

**Content of Premarket Submissions for Device Software Functions, Draft Guidance  
December 16, 2021**

**Moderator: Elias Mallis**

**Elias Mallis:** Hey, everyone, and welcome to today's CDRH webinar. This is Elias Mallis, Director of the Division of Industry and Consumer Education in CDRH's Office of Communication and Education, and I'll be your moderator for today's program.

Today's topic will cover the draft guidance on the content of premarket submissions for device software functions. Now, this is a substantial cross-cutting effort that impacts a wide range of medical devices, and this draft guidance is currently open for public comment. We're holding this webinar to provide you with an opportunity to learn more about the efforts and to answer your questions as you consider providing us with your feedback.

It's now my pleasure to introduce you to our presenters for today's program. Aneesh Deoras, Assistant Director of the Cardiac Ablation, Mapping, and Imaging Devices Team, Office of Cardiovascular Devices, Office of Product Evaluation and Quality, and Ian Marcus, Team Lead of the Digital Health Policy Leadership and Development Team in the Division of Digital Health, Office of Strategic Partnerships and Technology Innovation.

We'll kick off today's program with a presentation from our panelists and then come back around for discussion and field your questions about this topic. Ian will get us started today. Thank you, Ian.

**Ian Marcus:** Thank you for the introduction. Happy holidays, everyone, and thank you for joining us today for the Draft Guidance, Content of Premarket Submissions for Device Software Functions webinar. My name is Ian Marcus, and I am the Team Lead for the Digital Health Policy Team in the Division of Digital Health, and I will begin today's presentation.

Today's webinar will include three sections. First, we will share background information on the history of the guidance, its purpose, as well as our motivation and objectives for updating the guidance. Next, we will present a summary of the draft guidance and highlight notable proposed content with a focus on the differences between this draft guidance and the current version, which we will refer to as the 2005 guidance. After our presentation, we will open up the webinar for the question and answer session.

The objective of today's webinar is to provide an overview of the draft guidance to help inform your review and comments to the public docket. More specifically, we have structured today's program to provide information that will describe the purpose of the guidance, the scope of the proposed recommendations, and the intent of the requested software documentation.

Through the presentation, we highlight for your awareness how the proposed updates complement other existing guidance documents, align with current software practices and FDA-recognized voluntary consensus standards, and reflect changes to medical software policies resulting from the 21st Century Cures Act. Lastly, we will provide you with the information you need to submit comments to the public docket.

Let's start off with a brief background on the guidance. Consistent with the 2005 guidance, the draft guidance aims to address two important questions when software is submitted in a premarket

submission. One, what software documentation is recommended for a marketing submission, and two, what should the documentation demonstrate? To address these questions, the guidance provides recommendations that leverage a risk-based approach to identify the software information generally necessary for evaluating the safety and effectiveness of a device in a premarket submission.

The guidance's recommended documentation provides the review team with a complete narrative, providing a story that describes how traceability and good software engineering practices were employed to appropriately design, verify, and validate device software functions. We will discuss these recommendations in greater detail during my colleague Aneesh's portion of the presentation. Please note, the draft guidance published in November this year is not in effect at this time. The draft guidance is available for public comment and is intended to supersede the current 2005 guidance when it is finalized.

There have been a number of developments since the issuance of the 2005 guidance including Congress promulgating new laws related to software. The updates proposed in the draft guidance are intended to reflect the most up-to-date premarket software documentation expectations. Specifically, the updates proposed are intended to foster timely access to safe and effective software devices, promote least burdensome principles, provide clarity and simplicity, align with changes resulting from the 21st Century Cures Act, harmonize with FDA recognized voluntary consensus standards, and address FDA's MDUFA IV digital health commitments.

The purpose of the draft guidance is consistent with the 2005 guidance such that it identifies the software information generally necessary to evaluate the safety and effectiveness of a device in a premarket submission. This software information would be typically generated and documented during software development, verification, and design validation.

Please note the guidance is intended to complement other existing guidance documents that provide recommendations related to software, such as premarket submission recommendations for interoperable medical devices and the management of cybersecurity in medical devices. In developing the draft guidance, the least burdensome approach was applied to identify the minimum amount of information generally needed to support a premarket submission for a device that uses software.

When describing devices that use software, recent guidance documents, such as the Policy for Device Software Function and Mobile Medical Applications and the Policy for Multiple Function Device Products, have used the term device software function to describe software functions that meet the definition of a device as defined in Section 201(h) of the FD&C Act. These guidance documents use the term function to describe a distinct purpose of the product, which could be the intended use or a subset of the intended use of a product.

To reflect the most up-to-date digital health terminology, the draft guidance uses the term device software functions to account for all instances in which software performs the device function, including Software as a Medical Device, referred to as SaMD, and Software in a Medical Device, referred to as SiMD. The definition section of the guidance introduces these terms and provides additional clarity on their definition, including citation to relevant regulatory references.

The draft guidance is consistent with the 2005 guidance in that it applies to all types of premarket submissions that include one or more device software functions. These premarket submissions include 510(k) premarket notifications, De Novo classification requests, Premarket Approval applications, or

PMA, investigational device exemptions, humanitarian device exemptions, and biologics license applications.

The draft guidance also clarifies how the device constituent part of a combination product is generally within the scope of the draft guidance when the device constituent part includes a device software function or functions. As I previously mentioned, consistent with the 2005 guidance, the draft guidance recommendations are intended to complement other existing guidance documents that provide recommendations related to software.

While the recommendations in the draft guidance describe what software information should be included in a premarket submission, the draft guidance is not intended to provide recommendations regarding how device software should be developed, verified, and validated. This information can be found in other sources, such as the General Principles of Software Validation guidance document. Lastly, it is important to note that the draft guidance does not apply to automated manufacturing and quality system software, software that is not a device, nor does it apply to software-related documentation that may be needed to evaluate post-market software device issues.

The least burdensome approaches used by the 2005 guidance and draft guidance rely on risk-based factors to identify the minimum amount of software information to support a premarket submission. The 2005 guidance uses 12 questions to help distinguish between three levels of concern: minor, moderate, and major.

The draft guidance proposes to improve the risk-based approach by using four simplified factors to help identify two documentation levels: basic and enhanced. In the next few slides, I'll discuss in more detail the purpose of the documentation levels, the four factors used to identify the most appropriate documentation level, and I will walk through two examples of how the documentation levels may be used using the four simplified factors.

The purpose of the documentation level is to help identify the minimum amount of software information that would support a premarket submission. The draft guidance documentation levels are based on a device's intended use, including the design and risk to a patient, a user of a device, or others in the environment of use. This is consistent with the 2005 guidance.

However, as you'll see on the next slide, the draft guidance uses four simplified factors instead of 12 questions and three definitions to guide readers to identify the appropriate documentation level. Please note, the documentation level is determined by the intended use of the device as a whole, not individual device functions, such that a premarket submission for device software functions will have only one documentation level.

Now let's talk about the basis for determining the documentation level. On this slide, we see two boxes. On the left is basic documentation, and on the right is enhanced documentation. On the right, we see enhanced documentation should be provided for any premarket submission that includes device software functions where any of the four factors listed in the box apply. If none of the four factors apply, then basic documentation should be provided instead.

The specifics of the documentation will be covered in later slides by my colleague Aneesh. As a reminder, the four factors represent risk-based considerations simplified from the use of 12 questions in the 2005 guidance to promote greater consistency in their application. The first enhanced

documentation factor is the device is a constituent part of the combination product. This factor is consistent with a question from the 2005 guidance used to identify a major level of concern, but uses updated combination product terminology to improve readability.

The second enhanced documentation factor states the device is a, intended to test blood donations for transfusion-transmitted infections or b, is used to determine donor and recipient compatibility or c, is a blood establishment computer software. Like the first enhanced factor, the second factor is also consistent with a question from the 2005 guidance used to identify a major level of concern.

The third enhanced documentation factor states the device is classified as Class III. This factor is new when compared to the 12 questions in the 2005 guidance. Class III devices are commonly associated with the highest level of concern in the 2005 guidance. The intent of this factor is to utilize a well-understood regulatory consideration to provide for a simpler approach to identifying the appropriate documentation level.

Lastly, the fourth factor states a failure or latent flaw of the device software function could present a probable risk of death or serious injury, either to a patient, user of the device, or others in the environment of use. These risks should be assessed prior to the implementation of risk control measures. You should consider the risk in the context of the device's intended use, the direct or indirect impacts to safety, treatment, and/or diagnosis, and other relevant considerations.

This fourth factor is consistent with several questions used to identify a major level of concern in the 2005 guidance. The fourth factor is intended to concisely summarize any additional risk considerations that could present a probable risk of death or serious injury. The factor uses the term probable to help capture reasonably foreseeable software and hardware risks associated with the device, including those risks resulting from intentional or reasonably foreseeable misuse of the device prior to the implementation of risk control measures.

Probable risks also include the likelihood that device functionality is intentionally or unintentionally compromised by inadequate device cybersecurity. The term probable is intended to exclude the consideration of purely hypothetical risks, consistent with the use of the term probable and other FDA guidances. Now let's walk through two examples from the draft guidance to demonstrate how these factors can be used to determine the documentation level for a device.

Appendix A of the draft guidance includes six examples to demonstrate the implementation of the documentation level factors. These generalized examples do not necessarily account for every possible detail, risk, or consideration a sponsor should evaluate and should not be taken to mean that the devices described definitely do or do not require a certain documentation level. When addressing the factors, we encourage sponsors to leverage their device's risk assessment when providing a rationale for choosing a documentation level.

The draft guidance example on this slide is a non-contact infrared thermometer intended for intermittent measurement of body temperature from the forehead. The device is Class II and is not a constituent part of a combination product. The device is not a blood establishment computer software and is not intended for use in testing blood donations for transfusion-transmitted infections or determining donor and recipient compatibility.

A failure or latent flaw of the device software function would not present a probable risk of death or serious injury to either a patient, user of the device, or others in the environment of use prior to the implementation of risk control measures. Therefore, this device would likely fall under basic documentation level.

This next example is for a facility use continuous ventilator. The device is not a constituent part of a combination product, is not a blood establishment computer software, and is not intended for use in testing blood donations for transfusion-transmitted infections or determining donor-recipient compatibility. At this time, the device is Class II. However, a failure or latent flaw of the device software functions, such as an exploited cybersecurity vulnerability that compromises device functionality, would present a probable risk of death or serious injury to a patient prior to the implementation of risk control measures due to the potential loss of a life-supporting function. Therefore, this device would fall under enhanced documentation level.

We encourage you to review the examples in Appendix A to learn more about the implementation of the documentation levels. I will now turn the presentation over to my colleague, Aneesh, who will talk through the software documentation elements for the documentation levels.

**Aneesh Deoras:** Thank you, Ian. My name is Aneesh Deoras. I'm the Assistant Director for Cardiac Ablation, Mapping, and Imaging Devices in the Office of Cardiovascular Devices, Office of Product Evaluation and Quality. We will now discuss the individual software documentation elements discussed in the draft guidance.

On this slide, you'll find a list of the software documentation elements recommended in the draft guidance. For those of you familiar with the 2005 guidance, you'll find a few of the titles here similar. That includes software description, software requirements specification, and unresolved anomalies.

Some of the items have been modified from the 2005 guidance where there was a software development environment description and now state software development and maintenance practices. One item is missing from the 2005 guidance, and that is the traceability matrix. Traceability has been addressed through the remaining software documentation elements and will be discussed in later slides.

The first software documentation element we will discuss is the documentation level evaluation. For this element, we ask that you provide a statement indicating the documentation level for the device and a description of the rationale for that documentation level. The guidance encourages you to leverage your device's risk assessment when providing a rationale for choosing a documentation level. Appendix A includes examples to help demonstrate the implementation of the documentation level factors that Ian explained before. We do make a note in this section that during premarket review, FDA may request additional information if it is needed to evaluate the submission.

Our next software documentation element is the software description. For this element, we asked that you provide a comprehensive software description, including an overview of operationally significant software features, analyses, inputs, and outputs. For this section, we have provided a curated set of questions to help readers consider and share focused device description information. The section encourages the inclusion of additional information if needed to help streamline or further FDA's understanding of the device's functionality. The section includes recommendations for premarket submissions for modified devices, and it provides references to relevant guidance documents.

The next software documentation element we will discuss is the system and software architecture diagram. For this element, we ask that you provide detailed diagrams of the modules, layers, and interfaces that comprise the device, their relationships, the data inputs, outputs, and flow, and how users or external products, including IT infrastructure and peripherals, interact with the system and software. The draft guidance recommends that sponsors provide an appropriate level of detail to convey this information in a manner that facilitates an efficient premarket review. The section includes visual language and reference considerations that can be leveraged when developing diagrams for a premarket submission.

Appendix B includes example system and software architecture diagrams. The examples in Appendix B are for illustration purposes only. However, the approach illustrated we believe can be applied to any system and software architecture diagram, including those for standalone SaMD. The examples help demonstrate how the considerations in the text section can be implemented into a system in architecture diagram. The examples, though, are not intended to represent a complete system and architecture diagram.

The next software documentation element we will discuss is the risk management file. This element consists of three separate components. The first is the risk management plan, second is the risk assessment, and the third is the risk management report. This section replaces the device hazard analysis in the 2005 guidance. The recommendations of the section have been updated to better align with ISO 14971, which is an FDA-recognized voluntary consensus standard for risk management.

The next software documentation element we will discuss is the software requirement specification. For this element, we ask that you provide complete documentation describing their needs or expectations for a system or software, present that information in an organized format, and provide enough information to demonstrate traceability of the software requirements with other software documentation elements.

The recommendations in the draft guidance acknowledge modern development practices, and additional forms of software requirements might be included in the submission, such as well-elaborated stories, use cases, textual descriptions, screen mockups, and control flows. The section includes considerations for preparing SRS documentation to help facilitate a timely premarket review, such as tips for formatting, labeling, inclusion of traceability information, and a recommendation that manufacturers may highlight requirements they believe are most critical to the device's safety and effectiveness or those that were modified since a previous device's clearance or approval.

The next software documentation element we will discuss is the software design specification. The recommendations for software design specification are different for basic and enhanced documentation levels. For basic documentation level, we do not recommend that SDS documentation be included. For enhanced documentation level, we do recommend that you include the singular SDS document or set of SDS documents that provide technical design details of how the software functions, how the software design completely and correctly implements the SRS, and how the software design traces to the SRS in terms of intended use, functionality, safety, and effectiveness.

The next software documentation element is software development and maintenance practices. There are multiple ways to address this element. First, you may provide a Declaration of Conformity to the currently FDA recognized version of IEC 62304, Software Life Cycle Processes.

Alternatively, you may provide a summary of the processes and procedures that are in place to manage the software life cycle development, software configuration, change management, and software maintenance activities. For enhanced documentation level devices, we request that you provide the same information but provide the complete configuration, management, and maintenance plan documents in addition to the summary documentation for basic documentation.

The next element we will discuss is software testing as part of verification and validation. The element differs between basic and enhanced documentation levels. For basic documentation, we recommend that you provide a summary description of the testing activities at the unit, integration, and system levels and provide system level test protocols and results. For enhanced documentation, we recommend that you provide the same information, but also include unit and integration test level protocols and results.

The definition section of the draft includes important information pertaining to FDA's thinking on verification and validation as it relates to this specific guidance. Sponsors are encouraged to appropriately reference performance testing material provided elsewhere in the submission to facilitate navigation between submission sections, reduce duplication, and improve readability.

The next element we will discuss is the revision level history. For this section, we recommend that you provide a revision history tabulating the major changes to the software during the development cycle, including the date, version number, a brief description of the changes relative to the previous version, and an indication of the version on which testing was performed. The recommendations include tips on documenting changes that correspond to previously released software versions.

The last software documentation element we will discuss is unresolved anomalies. For this element, we recommend that you provide a list of the remaining software anomalies annotated with an explanation of the impact on safety and effectiveness, including operator usage and human factors, workarounds, and a time frame for correction.

The draft guidance recommends that the following information be provided for each unresolved anomaly; the problem, the impact on device performance, and any plans or time frames for correcting the problem. The draft guidance encourages the communication of unresolved anomalies to the end user to assist in the proper operation of the device. A reference is provided to ANSI/AAMI SW91, Classification of defects in health software, to help with developing this list.

The draft guidance includes additional information sections to help explain the software documentation elements. The first is regulatory considerations for software functions, which includes references to relevant guidance documents and to help readers learn more about FDA's regulatory considerations for device software functions. It also includes a section on off-the-shelf software use in medical devices and a description of how the concepts and the draft guidance could be represented in a future update to the off-the-shelf software guidance.

Finally, it includes a comparison of the draft guidance to IEC 62304 and ANSI/AAMI/IEC 62304. It provides clarification on the similarities and differences between the intents and information discussed in the draft guidance and the recognized consensus standard. Information is also provided to highlight how the draft guidance intends to leverage IEC 62304 where it is appropriate.

The draft guidance includes a definition section, providing definitions for terms like device software function, off-the-shelf software, serious injury, Software as a Medical Device, or SaMD, Software in a Medical Device, or SiMD, and software verification and software validation. You'll notice that SaMD and SiMD are defined for the first time in draft FDA guidance here.

A link to the draft guidance is available on this slide as well as a link to the Federal Register, Notice of Availability.

In summary, the draft guidance simplifies the organization and content of software documentation elements as well as the documentation categorization levels. It proposes clear recommendations to aid in the preparation of software documentation consistent with CDRH's least burdensome principles. It complements existing guidance documents that provide recommendations related to software, including multiple function device products.

It harmonizes with software-related consensus standards. It reflects changes to the Food, Drug, and Cosmetic Act made by the 21st Century Cures Act. And when final, this guidance will supersede the 2005 guidance, titled Content of Premarket Submissions for Software Contained in Medical Devices.

We ask that you please submit your comments on the draft guidance by February 2, 2022, which is within 90 days of its publication. While you may comment on a guidance at any time, in order to make sure that we consider your comments on the draft guidance before it becomes final, please submit your comments before February 2, 2022. A link to the docket is available below.

Thank you. We will now enter the question and answer session.

**Elias Mallis:** Thank you, Aneesh. And thanks, both you and Ian, for your overview of the draft software guidance. Let's now get started with the question-and-answer segment of our program.

I'd first like to welcome two additional panelists who are going to join this segment. Jessica Paulsen, Director of Cardiac Electrophysiology, Diagnostics and Monitoring Devices, Office of Cardiovascular Devices, Office of Product Evaluation and Quality. Jessica is also the Program Director for the OPEQ Digital Health Focal Point, and Dr. Matthew Diamond, Chief Medical Officer for Digital Health, based out of the CDRH Digital Health Center of Excellence. Welcome, Jessica and Matthew.

To ask a question, please click the Raise your hand button, which should appear on the bottom of your view screen. I'll announce your name and invite you to ask your question. Please unmute yourself for call, and then go ahead and ask the question.

Now, a few tips. Please just limit yourself to one question, please. And try to keep the questions as short as possible. This is going to help us try to get through as many of your questions during the segment we have.

After you've asked a question, please mute yourself again. And if you have more questions, no problem at all. Go ahead and raise your hand again, and we'll circle back to you if we have time.

So let's get started now. And I'd like to perhaps start off with an intro question for Jessica. So in my introduction to your title, I mentioned that one of your roles is the OPEQ Digital Health Focal Point program. Can you share a little bit about what's involved with this role as it relates to software.

**Jessica Paulsen:** Sure. Yeah, I'm happy to share. So I lead the Digital Health Focal Point program, which aims to promote consistency in our review practices as well as policy implementation for digital health.

So this program includes FDA staff across offices and device review areas that serve as what we call focal points for their groups. And these focal points help address software and digital health related review questions within their organizational unit. So as a group, we meet regularly to enhance our communication, collaboration, and really just general information sharing across device areas. So we found this to be a really helpful forum for our staff, especially given just the rapidly evolving nature of software and digital health.

**Elias Mallis:** Thank you, Jessica. That's great. Important role. And just another quick-off question for Can you can tell us a little bit about the Digital Health Center of Excellence, for which you represent?

**Matthew Diamond:** Yeah, thanks, Elias. Well, the Digital Health Center of Excellence is a cross-center entity that brings together subject matter experts focused on digital health technologies from all the different offices at CDRH. And our mission has three parts.

First, to foster digital health focused collaboration and coordination within and beyond FDA. Second, to promote awareness, transparency, and consistent application of digital health regulatory policies, also within and beyond FDA. And the Focal Point program that Jessica leads that you just mentioned, which is based in CDRH's Office of Product Evaluation and Quality, is an important part of these efforts.

And third, to pioneer the development of innovative digital health regulatory frameworks and paradigms that uphold FDA standards for safety and effectiveness. So this draft guidance that we're talking about today represents a cross center development effort that takes into account what we've heard from a broad array of stakeholders, and is intended to help update and innovate our regulatory approach to software. It's a great example of what the Center of Excellence was designed to accomplish.

**Elias Mallis:** Thank you, Matthew. That's great. And again, welcome to our panel. All right, let's get to our questions. We're going to try to get through as many as we have. And we are actually at capacity of this webinar. So for those who are in here, thank you for joining us. This is a great session, a great topic.

So EDaly, we're going to start with you. I'm going to unmute you, allow you to speak. And please go ahead and unmute yourself and share with us your question.

**EDaly:** Thank you. can you hear me OK?

**Elias Mallis:** You sound great, thank you.

**EDaly:** OK, thanks. My question is, if I'm in the middle of writing a submission, how do I approach that submission? Do I utilize both guidance documents? I guess I'm just kind of wondering, in the interim, when you are submitting to the FDA, is it appropriate to use both the 2005 and the draft guidance?

**Elias Mallis:** Excellent question. I bet many of your colleagues have the same one. Ian, may I ask you to-- welcome to the panel. And let's hear your answer.

**Ian Marcus:** Sure. Yeah, thanks, Elias. And thank you for that question. I think this really speaks to the question of, does this draft guidance affect products currently on the market or pursuing market clearance or approval at this time?

And so the short answer is no. This guidance is a draft, and it's not in effect at this time. The 2005 final guidance remains in effect at this time. And we encourage you to use that guidance as you prepare your marketing submission.

So I think just a reminder. When this guidance is finalized, which is going to take some time because we have to wait for the public comment session to end, and we'll look at those comments. At that point, it would replace the existing 2005 final guidance. But again, reminder, at this time, the draft guidance is just a draft, and it's not in effect.

**Elias Mallis:** Thank you, Ian. And EDaly, does that answer your question?

**EDaly:** It does. Thank you so much.

**Elias Mallis:** OK, awesome. Thanks for joining. Let's continue with Brian Shoemaker. I am now unmuting you. Go ahead and share your question.

**Brian Shoemaker:** Yes, you commented on the fact that the traceability matrix is not explicitly called out in this new draft guidance. I'm taking that and other information in the guidance as saying that the traceability matrix is treated as kind of supporting material that is recommended. Can you comment on that?

**Elias Mallis:** That is a great question about the traceability matrix. Ian, can I sent that one to you as well?

**Ian Marcus:** I think actually Aneesh--

**Elias Mallis:** OK.

**Aneesh Deoras:** Sure, yes, I can take this. Thank you so much for the question, Brian. Yeah, so this is a really great topic. And in our experience, translating traceability information, especially from automated systems, into a single matrix often results in pretty difficult-to-read documents. And it also doesn't really reflect how people are developing software nowadays. So it is incorporated throughout the guidance, especially in the risk management section. And then, we ask that you consider traceability when you look at the other documentation, really to help tell a story about how your device works and how you tested the device.

So it is not a single element anymore in this guidance. However, we've done similar things throughout to make sure, because traceability is still important. So we're hoping to achieve a similar purpose as the traceability matrix in the 2005 guidance, but do so in a way that's less burdensome because of fewer documents and a little bit more practical for regular use.

**Elias Mallis:** Thank you, Aneesh. Brian, does that answer your question?

**Brian Shoemaker:** That certainly helps.

**Elias Mallis:** OK, excellent. Thank you. Let's keep going. A lot of questions. Allison Komiyama, please join us. Welcome, and go ahead and share your question.

**Allison Komiyama:** All right. Thanks, Elias. First off, Ian and Aneesh, excellent presentation. Thanks for putting this on.

My question is with regard to demonstrating substantial equivalence. I know, for many of us, we'll look at 510(k) summaries and figure out if a competitor of predicate may have had a minor, moderate, or major level of concern. It sounds like, based on the draft guidance, that basic documentation level really captures or encapsulates the minor and moderate level. Is that your understanding and your thinking as well?

**Elias Mallis:** Thanks for the question. Let's pitch that to Aneesh.

**Aneesh Deoras:** Great. Thanks, Allison. Very, very good question. So that's generally the intent, is normally that things that would have been minor or moderate would fall under the basic documentation level. Things that were major would under the enhanced documentation level. Now, we would really recommend, though, that you apply the new criteria separately to the device, because the same considerations don't necessarily transfer over.

So we do expect, potentially, some devices that were moderate to be considered enhanced. We did do a lot of work to try and compare a number of devices, looking at how FDA reviewers would receive the new factors. We expect very few changes, really. So definitely understand from the substantial equivalence standpoint. And I would recommend independently working through the factors to help support your substantial equivalence argument.

**Allison Komiyama:** Excellent. Thank you.

**Elias Mallis:** Thank you. Let's go to Allison Sakara for your question. Go ahead and join us if you can.

**Allison Sakara:** Sorry. Satellite connection has a few seconds delay. My apologies.

For looking at enhanced versus basic, for diagnostic SAMDs, in vitro diagnostics, with factors 1 to 3 being no, I would presume to err on the side of caution to say yes, because one cannot always determine the risk of exposure. For instance, for diagnostics, that would be contagious disease. We'll pick on COVID because it's a little bit easy. So if COVID were the diagnostic, then that would be a yes to section 4, and follow the enhanced documentation?

**Elias Mallis:** Allison, let me try to take a stab at this. I think what we want to encourage is for you to look through the criteria. And Ian went through, in this presentation and also several examples.

Part of what we'd like to do is for you to walk through with your specifics of your device situation and answer those questions. And I think part of what we don't necessarily want to do in this webinar is give black-and-white answers for specific device scenarios. So I think we want to encourage you to work through them. If you do have questions, please come back to the review group who might be more appropriate or Q-Submission. So that's how I think we'd like to perhaps answer that type of question.

All right, so with that, we'll continue with Dina Sifri. I'm going to unmute you and have you continue with your question.

**Dina Sifri:** Thank you very much. I have a question regarding enhanced documentation. In many times, in major level of concern, we were asked to submit static or dynamic code analysis. And I was never sure when it will required and when no. Do we have, in the draft guidance, exact definition when static or dynamic code analysis is required for software testing documentation? And if it is required, is there a specific tool that it should be done, or it can be done with any tool?

**Elias Mallis:** Dina, thank you for the question. Aneesh, let me ask you to provide a response.

**Aneesh Deoras:** That's a really great question. So we do call out static and dynamic analysis in the software verification and software validation definition, specifically for verification. It's really going to depend on the device itself, especially for higher-risk devices, regardless of the enhanced documentation. That may be something you'd want to submit, because it's something you'd do anyway.

And that really reflects the intent of this whole draft guidance in that a lot of these documents are things that you're going to be preparing anyway as part of good software development. We were just trying to get a window into what you're working on. And if that includes static and dynamic analyses, then that might be appropriate. I wouldn't say there's any particular tool to use. We want to make sure that stays flexible, certainly, as things evolve in the future.

**Dina Sifri:** Thank you.

**Elias Mallis:** Thank you, Aneesh, for the answer. Thank you, Dina, for the question. Let's keep going. We have quite a few hands raised. Frank Pokrop, please join us on the panel and ask your question. Frank, are you able to join us?

**Frank Pokrop:** OK, sorry. Thanks to the FDA for a very nice effort, and appreciate the time of the panel. Simple question. The slides that were presented today, will they be made available to attendees?

**Elias Mallis:** Absolutely. Something I was going to say right at the end. That's a great question. The recording, the transcript of today, as well as the presentations, will all be available. Typically, it's about a week to two weeks.

**Frank Pokrop:** Thank you.

**Elias Mallis:** All right, Frank. Nice to meet you. Let's continue with the program. Michael-- forgive me if I mispronounce your last name-- Nketiah, you are unmuted. Please go ahead and join us and ask your question. Michael, can you join us?

**Michael Nketiah:** Hello?

**Elias Mallis:** Hello. Great, nice to hear from you. Please share your question.

**Michael Nketiah:** All right, thank you. Thanks for the presentation and your time. Can you kindly provide why the change from the 2005, the documentation structure, to the basic and enhanced? Yeah, thank you.

**Elias Mallis:** Excellent question. Think any one of our panelists might be able to answer this one. Jessica, how about we pick on you?

**Jessica Paulsen:** Sure. Yeah, thanks so much for that question. The change from three levels to two levels is a really important distinction between the 2005 guidance and the current draft guidance that we're discussing today.

So you know, 2005 guidance includes the three levels of concern that identify the recommended software documentation, those levels being minor, moderate, and major. In particular, minor, that level of concern is considered for a device if failures or latent design flaws are unlikely to cause any injury to the patient or operator. So as you probably know, given the 21st Century Cures Act and changes to our software policies since 2005 that really focused FDA's oversight on device software functions that could pose a risk of injury, we think it's unlikely for a device software function submission to meet that 2005 guidance definition for minor level of concern. So really by simplifying the documentation levels from 3 to 2 levels, being basic and enhanced, we believe the documentation recommendations better reflect the current risk-based considerations for these types of submissions.

**Elias Mallis:** Thank you, Jessica. Michael, does that answer your question?

**Michael Nketiah:** Yes, it does. Thank you.

**Elias Mallis:** Thank you for joining us.

**Michael Nketiah:** All right.

**Elias Mallis:** We'll continue. Tao Peng, I am unmuting you next. Please unmute yourself and ask your question.

**Tao Peng:** Hi. My question is about the four factors for determining whether it's enhanced documentation, right? Particularly, the second example given by our presenter. So I believe by understanding that if number four-- I mean, basically, if a device that can cause death or a severe harm, then device should be typically classified as a class 3, right? So I think there's probably some subtlety I don't quite understand about why factor number 3 and number 4 are listed separately. Can our presenter elaborate on that a little bit?

**Elias Mallis:** Tao, thank you for the question. That looks like a great question for Ian to field for us.

**Ian Marcus:** Sure. Yeah, and I think it's excellent question. And it's something that's, I guess, distinguishable between the 2005 guidance and the draft guidance in that we've added a factor related to what the classification of the device is, if it's class 3.

And so the question being, why have another question related to risk? And I think it's maybe illustrated in that example. And that's why we showed it, is, not all devices that pose a potential risk of death or serious injury are class 3. And we recognize that software could play a role in those risk factors. And we want to make sure that we had, more or less, a catch-all factor that excludes purely hypothetical risks but also makes it very clear that there are potential situations in which it may not be class 3, but there's

still that risk of death or serious injury that we want to be aware of and have appropriate documentation for it to assess.

**Elias Mallis:** Thank you, Ian. Tao, does that answer your question for us?

**Tao Peng:** Yes. Thank you.

**Elias Mallis:** OK, thank you. Let's keep rolling. I'm going to just make a little note, we have about 10 minutes left in the session. Started a little late, so I'm going to give us a few extra minutes.

We have a lot of hands raised. We won't be able to get to all of you. I apologize. We're going to just try to keep going as fast as we can. Jody Miller, you are next to speak to the panel with your question.

**Jody Miller:** Hello, thank you. My question was, I know the guidance says this applies to all premarket submissions. I assume that would mean either 510(k) or PMA. My question would be, is this also applicable to changes to software that may be submitted as a PMA supplement So if I were required for enhanced documentation because I'm a class 3 device for PMA supplement to a change to that software, would that also require enhanced documentation in the submission?

**Elias Mallis:** That's a great question. There is a scope section described in the guidance that addresses that. I think we'll field it to Aneesh. So Aneesh, how would you like to answer?

**Aneesh Deoras:** Sure, that's a great question. So it would really depend on whether or not the software is changing in your premarket approval device. But, yes it would apply. So if the software does change in a PMA device, you would be able to leverage this guidance document to decide what software document to submit with your supplement. And the same would go for a 510(k) for an existing device. So when you've modified software for that device, submit a new 510(k). This would support the documentation.

**Jody Miller:** OK, great. Thank you.

**Aneesh Deoras:** Mhm.

**Elias Mallis:** Thank you, Jody, for the question. Aneesh, for the response. Erhan Ilhan, you are up for you next.

**Erhan Ilhan:** Hi, can you hear me?

**Elias Mallis:** You sound great. Welcome.

**Erhan Ilhan:** OK. OK. Thank you for the presentation. My question was around the software architecture and the software design specs. And for this we typically, normally, follow IEC 62304, for the composition into software item and units. I was wondering if, with this new guidance, are there additional requirements on how to decompose and the rationale that we have to add?

**Elias Mallis:** Excellent question. Aneesh, I think this is one for you to share.

**Aneesh Deoras:** Yeah, another great question. The goal is not to impose more requirements than what we would already be doing for 62304 or just for your own practices when really, the perspective that's worth taking a look at how you're crafting your architecture, your software requirement specification, design specification, and putting it into forms to send to FDA is, how does this look to an external review?

And that's really the main point of this guidance, is, let's not ask you to do more work, but where possible, shape what you're sending to us in a way that we can understand it. And that will just reduce the time that we need to review things, because we can focus on, what does your device do and is it safe and effective versus you can't really understand what we're looking at. So the goal is not to ask you to do more work, but at least just make sure that work is translated in a way that we can understand.

**Erhan Ilhan:** Very well. Thank you so much.

**Aneesh Deoras:** Thank you.

**Elias Mallis:** Thank you for joining us. Jim Shults, you are next to speak to our panel with your question.

**Jim Shults:** OK, can you hear me?

**Elias Mallis:** Loud and clear. Welcome.

**Jim Shults:** OK, great. So my question is around the focus of the guidance--

**Elias Mallis:** Sorry about that. Can we start again with your question?

**Jim Shults:** Let's try it again. Can you hear me now?

**Elias Mallis:** You're good, yes.

**Jim Shults:** OK. OK, great. So the focus of the standard seems to be around device software functions. And it's got a very specific definition of it. And really looking at the traceability, though, it seems to go down to a much greater detail to every software requirement, down to the line spec. And it seems to create a lot of documentation there. And I just wonder if that's the intent, or if it's more that we focus on our existing documentation towards those software functions as they're defined.

**Elias Mallis:** Thank you, Jim. This is another great question for Aneesh.

**Aneesh Deoras:** Great. Thank you for the question. I think I may have seen this online.

So I definitely understand the concern, especially when you look at the example architecture that we have. It seems like we included every software requirement in there. And that would become pretty burdensome, especially when you would expand beyond anything that's pretty straightforward.

Really, the goal is just to provide enough clarity into what you're doing, but not necessarily do everything. So there are certain requirements that simply don't make sense to include just as a sort of separate block in the architecture. And so one way you could tackle that is just including textual descriptions, things that are a little bit more documentation-heavy.

And that's OK. It's one approach. And it would fulfill what our recommendations are. And ultimately, our goal is just to make sure that we're getting enough information to understand the device, look at it, and decide whether it meets the relevant regulatory standard. Again, it's a great, great question. Thank you so much.

**Jim Shults:** OK, great. Thanks.

**Elias Mallis:** Thank you, Jim. Dwiner, you are next to speak with our panel.

**Dwiner:** There we go. I think we're unmuted now.

**Elias Mallis:** You're great. Loud and clear. Welcome.

**Dwiner:** In a case where the only possible enhanced documentation element that might apply is being class 3, what level of documentation should be included in a De Novo submission that will actually be a determining factor if indeed the device is deemed to be class 2 or class 3? In other words, the desire is for the device to be class 2, but it will be the De Novo process that determines if it will be class 2 or class 3.

**Elias Mallis:** That's a great, great question. And it makes cross-promotion of our De Novo webinar we did on Tuesday. Aneesh, would you like to field this one again? You're on a roll.

**Aneesh Deoras:** Yes. And another great question. So it would really depend on the device. I think, in that case, there is the automatic class 3 designation that would apply in that sort of situation.

But I think for a De Novo, it would make sense to individually apply the requirements. Because if you are proposing that something is class 2 or class 1, it wouldn't necessarily need that class 3 factor. And in that case, you're likely just looking at the 4<sup>th</sup> factor and would decide what did you get.

So that would be my main recommendation there, that just because something's a De Novo, it wouldn't necessarily apply, is it class 3, and use that as the determining factor.

**Dwiner:** Thank you.

**Aneesh Deoras:** Mhm.

**Elias Mallis:** Great question. Thank you for sharing with us. We have enough time for a few more questions. We're going to just try to keep going. Winston Wu, you are next to speak with our panel.

**Winston Wu:** Oh, hi. Thank you for the presentation. My question is regarding the number 4 evaluation factor, just on the probable risk. Just for the device, that will-- the intended use is not directly on a patient.

There will be another device down the track. And after that, it will be used on a patient. Then how probable risk can be? How far it can go to say, theoretically, the failure of this device may have harm to the patient, but not directly. How far we can go on that assessment?

**Elias Mallis:** Thank you for the question. A great one for Ian.

**Ian Marcus:** Yeah, sure. Yeah, again, another good question. And I think I'll just highlight, in that fourth factor, the term "probable," and just go into this, that it is something we've added in comparison to 2005 guidance.

And as I tried to capture in the presentation, the intent of probable being included is to capture foreseeable-- reasonably foreseeable-- software and hardware risks and exclude those purely hypothetical risks. And that's consistent with how we use the term "probable" in other FDA guidances.

And I think, to your specific example, I encourage you to reach out to the review team that would be reviewing whatever device you intend to submit and ask for clarification on how they perceive that term as relates to controls and documentation expected.

**Winston Wu:** OK, thank you.

**Elias Mallis:** Thank you. Sam Engelman, you are next to speak with our panel.

**Sam Engelman:** Hello. I have a specific question about the application of the basic documentation to the 510(k) submission. The 510(k) submission does not typically include risk-management-related information. Yet because of the software guidance in 2005, that was required. I'm wondering why it is in this update you're choosing to include that information going forward, when in fact it still is not required or other devices in the 510(k) program.

**Elias Mallis:** Sam, thank you for the question. Aneesh, may we ask you for your reply.

**Aneesh Deoras:** Sure, yeah, that's a great question. So I think, at this time, looking at what we could change in this draft guidance, we decided to keep the risk management section from the hazard analysis section, because especially for software devices, it does provide useful information. But that is a good point, that for non-software devices, that is not a requirement right now. And we'll certainly take that feedback back. If you could include that in your comment to the docket, that would be very helpful.

**Elias Mallis:** Thank you for the question. I think we have time for one final question. Punita Christopher, I'm unmuting you. Please go ahead with your question for our panel.

**Punita Christopher:** Can you hear me?

**Elias Mallis:** Yes.

**Punita Christopher:** Thank you so much for the presentation. I think, related to one of the comments that was made during the presentation, that a premarket submission will have just one documentation level for a specific device. And say that we have a device that falls under enhanced documentation because of one of the four factors, but say we have some non-device functions, like an MDDS function, that doesn't negatively impact the device functions. I'm curious if it's sufficient in the submission to just provide a rationale for those functions as to why they don't impact the risk of the system versus providing any other documentation.

**Elias Mallis:** Thank you for the question. Ian, let me pass this one for you to answer.

**Ian Marcus:** Yeah, no. Great question, and a good opportunity to plug the multiple function device products guidance. I think it's a recent guidance relative to the 2005 guidance, and it's something we recognize is complementary to software documentation.

And in that guidance, it speaks to how to approach multiple function device products and address the impact of what they call other functions, device functions that are under review, including recommendations for how the different elements of software documentation could be addressed for those other functions, as you would assume. For example, maybe MDDS. And so you'll see in the draft guidance, where we could, we tried to comment and make reference to that multiple function device product guidance to really bridge the two and provide folks the clarity when they're submitting that type of device.

**Punita Christopher:** Thank you.

**Elias Mallis:** Thank you, Punita. And Ian, thank you for that answer. And let's stick with you, Ian, as we wrap things up, for you and your final thoughts for our audience today.

**Ian Marcus:** Yeah, I think-- thank you, Elias. And I just want to take this moment to recognize and thank everyone who's made today's webinar possible, starting with all of you who joined us today and actively participated on this call. Your thoughtful questions highlight the importance of stakeholder engagement in advancing digital health. We greatly appreciate your time and participation, and we hope through today's webinar you learn more about the ways the updates proposed to the draft guidance are intended to promote least burdensome principles and provide clarity and simplicity to help foster timely access to safe and effective software devices.

I also want to thank my colleagues, Elias, Aneesh, Jessica, Matthew, and the many, many other FDA staff who contributed to the development of the draft guidance and today's webinar. We look forward to considering your comments to the public docket as we work to finalize the draft guidance. And a quick reminder, please remember to submit your comments to the public docket by February 2nd, 2022, to ensure that FDA considers your comments. And I'll turn it back to you, Elias, to conclude the webinar.

**Elias Mallis:** Thanks, Ian. Thank you, everybody. This will conclude today's webinar.

I do want to, myself, thank all the panelists, Ian Marcus, Aneesh Deoras, Jessica Paulsen, and Dr. Matthew Diamond. Thanks for your great discussion on this important policy. My thanks to you, our audience, for your participation and all of your incredible questions to the FDA panel as well.

A recording of today's webinar, presentation, and transcript will be posted to CDRH Learn in a few weeks. Take a look at the CDRH Learn website for where we'll post this program, at the link shown here. And we're going to be posting it under this section, Specialty Technical Topics, under the Digital Health section. That's where you can find that.

For any other additional questions about today's presentation, we just add [DICE@fda.hhs.gov](mailto:DICE@fda.hhs.gov). We welcome your feedback about this continuing CDRH webinar program series. So we encourage you to give us your feedback and fill out the survey that you can see on link here.

This will conclude our CDRH webinar series for 2021. Hard to believe it. Thanks for joining us over the years. And we'll pick up with you with more topics in the new year. So this is Elias Mallis signing off, wishing you all a happy new year. And we will see you next time.

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