaller patients; and 3) younger patients have a longer expected lifetime over which the effects of radiation exposure may manifest as cancer.

To help reduce the risk of excessive radiation exposure, you should follow the ALARA (As Low As Reasonably Achievable) principle and seek to reduce radiation dose to only the amount necessary to obtain images that are adequate clinically.

[44]McDowell, M.A., C.D. Fryar, C.L. Ogden, and K. M. Flegal. 2008. Anthropomorphic Reference Data for Children and Adults, United States, 2003-2006. *National Health Statistics Reports*, *10*, 1-48.

A. References for pediatric dose optimization: The following resources provide information about pediatric imaging radiation safety and/or radiation safety for <insert your device modality, e.g., computed tomography, fluoroscopy, general radiography, dental radiography> devices:
<Insert references appropriate to your device>[45]

B. Device specific features and instructions: The <insert your device name> provides the following specific design features and instructions that enable safer use of our device with pediatric patients:[46]
<insert design features, noting whether they are standard or extra options>
<insert references to labeling, e.g., protocols, dosimetry information, safe use checklists, summary of any testing to evaluate pediatric use>

Design feature important to pediatric imaging[47]	**Page number reference in Instructions for use**
Protocols or exposure indices	p.
Removable grid	p.
Filter	p.
Variable focal spot size	p.
Post-processing application	p.
Reconstruction algorithm	p.
Automatic Exposure Control	p.
Etc.	

Testing information	**Page number reference in Instructions for use**
Estimated patient dosimetry covering pediatric size ranges	p.
Image quality assessment (especially to support any pediatric performance specifications; may be phantom-based)	p.
Quality Control instructions including tests to ensure proper operation across a broad patient size range	p.

[45]FDA's website provides radiation safety information references from a variety of groups including the Image Gently Alliance: Pediatric X-ray Imaging (http://www.fda.gov/Radiation-EmittingProducts/RadiationEmittingProductsandProcedures/ucm298899.htm; and Medical X-ray Imaging (http://www.fda.gov/Radiation-EmittingProducts/RadiationEmittingProductsandProcedures/MedicalImaging/MedicalX-Rays/default.htm). In addition, FDA's Pediatric X-ray Imaging Website (https://www.fda.gov/radiation-emittingproducts/radiationemittingproductsandprocedures/medicalimaging/ucm298899.htm) contains links to device-specific pages on Computed Tomography, Fluoroscopy, and Dental Cone-beam Computed Tomography.
[46]See *Section VII (Pediatic Device Features)* for examples.
[47]This list of examples is not meant to be exhaustive and it is not appropriate for every device. Some of the features you choose to list may not be limited for use on pediatric patients, but may be especially important for safe pediatric imaging (e.g., Automatic Exposure Control).

Appendix B: General Laboratory Image Quality and Dose Assessment, Tests and Standards

This Appendix lists common laboratory tests and the applicable standard for each modality. This list is included for reference and is not intended to be exhaustive. The tests listed in this Appendix focus on ensuring the imaging device is capable of producing acceptable quality images at a reasonable dose. The information may also be included in device-specific guidance, which should also be consulted. Inclusion of this list does not imply that all of these standards must be followed for every device or that every applicable test and associated standard has been listed. For additional standards applicable to specific devices, please refer to FDA's Recognized Consensus Standards Database.[48]

The guidance entitled "Recognition and Use of Consensus Standards"[49] describes how the agency will use information on conformance with recognized standards to satisfy premarket review requirements. In the case of 510(k)s, information on conformance with recognized standards may help establish the substantial equivalence of a new device to a legally marketed predicate in the areas covered by the standards. If a 510(k) contains declarations of conformity (and the standard to which conformance is claimed includes performance limits or acceptance criteria), this will, in most cases, eliminate the need for FDA to review the actual test data for those aspects of the device addressed by the standards. Instead of following a recognized standard, a firm may choose to submit alternative equivalent information demonstrating safety and effectiveness.

The list below focuses on test methods, but the Appendix also includes the performance and safety standards for each modality: computed tomography (International Electrotechnical Commission (IEC) 60601-2-44[50]); radiography and fluoroscopy (IEC 60601-2-54[51]); interventional fluoroscopy (IEC 60601-2-43[52]); dental extra-oral X-ray equipment (IEC 60601-2-63[53]); and dental intra-oral X-ray equipment (IEC 60601-2-65[54]). Some of these standards include features and labeling requirements which are specifically relevant to pediatric imaging, while others have feature and labeling requirements which are relevant to all sizes of patients (including smaller-sized adult and pediatric patients). For example, IEC 62985 (*Methods for calculating Size Specific Dose Estimate (SSDE) on Computed Tomography*) describes a method of determining patient dose, scaled from $CTDI_{vol}$, which provides a more accurate representation of the dose to patients across a wide range of sizes

[48] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm
[49] http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm077274.htm
[50] IEC 60601-2-44 *Medical electrical equipment – Part 2-44: Particular requirements for the basic safety and essential performance of X-ray equipment for computed tomography*
[51] IEC 60601-2-54 *Medical electrical equipment - Part 2-54: Particular requirements for the basic safety and essential performance of X-ray*
[52] IEC 60601-2-43 *Medical electrical equipment - Part 2-43: Particular requirements for the basic safety and essential performance of X-ray equipment for interventional procedures*
[53] IEC 60601-2-63 *Medical electrical equipment - Part 2-63: Particular requirements for the basic safety and essential performance of dental extra-oral X-ray equipment*
[54] IEC 60601-2-65 *Medical electrical equipment – Part 2-65: Particular requirements for the basic safety and essential performance of dental intra-oral X-ray equipment*

(including pediatric and small adult patients). Other standards address issues specific to the safety of pediatric patients; for example, as of early 2017 the IEC standards 60601-2-54 and IEC 60601-2-43 are being updated to include some of the issues addressed in the Medical Imaging & Technology Alliance (MITA) and Image Gently white paper "Essential Questions for Consideration in the Design of Interventional X-ray Equipment Intended for Pediatric Use." FDA continues to work with and encourage standards development organizations to address modality-specific features and concerns within their performance and safety standards.

Table 1. Physical Laboratory Tests and Applicable Standards

Test and brief description	Modality	Relevant standard or more detailed instructions
Sensitometric Response: The output digital signal value versus the radiation exposure curve provides the sensitometric response of the image acquisition system.	General radiography (excludes dynamic imaging/fluoroscopy and CT)	IEC 62220-1-1*Medical electrical equipment- Characteristics of digital x-ray imaging devices- Part 1: Determination of the detective quantum efficiency– Detectors used in radiographic imaging*
	Dynamic imaging x-ray devices (e.g., fluoroscopic or cardiac imaging)	IEC 62220-1-3 *Medical electrical equipment - Characteristics of digital X-ray imaging devices - Part 1-3: Determination of the detective quantum efficiency - Detectors used in dynamic imaging*
Modulation Transfer Function (MTF): Provides a quantitative measure of the spatial resolution properties of the image acquisition system.	CT	IEC 61223-3-5 *Evaluation and routine testing in medical imaging departments–Part 3-5: Acceptance tests–Imaging performance of computed tomography X-ray equipment*
	General radiography (excludes dynamic imaging/fluoroscopy and CT)	IEC 62220-1-1 *Medical electrical equipment- Characteristics of digital x-ray imaging devices- Part 1: Determination of the detective quantum efficiency – Detectors used in radiographic imaging*
	Dynamic imaging x-ray devices (e.g., fluoroscopic or cardiac imaging)	IEC 62220-1-3 *Medical electrical equipment - Characteristics of digital X-ray imaging devices - Part 1-3: Determination of the detective quantum efficiency - Detectors used in dynamic imaging*
Noise Power Spectrum (NPS): As a function of spatial frequency and exposure level, this test provides a quantitative measure of the noise properties of the image acquisition system.	General radiography (excludes dynamic imaging/fluoroscopy and CT)	IEC 62220-1-1 *Medical electrical equipment- Characteristics of digital x-ray imaging devices- Part 1: Determination of the detective quantum efficiency – Detectors used in radiographic imaging*
	Dynamic imaging x-ray devices (e.g., fluoroscopic or cardiac imaging)	IEC 62220-1-3 *Medical electrical equipment - Characteristics of digital X-ray imaging devices - Part 1-3: Determination of the detective quantum efficiency - Detectors used in dynamic imaging*
Detective Quantum Efficiency (DQE): This test provides a quantitative measure of the efficiency of signal-to-noise ratio (SNR) transfer of the image acquisition system. This measure is	General radiography (excludes dynamic imaging/fluoroscopy and CT)	IEC 62220-1-1 *Medical electrical equipment- Characteristics of digital x-ray imaging devices- Part 1: Determination of the detective quantum efficiency – Detectors used in radiographic imaging*

obtained by calculating the detective quantum efficiency (DQE) as a function of spatial frequency. SNR analysis should be performed using exposure levels covering the range normally encountered using your system to provide the dynamic range of the system.	Dynamic imaging x-ray devices (e.g., fluoroscopic or cardiac imaging)	IEC 62220-1-3 *Medical electrical equipment - Characteristics of digital X-ray imaging devices - Part 1-3: Determination of the detective quantum efficiency - Detectors used in dynamic imaging*
Image Erasure and Fading: For systems using a delayed readout of image data, such as a photostimulable phosphor, tests should include image decay as a function of time and temperature and signal retention as a function of the number of erasures and exposures.	General radiography/fluoroscopy	For testing recommendations appropriate for radiographic and fluoroscopic systems, please see *Section VI Nonclinical Considerations* of the guidance entitled "Guidance for the Submission of 510(k)s for Solid State X-ray Imaging Devices"[55]
Repeated Exposure test for ghosting: Tests for quantitatively assessing residual images/ghosts are described in IEC standards as "lag effect" tests.	General radiography	IEC 62220-1-1 *Medical electrical equipment- Characteristics of digital x-ray imaging devices- Part 1-1: Determination of the detective quantum efficiency – Detectors used in radiographic imaging*
	Dynamic imaging x-ray devices (e.g., fluoroscopic or cardiac imaging)	IEC 62220-1-3 *Medical electrical equipment - Characteristics of digital X-ray imaging devices - Part 1-3: Determination of the detective quantum efficiency - Detectors used in dynamic imaging*
Automatic exposure control (AEC) performance: A demonstration of the degree of control intended with respect to tube current modulation on non-uniform phantoms or with respect to temporal gating should be performed for a range of exam conditions (phantom sizes or time sequences).	CT: 60601-2-44 specifies that CT scanners provide an AEC feature, 61223-3-5includes a sample test of AEC performance as an informative annex	IEC 60601-2-44 *Medical electrical equipment – Part 2-44: Particular requirements for the basic safety and essential performance of X-ray equipment for computed tomography*; and IEC 61223-3-5 *Evaluation and routine testing in medical imaging departments–Part 3-5: Acceptance tests–Imaging performance of computed tomography X-ray equipment*
	Radiography and fluoroscopy	The following standard also applies to interventional fluoroscopy (with exceptions and additions noted in IEC 60601-2-43): IEC 60601-2-54 *Medical electrical equipment - Part 2-54: Particular requirements for the basic safety*

[55] http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm073781.pdf

		and essential performance of X-ray equipment for radiography and radioscopy[56]
Dose or exposure index measurement, display, automatic reporting of values, and documentation	CT: Dose indices based on Computed Tomography Dose Index 100 ($CTDI_{100}$) and radiation dose structured reporting standards	IEC 60601-2-44 *Medical electrical equipment – Part 2-44: Particular requirements for the basic safety and essential performance of X-ray equipment for computed tomography*;
	CT: Dose estimates scaled to a range of patient sizes, including pediatric patients	IEC 62985 *Methods for calculating Size Specific Dose Estimate (SSDE) on Computed Tomography*
	Radiography and fluoroscopy: defines reference air kerma and reference air kerma rate	IEC 60601-2-54 *Medical electrical equipment - Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy*
	Interventional fluoroscopy: defines reference air kerma, reference air kerma rate, dose-area product; specifies range of operating conditions for dose measurements; defines skin dose as air kerma for display purposes	IEC 60601-2-43 *Medical electrical equipment - Part 2-43: Particular requirements for the basic safety and essential performance of X-ray equipment for interventional procedures*
	Exposure index standard for general radiography	IEC 62494-1 *Medical electrical equipment - Exposure index of digital X-ray imaging systems - Part 1: Definitions and requirements for general radiography*
	Radiation dose structured reporting for radiography and fluoroscopy	IEC 60601-2-54 *Medical electrical equipment - Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy*[57]
	Reproducibility of radiation output for dental x-ray devices	IEC 61223-3-4 *Evaluation and routine testing in medical imaging departments - Part 3-4: Acceptance tests - Imaging performance of dental X-ray equipment* and IEC 60601-2-63 *Medical electrical equipment - Part 2-63: Particular requirements for the basic safety*

[56]Subclause 203.6.3.2.102 of IEC 60601-2-54 does not mention pediatrics specifically but it does specify a range of different-sized phantoms (10, 15, 20 cm thickness) for testing of automatic exposure control for direct radiography.

[57] Radiation dose structured reporting is included in Amendment 2 of this standard, which is currently being updated.

		and essential performance of dental extra-oral X-ray equipment and IEC 60601-2-65 *Medical electrical equipment – Part 2-65: Particular requirements for the basic safety and essential performance of dental intra-oral X-ray equipment*
Modality-specific tests not specified in above categories (examples included for reference; not exhaustive)	Dental x-ray imaging: Line pair resolution; Low contrast resolution; Image homogeneity; Accuracy of x-ray tube voltage and current	IEC 61223-3-4 *Evaluation and routine testing in medical imaging departments - Part 3-4: Acceptance tests - Imaging performance of dental X-ray equipment* and IEC 60601-2-63 *Medical electrical equipment - Part 2-63: Particular requirements for the basic safety and essential performance of dental extra-oral X-ray equipment* and IEC 60601-2-65 *Medical electrical equipment – Part 2-65: Particular requirements for the basic safety and essential performance of dental intra-oral X-ray equipment*
	CT: Sensitivity Profile; Patient-Support Positioning and Accuracy; Tomographic Section Thickness; Noise; Uniformity; Mean CT Numbers	IEC 61223-3-5 *Evaluation and routine testing in medical imaging departments–Part 3-5: Acceptance tests–Imaging performance of computed tomography X-ray equipment*; and IEC 60601-2-44 *Medical electrical equipment – Part 2-44: Particular requirements for the basic safety and essential performance of X-ray equipment for computed tomography*
	Fluoroscopy and radiography: Additional tests are specified in the standards on the right (some of these tests are also included in the FDA performance standards).	IEC 60601-2-54 *Medical electrical equipment - Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy* and

		IEC 60601-2-43 *Medical electrical equipment - Part 2-43: Particular requirements for the basic safety and essential performance of X-ray equipment for interventional procedures*

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