

**FDA Webinar: Pediatric Information for X-ray
Imaging Device Premarket Notifications: Final Guidance**

**Moderator: Irene Aihie
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3:00 pm ET**

Coordinator: Welcome and thank you for standing by. At this time all participants are in a listen-only mode until the question-and-answer session. If you would like to ask a question today please press star followed by 1 on your touch-tone phone. At that time you will be prompted to record your first and last name.

The conference is being recorded today. If you have an objection, you may disconnect at this time. Now I will turn the call over to your host, Ms. Irene Aihie. Thank you. You may begin.

Irene Aihie: Hello and welcome to today's FDA Webinar. I am Irene Aihie of CDRH's Office of Communication and Education. On November 27, 2017 the FDA released a final guidance encouraging manufacturers to consider radiation safety of pediatric populations in the design of X-ray imaging devices.

The purpose of the guidance is to provide industry with recommendations on the information that should be included in premarket submissions for X-ray imaging devices that may be used on pediatric patients.

These recommendations include pediatric youth instruction, safety information and a description of available pediatric-specific features which will help healthcare professionals to make more informed decisions about the use of the device on pediatric patients.

Today Laurel Burk, Biomedical Engineer in the Office of In Vitro Diagnostics and Radiological Health here in CDRH, will present an overview of the final guidance. Following the presentation, we will open the line for your questions related to information provided during the presentation.

Additionally, there are other center subject matter experts here with us today to speak to the Q&A portion of our Webinar. Now, I give you Laurel.

Laurel Burk: Thank you for that introduction, Irene. I want to start today's Webinar by discussing the motivation of this guidance document which is to recommend ways that manufacturers can promote a balance between the benefits of X-ray imaging and the possible risks of radiation exposure to pediatric patients.

Because we have an opportunity to reduce risk by reducing unnecessary dose to children, FDA has introduced this final guidance document. We'll discuss the guidance document contents in more detail starting with the scope and the types of medical devices that the guidance applies to.

We'll provide an overview of the specific 510(k) premarket notification submission content that are discussed in this guidance document like the indications for youth statements, the device risk assessment as it applies to pediatric use, pediatric features and the testing we need to support their use including a full range of patient sizes from the smallest children and labeling and instructions for use.

We'll then discuss ongoing collaborations among FDA, industry, medical professionals and professional societies who are all working together to promote pediatric safety and X-ray imaging. And at the end, we'll save plenty of time for your questions.

To start let's first define pediatric populations. The Center for Devices and Radiological Health defines pediatrics as birth through age 21 with breakdowns into different pediatric subpopulations based on different age ranges. But for X-ray imaging and radiation dose optimization, it's especially important for us to think about the patient's size or weight.

Smaller patients with smaller body thicknesses typically need less radiation to produce a good quality image. Because of this, FDA encourages manufacturers to divide pediatric subgroups for their protocols based on size or weight, not just age.

Since children's heads grow at a different rate than their bodies, appropriate age groupings for head imaging won't necessarily be the same as those for body imaging. Our guidance document suggests some size and age ranges for pediatric grouping for body imaging and for head imaging, keeping in mind that the patient's size or thickness is the most important factor for imaging and dose optimization.

Our motivation for this guidance document is to let manufacturers know how they can better support healthcare providers in balancing the benefits and risks of X-ray imaging with pediatric patients. As we know, X-ray imaging is often necessary for diagnosis, treatment planning and surgical intervention in children.

However, ionizing radiation exposure for X-ray exams could slightly increase lifetime risk of cancer. Although this is a small risk, we should try to minimize it as much as possible, and to do this we encourage imaging to be justified and optimized.

Justification means performing X-ray exams only when needed to diagnose a disease or to answer a medical question and when the benefits are believed to outweigh the possible risks. Optimization means performing that necessary exam using techniques with the lowest radiation dose that will still result in adequate image quality so that the image can be used for diagnosis.

Appropriate justification is the responsibility of medical professionals who order and perform X-ray imaging exams. Optimization however is an area where other experts and stakeholders like manufacturers can make significant contributions.

We want to take any opportunity we can to minimize risk from X-ray scans of pediatric patients. Most X-ray imaging devices in use today can be safely optimized for imaging children, but we've heard from healthcare providers that many of these devices lack clear instructions for pediatric use or instructions on how to optimize dose.

There are expert organizations who offer training materials and recommendations for dose optimization and radiation safety in pediatrics but imaging professionals may have difficulty locating and applying these recommendations without some extra support from manufacturers.

In addition you as the manufacturer are in the best position to understand what specific features can be applied to your imaging devices to enhance the safety

of pediatric use and to mitigate pediatric-specific risks that could occur from inappropriate use of your device.

Manufacturers can help support healthcare providers by following the recommendations and actions listed in the final guidance. You can ensure that your devices are optimized for pediatrics by default or with an easy setup, providing instructions for optimization and including pediatric instructions for youth.

You can help customers to optimize exams for children by promoting and providing educational tools developed by expert organizations, and we provide links to some of these educational tools on our newly-updated pediatric X-ray imaging Webpage on FDA's Website. Finally, you can develop device-specific features which enhance safety and mitigate pediatric-specific risks.

Of course, we can't forget that pediatric safety is a shared responsibility. Manufacturers' roles are discussed on the last slide and will be the focus of much of the rest of this talk but FDA, healthcare providers and patients and parents will work with you on the shared goals.

FDA's mission is to assure the safety and effectiveness of devices for all populations including children. We have issued our guidance document to support this goal. We also have the opportunity for public outreach in collaboration with stakeholders which we'll mention at the end of this presentation.

Healthcare providers are on the front lines. They are the ones prescribing and performing exams and they can practice those principles of justification and

optimization in their practices to protect children. Also, they can clearly communicate the benefits and risks of exams with patients and parents.

Finally, parents, caregivers and patients have a role to play. They can track a child's medical imaging history and ask questions like whether an exam will improve their child's healthcare or whether the exam has been correctly child-sized. Again, these are the justification and optimization questions we've mentioned a couple of times.

The goal of this guidance is to provide manufacturers with recommendations on the information that they should include in pre-market submissions or 510(k)s for X-ray imaging devices that may be used on pediatric patients.

We want manufacturers to design and test equipment and features across the full indicated size range including smaller pediatric patients, and we want equipment to be designed so that healthcare professionals can easily image smaller, younger patients with the appropriate child-sized exam.

We believe that if devices are designed, tested and labeled for safe and effective use in the pediatric population, they will be safe and effective for everyone. Now I'll discuss the contents of our final guidance in some more detail. This guidance is for industry and FDA and it covers the information that should be included in a 510(k) submission and in a device's labeling.

The guidance applies to X-ray imaging devices and to component parts such as detectors and some software. These are recommendations that manufacturers should follow when they are ready to market a new device or when they submit their next 510(k) for modifications to a currently-marketed device.

It applies to devices which are indicated either specifically for pediatric populations or for general use devices where significant pediatric use is anticipated.

X-ray

So, a little more about that last point. Most general use X-ray devices will have significant pediatric use. Unless a device is designed explicitly exclude safe pediatric imaging, we know most devices will be used on children and the number of exams performed annually on pediatric patients is quite significant. For example, by one estimate 10% of PT procedures are performed on pediatric patients.

Also, most pediatric exams are not performed in dedicated children hospitals but are done in community hospitals and general practices with equipment that is used for all patient sizes. This is why it's important for manufacturers of general use X-ray imaging devices to follow the guidance's recommendations as well.

We inserted one clarification sentence in the guidance document at the request of some end users and it was hard to find a good place to insert this in the presentation but I did it here, so I'll read the sentence in its entirety.

“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.” This is a very long sentence which was honed by our lawyers so I'll repeat the main takeaways.

If a customer reaches-out to you, the manufacturer, asking for individual help to optimize pediatric protocols or parameters, you can help without worrying

whether you need to submit a new 510(k) as a result. For more on this long sentence, you can refer to the protocol section of the guidance document.

A little bit about the indications for use statement of your device. The device's IFU statement should specify all populations for whom the device is intended. If a pediatric population or subpopulation's needs were specifically evaluated in the design and testing of the device, then the population or subpopulation should be clearly stated in the indications for use.

If a device is truly intended only for adult use, then this should also clearly be stated in the device's IFU statement. However, as we discussed earlier most general use X-ray devices can and will be used for pediatric patients if appropriate parameters and protocols are used.

So the language not for pediatric use should be reserved for the IFUs for devices only where there are physical design safety limitations preventing safety from children so one example could be an extremity-only cone beam CT which is designed for adults and adult-sized limbs and where pediatric size shielding isn't included.

The 510(k) submission should include pediatric populations anywhere applicable including in the following sections: the risk assessment, protocols, performance testing and labeling and instructions for use. On the next slide we'll look at each of these areas in some more detail.

A device risk assessment or hazard analysis should consider all foreseeable risks for all applicable populations. Because nearly all X-ray imaging devices will be used on children except for those excluded by design and excluded in the IFU, pediatric patients and pediatric-specific risks should be included in the device's risk assessment.

Consider that hazards may be different for patients of different sizes including different pediatric subpopulations like neonates versus adolescents. Also consider hazards that could result in low image quality or unnecessary radiation dose in children such as use of adult protocols or settings instead of pediatric-specific protocols or settings.

The device design prevents proper positioning of pediatric patients or the lack of safety features to block radiation to other anatomies. To mitigate any risks you find, you may choose to include pediatric-specific design features which we strongly encourage or additional labeling and instructions for use in some cases.

If you complete a pediatric risk assessment and you determine that you don't need to include the specific features or labeling to mitigate risk, then you should please justify this in your 510(k).

The performance testing of your device and its features should cover the full indicated patient size range which for pediatrics can range from small neonate to older pediatric patients who are similar to an adult size. If a specific test has a well-understood or linear size dependence, then you could provide tests for just the largest and smallest sizes with a justification.

For other tests where the size dependence of the results is not as well understood, your submission should include testing which covers all of the patient size ranges. Your test should include a justification of why the chosen test conditions are applicable to a full patient size range.

The settings used in testing should represent a typical clinical use and your test report should summarize the conditions and results and how they support

substantial equivalence in the device's intended use. For many X-ray imaging devices and device changes, FDA typically requests sample clinical images to be provided with the 510(k) to support substantial equivalence.

However, FDA doesn't typically request sample clinical images of pediatric patients due to the potential risks that could be involved in imaging children with devices that aren't yet cleared by FDA. In those cases we encourage the use of imaging phantoms or extrapolation from adult images if possible.

We'll only ask for images of pediatric patients for a 510(k) when the bench testing isn't sufficient to demonstrate safety and effectiveness and when extrapolation from adult images is also not sufficient.

An important new feature described in the final guidance is the requirement for a pediatric summary section in the device's user manual. XX-ray devices for which significant pediatric use is anticipated not just those indicated explicitly for pediatrics should include a pediatric summary section. The pediatric summary section contains A description of any special features and labeling information for pediatric use of the X-ray imaging device, appropriate pediatric cautions and warnings and instructions for use for the specific device type, and the following caution statement "use special care when imaging patients outside the typical adult size range."

The guidance document includes a sample pediatric summary section in Appendix A including examples both for when specific pediatric features exist for the device and for when no specific pediatric features are included. Finally let's discuss the sample protocols that are asked to be provided with X-ray imaging devices in device components.

The term protocol means the set of any program technical factors, control functions and settings including image processing settings designed to

optimize the image acquisition and display. In your 510(k) submission please provide pediatric-appropriate protocols for common procedures adjusted for the patient's size or weight.

You should include a list of all available pediatric protocols for your customers in downloadable electronic format with the following information: the protocol and exam name and purpose; the anatomical region; a patient's size-weight range; acquisition parameters and representative dose information.

So that covers the content of the guidance document and we answer more specific questions in detail at the end but I'd like to discuss some ongoing pediatric collaboration and acknowledge the results of hard work done in the medical imaging community to improve the safety of pediatric patients.

Since the draft guidance document was published, we've seen significant cooperation among industry, clinicians, businesses and regulators on this issue. This cooperation has driven innovation in pediatric safety features.

In 2010 FDA launched the initiative to reduce unnecessary ionizing radiation for medical imaging. In public meetings associated with this initiative and for the draft version of this guidance, we heard from physicists and clinicians that there were significant gains needed in the availability of pediatric safety and radiation safety features and information in X-ray imaging devices.

Since then, industry has been working alongside other stakeholders to develop many new updated consensus standards addressing radiation safety features for specific types of X-ray imaging devices such as NEMA standards for CT devices and IEC standards for fluoroscopy.

We specifically want to call-out a collaboration that took place between the Medical Imaging Technology Alliance and the Image Gently Alliance which led to the important white paper titled “Essential Questions for Consideration in the Design of Interventional X-ray Equipment Extended for Pediatric Use.”

The standards development efforts continue today with FDA involvement. For example IEC is working on a new design standard for CT size-specific dose estimates which is a better way of estimating radiation dose across a range of patient sizes including smaller pediatric patients.

We anticipate new updates to standards for dental X-ray imaging devices in the future and that will further enhance the safety of these devices for all patients. FDA continues to support industry and healthcare experts as they develop new consensus standards. We believe that by developing and adopting these standards, manufacturers can ensure that cutting-edge pediatric features continue to be developed and available in all X-ray imaging devices.

I wanted to close with a few final comments on the responsibility that we stakeholders share in communicating responsibly with the public about radiation in children. When communicating with the public, our goal is always to provide information but not to cause unnecessary alarm.

The cancer risk estimates from radiation exposure are uncertain but low and optimizing radiation dose to the lowest necessary level will minimize this risk. However, because the public may not be as familiar with epidemiological estimates and statistics, quoting numbers may not help parents understand the relative risks like we think they will.

For example, Dr. Donald Frush of the Society of Pediatric Radiology has said that when parents hear a phrase like “1 in 1000 risk of cancer,” this can be

interpreted as “my child and 999 other people’s children” and this sort of interpretation may create unnecessary and unwarranted alarm.

Because of this communication challenge, it can be more beneficial to discuss the benefits of the exam and how the X-ray will help care for the child. Instead of repeating numbers, you can explain the different types of possible risks such as cancer, tissue effect and non-radiation risks, and explain if appropriate that the risks are small in comparison with the benefit offered by the exam.

We know this type of communication is difficult even for experienced healthcare providers so we encourage you to consult resources on the topic from the American Academy of Pediatrics, the Image Gently Alliance and other organizations who are dedicated to promoting the safety of children and communicating with the public on these issues.

FDA has had many opportunities for public communications with this final guidance document including public blogposts, a Medscape interview, updates to our FDA Webpages and this very Webinar.

We encourage you to take this opportunity to responsibly and accurately communicate the benefits and risks of X-ray exams in pediatric patients because we’re all working together on this shared goal. We now have lots of time for your questions.

Coordinator: Thank you. If you would like to ask a question, please press star followed by 1 on your touch-tone phone. You’ll be promoted to record your first and last name and called-on at your turn. If you decide to withdraw your request, please press star followed by 2. One moment, please, for parties to queue-up.

Laurel Burk: What are the differences between the draft version of the guidance that was published a few years ago and this final guidance? I think there's three main issues that I'd like to point-out.

The first is the draft guidance encouraged manufacturers who weren't providing detailed testing for pediatric populations to put the language "not for pediatric use" on their IFU statement and we've heard from stakeholders that labeling X-ray devices as not for pediatric use could be misleading since most of these devices could safely be used in pediatric populations if the right settings and protocols are used that are appropriate for children.

So instead we're encouraging manufacturers to use the testing recommendations in our guidance document and to indicate their devices for pediatrics. But if they choose not to, then we really only want them to say "not for pediatric use" if it's actually unsafe to use the device for pediatric use. **but** we do strongly encourage manufacturers to provide pediatric features and to test and to provide good instructions for use.

A second difference is that we recommend manufacturers to consider pediatric use in their risk framework, their device risk analysis as I mentioned earlier in the presentation and to use this risk analysis as the basis for determining whether and how to include pediatric-specific features in their device.

And last we heard that it would be helpful to have a dedicated section in user manual of pediatric summary which summarizes all of the pediatric features, pediatric-specific labeling and instructions for use.

And we believe that this will allow healthcare providers to easily access and understand all of the features and safety information that's applicable to

pediatrics so they can appropriately optimize their patients' exams without having to hunt around for this information .

So we've got another question. Is FDA encouraging facilities to stop using their old equipment and purchase new equipment that has pediatric safety features? FDA isn't suggesting the facilities immediately replace their older equipment because as we mentioned imaging professionals can safely use the equipment that they have right now even if it doesn't have those instructions for use.

But we really encourage healthcare professionals to refer to guidelines and advice provided on our pediatric X-ray imaging Website for help in using their current equipment to optimize for pediatrics.

And we also refer to educational materials available from the American Association of Physicists in Medicine, the American College of Radiology, Image Gently Alliance and the World Health Organization among others. Our Website links to a lot of those resources.

Irene Aihie: Operator, do we have any questions?

Coordinator: There are no questions. Thank you. I'll turn it back over to you.

Irene Aihie: Thank you. This is Irene Aihie. We appreciate your participation and thoughtful questions. Today's presentation and transcript will be made available on the CDRH learn Webpage at www.fda.gov/training/cdrhlearn by Wednesday, January 17.

If you have additional questions about today's presentation, please use the contact information provided in the slide presentation. As always we appreciate your feedback. Following the conclusion of today's live Webinar, please complete a short 13-question survey about your FDA CDRH Webinar experience.

This survey can be found at www.fda.gov/cdrhwebinar immediately following the conclusion of today's live Webinar. Again thank you for participating. This concludes today's Webinar.

Coordinator: Thank you. This does conclude the call and you may disconnect your lines at this time. Speakers, please standby for your post-conference.

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