Welcome to Today's FDA/CDRH Webinar

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Pediatric Information for X-ray Imaging Device Premarket Notifications

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Overview of Today's Webinar

- Balancing benefits and risks of pediatric radiation exposure
  - Pediatric radiation exposure risks should be balanced with an exam's benefits; we have the opportunity to reduce dose
- Guidance scope
- Guidance overview: 510(k) submission contents for manufacturers
  - Indications for use
  - Device risk assessment
  - Features/protocols/testing
  - Pediatric labeling and instructions for use
- Ongoing collaborations to promote pediatric safety
- Questions

Pediatric Population

- CDRH defines pediatrics as birth through 21 years*
  - Age ranges: neonate (birth-1 month), infant (1 month-2 years), child (2-12 years), adolescent (12-21 years)
- For X-ray imaging and radiation dose optimization, patient size/weight matters more than age
  - Smaller patient thicknesses need less radiation to produce a good quality image
  - Children's heads grow at a different rate than their bodies, so age groupings for head imaging may differ from body imaging
- Guidance suggests size/age ranges for pediatric groupings

*See FDA's guidance entitled "Premarket Assessment of Pediatric Medical Devices" (http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM089742.pdf)."

Balancing Benefit and Risk

- X-ray imaging helps in the diagnosis, treatment planning, and surgical intervention in children
- However, ionizing radiation exposure from X-ray exams may slightly increase lifetime risk of cancer. To minimize risks to children, imaging should be *justified* and *optimized*:
  - *Justify: only prescribe X-ray exams when needed to diagnose or answer a medical question, and when benefits outweigh risks*
  - *Optimize: exams should use techniques for the lowest radiation dose that still allows image quality adequate for diagnosis / intervention*

Opportunities to Minimize Risk

- Most X-ray imaging devices can be safely optimized for pediatrics
  - Many may lack instructions for pediatric use and dose optimization use
  - X-ray imaging professionals may struggle to locate and apply these recommendations without help from manufacturers
- Pediatric device features can be developed to enhance safety and mitigate pediatric-specific risks

Role of Manufacturers

- Manufacturers can help by following recommendations and actions in the final guidance to support health care professionals in managing X-ray doses:
  - Optimizing for pediatrics by default, including instructions for optimization, and including pediatric instructions for use
  - Helping their customers encourage reduction of radiation dose through educational tools, some examples are available on FDA's Pediatric X-ray imaging webpage
  - Developing device features to enhance safety and mitigate pediatric-specific risks

Pediatric Safety is a Shared Responsibility

Manufacturers

- Provide safe and effective devices
- Consider pediatric needs and risks in device design – provide and test features
- Include instructions and information for users

FDA

- Assure safety & effectiveness of devices
- Outreach to public / collaborate with stakeholders

Health Care Provider

- Justify – order exams only when necessary
- Optimize – use the right dose for the patient, know and use your equipment's features
- Communicate benefits and risks with patients and parents

Parents, Caregivers and Patients

- Track the child's medical imaging history
- Ask the doctor whether the exam will improve child's healthcare
- Ask facility about safeguards and if the exam is "child-sized"

Goals for Pediatric X-ray Imaging Guidance Document

- Provide guidelines to manufacturers recommending actions manufacturers can take to support health care professionals in managing X-ray doses for pediatric patients:
  - Design and testing of X-ray imaging equipment and features should be related to patient size and cover all size ranges
  - Equipment should be designed so health care professionals can appropriately image smaller patients more easily
- Devices that are designed and labeled for pediatric use will help ensure the safety and protection of patients

Guidance Scope

- Guidance for Industry and FDA
  - The guidance provides an opportunity for Industry and FDA to discuss pediatric radiation safety with parents, health care professionals, and the public
- Information to include in a Premarket Notification [510(k)] submission and in device labeling
- X-ray imaging devices and component parts
- Indicated for:
  - Pediatric populations, OR
  - General use devices, where significant pediatric use is anticipated

Use of X- ray Devices with Pediatrics

- Most general use X-ray devices have significant pediatric use
  - Unless a device's design explicitly excludes pediatric imaging, we know most devices will be used to image children
  - In 2006, 10 percent of all CT procedures (60 million annually) were for pediatric patients*
  - Majority of pediatric exams not done in children's hospitals; equipment used for all patient sizes/ages

*[National Council on Radiation Protection and Measurements (NCRP). *Report 160: Ionizing Radiation Exposure of the Population of the United States.* March 3, 2009.]

Protocols and Optimization

- "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"
  - Clarification language requested by end users, so manufacturers are able to respond to customer requests
  - See Section XIII ("Protocols") of the guidance document

Indications for Use Statement

- Indications for use statement: specify all populations for whom device is intended
- If a pediatric population's needs were specifically evaluated in the design and testing, the population should be stated in the indications for use
- If a device is intended *only* for adult use, clearly state this as part of the device's indications for use statement
  - Most general use X-ray devices can be used in pediatrics
  - "Not for pediatric use" to be used only when there are physical design safety limitations (e.g., extremity-only cone beam CT designed for adults without pediatric-sized shielding)

Include in Your 510(k)

- In your 510(k) submission, address pediatrics in the following ways:
  - *Risk Assessment*: Address pediatric use, provide appropriate mitigations
  - *Protocols*: Provide default imaging protocols for pediatric subpopulations (different size/weight ranges)
  - *Testing*: Assess device performance across the entire indicated patient population size range
  - *Labeling*: Instructions/info specific to pediatric use; include a Pediatric Summary section

Risk Assessment

- Consider all foreseeable risks for all applicable populations
- Your device will be used on children – this is foreseeable
- Hazards may differ for patients of different sizes
- Consider hazards that can cause low image quality or unnecessary dose for children:
  - Use of adult protocols or settings instead of pediatric-specific
  - Design that prevents proper positioning of pediatric patients
  - Absence of safety features to block radiation to other anatomies
- Mitigations may include pediatric design features/labeling
  - If assessment result does not require the above, provide justification

Performance Testing

- Performance testing should cover full indicated patient size range (neonate to adults)
  - For tests with size dependence, test largest and smallest sizes; for others, test all size ranges
- Justify why conditions are applicable to full patient size range
- Settings used in testing should represent typical clinical use
- Summarize test conditions and results
- Images will be required only when laboratory testing is insufficient to demonstrate safety and effectiveness, and when extrapolation from adult images is not sufficient

Pediatric Summary Section

- X-ray devices for which significant pediatric use is anticipated should include a Pediatric Summary section
- The Pediatric Summary section of the labeling / user manual contains:
  - A description of any special pediatric features and labeling information for pediatric use of the X-ray imaging device
  - Appropriate pediatric cautions/warnings and instructions for use for the specific device type
  - The following caution statement: "*Use special care when imaging patients outside the typical adult size range*"
- The guidance features a sample summary in appendix A

Protocols – Across All Sizes

- The term “Protocol”, as used in the final guidance, is set of any programmed technical factors, control functions and settings, including image processing settings, designed to optimize the image acquisition and display
- Provide pediatric-appropriate protocols for common procedures, adjusted for the patient's size/weight
- Include a list of all available pediatric protocols (downloadable electronic format) with the following info:
  - Protocol, and exam name/purpose
  - Anatomical region
  - Patient size/weight range
  - Acquisition parameters
  - Representative dose information (appropriate to pediatrics)

Ongoing Pediatric Collaborations

- Cooperation among industry, clinicians, physicists and regulators for many years
- *Initiative to Reduce Unnecessary Ionizing Radiation from Medical Imaging* resulted in
  - Four computed tomography industry standards
  - New equipment that is used for calibration and testing purposes (phantoms) for quantitative dose reduction measurements
- Resulted in updates to International Electrotechnical Commission (IEC) standards
- Size specific dose estimate: a better way to estimate dose across all patient sizes will become a new IEC standard
- Upcoming work – dental X-ray standards

Communicating with the Public: Information, Not Alarm

- Remember the benefits, balance the risks
  - When medically justified, benefit of exams far outweigh radiation risk
  - Parents, caregivers and patients should ask questions about how the exam will improve the patient's health care and the risks involved
  - Cancer risk estimates are uncertain but low; optimizing radiation dose to lowest needed level will minimize this risk

Opportunities for Public Communication

- FDA Resources:
  - Pediatric X-ray Imaging webpage
  - Initiative to Reduce Unnecessary Radiation Exposure from Medical Imaging
  - FDA Voice Blog: X-rays and Children: FDA Issues Guidance to Minimize Dose
  - Medscape Article: Safety in Pediatric Imaging: FDA Releases New Guidance