FDA U.S. FOOD & DRUG ADMINISTRATION
CENTER FOR DEVICES & RADIOLOGICAL HEALTH

Welcome To Today's Webinar

Thanks for joining us!
We'll get started in a few minutes.

Today's Topic: Content of Premarket Submissions for Device Software Functions
Draft Guidance
December 16, 2021, 1-2 pm EST

Draft Guidance: Content of Premarket Submissions for Device Software Functions

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Agenda

- Background
- Summary of the draft guidance
- Q & A

Webinar Objectives

- ✓ Describe the purpose of the guidance, the scope of the proposed recommendations, and the intent of the requested software documentation
- ✓ Identify how the proposed updates:
  - ➢ Complement other existing guidance documents
  - ➢ Align with current software practices and FDA recognized voluntary consensus standards
  - ➢ Reflect changes to medical software policies resulting from Section 3060 of the 21st Century Cures Act
- ✓ Know how to submit comments to the public docket

Background

Questions addressed by the guidance:

- What software documentation is recommended for a marketing submission?
- What should the documentation demonstrate?

The Draft Guidance is:

- Not in effect.
- Available for public comment.
- Intended to supersede the current guidance, when final.

Motivation

Updates intended to:

- ✓ Foster timely access to safe and effective software devices
- ✓ Promote Least Burdensome Principles
- ✓ Provide clarity and simplicity
- ✓ Align with changes resulting from Section 3060 of the 21st Century Cures Act
- ✓ Harmonize with FDA-recognized voluntary consensus standards

- FDA committed to publishing a draft revised version of the "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" (issued in 2005) as part of the MDUFA IV Digital Health commitments

MDUFA = Medical Device User Fee Amendments

Draft Guidance Purpose

Identifies software information generally necessary to evaluate safety and effectiveness of a device in a premarket submission.

- Least burdensome approach was applied to identify minimum amount of information generally needed to support a premarket submission for a device that uses software.
- Draft guidance describes information typically generated and documented during software development, verification, and design validation.
- FDA may request additional information needed to evaluate submission during a premarket review.

Device Software Functions

The term "*function*" is a distinct purpose of the product, which could be the intended use or a subset of the intended use of the product.

"Device Software Functions" are software functions that meet the definition of a device under section 201(h) of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

- Recommendations pertain to device software functions, including software in a medical device (SiMD) and software as a medical device (SaMD).

- Reflects function-based approach described in guidance documents:
  - "Policy for Device Software Functions and Mobile Medical Applications" and
  - "Policy for Multiple Function Device Products: Policy and Considerations"

Scope

The draft guidance applies to all types of premarket submissions that include one or more device software function(s).

- Generally, recommendations apply to device constituent part of a combination product when device constituent part includes a device software function.
- Not intended to provide recommendations regarding how device software should be developed, verified and validated.
- Does not apply to:
  - automated manufacturing and Quality System software or software that is not a device
  - software-related documentation that may be needed to evaluate postmarket software device issues

Documentation Levels

Level of Concern (LoC) described in the 2005 Guidance is replaced by the simplified Documentation Levels proposed in the draft guidance.

- Two Documentation Levels Defined for Devices: **Basic** and **Enhanced**

- Next few slides will cover:
  - Purpose of the Documentation Level
  - Basis for determining the Documentation Level (that is, four factors)
  - Documentation Level Examples

Purpose of Documentation Level

Purpose of Documentation Level is to help identify minimum amount of software information that would support a premarket submission.

- Documentation Level is based on a device's intended use, including design; and a device's risk to a patient, a user of a device, or others in the environment of use.

- Documentation Level is determined by the intended use of the device as a whole – not the individual device function(s).

Basis for Determining the Documentation Level

Basic Documentation

Basic Documentation should be provided for any premarket submission that includes device software functions where Enhanced Documentation does not apply.

Enhanced Documentation

Enhanced Documentation should be provided for any premarket submission that includes device software functions, where any of the following factors apply:

1) The device is a constituent part of a combination product.
2) The device (a) is 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.
3) The device is classified as Class III.
4) A failure or latent flaw of the device software function(s) 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 risk(s) should be assessed prior to implementation of risk control measures. You should consider the risk(s) in the context of the device's intended use; the direct and indirect impacts to safety, treatment, and/or diagnosis; and other relevant considerations.

Example Documentation Level (Appendix A)

A non-contact infrared thermometer intended for intermittent measurement of body temperature from the forehead. **Outcome:** "**Basic Documentation Level**".

#	Factors	Yes/No
1	The device is a constituent part of a combination product.	No
2	The device (a) is intended to test blood donations for transfusion-transmitted infections; or (b) is used to determine donor and recipient compatibility; or (c) is Blood Establishment Computer Software.	No
3	The device is classified as Class III.	No
4	A failure or latent flaw of the device software function(s) could present a probable risk of death or serious injury either to the patient, user of the device, or others in the environment of use. These risk(s) should be assessed prior to implementation of risk control measures. You should consider the risk(s) in the context of the device's intended use; the direct and indirect impacts to safety, treatment, and/or diagnosis; and other relevant considerations.	No

Example Documentation Level (Appendix A)

A facility use continuous ventilator. **Outcome:** "**Enhanced Documentation Level**".

#	Factors	Yes/No
1	The device is a constituent part of a combination product.	No
2	The device (a) is intended to test blood donations for transfusion-transmitted infections; or (b) is used to determine donor and recipient compatibility; or (c) is Blood Establishment Computer Software.	No
3	The device is classified as Class III.	No
4	A failure or latent flaw of the device software function(s) could present a probable risk of death or serious injury either to the patient, user of the device, or others in the environment of use. These risk(s) should be assessed prior to implementation of risk control measures. You should consider the risk(s) in the context of the device's intended use; the direct and indirect impacts to safety, treatment, and/or diagnosis; and other relevant considerations.	Yes

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Overview of Software Documentation Elements

- Documentation Level Evaluation
- Software Description
- System and Software Architecture Design Chart
- Risk Management File
- Software Requirements Specification (SRS)
- Software Design Specification (SDS)
- Software Development and Maintenance Practices
- Software Testing as Part of Verification and Validation
- Revision Level History
- Unresolved Anomalies (e.g., Bugs, Defects, or Errors)

Documentation Level Evaluation

For Basic and Enhanced Documentation Levels:

Provide a statement indicating the Documentation Level for the device and a description of the rationale for such Documentation Level, as appropriate.

- Draft guidance encourages sponsors to leverage their device's risk assessment when providing a rationale for choosing a Documentation Level.
- Examples in Appendix A are provided to demonstrate the implementation of the Documentation Level factors.
- During premarket review, FDA may request additional information that is needed to evaluate the submission.

Software Description

For Basic and Enhanced Documentation Levels:

Provide a comprehensive software description, including overview of operationally significant software features, analyses, inputs, and outputs.

- Proposes a curated set of questions to help readers consider and share focused device description information.
- Encourages the inclusion of additional information, if needed, to streamline or further FDA's understanding of the device's functionality.
- Includes recommendations for a premarket submission of a modified device.
- Provides references to relevant guidance documents, such as "Multiple Function Device Products: Policy and Considerations", "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices", and "Guidance for Off-The-Shelf Software Use in Medical Devices."

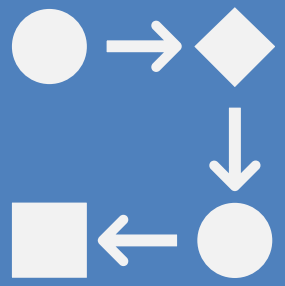
System and Software Architecture Diagram

For Basic and Enhanced Documentation Levels:

Provide detailed diagrams of the modules, layers, and interfaces that comprise the device, their relationships, the data inputs/outputs and flow of data, and how users or external products (including IT infrastructure and peripherals) interact with the system and software.

- Draft recommends for sponsors to provide the appropriate level of detail to convey information in a manner that can facilitate an efficient premarket review.
- Includes visual, language, and reference considerations that can be leveraged when developing the diagrams for a premarket submission.
- Appendix B of the draft includes example system and software architecture diagrams, illustrating how the considerations described in the guidance can be implemented and account for multiple modules and functions.

Appendix B: System and Software Architecture Diagram Chart Examples



- The examples are intended for illustration purposes only and are not intended to document a comprehensive system and software architecture diagram for a specific medical device or system.
- The approach illustrated can be applied to any system and software architecture diagram, including standalone SaMD.
- The examples demonstrate how the considerations described in section System and Software Architecture Design Chart can be implemented into a system and architecture diagram.
- The example is not intended to represent a complete system and architecture diagram.

Risk Management File

For Basic and Enhanced Documentation Levels:

Risk Management File should include documentation demonstrating the following three components:

- **Risk Management Plan:** demonstrate how a manufacturer plans to evaluate the overall residual risk against the benefits of the intended use of the device
- **Risk Assessment:** documents in a tabular format all reasonably foreseeable software and hardware hazards associated with the device and demonstrates traceability of risk control measures
- **Risk Management Report:** shows how the risk management plan has been appropriately implemented

- Draft recommendations have been updated to better align with ISO 14971 and account for the recommendations provided in the guidance "Multiple Function Device Products: Policy and Considerations."

Software Requirements Specification (SRS)

For Basic and Enhanced Documentation Levels:

Includes complete documentation, describing the needs or expectations for a system or software, presented in an organized format and with sufficient information to understand the traceability of the information with respect to the other software documentation elements.

- Recommendations acknowledge modern development practices. Additional forms of software requirements might be included in submission, such as well-elaborated stories, use cases, textual descriptions, screen mockups, and control flows.
- Section includes considerations when preparing SRS documentation to help facilitate a timely premarket review, such as:
  - Tips for formatting and labeling
  - Inclusion of traceability information
  - A manufacturer may highlight requirements they believe are most critical to the device's safety and effectiveness, and/or those that were modified since a previous clearance or approval.

Software Design Specification (SDS)

Basic Documentation Level

No SDS documentation recommended in the premarket submission.

Enhanced Documentation Level

Includes singular SDS document or set of SDS documents that provide the technical design details of how the software functions, how the software design completely and correctly implements all the requirements of the SRS and how the software design traces to the SRS in terms of intended use, functionality, safety, and effectiveness.

- Recommendations leverage and include reference to the “Multiple Function Device Products: Policy and Considerations” and “General Principles of Software Validation” guidance documents.

Software Development and Maintenance Practices

Recommends providing a Declaration of Conformity to currently FDA-recognized version of ANSI/AAMI IEC 62304 Medical Device Software - Software Life Cycle Processes

OR

For Basic Documentation Level

Alternatively, recommends providing a summary of processes and procedures that are in place to manage the software life cycle development, software configuration and change management and software maintenance activities.

For Enhanced Documentation Level

Alternatively, recommends providing a complete configuration management and maintenance plan document in addition to summary documentation requested for Basic Documentation Level.

Software Testing as part of Verification and Validation

Basic Documentation Level

Recommends providing a summary description of testing activities at the unit, integration and system levels. System level test protocol including expected results, observed results, pass/fail determination, and system level test report.

Enhanced Documentation Level

Recommends providing the Basic Documentation Level PLUS unit and integration level test protocols including expected results, observed results, pass/fail determination, and unit and integration level test reports.

- Definition section includes important information pertaining to FDA's thinking on verification and validation, as it relates to this guidance.

- Sponsor is encouraged to appropriately reference performance testing material in submission to facilitate navigation between submission sections, reduce instances of duplication, and improve readability.

Revision Level History

For Basic and Enhanced Documentation Levels:

Recommends providing a revision history tabulating major changes to software during the development cycle, including date, version number, a brief description of the changes relative to the previous version, and indication of the version on which testing was performed.

- Recommendations include tips on documenting changes that correspond to previously-released software versions.

Unresolved Anomalies

For Basic and Enhanced Documentation Levels:

Recommends to provide a list of remaining software anomalies annotated with an explanation of impact on safety or effectiveness, including operator usage and human factors, work-arounds, and timeframe for correction.

- Recommends this information be provided for each unresolved anomaly:
  - Problem;
  - Impact on device performance; and
  - Any plans or timeframes for correct the problem (where appropriate).

- Encourages communication of unresolved anomalies to end user(s) as appropriate to assist in proper operation of the device.

- Reference to ANSI/AAMI SW91 *Classification of defects in health software* is provided.

Additional Information Sections

Regulatory Considerations for Software Functions

- Relevant guidance documents are referenced and linked to help readers learn more about FDA's regulatory considerations for software functions.

Off-The-Shelf (OTS) Software Use in Medical Devices

- Description of how the concepts in the draft guidance could be represented in a future update to the OTS guidance.

Comparison of Guidance to IEC 62304 and ANSI/AAMI/IEC 62304

- Clarification provided on the similarities and differences between the intents and information discussed in draft guidance and IEC 62304.

- Information is provided to highlight how the draft guidance intends to leverage IEC 62304.

Definitions

Draft guidance provides definitions of terms for the purpose of the guidance and includes references to definition sources.

Terms include:

- Device software function
- Off-the-Shelf Software
- Serious Injury
- Software as a Medical Device (SaMD)
- Software in a Medical Device (SiMD)
- Software Verification and Software Validation

Guidance References

- **Content of Premarket Submissions for Device Software Functions, Draft Guidance for Industry and Food and Drug Administrative Staff**

  www.fda.gov/regulatory-information/search-fda-guidance-documents/content-premarket-submissions-device-software-functions

- **Federal Register: Notice of Availability**

  www.federalregister.gov/documents/2021/11/04/2021-24061/content-of-premarket-submissions-for-device-software-functions-draft-guidance-for-industry-and-food

Summary of Highlights from the Draft Guidance

- ✓ Simplifies organization and content of software documentation elements and documentation categorization levels
- ✓ Proposes clear recommendations to aid in preparation of software documentation, consistent with the Least Burdensome Principles
- ✓ Complements existing guidance documents that provide recommendations related to software (e.g., “Multiple Function Device Products: Policy and Considerations”)
- ✓ Harmonizes with software-related voluntary consensus standards
- ✓ Reflects changes to the FD&C Act made by the 21st Century Cures Act
- ✓ When final, this guidance will supersede Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, May 2005

Please Submit Your Comments

- **Submit comments by February 2, 2022 (within 90 days of publication)**
  - Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), in order to ensure that the FDA considers your comment on a draft guidance before it begins work on the final version of the guidance, please submit comments on the draft guidance before the closure date.
  - Docket Number: FDA-2021-D-0775

    www.regulations.gov/docket/FDA-2021-D-0775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Let's Take Your Questions

- **To Ask a Question:**
  1. Please "Raise Your Hand" 

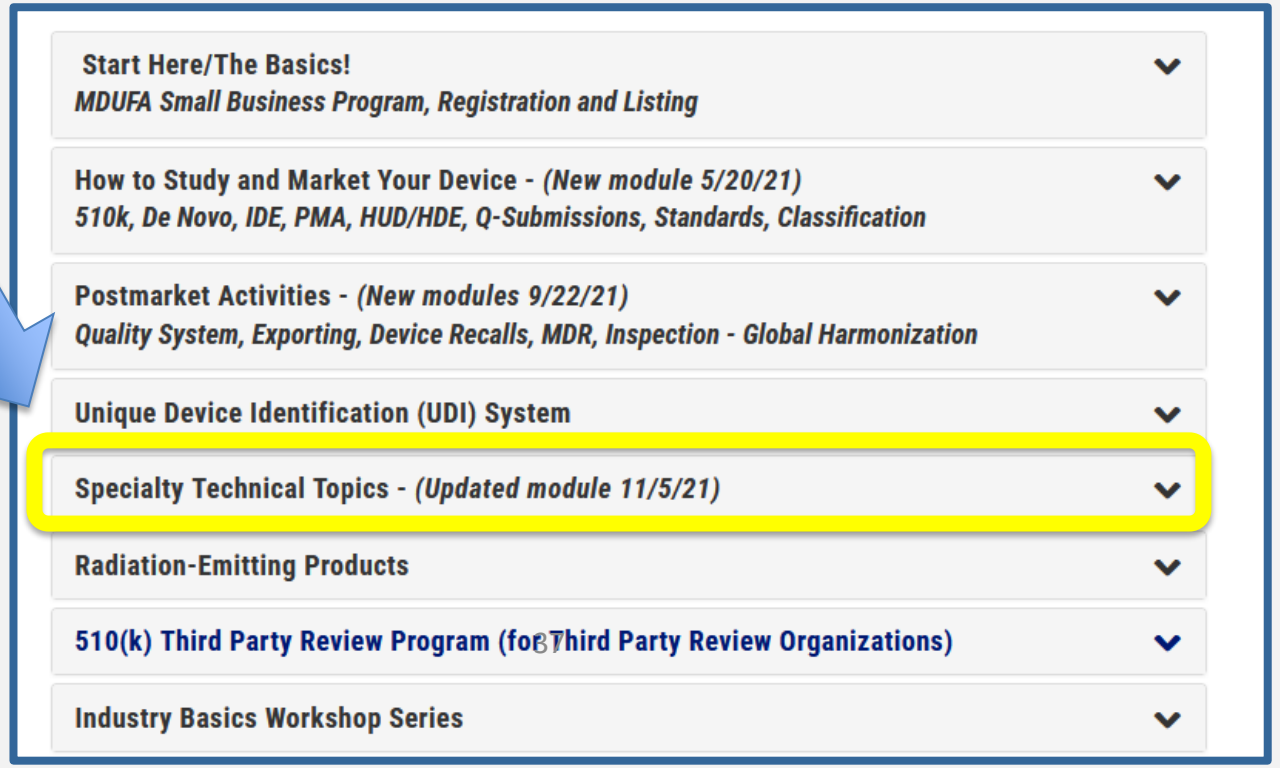
  2. Moderator will Announce Your Name to Invite You to Ask Your Question
  3. Unmute yourself when called

- **When Asking a Question:**
  - Ask 1 question only
  - Keep question short
  - No questions about specific submissions or data-specific

- **After Question is Answered:**
  - Please mute yourself again
  - If you have more questions - raise your hand again

Thanks for Joining Today!

- **Presentation and Transcript will be available at CDRH Learn:**
  - www.fda.gov/Training/CDRHLearn



- **Additional questions about today's presentation**
  - Email: DICE@fda.hhs.gov

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Happy Holidays and See You in 2022!


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